VOL. 30, NO. 9 SEPTEMBER 1975

Food Drug Cosmetic Law JOURNAL

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

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

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

September, 1975
Volume 30 • Number 9

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

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . September, 1975

Volume 30 Number 9

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

"Free Speech and the Regulation of Labeling and Advertising" is a thoughtful analysis of the First Amendment to the Constitution in relation to the protection of labeling and advertising claims. *Thomas H. Christopher,* a senior law student at the University of Alabama School of Law, discusses the standards by which cases involving free speech are measured and applies them to advertising claims. The article begins on page 512.

Stephen H. McNamara explores the problems inherent in developing new protein sources for an ever-expanding population. As Associate Chief Counsel for Food in the General Counsel's Office in the Food and Drug Administration, Mr. McNamara expresses the conflict faced by the Agency in weighing the need for new food sources with the need to protect consumers from unsafe and adulterated food. "Some Legal Aspects of Providing a Sufficient Food Supply for a Hungry Population," beginning on page 527, was presented at the Annual Meeting of the American Association for the Advancement of Science on January 29, 1975 in New York City.

Advisory committees and their importance in agency procedures are discussed by *Jane Lang McGrew* in "How to Let in the Sunshine Without Getting Burned: Protecting Your Rights Before Advisory Committees." The article, presented at the Food and Drug Law Institute's Pharmaceutical Update V in New York City on May 23, 1975, deals with many aspects of advisory committees, including the question of public access versus the right to privacy. Ms. McGrew, whose article begins on page 536, is a member of the law firm of Steptoe and Johnson.

In a discussion of property rights and pharmaceuticals, *Jefferson B. Hill,* a Trial Attorney in the Patent Section of the Antitrust Division of the United States Department of Justice, outlines the antitrust laws of the United States and relates them to patents and trademarks. "Some Fundamentals of United States Antitrust Law" begins on page 545. It was presented at the Food and Drug Law Institute's Pharmaceutical Update V, held in New York City on May 22 and May 23, 1975.

"The Consumer Product Safety Act—A Brief Overview" is the subject and the title of an article by *Tomas M. Russell.* Presented at a meeting of the Chicago Bar Association on October 16, 1974, it not only recites the history of the Act but it also summarizes many of its far-reaching provisions relating to products in use. Mr. Russell is a partner in the law firm of Sidley & Austin and his article begins on page 555.

The advantages and the disadvantages of federal pre-emption of state and local powers over food and drug laws are outlined by *Merrill S. Thompson* in his article, "What Price Uniformity?" which begins on page 567. Mr. Thompson is a partner in the law firm of Chadwell, Kayser, Ruggles, McGee & Hastings. The paper was prepared for presentation at the 58th Annual Conference of the Central Atlantic States Association of Food and Drug Officials, which was held on May 23, 1974.

Vol. 30, No. 9 September, 1975

Food·Drug·Cosmetic Law
Journal

Free Speech and the Regulation of Labeling and Advertising

By THOMAS H. CHRISTOPHER

Mr. Christopher Is a Senior Law Student at the University of Alabama School of Law.

I. Introduction

THE FIRST AMENDMENT to the United States Constitution states: "Congress shall make no law . . . abridging the freedom of speech or of the press."[1] Yet Congress has passed laws which forbid mislabeling[2] and false advertising[3] of products by either written or spoken words. The purpose of this presentation is to explore the possibility of conflict in this situation, to see if freedom of expression can be reconciled with these consumer protection measures, and to evaluate possible justifications for doing so.

Speech which comes under the First Amendment is entitled to substantial protection by the courts. The most famous standard by which cases involving freedom of expression are measured is the "clear and present danger" test of Holmes and Brandeis. According to them, words of a subversive nature can only be regulated when they create a "clear and present danger that they will bring about the substantive

[1] U. S. Constitution, Amendment 1.
[2] Federal Food, Drug and Cosmetic Act of 1938, 21 U. S. C. Secs. 321—392 (1970).
[3] Federal Trade Commission (FTC) Act, 15 U. S. C. Secs. 41—58 (1970).

evils that Congress has a right to prevent."[4] Further, they can be suppressed only in an "emergency."[5] A second type of analysis was advocated by Justice Frankfurter. He stated that the problem should be approached by a "candid and informed weighing of the competing interests,"[6] and that the primary responsibility for doing this belongs to Congress.[7] However, the Supreme Court adopted a much tougher test in *Brandenburg v. Ohio*.[8] It held that political speech must constitute incitement to violence in order to be subject to control. Justices Douglas and Black said that only speech "brigaded with action" could be regulated.[9] Further, any sort of prior restraint is much disfavored by the Court.[10] *New York Times v. United States*[11] stated that prior restraint bears "a heavy presumption against its constitutional validity,"[12] and Justices Black and Douglas maintained that publication of a newspaper could never be enjoined.[13]

Despite the protection that the First Amendment gives to expression, federal consumer protection laws exercise considerable control over words in certain situations. The Federal Food, Drug and Cosmetic Act of 1938 forbids the misbranding of food, drugs, cosmetics or any type of medical device in interstate commerce.[14] The ban may be enforced by seizure of the product,[15] by criminal conviction of violators,[16] and by injunction.[17] Violators are subject to criminal sanctions, even if they have no knowledge of the falsity of the labels. However, if an intent to mislead is established, the penalty is greater.[18] And the interpretation of misbranding has not been limited to words pasted onto containers. In the instance of a vitamin company which advertised on the radio program of a nutritionist who made extravagant claims about vitamins in general, and in which written inquiries to the nutritionist were turned over to

[4] *Schenck v. United States*, 249 U. S. 47. 52 (1919). The standard was first put forward by Holmes in *Schenck* and two companion cases. *Frohwerk v. United States*, 249 U. S. 204 (1919), and *Debs v. United States*, 249 U. S. 211 (1919).

[5] *Whitney v. California*, 274 U. S. 357, 377 (1927). This was a concurring opinion by Brandeis, in which Holmes joined. The necessity of the danger being immediate and serious was further stressed by Holmes' dissent in *Gitlow v. New York*, 268 U. S. 652, 672 (1925). These two opinions were adopted by the Court in *Dennis v. United States*, 341 U. S. 494 at 507 (1951).

[6] *Dennis v. United States*, 341 U. S. 494, 525 (1951).

[7] *Id.*

[8] 395 U. S. 444 (1969).

[9] *Id.* at 456.

[10] An attempt to block publication of a newspaper containing defamatory articles was declared unconstitutional in *Near v. Minnesota*, 283 U. S. 697 (1931).

[11] 403 U. S. 713 (1971).

[12] *Id.* at 714, quoting *Bantam Books v. Sullivan*, 372 U. S. at 70 (1963).

[13] 403 U. S. at 715 (1971).

[14] 21 U. S. C. Secs. 321—392 (1970).

[15] *Id.* at Sec. 334.

[16] *Id.* at Sec. 333.

[17] *Id.* at Sec. 332.

[18] *Id.* at Sec. 333(b).

the company and answered with a company catalogue, the broadcasts themselves were considered labeling. The company's product was seized on the basis of false statements in the broadcasts.[19] When an independently written book, which praised the value of blackstrap molasses, was displayed beside jars of "Plantation" blackstrap molasses, and customers who came in to look at molasses were referred to the book, it was considered labeling. On the basis of several false statements in the book regarding the curative powers of molasses, such as its purported ability to prevent menstrual abnormalities and to cure baldness, both the molasses and the books in the store were seized.[20] The Federal Trade Commission (FTC) Act[21] makes it unlawful to disseminate false advertisements. This may be enforced by injunction.[22] If the use of the commodity in accordance with the ad is dangerous or if intent to mislead is found, criminal penalties may be imposed in certain situations.[23]

II. The Commercial Speech Exception

The First Amendment ramifications of this type of federal regulation have not been fully explored by the courts. A possible justification is the theory that commercial speech is not entitled to First Amendment protection.[24] Advertising and branding of products obviously fall in this category and, thus, would not be subjected to any of the tests previously mentioned.

The idea that some expression is excluded from First Amendment protection was clearly articulated in *Chaplinsky v. New Hampshire*.[25] That case involved the conviction of a Jehovah's Witness for directing fighting words at a policeman. An unanimous Court upheld the conviction. Justice Murphy said,

"The right of free speech is not absolute at all times and under all circumstances. There are certain well-defined and narrowly limited classes of speech, the prevention or punishment of which have never been thought to raise any Constitutional problem. These include the lewd and obscene, the profane, the libelous and the insulting or "fighting" words—those which by their very utterance inflict injury or tend to incite an immediate breach of the peace. It has been well observed that such utterances are no essential part of any exposition of ideas, and are of such slight social value as a step to truth that any benefit that

[19] *United States v. Article of Drug . . . B-Complex Cholinos Capsules*, 362 F. 2d 923 (CA-3 1966).

[20] *United States v. 8 Cartons . . . Molasses*, 103 F. Supp. 626 (DC WD NY 1951).

[21] 15 U. S. C. Secs. 41—58 (1970).

[22] *Charles of the Ritz Distributors v. FTC*, 143 F. 2d 676 (CA-2 1944); 15 U. S. C. Sec. 45 (1970).

[23] FTC Act, 15 U. S. C. Secs. 52, 54 (1970).

[24] *Valentine v. Chrestensen*, 316 U. S. 52 (1942).

[25] 315 U. S. 569 (1942).

may be derived from them is clearly outweighed by the social interest in order and morality."[26]

In *Roth v. United States,* the Court relied on the language of *Chaplinsky* to hold that "obscenity is not within the area of constitutionally protected speech or press."[27] When dealing with obscenity, the "clear and present danger" test was found to be inapplicable, and the government was left free to punish it.[28]

Political Message

The idea that speech of a purely mercantile nature is, like obscenity and fighting words, excluded from constitutional protection, is the so-called "commercial speech exception." It first arose in *Valentine v. Chrestensen*[29] which was decided in the same year as *Chaplinsky. Chrestensen* involved an entrepreneur who charged admission to a submarine that he was displaying in New York. In order to drum up business, he had handbills printed and distributed, an act which was a violation of a city ordinance. When he learned of this, he had a message protesting the refusal of city officials to let him use a city dock printed on the back of the handbills. City officials still refused to permit distribution, and he sought an injunction. He argued that his First Amendment rights were being violated, especially since one side of the handbill contained a political message. However, the Supreme Court, speaking through Justice Roberts, unanimously rejected this contention. It said that the government could not "unduly burden or proscribe" freedom of expression on the streets.[30] But, it continued, "We are equally clear that the Constitution imposes no such restraint on government as respects purely commercial advertising."[31] Pre-

[26] *Id.* at 571, 572.

[27] 354 U. S. 485 (1957).

[28] *Roth v. United States,* 354 U. S. 476 (1957). Justice Brennan's majority opinion concluded: "In the light of history, it is apparent that the unconditional phrasing of the First Amendment was not intended to protect every utterance." P. 483. Fifteen years later, Justice Brennan and three others repudiated *Roth,* but the change of heart was too late. His dissent in *Paris Adult Theater I v. Slaton,* 413 U. S. 49 (1973), in which Justice Stewart and Justice Marshall joined, maintained that outright suppression of obscenity cannot be reconciled with the fundamental principles of the First and Fourteenth Amendments. For we have failed to formulate a standard that sharply distinguishes protected from unprotected speech. It is significant to note that the stated reason for this position was the lack of ability to distinguish between protected and unprotected speech, not a claim that all classes of speech are protected. In *Miller v. California,* 413 U. S. 15 (1973), to which Brennan's *Paris Adult Theater* dissent applied, the majority reaffirmed the *Roth* holding that obscenity was not protected speech. It diverged from *Roth* only in broadening the definition of obscenity.

[29] 316 U. S. 52 (1942).

[30] *Id.* at 54.

[31] *Id.* at 54.

sumably, therefore, the government could "unduly burden and proscribe" commercial speech. And since the political message was added to the other side of the handbill only to rescue the commercial message from regulation, its presence could not save the leaflet from control.[32] Thus commercial speech was rather clearly taken out from First Amendment protection by this case.

Valentine v. Chrestensen was cited with approval the next year by two decisions. *Murdock v. Pennsylvania*[33] and *Jamison v. Texas*[34] dealt with the advertising or sale of religious works. The Court distinguished the situations from *Chrestensen* when it invalidated state control of these activities and reaffirmed the commercial speech exception.

In *Breard v. City of Alexandria*,[35] the Court upheld an ordinance which banned door-to-door solicitation when it was applied to the sale of the *Saturday Evening Post*. The presence of a commercial element was a factor weighing in favor of the ordinance and helping to uphold it, despite the fact that this was clearly material of public interest.[36]

Interference with Editorial Function

The Supreme Court dealt more directly with the commercial speech exception in a recent decision, *Pittsburgh Press Co. v. Pittsburgh Commission on Human Relations*.[37] It involved a newspaper listing job advertisements in sex-designated columns, in violation of an anti-sex discrimination ordinance. The paper maintained that this was interference with its editorial function and thus a violation of freedom of the press. However, Justice Powell, speaking for a majority of five, rejected this argument and relied on the commercial speech exception to uphold the ordinance. He said that the advertisement, together with the column heading, formed "an integrated commercial statement"[38] and that it was, therefore, not entitled to First Amendment protection. *Valentine v. Chrestensen* was cited to support this proposition. Though the commercial speech exception was challenged generally by the newspaper, Powell declined to endorse it in all situations. He simply stated that, at least where the commercial activity is illegal, the First Amendment provides no protection.[39]

---

[32] *Id.* at 55.
[33] 319 U. S. 105 (1943).
[34] 318 U. S. 413 (1943).
[35] 341 U. S. 622 (1951).
[36] *Id.* at 642.
[37] 413 U. S. 376 (1973).
[38] *Id.* at 388.
[39] *Id.*

Two Courts of Appeals decisions have also taken this line. *United States v. Hunter*[40] involved a Civil Rights Act ban on discriminatory advertising. The Fourth Circuit upheld it, distinguishing between "commercial advertising in a business context" and protected speech. *United States v. Bob Lawrence Realty, Inc.*[41] upheld the "anti-blockbusting" provision of the Fair Housing Act of 1968. This provision makes it illegal to falsely spread rumors, in order to lower housing prices, that blacks were moving into a neighborhood. Thus certain kinds of speech are prohibited. The Fifth Circuit cited *Hunter* and *Valentine v. Chrestensen* in justifying its decision. It said, "The federal government may in some circumstances prohibit *purely commercial* speech made in connection with conduct which Congress can permissibly regulate or prohibit."[42] Like *Pittsburgh Press,* this is only a qualified endorsement of the commercial speech exception.

Religious Speech

The Supreme Court has held that not all speech which is attempting to obtain money for the speaker is beyond First Amendment protection. In *Murdock v. Pennsylvania,*[43] a religious group was selling religious pamphlets and trying to convince people to buy religious books. The Court admitted that it was difficult to distinguish between commercial and religious speech, but it said that this was religious speech and, thus, was protected. In *New York Times v. Sullivan,*[44] the National Association for the Advancement of Colored People (NAACP) criticized the Montgomery police commissioner in an advertisement that appealed for funds. The Supreme Court reversed a libel judgment against the *Times* for carrying the ad, despite the fact that the ad was trying to obtain money. Justice Brennan stated in his majority opinion: "The present advertisement, as an expression of grievance and protest on one of the major public issues of our time, would seem clearly to qualify for constitutional protection."[45]

There has been direct opposition to the commercial speech exception in recent years. There were four dissents to the decision in *Pittsburgh Press Co. v. Pittsburgh Commission on Human Relations,*[46] which had relied on *Chrestensen.* Chief Justice Burger concentrated his fire in other directions,[47] but Justice Stewart and Justice Blackmun

[40] 459 F. 2d 205 (CA-4 1972), *cert. denied* 409 U. S. 934 (1972).
[41] 474 F. 2d 115 (CA-5 1973).
[42] *Id.* at 122.
[43] 319 U. S. 105 (1943).
[44] 376 U. S. 254 (1964).
[45] *Id.* at 271.
[46] 413 U. S. 376 (1973).
[47] *Id.* at 393—397.

wanted to limit the commercial speech exception.[48] Justice Douglas, who was a member of the unanimous Court that had first enunciated the commercial speech exception in *Chrestensen,* said, "I believe that commercial materials also have 'First Amendment protection.' "[49] He had attacked *Chrestensen* fourteen years before, in *Cammarano v. United States,*[50] when he stated: "The ruling was casual, almost offhand. And it has not survived reflection."[51]

Commercial Advertising

The current effect of the exception for commercial speech was called into question by the recent Supreme Court decision in *Bigelow v. Virginia.*[52] In that case, a Virginia newspaper editor was prosecuted for publishing the advertisement of a New York abortion referral agency, in violation of a Virginia statute forbidding the encouragement of abortions. The Virginia Supreme Court upheld the editor's conviction on the basis of *Valentine v. Chrestensen*[53] and the commercial speech exception. However, the United States Supreme Court, in a decision by Justice Blackmun, reversed. He interpreted *Chrestensen* as "a reasonable regulation of the manner in which commercial advertising could be distributed,"[54] despite the fact that, in *Chrestensen,* all distribution on public streets was forbidden for commercial advertising, and other types of speech received broad protection. Justice Blackmun further asserted that "commercial advertising enjoys a degree of First Amendment protection."[55] In support of the "legitimacy" of the editor's "First Amendment claim," the Court pointed to the presence of factual statements of public interest in the ad. These mainly concerned the legality of abortions and the absence of a residency requirement in New York.[56] The Court then said that a balancing of interests was appropriate to determine whether this particular ad should receive protection. While the commercial nature could be considered in this process, it did not automatically decide the issue.[57] The Court concluded that the First Amendment interest outweighed the governmental one, and that the advertisement was thus protected.[58] Justice Blackmun appears to be employing the Frankfurter balancing approach

[48] *Id.* at 401, 402 and 404.
[49] *Id.* at 398.
[50] 358 U. S. 498 (1959).
[51] *Id.* at 514.
[52] 95 S. Ct. 2222 (1975).
[53] 316 U. S. 52 (1942).
[54] *Bigelow v. Virginia,* 95 S. Ct. 2222, 2231 (1975).
[55] *Id.* at 2232.
[56] *Id.* at 2232—2234.
[57] *Id.* at 2234, 2235.
[58] *Id.* at 2235, 2236.

in this situation,[59] rather than exempting commercial speech from any First Amendment protection as *Valentine v. Chrestensen* has been interpreted as doing.[60] The dissent charges that the advertisement involved was "a classic commercial proposition";[61] there is much to support this analysis. After all, it solicited customers for a profit-making business. And though it might be considered as conveying some information of public interest, surely many ads now supply as much, or could easily be made to do so. Thus, *Bigelow* casts much doubt on the continued viability of the commercial speech exception, at least as it is applied to a considerable amount of commercial speech.

Balancing Approach

Though governmental authority is in some ways limited by the *Bigelow* decision, the balancing approach that it requires for commercial speech is still useful in controlling false advertising and misbranding. Surely, the need to protect the public from these practices would far outweigh any First Amendment interest in continuing them. Thus, *Bigelow* has done considerable damage to the commercial speech exception, but it does not seem to have undermined vital consumer protection legislation.

It would not be wise, however, to rest the constitutionality of the laws against false advertising and misbranding solely on the basis of this balancing approach. The "clear and present danger" test, not the Frankfurter balancing concept, has been the dominant analysis of the Court in freedom of press cases.[62] And balancing to determine First Amendment rights is certainly contrary to the absolutist position of Justice Black and Justice Douglas.[63] *Bigelow* limited governmental authority. We should not assume that Justice Douglas, for instance, would join an opinion justifying government intervention on the basis of a balancing approach, simply because he joined in *Bigelow*. It may be that the weighing of interests is the approach that the Court is to take in cases of commercial speech, without regard to the approach to be taken in other types of cases. However, the Court said, "To the extent that commercial activity is subject to regulation, the

[59] See *Dennis v. United States*, 341 U. S. 494, 525 (1951).

[60] See *Pittsburgh Press Co. v. Pittsburgh Commission on Human Relations*, 413 U. S. 376 (1973); *Murdock v. Pennsylvania*, 319 U. S. 105 (1943); *Jamison v. Texas*, 318 U. S. 413 (1943).

[61] *Bigelow v. Virginia*, 95 S. Ct. 2222, 2237 (1975).

[62] See *Brandenburg v. Ohio*, 395 U. S. 444 (1969); *Dennis v. United States*, 341 U. S. 494 (1951); and B. Schwartz, *Constitutional Law* (1972), pp. 264—265.

[63] See *Brandenburg v. Ohio*, 395 U. S. 444, 456 (1969).

relationship of speech to that activity may be one factor, among others, to be considered in weighing the First Amendment interest against the governmental interest alleged."[64] This indicates that the commercial feature of expression may be part of the weighing process, not that it invokes that process. Because of this uncertainty, it is important to seek a broader-based justification for regulating false advertising and misbranding.

III. Constitutional Protection for False Statements

Another possible justification for federal control of advertising and branding is found in *Gertz v. Welch*,[65] which upheld libel verdicts for the defamation of private individuals. In the course of his majority opinion, Justice Powell said that "the erroneous statement of fact is not worthy of constitutional protection."[66] Since misbranding and false advertising involve false statements, no constitutional test, such as clear and present danger, would have to be applied under the *Gertz* rationale. It is true that, even under *Gertz*, some false statements are protected, but according to Powell, this is to avoid deterring important speech.[67] As *New York Times v. Sullivan*[68] indicated, fear of being wrong or of not being able to prove that you are right can discourage perfectly accurate statements. However, such a "chilling effect" is not likely in regard to advertising and branding. False advertising has been controlled since 1914, yet, in 1966, sixteen and one half billion dollars was spent on advertising.[69] Federal regulation seems not to have deterred that many true statements. However, there is judicial expression contrary to Powell's position. Justice Brennan stated in *NAACP v. Button* that, "The Constitution protects expression and association without regard to . . . the truth, popularity or social utility of the ideas and beliefs which are offered."[70] The two positions might be distinguished because Powell was talking about statements of fact; Brennan, about "ideas and beliefs." But a statement as to the curative powers of vitamins, though a statement of fact, is also one of belief. After all, can we really "know" whether something prevents disease in the way that we know that two plus two equals four? Many "statements of fact" in advertisements are, in a sense, "beliefs" too.

[64] *Bigelow v. Virginia*, 95 S. Ct. 2222, 2234, 2235 (1975).

[65] 418 U. S. —, 41 L. Ed. 2d 789 (1974).

[66] 418 U. S. —, 41 L. Ed. 2d 789, 805, 806 (1974).

[67] *Gertz v. Welch*, 418 U. S. —, 41 L. Ed. 2d 789, 806 (1974); See *New York Times v. Sullivan*, 376 U. S. 254, 279 (1964).

[68] 376 U. S. 254 (1964).

[69] P. Samuelson, *Economics* (1970), p. 77.

[70] 371 U. S. 415, 445 (1963).

In any case, the current position of the Court is that "there is no constitutional value in false statements of fact"[71] and this provides a basis for control of misbranding and false advertising. But because of the recent origin and limited application of this principle—Powell cited no authority to support it—and the possible conflict with another holding of the Court,[72] it would be best not to rely on it as the sole basis for control of misbranding and false advertising.

IV. The Application of Traditional First Amendment Tests

If consumer protection legislation does concern speech within the First Amendment, what effect does the Amendment have? Consumer protection should have little trouble passing the balancing test that Justice Frankfurter enunciated in *Dennis v. United States*.[73] The interest in sheltering the public from being misled is substantial,[74] while the value of false advertising is considered slight, even by those who value commercial speech in general.[75] Whether it passes the traditional "clear and present danger" test is a somewhat different question. To meet this test, the danger must be one which the legislature has a right to prevent.[76] The government has the right to protect consumers from being misled by merchants.[77] It seems indisputable that making false statements about a product will cause some people to immediately buy the product, and under a mistaken impression. There would be no reason to advertise and label products if it did not help to sell them. Thus, there is a "clear and present danger that . . . (the regulated words) will bring about the substantive evils that Congress has a right to prevent."[78] However, there is difficulty with the opinion of Justice Brandeis in *Whitney v. California*.[79] It says that the evil apprehended must occur before there is time for full discussion. Arguably there often is time for full discussion of the issues involved in product advertising. In fact, in some circumstances, medical and scientific advertising and labeling cannot be suppressed at all unless they are contrary to knowledge which has been "crystallized in the crucible of

[71] *Gertz v. Welch*, 418 U. S. —, 41 L. Ed. 2d 789, 805 (1974).

[72] See *New York Times v. Sullivan*, 376 U. S. 254, 271 (1964); and *NAACP v. Button*, 371 U. S. 415, 445 (1963).

[73] 341 U. S. 494, 525 (1951).

[74] *Kordel v. United States*, 335 U. S. 345 (1948).

[75] Redish, "The First Amendment in the Marketplace: Commercial Speech and Values of Free Expression," 39 *Geo. Washington L. Rev.* 429, 458 (1971).

[76] *Schenck v. United States*, 249 U. S. 47, 52 (1919).

[77] *Kordel v. United States*, 335 U. S. 345, 349 (1948).

[78] *Schenck v. United States*, 249 U. S. 47, 52 (1919).

[79] 274 U. S. 357 (1927) (concurring opinion).

experience."[80] Thus, there must be time for discussion before government may act in these cases. And there is nothing in the statutes to indicate that the ban will be lifted when there has been full discussion.[81] So consumer protection, at least in large areas, does not seem to pass the "clear and present danger" test as Brandeis articulated it. It is even more difficult to fit consumer protection into the incitement analysis used in *Brandenburg v. Ohio*.[82] If the majority opinion tells us anything, it is that any penalty on speech is put to a stiff test.[83] But, in their concurring opinions, Justice Black and Justice Douglas rejected "clear and present danger"[84] altogether and maintained that only when "speech is brigaded with action" may it be punished.[85]

Prior Restraint

The constitutional limitations on prior restraint raise another problem. *New York Times v. United States*[86] held that any prior restraint bears a heavy presumption against it. Some justices indicated that they would permit prior restraint only in very limited circumstances; Justices Black and Douglas opposed prior restraints in all circumstances. Yet both the Federal Food, Drug and Cosmetic Act[87] and the FTC Act[88] authorize injunctions which can be directed against expression.

The First Amendment tests such as "clear and present danger" and the burdens on prior restraint are applied to political speech, for the most part.[89] It is quite possible that such ideas as Brandeis' restriction of supression to an emergency[90] are tailored for political speech and that they should not be literally applied to other types of expression. In any case, there seems to be a substantial problem with treating advertising and labeling exactly like political speech.

---

[80] *Reilly v. Pinkus*, 338 U. S. 269, 274 (1949). The *Pinkus* decision application appears to be rather narrow now. Under the "new drug" provisions of the Federal Food, Drug and Cosmetic Act, a "new drug" may not be sold until a permit is obtained, and the burden is on the producer to prove that the product will do what is said for it before a permit may be obtained.

[81] See Federal Food, Drug and Cosmetic Act, 21 U. S. C. Secs. 321—392; FTC Act, 15 U. S. C. Secs. 41—58.

[82] 395 U. S. 444 (1969).

[83] *Id.*

[84] *Id.* at 450, 452.

[85] *Id.* at 456.

[86] 403 U. S. 713 (1971).

[87] 21 U. S. C. Sec. 332 (1970).

[88] 15 U. S. C. Sec. 45 (1970).

[89] See *Brandenburg v. Ohio*, 395 U. S. 444 (1969); *Dennis v. United States*, 341 U. S. 494 (1951); *Whitney v. California*, 274 U. S. 357 (1927); *Gitlow v. New York*, 268 U. S. 652 (1925); *Schenck v. United States*, 249 U. S. 47 (1919).

[90] See *Whitney v. California*, 274 U. S. 357 (1927).

V. Advertising and Labeling as "Verbal Acts"

Even if none of the previously discussed theories avoid a clash between consumer protection legislation and the First Amendment, there is another basis for upholding these laws.[91] Advertising and labeling may be thought of as "verbal acts." They are a means of making a sale and, therefore, of obtaining the consumer's money. They are a part of selling a product, just as statements of how much money a person is betting are a part of gambling.[92] And "verbal acts," such as those involved in gambling, may be controlled as part of controlling the overall activity.[93] This was the clear holding of the Supreme Court in *Giboney v. Empire Storage Co.*[94] That case involved the arrest of several persons for picketing in violation of a court injunction. The defendants were union peddlers, picketing a supplier to force him not to sell to nonunion peddlers. The picketers' activity was contrary to state law, but they claimed that the words on their signs were constitutionally protected. However, Justice Black said:

> "It has never been deemed an abridgement of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed. . . . Such an expansive interpretation of the constitutional guarantees of speech and press would make it practically impossible ever to enforce laws against agreements in restraint of trade as well as many other agreements and conspiracies deemed injurious to society."[95]

The unanimous decision was joined in by Justice Douglas. Neither he nor Justice Black are noted for taking the First Amendment lightly. Justice Douglas only favors suppressing speech which is "brigaded with action." But a "verbal act" is "brigaded with" or classified with[96] action, so its suppression meets even this stringent test.

Holmes' famous example of falsely shouting fire in a crowded theater[97] involves a verbal act. The speaker is not really expressing himself; he is murdering someone in the crowd by causing him to be trampled to death. The words that he utters are merely vehicles used

---

[91] *E. F. Drew & Co. v. FTC*, 235 F. 2d 735 (CA-3 1955); *American Medicinal Products v. FTC*, 136 F. 2d 426 (CA-9 1943).

[92] B. Schwartz, *Constitutional Law* (1972), p. 263.

[93] *Id.* This rationale may be applicable to the "new drug" provisions of the Federal Food, Drug and Cosmetic Act, where the purpose is to keep "new drugs" off the market until their safety and efficacy have been positively established.

[94] 336 U. S. 490 (1949).

[95] *Id.* at 502.

[96] See *Webster's New World Dictionary*, World Publishing Co., Cleveland, 1962, p. 182. (The verb "brigade" is defined as "1. to gather into a brigade. 2. to sort into groups; classify.")

[97] *Schenck v. United States*, 249 U. S. 47, 52 (1919).

to carry out the crime.[98] In the same way, advertisements and labels are merely vehicles used to make a sale.

Cases of Fraud

An even closer parallel to misbranding and false advertising is found in the statute against fraud. In cases of fraud, as with misbranding and false advertising, the speaker is inducing the listener to pay him money by giving him incorrect information. In another decision by Justice Black, *Donaldson v. Read Magazine,*[99] the Supreme Court held that fraud was not constitutionally protected. The Court permitted the government to suppress fraudulent expression by refusing to have the Postal Service deliver it. Justice Black specifically rejected a contention that the First Amendment protected such material. It is true that fraud involves intent to deceive, whereas this is not a necessary element under parts of the Federal Food, Drug and Cosmetic Act and of the FTC Act. However, the government does define crimes without *mens rea.*[100] And whether or not there was intent to deceive applies to the character of the sale, not whether the branding and advertising are a part of the act of selling. It might be argued that in cases where products are seized under consumer protection laws, there is, in fact, no completed sale. However, in *Donaldson v. Read Magazine*, there was no actual fraud, because the government prevented delivery of the material. But it was still within the government's power to suppress.

The reasons that verbal acts may be controlled are not difficult to see. Gambling, fraud, extortion and blackmail all are perpetrated principally by means of verbal acts.[101] To give protection to verbal acts would be to legalize these pursuits. False pretenses,[102] extortion[103] and blackmail[104] were all common law crimes when the Congstitution was written but there is no evidence that the founders intended to do away with any of them. If there is any value to the words uttered in carrying them out, it certainly is outweighed by

[98] B. Schwartz, *Constitutional Law* (1972), p. 263.

[99] 333 U. S. 178, 191 (1948).

[100] See *United States v. Park*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 38,018, 95 S. Ct. 1903 (1975); *Morissette v. United States,* 342 U. S. 246 (1952); *United States v. Dotterweich,* 320 U. S. 277 (1943).

[101] B. Schwartz, *Constitutional Law* (1972), p. 263.

[102] R. Perkins, *Criminal Law* (1969), p. 297; *Durland v. United States,* 161 U. S. 306 (1896).

[103] R. Perkins, *Criminal Law* (1969), p. 367; 4 *Blackstone's Commentary* 141.

[104] R. Perkins, *Criminal Law* (1969), p. 372; 4 *Blackstone's Commentary* 215.

the harm that they do society. This also can be said of misbranding and false advertising.

VI. Judicial Pronouncements of Constitutionality

The Supreme Court has not spoken squarely on the First Amendment ramifications of controlling misbranding and false advertising. However, *Seven Cases of Eckman's Alterative v. United States*[105] dealt with a Fifth Amendment (due process) challenge to the fraud provision of the Food and Drug Act of 1906.[106] In the course of attacking the Act's validity, it was asserted that the manufacturer had a right to express his opinion on his product's worth. Justice Hughes, who was not insensitive to First Amendment problems,[107] rejected this argument. At the least, Justice Hughes asserted, the manufacturer had no constitutional right to lie about his opinion.[108] Two Court of Appeals cases have ruled on the point. *E. F. Drew & Co. v. FTC*[109] held that "Congress can prohibit or control misleading advertising under the postal fraud statutes . . . or under its commerce power . . . without deprivation of First Amendment rights. There is no constitutional right to disseminate false or misleading advertisements."[110] The decision cited *Donaldson v. Read Magazine* and *American Medicinal Products v. FTC* in support of this proposition.[111] In *American Medicinal Products v. FTC*,[112] the Ninth Circuit said,

outweighing the value of misbranding and false advertising. Even if the more stringent "clear and present danger" or "absolutist" tests are applied, the theory of *Gertz v. Welch* or of "verbal acts" can save consumer protection legislation in this area. Though the doctrine of *Gertz* that false statements are of no constitutional value is of apparently recent origin and seems in conflict with an earlier decision, it is now the law. And in any case, false advertising and misbranding can be classified as verbal acts, which even Justice Black and Justice Douglas said were within the government's power to control. Thus, reasonable laws against misbranding and false advertising should not fall to the First Amendment. **[The End]**

ADMINISTRATIVE PRACTICE AND PROCEDURE RULES REVOKED AND PROPOSED

Regulations governing the administrative practices and procedures of the Food and Drug Administration (FDA) have been proposed by the Agency and the final regulations that were issued by the FDA in May 1975 have been revoked. In July 1975, a federal district court issued an order permanently enjoining the FDA from issuing the regulations as final without first publishing them as a proposal pursuant to the provisions of the Administrative Procedures Act.

The FDA is of the opinion that the court's action is in error, but has decided that rather than attempt to obtain a reversal of the decision, it will issue the regulations as proposed rules with an additional opportunity for comment. The Agency said it interprets the court's order as permitting it to follow the procedures in carrying out its activities, even without the regulations.

To avoid controversy, the FDA has included the May 27, 1975 notice, including the bulk of the preamble, in its new notice of proposed regulations. Although the regulations are proposed as a single document, the FDA may either issue them in final form as one document or as several documents published at different times.

Interested persons have until October 3, 1975 to file comments on the proposed regulations. Comments submitted in response to the May 27 order need not be resubmitted.

Revoked 21 CFR Parts 2 and 5,
CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 3800 and 4950

Some Legal Aspects of Providing a Sufficient Food Supply for a Hungry Population

By STEPHEN H. McNAMARA

Mr. McNamara Is Associate Chief Counsel for Food in the General Counsel's Office in the Food and Drug Administration.

MUCH IS SAID concerning the challenge of developing nutritious new foodstuffs and otherwise providing a food supply which is sufficient to feed a hungry and growing world population. In this context, as a lawyer for the Food and Drug Administration (FDA), I will discuss some of the basic principles and current developments in the law which must be encountered in meeting this challenge.

I. Introducing a New Food Substance; Premarketing Clearance for Safety by the FDA

A manufacturer who develops a substance which it believes to be a nutritious new food ingredient is not free simply to begin extolling its virtues and selling it in the United States. Any new food ingredient is likely to be a "food additive" within the meaning of the law. For the purpose of assuring safety, the Federal Food, Drug and Cosmetic Act[1] requires that the FDA approve the use of any substance which is a food additive *before* it may be employed as a food ingredient. The Act defines a food additive as including:

"any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958,

[1] 21 U. S. C. 301 *et seq.* While the Act vests its food additive functions in the Secretary of Health, Education and Welfare, all functions vested in the Secretary under the Act have been delegated to the Commissioner of Food and Drugs, who heads the FDA. 21 CFR 2.120(a)(1).

through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use. . . ."[2]

A food additive legally may not be used unless a regulation is first promulgated by the FDA permitting its use.[3] Such a regulation may restrict the quantity of use, impose qualitative requirements, prescribe methods of manufacture necessary to assure safety and, in addition, impose labeling requirements necessary for safe use. Any use of a food additive which is not consistent with the terms of an existing food additive regulation causes the subject food to be deemed to be adulterated[4] and can lead to criminal prosecution[5] or an injunction proceeding[6] against the responsible person as well as to seizure and destruction[7] of the food.

Anyone may file a food additive petition with the FDA requesting the establishment of a food additive regulation. Detailed requirements for such a petition appear in the *Code of Federal Regulations*.[8] The petition must document the safety of the proposed use; considerable delay and expense may be occasioned by the need for convincing safety data. A good example of a food additive regulation governing use of a nutritious new foodstuff is 21 CFR 121.1202, which deals with whole fish protein concentrate.

GRAS Substances

Pursuant to the Act's definition of a food additive, if the intended use of a food ingredient is generally recognized as safe (GRAS), the substance is not a food additive and no food additive regulation is required. The FDA has promulgated regulations listing many of the substances which are GRAS.[9] If a manufacturer believes that a substance is GRAS but does not find it listed in the Agency's GRAS regulations, it may petition the FDA to publish a regulation affirming the GRAS status of the substance, that is, to recognize formally that it is not a food additive. Alternatively, the manufacturer may assume the risk of using the substance without an approving regulation. In that case, if the FDA does not agree with the manufacturer's assessment of the GRAS status of the substance, regulatory action (criminal prosecution, injunction proceeding or civil seizure action) may be initiated by the Agency and the status of the substance fought out in court.

---

[2] 21 U. S. C. 321(s).
[3] 21 U. S. C. 348.
[4] 21 U. S. C. 342 (a)(2)(C).
[5] 21 U. S. C. 331, 333.
[6] 21 U. S. C. 332.
[7] 21 U. S. C. 334.
[8] 21 CFR 121.51.
[9] 21 CFR 121.40, 121.101, 121.104, 121.105.

The FDA has recently proposed to establish new regulations to determine whether a food ingredient will be subject to food additive status, thereby requiring a food additive regulation prior to use.[10] Among other things this proposal provides that "[g]eneral recognition of safety [*i.e.*, exemption from food additive status] requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of food ingredients."

The proposal further states that general recognition of safety, that is, exemption from food additive status, through scientific procedures must ordinarily be based upon published studies (which may be corroborated by unpublished studies and other data and information).

The proposal also provides that a food ingredient of natural biological origin which has been widely consumed for its nutrient properties in the United States prior to January 1, 1958 without known detrimental effects and which is subject only to conventional processing as practiced prior to January 1, 1958 and for which no known safety hazard exists, will ordinarily be regarded as GRAS without specific listing in the regulations.

Under the proposal, an asserted history of safe food use outside the United States is not, by itself, sufficient to establish general recognition of safety through experience based on common use in food. Thus, for example, a sweetener with an asserted history of safe food use in West Africa would nevertheless be classified as a food additive if offered for use in the United States.

II. Labeling Restrictions

Even if no food additive issues are raised by the development of a new food, issues involving its proper labeling may cause a manufacturer to delay marketing pending resolution with the FDA. Furthermore, the nature of the labeling ultimately required may have a substantial effect upon the marketability and, thus, upon the scope of availability and price of a product. Some current developments are of particular interest.

A. Plant Protein Products: Rule-making is currently pending regarding the proper names for plant protein products, which may be used as protein-providing extenders or replacements for meat, seafood, poultry, eggs or cheese.[11] This proposed labeling regulation

[10] Proposed amendment of 21 CFR 121.3, 39 *F. R.* 34194 (Sept. 23, 1974).

[11] Proposed establishment of 21 CFR 102.22, 39 *F. R.* 20892 (June 14, 1974).

first establishes the proper names to be used for the various types of plant protein products and then goes on to establish minimum nutritional standards which must be met by such products. Among other things, the proposal sets forth minimum protein content and minimum protein quality criteria for all plant protein products and also requires that such foods contain specified levels of certain vitamins and minerals.

B. Imitation Foods: The Federal Food, Drug and Cosmetic Act provides that a food which is an "imitation" of another shall clearly be labeled as such.[12] Regardless of a food's nutritional merit, labeling as "imitation" has a substantial adverse impact on marketing because of the term's connotations of inferiority.

Substitute Foods

The FDA, in part pursuant to a recommendation of the 1969 White House Conference on Food, Nutrition and Health,[13] has concluded that the "imitation" section of the Act should not be interpreted so as to become a trade barrier which would present a serious obstacle to the development and marketing of modified products with improved nutritional content. Indeed, in light of the connotations of inferiority applicable to the term "imitation," it would be misleading to consumers to require that a new substitute food be so labeled if such a food is nutritionally equivalent, or superior, to its traditional counterpart. Accordingly, in 1973, the FDA promulgated a regulation providing that a new food which is a substitute for and resembles another food need not be labeled as an imitation if: (1) it is not nutritionally inferior to the food for which it substitutes and which it resembles; and (2) it bears a distinctive name which accurately identifies or describes its basic nature.[14]

In part, the Agency sees this new regulation as a "carrot" to encourage that new substitute foods be formulated so as to be nutritionally equivalent to their traditional counterparts. A food sold as an "imitation" need not be nutritionally equivalent. Interestingly, a consumer group is attacking the regulation in court. The group, the Federation of Homemakers, believes that all substitute foods should be labeled as imitations of the traditional foods for which

[12] 21 U. S. C. 343(c).

[13] White House Conference on Food, Nutrition and Health (1969), Final Report, p. 120.

[14] 21 CFR 1.8(e), published as a final regulation in 38 *F. R.* 20702 (Aug. 2, 1973). The proposed regulation was published in 38 *F. R.* 2138 (Jan. 19, 1973).

they substitute and which they resemble, except when the FDA promulgates a standard of identity for a new substitute food. A United States district court upheld the Agency's regulation and dismissed the Federation's suit,[15] but the Federation filed a notice of appeal.

An example of the ways in which the FDA's regulation defining "imitation" is to the advantage of the consumer is provided by reference to the new egg-substitute products which are now appearing on the market. Under the Federation of Homemakers' approach to the definition of the term "imitation," a liquid egg substitute resembling beaten eggs and offered for use in place of eggs would be labeled as "imitation eggs." While this term does effectively communicate to the consumer that the product is not eggs, it does nothing else. Furthermore, an imitation food sold as such need not be fortified with vitamins, minerals or protein so as to be nutritionally equivalent to the traditional food. Nor is it required to bear any nutrition labeling.

Consider instead the effect of the FDA regulation. Rather than selling an egg-substitute product with the relatively uninformative "imitation" labeling, a manufacturer may avoid use of that terminology if: (1) the product is fortified with protein, vitamins and minerals as needed to assure nutritional equivalence with eggs; and (2) the product is labeled with a name which effectively and accurately conveys to the consumer the nature of the product. An example of such a name is "vegetable derived egg substitute containing no cholesterol," assuming, of course, that it is a fair and accurate description of the product. Furthermore, note that by adding nutrients (required in order to avoid nutritional inferiority), the manufacturer will trigger the FDA's nutrition labeling regulation,[16] which will require a detailed statement on the label of the nutritional value of the product.

III. Aesthetic Considerations

Even if a food is nutritionally useful and accurately labeled, it may nevertheless encounter legal difficulties because of aesthetic considerations.

Section 402(a)(3) of the Federal Food, Drug and Cosmetic Act provides that a food shall be deemed to be adulterated "if it consists in whole or in part of any filthy . . . substance, or if it is

[15] *Federation of Homemakers v. Schmidt*, Civil Action No. 2113-73, DC DofC. Summary judgment for defendants was entered on October 29, 1974.

[16] 21 CFR 1.17.

otherwise unfit for food."[17] Approval for food use of whole fish protein concentrate was delayed for a considerable time in part because of objections that such a product would be adulterated pursuant to Section 402(a)(3) by including the "viscera, intestines, and other portions of fish that are not normally used for food."[18] This objection, of course, was essentially aesthetic.

Our traditional perceptions of "filth" and "unfit for food" may be expected to change as the world's food supply shrinks in relation to the world's population. Aesthetic considerations increase costs and reduce available food supplies, but are so ingrained in us that they cannot be ignored. If, for example, animal excrement is a useful source of nutritious and needed food ingredients and can be processed so as to impose no risks to health, should such a source of food be banned for aesthetic reasons? This is not an idle hypothetical issue. The FDA is currently considering whether chicken feed should be permitted to consist in part of processed chicken excrement. As time goes by, it is not at all inconceivable that petitions will be presented to the Agency on behalf of useful and nutritious foods for human use which will seriously challenge our traditional concepts of filth and fitness for food.

Whole Fish Protein Concentrate

In this regard, the food additive regulation for whole fish protein concentrate,[19] again becomes pertinent. According to this regulation, the natural fluorine content of such concentrate may not exceed a specified limit though necessary to prevent causing cosmetic disfigurement of the teeth of children. The day may come when the FDA will be asked to respond to a need for more sources of protein by permitting use of concentrate with a higher fluorine level, thereby accepting some risks of mottled teeth.

Indeed, we may ultimately face many other changes in our notions about filth and the fitness of our food supply if we wish to have sufficient food in future generations. The FDA's current regulatory action level for wheat contaminated by rodent excreta pellets in spite of handling and storage in a sanitary manner consistent with current good manufacturing practice is one pellet per pint of

[17] 21 U. S. C. 342(a)(3).

[18] See preamble to order establishing a food additive regulation for whole fish protein concentrate, 21 CFR 121.1202, 32 *F. R.* 1173 (Feb. 2, 1967).

[19] 21 CFR 121.1202.

the grain.[20] When the FDA made public this and all of its other defect action levels for natural or unavoidable defects in food which present no health hazard, the levels were subjected to considerable abuse by the press and various consumer groups. Without attempting to speak to the merits of any particular level, it is nevertheless appropriate to observe that as we insist upon purer and cleaner food and reject that which does not meet our standards, we thereby reduce the available food supply and increase its cost. Where safety is not a factor, at some point considerations of aesthetics must give way to considerations of human need.

Consider as well the recurring "blending" issue. When a lot of food with a contaminant in excess of a defect action level is detected, it is a well-established FDA rule to refuse to permit such a food to be mixed with another lot of food with a low level of contaminant to produce a conglomerate lot below the defect action level.[21] Particularly where the level has been exceeded through no fault of a manufacturer or processor (and assuming that no health hazard exists), it may become more difficult in the future to justify condemnation of food which violates a defect action level when such food might be blended with other food to produce a level of contaminant below the action figure.

IV. Standards of Identity

The FDA is authorized by the Federal Food, Drug and Cosmetic Act to establish a "definition and standard of identity" for a food when such action "will promote honesty and fair dealing in the interest of consumers."[22] The Agency has used this authority

[20] *Current Levels for Natural or Unavoidable Defects in Food for Human Use that Present No Health Hazard,* Office of the Assistant Commissioner for Public Affairs, FDA, fifth revision, March 1, 1974. Regulations governing the issuance and amendment of these defect action levels appear at 21 CFR 128.10. Of particular importance concerning the effect of these levels, 21 CFR 128.10(c) provides as follows:

"Compliance with defect action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act [21 U. S. C. 342(a)(4)] that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this part that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection indicating such a violation renders the food unlawful, even though the amounts of natural or unavoidable defects are lower than the currently established action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce natural or unavoidable defects to the lowest level currently feasible."

[21] 21 CFR 128.10(d).

[22] 21 U. S. C. 341; 21 CFR 2.120 (a)(1).

to establish standards of identity for "enriched" foods, thereby assuring a minimum nutritional quality for such foods. For example, pursuant to evidence of a lack of sufficient iron intake in the diet of certain segments of the American public, the FDA recently took action to increase the level of iron in enriched flour and in enriched bread.[23] Rule-making has not been completed because of objections from persons who assert that the increased level of iron might be dangerous for certain other segments of the population.[24] A formal administrative hearing has been held on this issue, but the Commissioner of Food and Drugs has not yet issued a final order. In any event, the standards of identity for enriched bread and enriched flour, which require the addition of specified amounts of thiamine, riboflavin, niacin and iron, are a good example of use of the legal mechanism of a standard of identity to establish a product which has improved nutritional value. In the future if our traditional food sources of certain nutrients should become so scarce and so expensive as to be unavailable to many (for example, meat and milk products as a source of protein), it would be possible (assuming technological feasibility) to revise or establish standards of identity for other foods which remain pervasively consumed and relatively inexpensive so as to require the addition of needed nutrients.

V. General Principles Governing the Addition of Vitamins, Minerals and Protein to Foods

The FDA has recently proposed new rules to govern the addition of vitamins, minerals and protein to foods.[25] The proposal is an attempt to articulate comprehensive general principles to govern the addition of nutrients to food products.

Among other things, the proposed regulation would sanction addition of vitamins, minerals and protein to a food to "balance" the caloric contribution of the food. For example, if a serving of a food which is fortified provides five percent of the normal daily caloric intake (estimated to be 2800 kilocalories for the purposes of this proposal), such such, under this proposal, would be required to contain five percent of the U. S. Recommended Daily Allowance of protein and of nineteen essential vitamins and minerals.

The proposed regulation would also sanction the addition of a vitamin, mineral or protein (without addition of other nutrients) where the addition is necessary to restore a nutrient shown, by adequate scientific documentation, to be lost in processing.

---

[23] 38 *F. R.* 28558 (Oct. 15, 1973).
[24] 39 *F. R.* 5188 (Feb. 11, 1974).
[25] 39 *F. R.* 20900 (June 14, 1974).

The proposal would also provide general principles to determine whether a regulation should be promulgated to authorize the addition of a nutrient to a food. For example, establishment of a standard of identity for a nutrient-enriched food would be appropriate if all of the following conditions are met:

(1) the intake of the nutrient is below a desirable level in the diets of a significant number of people;

(2) the food to which the nutrient is added is generally consumed by a significant segment of the population in need;

(3) the amount of the nutrient added makes a significant contribution to the diet of the population in need;

(4) the added nutrient is stable in the food under customary conditions of storage and use;

(5) the added nutrient is physiologically available from the food; and

(6) there is a reasonable assurance that an excessive intake which could reach a toxic level will not occur.

VI. Export

A final observation, concerning food destined for export, should be included.

Under certain conditions, it is permissible to export a food which may not legally be sold within the United States. The Federal Food, Drug and Cosmetic Act provides that:

"A food . . . intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export."[26]

Thus, American aesthetic concerns, or even the FDA's conclusions regarding safety, do not prevent the delivery of food products to other nations which have different criteria of acceptability. For example, if another nation with greater present needs for dietary sources of protein permits the use of whole fish protein concentrate with a higher level of fluorine than is allowed by the FDA's food additive regulation, an American firm can prepare and ship such a product without violating the Federal Food, Drug and Cosmetic Act.

In the foregoing remarks I have tried to discuss some basic principles and current developments in the law bearing upon the problem of providing a sufficient food supply for a growing population. I hope this survey has been of some interest and use. **[The End]**

[26] 21 U. S. C. 381(d).

How to Let in the Sunshine Without Getting Burned: Protecting Your Rights Before Advisory Committees

By JANE LANG McGREW

Ms. McGrew Is a Member of the Law Firm of Steptoe and Johnson.

DESPITE HUMAN EXPERIENCE to the contrary, legal scholars have insisted for several centuries that where there is a right, there is also a remedy. However, the lack of recourse to enforce a right has frequently resulted in the most innovative approaches to problem-solving. One such example is provided by the 19th century Colorado state judge who wished to dissolve his marriage but found no divorce laws on the books. Taking matters into his own hands, he drafted a quitclaim deed divesting himself of all right, title and interest to his erstwhile wife "plus all appurtenances constructed thereon."

You may have already found that a similar degree of inventiveness is required to deal with problems presented by Food and Drug Administration (FDA) advisory committees where established remedies are hard to come by. Your problems will not be over at the end of my presentation, but I hope you will have a better notion of how to get along on this frontier.

Advisory Committee Participation

Notwithstanding my profession, it is not my intention to turn FDA advisory committees into courtrooms. Advisory committees are established and utilized for the sole purpose of offering the FDA advice or recommendations, not legal arguments.[1]

In order to formulate this advice, however, the committees need input from the industry, the consumer and the scientific and medical

[1] Federal Advisory Committee Act (FACA), 5 U. S. C. App. I, Sec. 3(2).

communities. Despite this obvious dependency, Congress gave advisory committees no means, other than the cooperation of concerned parties, to secure the necessary input. Participation in the advisory committee process is thus wholly optional in the sense that there are no subpoenas or complaints to compel a response.

The option is essentially theoretical, however. As a practical matter, advisory committee conclusions form the basis for FDA decisions, as the 1973 Supreme Court decisions recognized.[2]

For this reason, common sense and good judgment, rather than legal obligations, should guide the decision as to participation in advisory committee proceedings.

The industry's experience with FDA advisory committees should also weigh in this decision. Generally, the experience has been good. There has been no lack of opportunity to present data before the 64 committees in existence as of the end of 1974—a year which saw the creation of seven new committees and the termination of eleven others. Little skepticism has been expressed regarding committees' motivations, and little reluctance to participate is evident in either the industry or the public. Both are healthy signs for the process.

Nevertheless, the industry's experience with these committees has not been without problems. The source of most of these problems lies in the Federal Advisory Committee Act (FACA)[3] which dovetails with the equally troublesome Freedom of Information (FOI) Act.[4] The pervasive difficulty is that Congress created numerous statutory rights but few remedies, thus leaving it to the players, the industry, the consumer groups, the FDA, the Congress and the committees to make and enforce their own rules to the best of their ability.

Committee Balance

One of these rights without remedies is derived from the FACA requirement that the membership advisory committee "be fairly balanced in terms of the points of view represented, and the functions to be performed by the advisory committees."[5]

Now views are inherently difficult to balance. It is easier to think of balance in the context of more perceptible criteria, for example, race, sex or geographic distribution. Thus, while proposed Department of Health, Education and Welfare (HEW) rules say that "No strict

[2] See, for example, *Weinberger v. Hynson, Westcott and Dunning, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,930, 412 U. S. 609, 614-15 (1973); *USV Pharmaceutical Corp. v. Weinberger*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,931, 412 U. S. 655, 657 (1973).

[3] 5 U. S. C. App. I.

[4] 5 U. S. C. Sec. 552.

[5] FACA, 5 U. S. C. App. I, Sec. 5(b)(2) and (c).

rule of proportional representation of various types of groups is applicable,"[6] members are selected with a view to assuring that no discrimination could be inferred from the profile of the committee.

The tendency has also been to equate balanced views with "no views at all," by reading this provision of the FACA together with the conflict of interest statutes.[7] From this perspective, participation in private industry through employment or research grants, or as an investigational new drug/new drug application (IND/NDA) investigator, can disqualify a person from membership on a committee where the potential for conflict may exist.[8] Yet, neither the "balance" nor the "conflict" criteria take into account more subtle influences on committee members' views, such as the prescribing practices of a physician member or personal experience with the drug in question.

The FDA deals with the visible signs of bias and balance in selecting members. It applies the balance requirement to assure that the needed kinds of expertise are available to consider the questions before the committee. However, expertise in carcinogenesis may not equip a person to judge the benefit-risk ratio with respect to a particular drug with some potential for producing cancer.[9] The need for expertise can be met by obtaining the input of outside experts; the need for good and balanced judgment can only be met from within the committee. Thus, it would be unproductive, if it were not infeasible, to implement the balance requirement by composing a committee of medical practitioners or researchers from every conceivable speciality.

It should be noted that the FDA's choice of advisory committee members has not been widely criticized. It is, however, a source of concern with the potential for serious dissatisfaction. Should that potential materialize, various courtroom remedies can be imagined. But, frankly, any such remedies are highly speculative and impractical. More realistic protection may be sought through FDA procedures for nomination and, in some cases, election of committee members. While these procedures do not provide any recourse against imbalance or any ultimate assurance of balance, they are probably the best insurance that can be had.

Public Access v. Privacy

One witness suggested during the Fountain Subcommittee hearings last year that openness in advisory committee proceedings is the

[6] 40 *F. R.* 3713 (Jan. 23, 1975).

[7] 18 U. S. C. Secs. 207 (disqualification of former federal employees) and 208 (disqualification of persons with financial interest).

[8] Fountain hearings at 245.

[9] See, for example, Fountain hearings at 435-436.

safety factor which protects against covert bias.[10] There is a simple appeal to this theory which, in post-Watergate days, may find many adherents, and I don't mean to denigrate it. However, openness compromises privacy, another concept which deserves respect. Congress tried to meld principles of openness with principles of privacy in the FACA and FOI Acts. The blend has not been altogether successful and has raised some serious legal problems which affect the operations of advisory committees.

Together, these two statutes are intended to maximize public access to documents and to advisory committee meetings. There are, however, conditions under which the confidentiality of documents can be maintained, and the privacy of meetings can be authorized. The applicable conditions are set forth in the FOI Act as nine exemptions from disclosure.[11] The two most frequently invoked in connection with FDA advisory committee documents, transcripts and meetings are exemption 4, which covers trade secrets and privileged or confidential commercial or financial information, and exemption 5, which protects inter-agency or intra-agency memoranda which would not be available by law to a party in litigation other than an agency.[12] In practice, information submitted to an advisory committee or to the FDA usually will not be available to the public under an FOI Act request. Moreover, any advisory committee meeting "concerned with" such information may be closed to the public.[13] Over the past two years, the courts have had several opportunities to construe exemptions 4 and 5. While the decided cases provide some guidance, the application of the exemptions will probably continue to be on an *ad hoc* basis.

To begin with, I doubt that there will ever be a definitive definition of what constitutes confidential commercial information under exemption 4, despite the attempt by the FDA to accomplish this through regulations.[14] There is a broad variety of information, such as clinical data, research protocols, research status reports or prospective advertising campaigns, for which confidentiality may be claimed. The criteria used by the federal courts in the District of Columbia to test confidentiality include whether disclosure of the information claimed to be confidential would: (1) impair the government's ability to get in-

[10] Fountain hearings at 195.

[11] FOI Act, 5 U. S. C. Sec. 552(b)(1)-(9).

[12] FOI Act, 5 U. S. C. Sec. 552(b)(4) and (5).

[13] FACA, 5 U. S. C. App. I, Sec. 10(d).

[14] 21 CFR Sec. 4.61 (1975).

formation; and (2) cause substantial competitive harm.[15] These criteria are, to say the least, indefinite. Nor are they helped by the recent observation by the same court of appeals that "The reach of the exemption for 'trade secrets or commercial or financial information' is not necessarily coextensive with the existence of competition in any form."[16]

The uncertainty about the proper scope of exemption 4 contributes to the FDA's general reluctance to withhold data from the public. In addition, the FDA is influenced by the fact that the Agency must ultimately bear the burden of proving that the exemption was properly invoked.[17] It can be a difficult chore to prove by "relatively detailed analysis in manageable segments" that certain subject matter constitutes confidential commercial information,[18] particularly where substantial volumes of material are involved. For this reason, FDA regulations now provide that if a court compels the Agency to itemize and index records which are claimed to be confidential under exemption 4, the person or company involved will be required to intervene, index the records, and defend the exempt status of the material.[19] If comparable procedures to defend the closing of an advisory committee meeting are established, the burden of defense will also fall on the company whose presentation or data are involved where exemption 4 is at issue.

Presubmission Review

In submitting data to the FDA, and presumably to an advisory committee, you initially have the option of seeking a presubmission review of a request for confidential treatment of the information.[20] If a favorable determination is made, the FDA will deny a request for disclosure. If confidential treatment is refused, you may either withdraw the information or proceed with the submission at the risk of disclosure. In the latter situation, you would be wise to notify the committee and the FDA that you have not thereby waived your claim of confidentiality as to the designated portions of the material. Moreover, you should state your understanding that the submission presents a situation where the confidentiality of the data is uncertain within the

[15] *Charles River Park Association Inc. v. HUD*, 71 DWLR 629, 633 (1975); *National Parks & Conservation Association v. Morton*, 498 F. 2d 765, 770 (1974).

[16] *Washington Research Project Inc. v. HEW*, 504 F. 2d 238 (CA DofC 1974). In that case, a research design prepared by a noncommercial scientist was found to be nonexempt.

[17] FOI Act, 5 U. S. C. Sec. 552(a)(4)(B) incorporated by reference in the FACA, 5 U. S. C. App. I. Sec. 10(b).

[18] *Vaughn v. Rosen*, 484 F. 2d 820 (CA DofC 1973). See also *Environmental Protection Agency v. Mink*, 410 U. S. 73 (1973).

[19] 21 CFR Sec. 453 (1975).

[20] 21 CFR Sec. 4.44 (1975).

meaning of the FDA regulations.[21] Under these circumstances, the FDA must advise you in advance of any disclosure of the material, reach a final decision regarding disclosure and give you an opportunity to sue to enjoin the release of the records involved.[22]

But let me warn you not to be too comforted by the availability of a judicial remedy. The courts have the responsibility to make a *de novo* determination of the applicability of the exemption claimed,[23] and the trend has been for them to favor public access to all but limited categories of data and documents. In fact, even if the information falls within exemption 4, both the FDA and the District of Columbia federal courts have concluded that the Agency is not prohibited from disclosure.[24] As a practical matter, agencies will generally protect documents which come clearly within exemption 4. However, to the extent that your information may relate to one of the federal statutes which provide criminal penalties for disclosure of certain data,[25] for example, trade secrets contained in an NDA, you would be wise to assert that protection too. In any event, be aware that when you submit material to an advisory committee, even after a favorable presubmission review, you get no guarantee of its confidentiality. Neither the committee nor the FDA can make any promises about nondisclosure.

Oral Presentation

Similar problems are presented where the company, in preparing its oral presentation before a committee, needs the assurance that the session will be closed. Here, too, the burden is on the agency to justify closing a meeting.[26] The FDA generally seeks to meet this burden with a boiler plate notice in the *Federal Register,* citing the various FOI Act exemptions as justifications. The notice typically claims privacy for consideration of law enforcement activities, for committee deliberations and for discussion of trade secrets. Because of its lack of particularity, this broad-brush approach may jeopardize the claim of confidentiality when combined with a nonspecific agenda, such as the "continued review of products in this category." This is the lesson of the *Nader v. Dunlop* case.[27] Although the FDA cannot ultimately insure against disclosure or guarantee that its rationale for closing an advisory committee meeting will be upheld, it would be reassuring to have a notice with enough specificity to satisfy the courts.

---

[21] 21 CFR Sec. 4.45 (1975).

[22] 21 CFR Sec. 4.46 (1975).

[23] FOI Act, 5 U. S. C. Sec. 552(a)(4)(B).

[24] *Charles River Park, supra,* 71 DWLR at 633.

[25] 21 U. S. C. Sec. 331(j); 18 U. S. C. Sec. 1905.

[26] FACA, 5 U. S. C. App. I, Sec. 10 (b) and (d), incorporating by reference 5 U. S. C. Sec. 552(a)(4)(B).

[27] 370 F. Supp. 177 (DC DofC 1973).

The problems of confidentiality in connection with both documents and meetings merge in considering whether advisory committee transcripts can be disclosed. The mere fact that an advisory committee meeting has been closed does not establish *per se* the confidentiality of the transcript of that session. The person who seeks disclosure of the transcript can still demand that the Agency show that the discussions recorded in the transcript are subject to an FOI Act exemption. To the extent that secret NDA data, product formulations or manufacturing methods are involved, public access to the transcript will, with some certainty, be denied. However, the sanctity of advisory committee deliberative sessions and their transcripts thought to be protected by exemption 5 may be in jeopardy. Despite the decision of a federal district court judge in California last year who, relying upon exemption 5, refused to permit disclosure of a transcript,[28] other courts have expressed skepticism about this basis for nondisclosure. For practical reasons, it is worth taking a hard look at the rationale involved.

Agency Memoranda

It should be understood that there is nothing in the FOI Act or FACA which explicitly protects advisory committee deliberations as such from public view or authorizes the withholding of transcripts of the closed sessions. The FDA and other agencies have derived this authority from exemption 5 of the FOI Act which protects inter-agency or intra-agency memoranda on the theory that the committee discussions, if reduced to writing, would be exempt from disclosure.[29] Recently, however, one court pointed out that *committee* memoranda—which would arise from the committee discussions—are not the same as *agency* memoranda and that only the latter are protected.[30] In another decision, *Aviation Consumer Action Project v. Washburn*, the same court refused protection to a bona fide inter-agency memo which had been disclosed to advisory committee members. It held that exemption 5 had been waived by making the document available to persons other than full-time federal employees.[31] Equally ominous is the order entered by that court directing the Cost of Living Council to keep its meetings open "except to the extent that there is a specific finding made . . . that the meeting, or a portion thereof, *is to discuss a document* which is

[28] *Smart v. FDA*, No. C-73-0118-SW (DC ND Cal. April 19, 1974).

[29] See Fountain hearings at 492—493.

[30] *Gates v. Schlesinger*, 366 F. Supp. 797 (DC DofC 1973). But see, *Washington Research Project, Inc. v. HEW*, 504 F. 2d 238 (CA DofC 1974).

[31] *Aviation Consumer Action Project v. Washburn*, C. A. No. 1838-73 (DC DofC Sept. 10, 1974).

specifically exempt from public disclosure under the FOI Act."[32] These decisions taken together suggest that, if you are relying on exemption 5 with respect to advisory committees, you ought to keep your sunglasses handy.

Pre-Decisional Documents

Some degree of comfort may be found in the recent decisions of the Supreme Court[33] which defined exemption 5 to cover pre-decisional documents reflecting advisory opinions, recommendations or deliberations which are part of a policy-making process. *If,* despite the district court decisions in the *Gates* and *Washburn* cases,[34] advisory committee deliberations are construed to be part of this pre-decisional agency process, then the freedom to close meetings on the basis of FOI Act exemption 5 will be preserved. Under these circumstances, the confidentiality of transcripts of the pre-decisional sessions would also be re-enforced by the Supreme Court ruling. However, I emphasize that there is not yet a dispositive ruling as to whether advisory committee deliberations are entitled to the same protection as the agency decision-making process.

I mention these problems with exemption 5 for very pragmatic reasons. First, you do not want to find yourself on a sinking ship. Second, because only the FDA can assert a right to maintain the privacy of its advisory committee discussions, you do not have standing to forestall either disclosure or an open meeting on this basis. And, third, as Dr. Crout testified last year, a transcript of advisory committee meetings can be very helpful "because it is true that without that, you may fail to capture important information."[35] For this reason, there can come a time when you want to know just what it was that led an advisory committee to a particular conclusion or recommendation. A transcript could provide a basis for impeaching advice which is the cornerstone of an FDA decision. I suggest this, of course, only as a measure of last resort since it is a double-edged sword. But, when faced with the current trend in the sunshine laws, why be a victim if you can be a beneficiary?

De Facto Advisory Committees

The threat to privacy comes not only from courts, Congress and consumerists. You may be unwittingly letting yourself in for a bad

[32] *Nader v. Dunlop,* 370 F. Supp. 177 (DC DofC 1973).

[33] *NLRB v. Sears, Roebuck & Co.,* 43 U. S. L. W. 4491, 4496 (1975); *Renegotiation Board v. Grumman Aircraft Engineering Corp.,* 43 U. S. L. W. 4502, 4507-4508 (1975).

[34] See footnotes 30 and 31, *supra,* and accompanying text.

[35] Fountain hearings at 143.

burn through informal contacts with the FDA if you are being used on an advisory committee. Several recent court decisions make it clear that a group which is being *utilized* by an agency to obtain advice or recommendations is a *de facto* advisory committee and is subject to the provisions of FACA. Failure to comply with the FACA requirements for such items as charters "cannot be employed as a subterfuge for avoiding the Act's public access requirements," said one federal district court in the *Food Chemical News* case last year.[36] Thus, a group of travel agents and air carrier representatives recently found themselves designated an advisory committee by a federal district judge.[37] They, like the representatives of distillers and consumers involved in the *Food Chemical News* case, never imagined that they had been elevated to the status of an advisory committee.

The logic of these decisions is hard to escape. HEW has tried to do so by embroidering upon the FACA definition of advisory committees to call for fixed membership, an organizational structure and staff, and regular meetings.[38] Despite the deference due to federal agencies, it must be acknowledged that these additional criteria depart from the FACA definition and carve out exceptions which may not have been intended. Whether the HEW definition will be accepted by courts cannot be told yet. The better counsel is to be sure that you are not in the business of offering advice or recommendations to the FDA—or any other agency—if you do not want a full house. It should be made clear that any individual conferences are for the purpose of providing or exchanging information or seeking FDA guidance. Those who fail to follow this advice may find themselves recorded in the annual FDA advisory committee report, albeit in a terminal condition.

It is unlikely that the demand for public access to meetings and documents will abate over the next few years. The FDA, as well as the courts, are obliged by the law to be responsive to these demands. Throughout these post-Watergate days, however, the values inherent in confidentiality and privacy should not be totally forgotten. The FDA, the advisory committees, the courts, the Congress and the industry share the responsibility for balancing these values with the public's right to know. If we can achieve the right balance, we can all enjoy the sunshine and be a lot healthier for it. **[The End]**

---

[36] *Food Chemical News, Inc. v. Davis*, 378 F. Supp. 1048 (DC DofC 1974).

[37] *Aviation Consumer Action Project v. Yohe*, C. A. No. 707-73 (DC DofC 1973).

[38] HEW Proposed Regulations on Committee Management, Sec. 11.2(b)(1), 40 *F. R.* 3712 (Jan. 25, 1975).

Some Fundamentals of United States Antitrust Law

By JEFFERSON B. HILL*

Mr. Hill Is a Trial Attorney in the Patent Section of the Antitrust Division of the United States Department of Justice.

I UNDERSTAND THAT PATENTS AND TRADEMARKS, as well as the antitrust laws, are, on occasion, of particular interest to the pharmaceutical industry. I will attempt in this discussion to summarize the antitrust laws, and to point out their relationship to patents and trademarks. I should point out, however, that the antitrust laws are in no way limited to the pharmaceutical industry but are, instead, generally applicable throughout the American economic system.

I. Summary of Antitrust Laws

The antitrust laws in the United States are basically four in number and they are remarkable in their simplicity. The earliest —the Sherman Act—became law in 1890.

Section 1 of the Sherman Act[1] prohibits "every contract, combination . . . or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations . . . ."

Section 2 of that Act[2] provides that "every person who shall monopolize, or attempt to monopolize, or combine or conspire . . . to monopolize any part of the trade or commerce among the several States, or with foreign nations . . ." is to be punished.

Section 7 of the Clayton Act,[3] originally enacted in 1914 and amended in 1950, prohibits any merger or acquisition whose effect "in any line of commerce in any section of the country . . . may be

* The views expressed are those of the speaker, and they do not necessarily reflect those of the Department of Justice.

[1] 15 U. S. C. Sec. 1.
[2] 15 U. S. C. Sec. 2.
[3] 15 U. S. C. Sec. 18.

substantially to lessen competition, or to tend to create a monopoly." I should point out, incidentally, that sales of patents or trademarks may raise antitrust problems under Section 2 of the Sherman Act or Section 7 of the Clayton Act, because they may represent valuable business assets, the acquisition of which may substantially lessen competition.[4]

These three statutes are enforced by the United States Department of Justice, though with respect to the Clayton Act, jurisdiction is shared with the Federal Trade Commission (FTC).

The fourth basic antitrust law of the United States is enforced solely by the FTC. That statute—Section 5 of the FTC Act[5]—declares unlawful "unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce...."

Sue to Recover Damages

In this context, moreover, I should note that the American antitrust laws may also be enforced by private parties injured by a violation of Sections 1 or 2 of the Sherman Act or Section 7 of the Clayton Act.[6] Our antitrust laws provide that any person injured by a violation of these laws may sue to recover three times the actual damages he has sustained. Short of a jail sentence, I think perhaps this is the sanction which strikes real fear into the hearts of businessmen.

These four statutes provide the legislative foundation for most of American antitrust law. They reflect a fundamental commitment to the proposition that the economy of the United States shall be governed primarily by the principles of competition. As the Supreme Court stated in 1958:

"The Sherman Act was designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition as the rule of trade. It rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress, while at the same time providing an environment conducive to the preservation of our democratic political and social institutions. But even were that premise open to question, the policy unequivocally laid down by the Act is competition."[7]

---

[4] *FTC v. Procter & Gamble Co.*, 386 U. S. 568 (1967) (trademark as asset); *Automated Building Components, Inc. v. Truckline Truss Co.*, 318 F. Supp. 1252, 1260-61 (DC Ore. 1970) (patent application as asset); *Dole Valve Co. v. Perfection Bar Equipment, Inc.*, 311 F. Supp. 459, 463 (DC ND Ill. 1970) (patent as asset).

[5] 15 U. S. C. Sec. 45.

[6] Section 4 of the Clayton Act, 15 U. S. C. Sec. 15.

[7] *Northern Pacific Railway v. United States*, 356 U. S. 1, 4 (1958).

There are a few general points that should be made. The first relates to the applicability of antitrust enforcement to foreign commerce. The Sherman Act applies both to domestic and foreign commerce of the United States. It has been interpreted to apply to all those activities of both American and foreign persons and business entities, acting within or outside of the United States, which violate the prohibitions contained in these laws. The concern is whether the activities of such persons adversely affect competition in the United States or its foreign commerce.

Import and Export Opportunities

We are particularly concerned about conspiracies, or other joint activities, which restrict imports into the United States and restrict exports (and licensing) opportunities by competing American exporters. For example, to be specific, if a British licensor imposes restrictions on a French licensee selling in Britain, it is unlikely, without more, that such a restriction would have any adverse effect upon the foreign commerce of the United States. Such a restriction would seem to me to be a matter for the countries concerned. On the the other hand, if the French licensee of an American company were to be restricted with respect to sales in the United States, this might very well have the required impact on the American economy and give rise to an antitrust violation. It would be a mistake, therefore, to enter into anticompetitive activity which affects United States import and export opportunities under the misapprehension that it is easy to evade American antitrust enforcement, "extraterritorially."

The second general point is that an antitrust inquiry is essentially the same regardless of the formality or informality of the contractual and corporate arrangements entered into. Restrictive or anticompetitive arrangements are most properly viewed as a whole. As the Supreme Court stated: "The character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole."[8] Also, as the Supreme Court stated in another case: "It is not necessary to find an express agreement in order to find a conspiracy. It is enough that a concert of action is contemplated and that the defendant conformed to the arrangement."[9] The Court of Appeals for the Ninth Circuit

[8] *Continental Ore Co. v. Union Carbide & Carbon Corp.*, 370 U. S. 690, 699 (1962).

[9] *United States v. Paramount Pictures*, 334 U. S. 131, 142 (1948).

elaborated upon this general doctrine recently, in the context of a criminal case involving a price-fixing conspiracy:

"A knowing wink can mean more than words.... Mutual consent need not be bottomed on express agreement, for any conformance to an agreed or contemplated pattern of conduct will warrant an inference of conspiracy. An exchange of words is not required. Thus, not only action, but even a lack of action may be enough from which to infer a combination or conspiracy."[10]

Per Se Violations

My third general point concerns *per se* violations, that is, conduct that in and of itself violates the antitrust laws. In the 1958 *Northern Pacific* case, the Supreme Court explained the appropriateness of *per se* rules: "[T]here are certain agreements or practices which because of their pernicious effect on competition and lack of any redeeming virtue are conclusively presumed to be unreasonable and therefore illegal without elaborate inquiry as to the precise harm they have caused or the business excuse for their use."[11] Once it becomes a rule of thumb that a certain practice impairs competition, many antitrust cases become simple matters of fact.

For example, combinations dividing or allocating business among competitors are illegal *per se*. The courts have so held in a wide variety of contexts, such as dividing up territories, allocating particular customers, dividing channels of distribution, and allocating the manufacture and sale of particular products.

In a 1972 supermarket case, the Supreme Court held a grocery marketing and trademark licensing program illegal *per se* because it divided territories among competitors.[12] The 1967 *Sealy* mattress case involved a similar arrangement among regional manufacturers of mattresses, who divided up the territories in which their joint "Sealy" mark might be used.[13] Since the program gave "each licensee an enclave in which it could and did zealously and effectively maintain resale prices, free from the danger of outside incursions,"[14] the Supreme Court held it in *per se* violation of the Sherman Act.

The same general rule has been applied to agreements allocating customers. In the 1961 *Consolidated Laundries* case, the defendant linen suppliers agreed to allocate customers among themselves, to refrain from competing with each other for the customers so allocated,

[10] *Esco v. United States*, 340 F. 2d 1000, 1007, 1008 (CA-9 1965).

[11] *Northern Pacific Railway v. United States*, 356 U. S. 1, 5 (1958).

[12] *United States v. Topco Associates & Co.*, 405 U. S. 608 (1972).

[13] *United States v. Sealy, Inc.*, 388 U. S. 350 (1967).

[14] *Id.* at 356.

and to compel non-member linen suppliers to join the combination or else to exclude them from the linen supply business.[15] The court failed to see any significant difference between an allocation of customers and an allocation of territory, and held that the combination allocating customers was in *per se* violation of the Sherman Act.

Joint Holding Company

The allocation of product lines among competitors was held illegal in the 1955 *Associated Patents* case.[16] In that case, five machine tool manufacturers formed and jointly owned a patent holding and licensing company. This patent holding company then licensed the five companies; each was to use the patents to make and sell different machine tool products. The court found that the "purposes" of the joint holding company were to "suppress competition between the parties" to the agreement and to "restrict outside parties" from competing with them. It concluded that Section 1 of the Sherman Act had been violated since "the purpose and effect of . . . [the combination and conspiracy] has been to confine the manufacture of machine tools by each of them to fields of specialization that were not competitive with each other."[17]

As another example, the Sherman Act forbids combinations of businessmen to suppress competition.[18] It not only forbids competitors to form combinations by meeting together and agreeing not to compete, but also forbids a manufacturer to "put together a combination" suppressing or restraining competition.[19] In the 1960 *Parke, Davis* case, the Supreme Court held that the defendant drug manufacturer "put together" a restrictive combination among its customers when it announced a policy of refusing to deal with price cutters, threatened to terminate price cutters, and then reported to some retailers that other retailers "indicated willingness to go along" with the program.[20]

Parke, Davis put together a combination among its customers. In an earlier case, the defendant (a film exhibitor) put together a similar combination among its suppliers.[21] This too was held illegal.

---

[15] *United States v. Consolidated Laundries Corporation*, 291 F. 2d 563 (CA-2 1961).

[16] *United States v. Associated Patents, Inc.*, 134 F. Supp. 74 (DC ED Mich 1955), affirmed *per curiam*, 350 U. S. 960 (1956).

[17] *Id.* at 79, 83.

[18] *United States v. Parke, Davis & Co.*, 362 U. S. 29, 44 (1960).

[19] *Ibid.*

[20] *Id.* at 46.

[21] *Interstate Circuit, Inc. v. United States*, 306 U. S. 208 (1939).

As a final example, it is well established that competitors who agree to take actions or engage in practices that have the natural consequence of suppressing or limiting price competition in products which they sell do so in violation of Section 1 of the Sherman Act. The Supreme Court has found such actions to be as offensive to the antitrust laws as directly fixing the prices at which the products are sold. In the 1966 *General Motors* case, the Supreme Court condemned as *per se* illegal a joint collaborative action to eliminate price cutters —discount houses—from access to automobiles, because it was equivalent to a group boycott of the price cutters.[22] "The principle of these [boycott] cases is that where businessmen concert their actions in order to deprive others of access to merchandise which the latter wish to sell to the public, we need not inquire into the economic motivation underlying their conduct."[23]

II. Relationship of Antitrust Laws to Patents and Trademarks

To summarize, free competition is supposed to be the general rule throughout the United States economy. The antitrust laws are designed to protect and promote this competition. To this end they prohibit agreements which limit competition unreasonably. They, prohibit attempts to create, exercise or maintain illegal monopoly power, the power to control market prices or to exclude competition. The antitrust laws are designed to foster competition by providing free access to markets, and by preventing barriers to entry. Their purpose is to minimize restrictions on the flow of goods, services and technology.

The patent laws seek to spur technological progress. They do so by giving inventors, in return for disclosure, the 17-year right to exclude others from making, using or selling the patented invention. The law of trademarks protects the distinctive way a product or service is identified and distinguished through the use of a symbol or mark and the goodwill it carries.

Constitutional Authorization

The limits of the patent grant are defined by the patent clause of the United States Constitution, which grants to Congress the power "to promote the Progress of Science and the Useful Arts for limited Times" by securing to inventors a limited "exclusive right" in their invention.[24] This constitutional authorization to the

[22] *United States v. General Motors Corp.*, 384 U. S. 127, 146 (1966).

[23] *Ibid.*

[24] Article I, Sec. 8.

Congress is "both a grant of power and a limitation" on that power.[25] It has also long been recognized that, under the *patent system, the public interest is the primary interest,* and reward to inventors is only secondary. Thus, the Supreme Court stated in 1917: "The primary purpose of our patent laws is not the creation of private fortunes for the owners of patents, but is 'to promote the progress of science and the useful arts.' "[26] Consequently, five major points must be recognized when considering patents. So as not to unduly impede subsequent invention by others and resulting technological progress, an invention, before it may be patented, must be disclosed adequately so that others can use the invention or further develop or improve it. Second, the patentee's right to exclude is limited in time, so that the patented subject matter itself will not be removed forever from the public's store of technology. Third, federal patent policy requires that all ideas in general circulation be dedicated to the common good, unless they are protected by a valid patent.[27] Fourth, the patentee's right to exclude is confined "strictly to the terms of the statutory grant."[28] Fifth, the patentee's commercial exploitation of the right to exclude others remains subject to all the general rules of the marketplace, including the common law of restraint of trade and the antitrust laws.[29] This same principle applies with respect to the licensing and assignment of trademark rights, especially since trademarks even lack the statutory 17-year limited monopoly right of American patents,[30] and licenses under trademark rights may last in perpetuity. Congress was well aware of the potentiality of antitrust violations where trademarks are involved. Violation of the antitrust laws with respect to the use of a trademark is expressly provided for as a defense to trademark incontestability.[31]

Rule of Reason

The basic principle we use to analyze cases involving the exchange or grant of patents and trademarks is the "rule of reason." Since at least the reign of Queen Anne, when it was applied to the

[25] *Graham v. Deere,* 383 U. S. 1, 5 (1966).

[26] *Motion Picture Patents Co. v. Universal Film Manufacturing Co.,* 243 U. S. 502. 511 (1917).

[27] *Sears, Roebuck & Co. v. Stiffel Co.,* 376 U. S. 225 (1964); *Compco Corp. v. Day-Brite Lighting,* 376 U. S. 234 (1964); *Lear, Inc. v. Adkins,* 395 U. S. 653 (1969).

[28] *United States v. Univis Lens Co.,* 316 U. S. 241, 251 (1942).

[29] *United States v. Line Material, Inc.,* 333 U. S. 287 (1948).

[30] Sec. 9 of the Trademark Act, 15 U. S. C. Sec. 1059, permits renewal of registrations every 20 years in perpetuity.

[31] Sec. 33(b)(7) of the Lanham Act, 15 U. S. C. Sec. 1115(b)(7).

sale of a bakery in North London in 1711,[32] this principle has been a keystone of common law. It has also been specifically included in the application of our statutory antitrust laws by the 1899 *Addyston Pipe* case.[33]

The rule of reason provides three elements for testing the legality of a trade restraint under this ancient rule of necessary and ancillary restraints. First, the restriction or limitation must be ancillary to the lawful main purpose of a contract. Second, the scope and the duration of the limitation must not be substantially greater than necessary to achieve that purpose. Third, the limitation must be otherwise reasonable in the circumstances. The three standards embodied in this principle can be applied consistently and effectively to the myriad of technology licensing agreements or arrangements involving trade restraints.

I should also outline nine licensing practices which are generally considered unlawful. That is, they are in the category of *per se* illegals discussed earlier. As to these practices, the threshold point for applying the rule of reason is not even reached. This is either because the primary purpose of an anticompetitive restriction is unlawful, the scope and duration of the restraint is so clearly overbroad, or the restriction is otherwise so offensive as to be unereasonable under virtually any circumstance.

Illegal Licensing Practices

First, it is clearly unlawful to require a licensee to purchase separate products as a condition of obtaining the license.[34]

Second is the related practice of mandatory package licensing which is likewise illegal.[35]

Third, it is clearly unlawful where reciprocal cross-licenses form the basis of a cartel,[36] or otherwise limit existing competition by fixing prices or allocating territories.[37]

---

[32] *Mitchell v. Reynolds*, 1 P. Wms. 181, 24 Eng. Rep. 347 (KB 1711).

[33] *Addyston Pipe & Steel Co. v. United States*, 175 U. S. 211 (1899).

[34] *International Salt Co. v. United States*, 332 U. S. 392 (1947). But see *Susser v. Carvel Corp.*, 206 F. Supp. 636 (DC SD NY 1962), affirmed 332 F. 2d 505 (CA-2 1964), *cert. granted*, 379 U. S. 885, *cert. dismissed*, 381 U. S. 125 (1965) based on an idiosyncratic situation.

[35] *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U. S. 100 (1969); *American Security Co. v. Shatterproof Glass Corp.*, 268 F. 2d 769 (CA-3 1959).

[36] *United States v. General Electric Co.*, 82 F. Supp. 753 (DC NJ 1949); *United States v. National Lead Co.*, 63 F. Supp. 513 (DC SD NY 1945).

[37] See, for example, *United States v. Line Material Co.*, 393 U. S. 287 (1948); *United States v. Imperial Chem. Indus., Ltd.*, 100 F. Supp. 504 (DC SD NY 1951).

Fourth, the existence of a patent, trade secret or trademark cannot justify an agreement which restrains where, how or to whom a patented product is disposed in the United States after the licensor has once sold the product to an independent purchaser.[38]

Fifth, it is unlawful for a licensor to agree with a licensee that it will not grant further licenses to any third party without the licensee's consent.[39]

Sixth, it is unlawful for a licensor to require a licensee to adhere to any specified or minimum price with respect to the licensee's sale of the licensed products.[40]

Seventh, it is unlawful for a licensor to insist as a *condition* of the license that a licensee pay royalties in an amount not reasonably related to the licensee's sales of products covered by the licensed rights.[41]

Eighth, it is a violation of our antitrust laws to attempt to enforce a patent license, or collect a royalty on it, beyond its term of years.[42] It seems that the same reasoning would apply to attempts to enforce, or collect royalties on, a know-how license based on information which has entered into the public domain.

Ninth, it is very likely to be illegal to require a licensee to agree in advance to grant-back to the licensor title or an exclusive license on any new patents or trade secrets the licensee may obtain or develop related to the licensed technology rights. This is because a nonexclusive grant-back clause should meet the legitimate needs of the licensor, while an exclusive grant-back may both perpetuate a monopoly and discourage innovation by the licensee.[43]

III. Conclusion

In conclusion, I want to stress that the formulation of the rule of reason and other summaries of the law just discussed is short-

[38] *United States v. Glaxo Group, Ltd.*, 302 F. Supp. 1 (DC DofC 1969).

[39] *United States v. Krasnov*, 143 F. Supp. 184 (DC ED Pa. 1956), affirmed *per curiam* 355 U. S. 5 (1957).

[40] For a discussion of the erosion of the 1926 *General Electric* case, see the remarks of now Deputy Assistant Attorney General Bruce B. Wilson before the Fourth New England Antitrust Conference, Boston, Massachusetts, November 6, 1970, pp. 7-8.

[41] *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 385 U. S. 100 (1969).

[42] *Brulotte v. Thys Co.*, 379 U. S. 29, 32 (1964).

[43] *United States v. Associated Patents, Inc.*, 134 F. Supp. 74 (DC ED Mich. 1955), affirmed *per curiam subnom. Mac Inv. Co. v. United States*, 350 U. S. 960 (1956).

hand; it is a generalized statement of doctrines that have developed over many years. As to any specific licensing limitation, there is an extensive body of particular case law. If a lawyer needs guidance in advising clients, he or she should turn to these particular cases and to the refinements and principles expressed in them. And if these cases do not yield sufficient guidance, the business review and clearance procedures of the Justice Department and the FTC are always available.

I am reminded by the claims of uncertainty now being made by some in the patent area that similar arguments have been made about the antitrust laws for many years. More than 60 years ago, in fact, the man who was later to become Mr. Justice Brandeis remarked as follows:

"I have been asked many times in regard to particular practices or agreements as to whether they were legal or illegal under the Sherman law. One gentleman said to me, 'We do not know where we can go.' To which I replied, 'I think your lawyers or anyone else can tell you where a fairly safe course lies. If you are walking along a precipice no human being can tell you how near you can go to that precipice without falling over, because you may stumble on a loose stone, you may slip, and go over; but anyone can tell you where you can walk perfectly safely within convenient distance of that precipice.' The difficulty which men have felt generally in regard to the Sherman law has been rather that they have wanted to go the limit than that they have wanted to go safely."[14]

I think this is probably equally as true today as it was in 1911. The private bar—for which I have the utmost respect—applying the rule of reason and judging licensing practices in objective contexts, can render reliable advice concerning the legality of particular restrictions. Any real difficulty, I suspect, has been experienced by those who "have wanted to go the limit"—and perhaps just a little beyond. **[The End]**

[14] Senate Committee on Interstate Commerce, Hearings on Control of Corporations, Persons and Firms Engaged in Interstate Commerce, 62nd Congress, p. 1161.

The Consumer Product Safety Act— A Brief Overview

By TOMAS M. RUSSELL

Mr. Russell Is a Partner in the Law Firm of Sidley & Austin.

SINCE THE NEW DEAL, Congress has frequently responded to problems by establishing new administrative agencies. Each new agency has added a subject matter area to the practice of law. The Consumer Product Safety Commission (CPSC) is the latest addition and the bar must become acquainted with this Agency and its statute.[1]

First of all, what is this Agency? It is a new, separate and independent major regulatory Agency charged with improving the safety of consumer products. The four statutory purposes of the Agency are:

(1) to protect the public against unreasonable risks of injury associated with consumer products;

(2) to assist consumers in evaluating the comparative safety of consumer products;

(3) to develop uniform safety standards for consumer products and to minimize conflicting state and local regulations; and

(4) to promote research and investigation into the causes and prevention of product-related deaths, illnesses, and injuries.[2]

The CPSC is but an infant. However, it has grown to a staff approaching 1,000, 14 regional offices, a headquarters in Washington, D. C. and an Operations Center in Bethesda, Maryland. The Agency's

[1] Consumer Product Safety Act (CPSA), Public Law 92-573, 86 Stat. 1207 (Oct. 27, 1972), 15 U. S. C. Secs. 2051—2081.

[2] CPSA Sec. 2(b), 15 U. S. C. Sec. 2052(b).

initial budget was $31 million for fiscal year 1973. In that same fiscal year, the entire Federal Trade Commission (FTC) received $850,000 less than the CPSC. In fiscal year 1975, the CPSC will receive over 20 percent more ($37.5 million) and has requested $49.8 million for fiscal year 1976.

Historical Perspective

How and why did a new Agency with such a large staff and budget originate? It is helpful to place the Agency in its historical perspective. Until the mid-1960's, Congress responded to each new safety issue with a new statute to regulate the specific product type involved. A few examples are the Flammable Fabrics Act,[3] the Federal Hazardous Substances Act,[4] the Federal Insecticide, Fungicide and Rodenticide Act[5] and even a Refrigerator Door Safety Act.[6] During the 1960's, the emerging consumer groups began calling for a new agency to regulate the safety of products generally. They argued that what was needed was a *comprehensive system of regulation* rather than a hodge-podge of narrow statutes administered separately and often inconsistently by a number of different agencies. Congress was reluctant to create such an agency, largely because it was not convinced that the need existed. In 1967, Congress created a study commission, the National Commission on Product Safety (NCPS),[7] gave it broad powers and a substantial budget and told it to study product hazards and the adequacy of existing statutes and private remedies.[8]

After two and a half years of hearings and research, its report issued. The NCPS found that each year 20 million persons were injured from consumer products, 110,000 were permanently disabled and 30,000 were killed. The annual loss was estimated at $5.5 bil-

[3] 15 U. S. C. Secs. 1191—1204.

[4] 15 U. S. C. Secs. 1261—1274.

[5] 7 U. S. C. Secs. 135—135k. Amended and re-enacted by Public Law 92-516, 86 Stat. 973 (Oct. 21, 1972), 7 U. S. C. Secs. 136—136y.

[6] 15 U. S. C. Secs. 1211—1214.

[7] Public Law 90-146, 81 Stat. 466 (Nov. 20, 1967). This statute is not codified. It appears at 1967 U. S. Code, Cong. and Adm. News 499.

[8] The Commission was appointed by President Johnson on March 27, 1968. The Chairman was Arnold B. Elkind, an attorney from New York, New York. Other members of the Commission were Emory J. Crofoot, an attorney from Portland, Oregon; Henry Aaron Hill, President of Riverside Research Laboratory, Haverhill, Massachusetts; Sidney Margolis, syndicated columnist, New York, New York; Michael Pertschuk, Chief Counsel, Senate Commerce Committee, Washington, D. C.; Hugh L. Ray, Director, Merchandise Development and Testing Laboratory, Sears, Roebuck and Company, Chicago, Illinois; and Dana Young, Senior Vice President, Southwest Research Institute, San Antonio, Texas.

lion. The report concluded: "The exposure of consumers to unreasonable product hazards is excessive by any standards of measurement."[9]

Federal regulatory laws, industry self-regulation and the common law of product liability were all found woefully inadequate to insure safe products.[10] The report proposed what the consumer groups urged half a decade before—a new Agency, the Consumer Product Safety Commission.[11]

With the identification of a domestic problem that was roughly comparable in monetary size to the Viet Nam War, the study commission certainly aroused the interest of Congress. A consensus to enact a bill quickly developed but a snag arose. Many strong consumer groups were unsatisfied and wanted to abolish the Food and Drug Administration (FDA). They wanted the new Agency to take over the administration of the Federal Food, Drug and Cosmetic Act[12] and of the other statutes the FDA administered. Finally, after protracted consideration, a compromise was reached. The FDA would stay alive but would regulate *only* foods, drugs, cosmetics and medical devices, historically its area of primary responsibility. Administration of other regulatory statutes including the Federal Hazardous Substances Act,[13] the Poison Prevention Packaging Act,[14] the Flammable Fabrics Act[15] and the Refrigerator Door Safety Act[16] were transferred to the CPSC from the FDA, the FTC and the Department of Commerce. The compromise bill sailed through Congress and was signed by President Nixon on October 27, 1972.[17] The

[9] Final Report of the National Commission on Product Safety, June 1970 p. 1, hereinafter cited as NCPS Final Report.

[10] *Id.* pp. 2—3. See also *Federal Consumer Safety Legislation* (June 1970), a special report to the NCPS on the scope and adequacy of the automobile safety, flammable fabrics, toys, and hazardous substances programs, prepared by Howard A. Heffron.

[11] The NCPS Final Report included a 32-page draft bill to establish the CPSC.

[12] 21 U. S. C. Secs. 301—392.

[13] 15 U. S. C. Secs. 1261—1274.

[14] Public Law 91-601, 84 Stat. 1670 (Dec. 30, 1970), codified in scattered sections of 15 U. S. C. Secs. 1261—1274.

[15] 15 U. S. C. Secs. 1191—1204.

[16] 15 U. S. C. Secs. 1211—1214.

[17] The original bill was S. B. 3419, 92nd Congress, 2nd Session (1972). It passed the Senate on June 21, 1972 after consideration by the Commerce and Labor Committees. The House version, H. R. 15003, 92nd Congress, 2nd Session, was introduced as a "clean bill" from the House Interstate and Foreign Commerce Committee on May 16, 1972. On September 20, 1972, the House passed S. B. 3419, after amending the bill to contain its version. The House-Senate Conference Committee reported a bill containing primarily the House language. The Conference Report was adopted by the House on October 13, 1972 and by the Senate on the next day. Senate Report No. 92-1593.

Agency came into existence on May 14, 1973 with the swearing-in of four of the five Commissioners.[18]

Organization

The Agency is composed of five Commissioners with staggered seven-year terms appointed by the President with the advice and consent of the Senate. The President designates one as Chairman.[19] The Chairman is a powerful chief executive officer along corporate lines, something unusual for government agencies.[20] The other Commissioners function as an active Board of Directors.[21] Other statutory officers are Executive Director, General Counsel, and Directors of Engineering Sciences, Epidemiology, and Information.[22]

Unlike other agencies, the CPSC is independent of the Executive Branch. Its budget requests and legislative recommendations go directly to Congress without prior White House approval.[23] The only other agency with independence approaching that of the CPSC is the Board of Governors of the Federal Reserve System.[24]

The CPSA is also unique in that it has tough conflict of interest provisions to afford independence from industry.[25] Because it is a *consumer* protection agency, there is no provision for independence from *consumer* groups. If anything, the "tilt" favors consumers.

The Participatory Concept

The statute breaks new ground in another significant respect. In the past, Congress has delegated broad authority under rather

[18] Chairman Richard O. Simpson and Commissioners Lawrence Kushner, Barbara Hackman Franklin and Constance Newman. Commissioner R. David Pittle took office on October 10, 1973.

[19] CPSA Sec. 4(a) and (b)(1), 15 U. S. C. Sec. 2053(a) and (b)(1).

[20] CPSA Sec. 4(f), 15 U. S. C. Sec. 2053(f). The Chairman exercises all of the executive and administrative functions including appointment and supervision of personnel, distribution and supervision of business and the use and expenditure of funds.

[21] CPSA Sec. 4(f)(2), 15 U. S. C. Sec. 2053(f)(2). The Chairman in carrying out his duties as chief executive officer is governed by the general policies established by the entire Commission.

[22] CPSA Sec. 4(g)(1), 15 U. S. C. Sec. 2053 (g)(1).

[23] CPSA Sec. 27(k), 15 U. S. C. Sec. 2076(k).

[24] Those members serve 14-year terms which put them beyond the reach of any single President. Furthermore, the operating funds of the Board are derived from semi-annual assessments on the stock of federal reserve banks. Such funds are not government funds nor appropriations, except for audit purposes. 12 U. S. C. Secs. 243 and 244, 30 Op. Atty. Gen. 308 (1914).

[25] CPSA Sec. 4(c) and (g)(2), 15 U. S. C. Sec. 2053(c) and (g)(2).

vague standards to agencies, funded them amply and permitted them to regulate the industry with "oversight" review and supervision by Congress. A good example is the FDA. Direct participation in the regulatory process *itself* by *private* entities has been historically limited, generally to advisory committees. In contrast, the CPSA is a novel experiment in direct participation in regulation by consumer groups, industry and state and local governments. This "participatory concept" manifests itself in many ways and helps to explain the Agency's actions. The several following examples may be helpful.

(1) The main thrust of the statute is improving safety by standards-making, rather than by governmental regulatory fiat. Any interested person, including a consumer group, industry or a unit of government, can initiate the process by filing a simple petition.[26] The Agency must grant or deny that petition in 120 days.[27] If it does not, the petitioner may sue in a United States district court to compel the Agency to initiate a proceeding to take the action requested. In that proceeding, the petitioner receives a *de novo* hearing.[28]

(2) If the petition is granted or if the court so orders or if the Agency initiates standards-making on its own, any interested person—again including a consumer group, industry or governmental unit—can offer to develop and write the standard itself.[29] Furthermore, funding for the costs involved is available in certain circumstances.[30] The offeror develops the standard under the procedures of Sections 7 and 9[31] and the implementing regulations[32] that provide for wide public participation. In short, it is entirely possible that Ralph Nader or Consumers Union can raise an issue affecting your client, write the standard—and get paid for it! However, it is also possible for industry to do the same. Since industry has the

[26] CPSA Sec. 10, 15 U. S. C. Sec. 2059.

[27] CPSA Sec. 10(d), 15 U. S. C. Sec. 2059(d). Note, however, that this provision applies only to petitions filed after October 27, 1975 in order to give the Agency an opportunity to organize itself and establish its priorities. CPSA Sec. 10(g), 15 U. S. C. Sec. 2059(g).

[28] CPSA Sec. 10(e)(2), 15 U. S. C. Sec. 2059(e)(2). There is authority that in some situations "administrative inaction is the equivalent of an order denying relief" and is judicially reviewable. *Environmental Defense Fund, Inc. v. Hardin*, 428 F. 2d 1093, 1099 (CA DofC 1970); *Medical Committee for Human Rights v. Securities and Exchange Commission (SEC)*, 432 F. 2d 659, 668 (CA DofC 1970).

[29] CPSA Sec. 7(b)(4) and (d)(1), 15 U. S. C. Sec. 2056(b)(4) and (d)(1).

[30] CPSA Sec. 7(d)(2), 15 U. S. C. Sec. 2056(d)(2).

[31] CPSA Secs. 7 and 9, 15 U. S. C. Secs. 2056, 2058.

[32] 39 *F. R.* 16206 (May 7, 1974).

greater access to the needed technology and economic data, the Act may provide the vehicle as well as the impetus for industry to make its products safer.

(3) We all are aware of case law that holds that enforcement of federal regulatory laws is a matter for the government only. For example, Section 5(a)(1) of the FTC Act does not create a private cause of action.[33] Not so under CPSA. The statute adopts the concept of "private Attorneys General" and creates a cause of action for private enforcement with recovery of attorneys fees.[34]

(4) The "participatory concept" also affects the internal affairs of the Agency. To facilitate participation, the CPSC has adopted a "goldfish bowl" policy of conducting its affairs in public view.[35] The Agency publishes weekly a "Public Calendar" announcing in advance all meetings with non-Agency personnel that are of significance. These meetings are open to the public.

If you study the statute with this participatory concept in mind, you will find other examples. A lawyer in private practice dealing with this Agency, as distinguished from other agencies, should bear this participatory concept in mind because the policy may have a marked effect on the alternative courses of action that can be taken.

Jurisdiction

Let us shift from philosophy of regulation and the general to the technical and the specific. Let's start with jurisdiction.

Jurisdiction runs to transactions "affecting" commerce[36] and is limited to "consumer products," a defined term.[37] The language is a lawyer's dream—or nightmare, depending on your viewpoint.

---

[33] 15 U. S. C. Sec. 45(a)(1). *Holloway v. Bristol-Myers Corp.*, 327 F. Supp. 17 (DC DofC 1971); *Frederick Chusid & Co. v. Marshall Leeman & Co.*, 326 F. Supp. 1043, 1063 (DC NY 1971); *La Salle Street Press, Inc. v. McCormick and Henderson, Inc.*, 293 F. Supp. 1004 (DC ND Ill. 1968), affirmed 445 F. 2d 84 (CA-7 1971).

[34] CPSA Sec. 24, 15 U. S. C. Sec. 2073.

[35] The original regulations on meetings, prior public notice and records of proceedings were promulgated on October 1, 1973. 38 *F. R.* 27214. 16 CFR Sec. 1001.60. The proposal is being applied as an "interim policy" pending issuance of a final order. There is an emerging trend by other agencies to follow this lead.

[36] CPSA Sec. 3(a)(12), 15 U. S. C. Sec. 2052(a)(12). Note that specific proof that challenged products or practices were "in, or mingled with or found to affect (interstate) commerce" is not necessary. *United States v. Five Gambling Devices*, 346 U. S. 441 (1953); *Perez v. United States*, 402 U. S. 146 (1971).

[37] CPSA Sec. 3(A)(1), 15 U. S. C. Sec. 2052(A)(1).

The term "consumer product" means "any article or component part thereof." Thus, jurisdiction runs to parts, ingredients and subassemblies. If your client makes light switches for homes or the solvent in a model airplane glue, both products and both clients are subject to the Act and must comply with all requirements, including record keeping,[38] reporting generally,[39] factory inspection,[40] certification,[41] substantial product hazard reporting[42] and all the rest.

The next part of the definition of "consumer product" reads, "(1) produced or distributed." Jurisdiction thus runs to the whole chain of manufacturers and distributors including wholesalers, jobbers, retailers and those that sell directly, either by mail or house-to-house. This would also include assembly of parts or filling of packages under contracts with private labelers.

"For sale to a consumer" is the next part of the definition. The term "consumer" is not defined anywhere in the Act. It means roughly "any natural person."

The definition continues: "for use in or around a permanent or temporary household, or residence, a school, in recreation." And just to be sure that nothing was left out, Congress added "or otherwise." The words "or otherwise" cannot be taken lightly because they leave the outer limits of jurisdiction imprecise.

Examples of goods covered which ordinarily would not be considered "consumer products" within the common meaning of that term are, for example, the electric meter, the telephone switchbox and the other utility connections behind a home. Such structural items in homes as stairs, ramps, landings, window sills, retaining walls, doors, architectural glass and electrical wiring are covered.

No Sale Required

The next part of the definition provides that the term "consumer product" means any article or component part thereof, pro-

[38] CPSA Secs. 16(b), 17(g) and 19(a)(3), 15 U. S. C. Secs. 2065(b), 2066(g) and 2068(a)(3). Regulations were proposed at 39 *F. R.* 31916 (Sept. 3, 1974). Extensive comments were filed.

[39] CPSA Sec. 27(b)(1), 15 U. S. C. Sec. 2076(b)(1).

[40] CPSA Secs. 16(a), 17(g), 19(a)(3), 15 U. S. C. Secs. 2065(a), 2066(g) and 2068(a)(3).

[41] CPSA Sec. 14, 15 U. S. C. Sec. 2063.

[42] CPSA Sec. 15(b), 15 U. S. C. Sec. 2068(b). Implementing regulations were proposed at 38 *F. R.* 20902 (Aug. 3, 1973) and adopted at 39 *F. R.* 6067 (Feb. 19, 1974). 16 CFR Part 1115. The regulations became effective March 21, 1974. The reporting obligation arose May 14, 1973 since the statutory provision is self-executing.

duced or distributed "(2) for personal use, consumption or enjoyment of a consumer." Thus, *no sale is required.* Free samples and promotional premiums are covered. Goods furnished but not separately paid for are covered, such as plastic dry cleaner's bags. Those companies that will rent you almost anything are subject to the Act as are other leased goods. Also included are artificial turf on athletic fields, football helmets and those items furnished for the use of the public at large, such as the automatic doors at airports and the seats in theaters.

In short, the definition is extremely vague and broad. Lawyers must examine the facts of each client's situation before reaching a conclusion. A review of the advisory opinions of the CPSC General Counsel may be helpful. They are available at the Secretary's office and at all regional offices.

There are two types of exclusions from the definition of a "consumer product," complete and partial.[43] The complete exclusions are *purely* industrial articles, tobacco products, motor vehicles, economic poisons, firearms and ammunition, aircraft, foods, drugs, cosmetics and medical devices. The partial exclusion is for marine products to the extent their hazards could be reduced or eliminated under certain marine safety statutes.

Also, the CPSC lacks jurisdiction over risks that could "be eliminated or reduced to a sufficient extent"[44] under the Occupational Safety and Health Act (OSHA),[45] the Atomic Energy Act of 1954[46] or the Clean Air Act.[47] Lastly, the CPSC lacks jurisdiction over those radiation hazards regulated by the 1972 amendments to the Public Health Service Act.[48]

Transferred Acts

The CPSC administers the four transferred Acts as well as the CPSA. The Agency must proceed under these transferred Acts where they are capable of eliminating or reducing the risk to a "sufficient extent."[49] In practice, the Agency has proceeded under the CPSA when it serves its regulatory purposes. For examples, see the proposed regulations on record keeping[50] and the final regulations on

[43] CPSA Sec. 3(a)(1)(A)-(I), 15 U. S. C. Sec. 2052(a)(1)(A)-(I).

[44] CPSA Sec. 31, 15 U. S. C. Sec. 2080.

[45] 29 U. S. C. Secs. 651—678.

[46] 42 U. S. C. Sec. 2011 and following.

[47] 42 U. S. C. Sec. 1857—1857-*l*.

[48] Radiation Control for Health and Safety Act of 1968, 42 U. S. C. Sec. 263b—263h.

[49] CPSA Sec. 30(d), 15 U. S. C. Sec. 2079(d).

[50] See footnote 38.

"self-tattling"[51]—that is, reporting to the Agency that your client is in violation of a standard or that your client's product presents a substantial product hazard.

Self-Tattling

Section 15(b) provides that clients "immediately" inform the CPSC of the discovery of a defect which *could* create a substantial product hazard or of a discovery of a failure to comply with a safety standard.[52] The regulations interpret "immediately" to mean 24 hours.[53] Although the regulations state that the time requirements "pertain to notification during working hours within the business week,"[54] the Agency has installed a device to divert calls from 301-496-7631 to the homes of staff members during nonbusiness hours so that reports can be made at any time. These reports are commonly followed by recalls and widespread publicity.

This article will not go into the details of the self-tattling regulations. They are reasonably straightforward and clear. In sum, they require the filing of 23 categories of information. This mass of data does not have to be filed within 24 hours, but be assured that the CPSC will exert pressure on your clients to file the information promptly if the hazard is deemed serious.

In the last year there were approximately 140 such reports filed and we can now draw on that experience. It is obvious that preparation of the report is a task that is fraught with legal, business and public relations implications. Clients in Section 15(b) situations are in desperate need of sophisticated counseling by lawyers seasoned in dealing with regulatory agencies and with knowledge of the practice of corporate product liability and even criminal law. The bar has learned that counsel must keep their eyes on enforcement proceedings that may quickly follow the passing of the initial reporting crisis. It is becoming rather common to have Section 15(b) reporting situations interlaced with existing or potential product liability litigation and claims. The lawyer *must* constantly assess the impact of the handling of the regulatory problem on private litigation. Be very wary of statements that could be used as admissions-against-interest because nonproprietary portions of these reports are public.[55]

---

[51] See footnote 42.

[52] *Id.*

[53] 16 CFR Sec. 1115.6(a).

[54] 16 CFR Sec. 1115.6(b).

[55] In discussing this subject, Paragraph G of the preamble to the final order promulgating the reporting regulations consistently cites Sec. 1115.7 (a)(24), which does not exist. The intended reference apparently is to Sec. 1115.7(f) which requires the person

(Continued on the following page.)

Prompt Public Disclosure Policy

There are a number of less obvious implications that a lawyer may face. Counsel will have to review the situation with the client to determine if the effects are "material." If so, legal problems of disclosure will arise. The "prompt public disclosure" policy of the New York Stock Exchange and American Stock Exchange will require a public announcement by listed companies.[56] If the company is "in registration," the registration statement will have to be amended.[57] If a private placement is in progress, disclosure to the buyers will be necessary. Surprisingly, recent dicta[58] interpret the provisions of SEC Rule 10(b)-5,[59] the securities fraud rule, to require timely disclosure *even though* securities are *not in registration* and the issuer and insiders are *not buying or selling* the company's stock. The company may wish to make an optional disclosure in an 8-K report to the SEC.[60] Lastly, disclosure may be necessary in the company's next annual report to shareholders. In addition, reports and other disclosure documents may be required during the next four years.[61]

If the client is selling the business, counsel will need to examine the need not only for disclosure to the buyer, but liability for breach of the representations and warranties in the merger or acquisition agreement. If you are on the buyer's side, perhaps you will wish to make inquiries and obtain representations and warranties as to the existence of substantial hazards or other open matters with the CPSC or other agencies. It is becoming increasingly important that lawyers determine if there is a need to update any recent audit letter from the law firm to the client's accountants.

The Agency has developed a novel procedure not mentioned in the statute or regulations. They issue what is called a "pre-15(b) notice," that is, a Western Union Mailgram to clients inquiring whether a certain hazard is reportable under Section 15(b). The

(Footnote 55 continued.)
making the report to identify those portions that are confidential. 39 *F. R.* 6061 at 6065 (Feb. 19, 1974). The Agency has proposed regulations implementing the Freedom of Information Act. 5 U. S. C. Sec. 552. 39 *F. R.* 30298 (Aug. 21, 1974).

[56] *New York Stock Exchange Company Manual*, p. A-18 and following; *American Stock Exchange Company Manual*, Secs. 401—406.

[57] SEC Securities Act Release No. 5180 (Aug. 16, 1971).

[58] *Financial Industrial Fund, Inc. v. McDonnell-Douglas Corp.*, 474 F. 2d 514 (CA-10 1973), rehearing denied, *cert. denied* 414 U. S. 874 (1973).

[59] 17 CFR 240.106-5.

[60] Item 13, Form 8-K, under Securities Exchange Act of 1934, 15 U. S. C. Secs. 78m, 78o.

[61] SEC Securities Exchange Act Release No. 11079 (Oct. 31, 1974).

Agency is currently issuing about three of these notices a day. If your client receives one, treat it as a priority matter and proceed immediately to investigate what facts the company has on the hazard. Be sure to review product liability litigation and claims as well as consumer complaint letters, whether closed or open.

Enforcement

Let us briefly outline enforcement, even though there is not a body of case law to give us guidance.

When a new hazard has been identified, the Agency has four options: standards-setting;[62] banning orders;[63] Section 15(f) proceedings[64] and injunctions and seizures of imminently hazardous products.[65]

Standards-setting has been discussed above. Banning orders are administratively imposed on a record and upon findings that: (1) the product presents an unreasonable risk of injury; and (2) that no feasible safety standard would adequately protect the public.[66] The procedures are governed by the informal rule-making provisions of the Administrative Procedure Act (APA) which provide for a written proposal, written comments and a final order.[67] Although hearings are discretionary under these provisions, the CPSA provides for a mandatory "bobtailed" hearing in which you get the opportunity to present oral argument.[68] However, this is not a trial-type hearing.

Full Adjudicatory Hearing

The third option is to initiate a hearing under Section 15(f) of the CPSA. That hearing is a full adjudicatory hearing under the APA with full rights to cross-examine.[69] The only departure from APA practice is that identical interests may be required to proceed through a single representative or spokesman. The Agency's remedy is an order under Section 15(c) to give various types of notice to the public and the trade, and an order under Section 15(d) requiring the manufacturer to elect among repair, replacement or refund of the purchase price. The Agency has published proposed adjudicative procedures for these hearings.[70] These procedures will also apply to

[62] CPSA Secs. 7 and 9, 15 U. S. C. Secs. 2056 and 2058.
[63] CPSA Sec. 8, 15 U. S. C. Sec. 2057.
[64] 15 U. S. C. Sec. 2064(f).
[65] CPSA Sec. 12, 15 U. S. C. Sec. 2061.
[66] CPSA Sec. 8, 15 U. S. C. Sec. 2070.
[67] 5 U. S. C. Sec. 553.
[68] CPSA Sec. 9(a)(2), 15 U. S. C. Sec. 2058.
[69] 5 U. S. C. Sec. 554.
[70] 39 *F. R.* 26848 (July 23, 1974).

hearings under the Flammable Fabrics Act in proceedings initiated after July 23, 1974. The proposed procedures will be used until superseded by a final order on the proposal.

The fourth option is to file suit in a United States district court to enjoin distribution of or to seize a product presenting an "imminent hazard."[71] The courts in these proceedings are empowered to grant ancillary relief, temporary or permanent, as is necessary to protect the public. This includes notice, recall, repair, replacement and refund.

Three Options

When faced with a violation of the statute, the CPSC has three options:

(1) File suit in a United States district court to seize violative products and enjoin further violation and distribution.[72]

(2) Seek civil penalties of up to half a million dollars. The statute does not expressly state whether these civil penalties are imposed by the Agency or a court. The legislative history contemplates the Agency's imposing the fines.[73]

(3) Seek criminal penalties. Presumably these are judicially imposed although the statute is curiously silent on this point. Corporate directors, officers and agents can be personally liable for a knowing violation after the CPSC issues a notice of noncompliance.[74]

A detailed discussion of all the provisions of the new statute is beyond the scope of this article. There are provisions for information gathering and release, record keeping, certification, imports and exports, new product notification, private damage actions and a host of others.

If at this point you are convinced that the Agency is a force to be reckoned with and that the bar needs to acquaint itself with this new statute and Agency, then my purpose has been accomplished.

[The End]

---

[71] CPSA Sec. 12, 15 U. S. C. Sec. 2061.

[72] CPSA Sec. 22, 15 U. S. C. Sec. 2071. Compare with Federal Food, Drug and Cosmetic Act, Sec. 302, 21 U. S. C. Sec. 332.

[73] House Report No. 92-1153, 92nd Congress, 2nd Session, p. 46.

[74] CPSA Sec. 21, 15 U. S. C. Sec. 2070.

What Price Uniformity ?

By MERRILL S. THOMPSON

Mr. Thompson Is a Partner in the Law Firm of Chadwell, Kayser, Ruggles, McGee & Hastings.

WHENEVER I'M MULLING OVER PRE-EMPTION as a possible solution to our lack of uniform food and drug laws, I think of it in terms of it being the most drastic and dangerous solution of all. I am frightened by the thought of such major surgery to correct even the acknowledged inconveniences of the system. As my title suggests, I am still asking myself—and you: Do we really want to pay such a high price for uniformity?

I promised to present the case favoring federal pre-emption, and I will. After presenting that case, however, I intend to go on to tell you why I remain genuinely undecided, and I'll make a suggestion as to what I think we should do before Congress makes its decision.

Those who favor increased federal pre-emption with respect to food and drug laws generally raise one or more of the following supporting arguments.

(1) Regional differences are disappearing. The country has become almost a single economic and health unit, rather than being a collection of 50 units. We may not like it, but the distinction between interstate and intrastate commerce in foods and drugs is all but obsolete.

(2) The demands we are trying to satisfy through our food and drug laws cry out for a uniform national policy. The problems facing consumers across the country are virtually uniform, so responses to those problems should be uniform.

(3) Certainly the safety and abundance of our foods and drugs are matters of such ultimate importance that they deserve regulation at the very highest level. Most would agree that we should have a supreme court for safety.

(4) While the present system does reflect a large degree of success, uniformity will never really be achieved without federal pre-emption. Moreover, to the extent that state and local officials already give substantial deference to federal laws and regulations, statutory pre-emption would actually result in very few changes.

Explosion in Technology

(5) The need for further at least selective pre-emption is greater now than ever before. The post-war explosion in technology caused a flood of problems to challenge state resources in the 1950's and early 1960's, but they were nothing when compared with the upheaval caused by the consumerism of the late 1960's and the 1970's. The resulting proliferation of well-intentioned but conflicting points of view combined with a sometimes irrational urgency or even ill-disguised wish for notoriety has resulted in an ever increasing lack of uniformity. Open-date labeling is a prime example. We can all recognize that very real dangers lie in leaving the evolution of such politically popular consumer protection laws to the competitive instincts of the multitude of state and local office seekers. It seems probable that our system cannot control and avoid these dangers without federal pre-emption.

(6) When we suggest pre-emption, we are not suggesting something new and strange. By reason of the supremacy clause in the Constitution, federal pre-emption has been a fact of life since the founding of the country. There are numerous pre-emptive federal laws already on the books. The Wholesome Meat Act, for example, is just one of them. The question being considered is whether to expand pre-emption into new areas by new legislation. It is more a matter of degree than a matter of approaching the threshold of a new era.

(7) Any individual state is even now at least partially subject to the pre-emptive powers of its neighboring states. So few articles in commerce are both created and consumed within a single state that the products of an industry are inevitably governed by the lowest common denominator of the laws of its neighbor states. Most of the goods consumers purchase are produced and labeled to meet the special requirements of neighboring states. In effect, the single neighboring state—or city, for that matter—with the most stringent law or regulation pre-empts a manufacturer's prerogative simply by its action. As the country shrinks into a more closely tied bundle of

interdependent units, the potential chaos from having at least fifty and maybe hundreds of pre-emptive powers brought to bear on any given issue becomes more and more real and threatening to the industry-consumer-state agency triad.

Economic Burdens

(8) If increased federal pre-emption is not sought through new legislation, then it will be hammered out in the courts. The economic burdens created by non-uniform laws are simply too great. Personnel will be tied up and individual programs will be held in confusing abeyance while an array of lawyers with varying talents argue such questions as implied pre-emption, state and federal conflicts, burdens on interstate commerce, trade barriers, and deprivation of property without due process. These are the tools which are used to forge an involuntary uniformity in the absence of explicit federal pre-emption. Perhaps the legislative route is better for all concerned.

(9) Through selective federal pre-emption, state agencies and state officials might be relieved of responsibilities they find impossible to carry out. In many states, such officials are placed squarely in the middle of conflict and controversy by the lack of resources to carry out assigned tasks. Federal pre-emption could ease these burdens.

There is, no doubt, an argument or two which I have failed to raise but I believe I have covered those having the greatest weight. Taken together, they are quite persuasive.

But it is possible to relate another side to virtually every argument just presented. I do feel obligated to tell you what bothers me the most about federal pre-emption. Simply stated, I am troubled by the philosophy of centralized authority and the attendant corruptible power which must be embraced as unavoidable consequencs of pre-emption. My instincts, principles and 17 years of professional experience tell me that pre-emption is a road we should follow only as a last resort.

Excellence and Efficiency

Are we so sure that a single federal agency promises excellence and efficiency? Are we confident that it will not abuse its ever-increasing power? Will we merely be substituting one highly overextended federal agency for our present under-funded state agencies?

As of now, the states act as checks and balances on federal power. For example, one would think that the Food and Drug Administration (FDA) has to be conscious of its burden of proving that it is right and reasonable before it creates conflicts with the states. This inhibition is even more valuable now than it was in years past because the FDA is presently finding it necessary to cut procedural corners. The flavor labeling regulations suggest that the FDA, in its desperation, may be more concerned about getting the job done somehow than it is about doing it carefully. Concurrent responsibility makes it mandatory that the federal establishment at least listen to the views of state officials.

Consider also that the existence of viable state power and state agencies is some measure of insurance against serious breakdowns in federal effectiveness. Were we to repose all responsibility in the FDA, the consequences would be horrendous if the Agency should experience its own Watergate.

Another danger lies in accepting too readily the premise that there are no parochial needs meriting recognition. It could be very important to preserve for each state the prerogative to act for itself when the need arises. It may be imperative to somehow accommodate the differing interests of the individual states and local units of government, in addition to achieving uniformity.

Federal-State Jurisdiction

Still another line of thought presents itself whenever pre-emption is discussed. If we eliminate concurrent federal-state jurisdiction, will we, in fact, be eliminating the chief source of our most troublesome lack of uniformity? I don't think so.

When will we have uniformity among the FDA, the Federal Trade Commission and the United States Department of Agriculture? What will happen to uniformity when we have a Consumer Protection Agency? Can we ever hope for uniformity if Congress gives individuals the private right to bring lawsuits against the government and against industry for alleged violations of consumer protection laws?

How much day-to-day uniformity would we have now if we had only the FDA's regulations and interpretations to comply with? Four versions of the Agency's flavor labeling regulations were published in the *Federal Register* in 1973 and the regulated industries had

to talk in terms of lawsuits to correct the lack of practical knowledge reflected in the final regulations. Is that uniformity? The nutrition labeling regulations were in a constant state of flux for more than two years before their adoption. The FDA's actions with respect to the flour and bread standards surely reflect many things, but not uniformity. For example, in the *Federal Register* of February 11, 1974,[1] the Commissioner was forced to condone in print the outright misbranding of the amount of iron in bread products because he had only weeks earlier advised the bread industry that it could switch to higher levels of iron even before the public had an opportunity to object. Now we presumably will find two competing loaves of bread on the market, each containing the same amount of iron but labeled to indicate that one contains more than the other. I'd say that's the worst lack of uniformity of all.

Turnover in Personnel

Perhaps another factor which tends to make federal uniformity rather ephemeral or illusory is the turnover in federal personnel. Stated another way, each year there seem to be fewer and fewer career personnel in the key policy-making positions at the FDA. Yet, more than ever before, as a practical matter, the law seems to parallel that which the individual administrator says it is. Thus, a rule of law can change with each change of personnel, thereby detracting from any sense of continuity or uniformity. Contradictory interpretations among successive federal officials are just as expensive and counterproductive as are conflicts between state and federal officials.

If I had to estimate the practical impact of the current non-uniformity within the federal establishment and compare the resulting costs and concerns against those attributable to the lack of federal-state uniformity, I believe I would conclude that the federal problem demands more of our attention and is presently wasting far more of our valuable resources.

Since I cannot seem to make up my own mind whether federal preemption would be good or bad, I would prefer to see the matter studied and explored in depth, on a non-political basis, before a decision is made. I wish that the Congress would hold off legislation until an advisory legal committee could be appointed by the Commissioner of Food and Drugs to fully consider the impact of pre-emptive legislation on state programs. The same committee could review the capacity

[1] 39 *F. R.* 5188.

and ability of the FDA to absorb still further extensions of the responsibilities which are already straining its resources to the point of inaction on the economic front.

Formation of Committee

A committee consisting of a consumer activist, a judge (if practicable), an FDA lawyer, a law school professor, a representative of the Association of Food and Drug Officials of the United States, an industry lawyer and the president of the Food and Drug Law Institute might well come up with a truly innovative recommendation to the Commissioner and, eventually, to the Congress. They might explore, for example, the feasibility of substituting for pre-emption an affirmative legislative program providing for the subsidization of state administrative and enforcement costs whenever an individual state achieves substantial uniformity with all parallel federal laws concerning foods, drugs and cosmetics. Perhaps it could work somewhat like the present federal aid to local education or state highways. In both cases, those federal programs appear to be designed to promote and encourage uniform quality and coordination across the country. Would not such a plan promote uniformity while preserving viable state agencies capable of acting independently?

Perhaps this idea has very little merit. It probably isn't new. But it serves my purpose of suggesting that there may be a number of compromises which ought to be more fully explored while we contemplate the price of uniformity. **[The End]**

FOOD DRUG COSMETIC LAW JOURNAL

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

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

BUSINESS REPLY MAIL

No Postage Stamp Necessary if Mailed in the United States

POSTAGE WILL BE PAID BY–

COMMERCE CLEARING HOUSE, INC.

PUBLISHERS of TOPICAL LAW REPORTS

4025 W. PETERSON AVE.

CHICAGO, ILL. 60646

ORDER
CARD

MAIL TODAY!

FIRST CLASS
PERMIT NO. 57
CHICAGO, ILL.

FOOD DRUG COSMETIC
LAW JOURNAL

ORDER FORM

MAIL TODAY!

CCH:

Promptly when ready in November, send ..... copies of the 1976 U. S. MASTER TAX GUIDE (5956) at the following prices: 1-4 copies, $7.00 each; 5-9, $6.50 ea.; 10-24, $5.90 ea.; 25-49, $5.00 ea.

To save postage, handling and billing charges, you may elect to send remittance with order. Include sales tax where required.

☐ Remittance herewith ☐ Send bill

Signature .....

Firm .....

Attention .....

Street & No. .....

City & State ..... **Zip** .....

(Subscribers to CCH's Standard Federal Tax Reports and Current Law Handybooks receive this item and should order only for additional copies.)

Please Indicate Your CCH Account No.

.....

(5199) 5956—2656