VOL. 19, NO. 4 APRIL 1964

Food Drug Cosmetic Law JOURNAL

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $20; 3 years, $49; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

April, 1964
Volume 19 • Number 4

Second-class postage paid at Chicago, Illinois.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . April, 1964

VOLUME 19 NUMBER 4

REPORTS

TO THE READER

Armour v. Freeman.—*Kenneth R. Myers* probes into the background of the significant decision in this case which is commonly referred to as the "wet ham" controversy. In a paper which begins on the following page, he examines the subtleties and complications that have attended this recent application of the Meat Inspection Act to sales in interstate commerce of smoked ham. Mr. Myers is with the Chicago law firm of Ross, Hardies & O'Keefe.

Quality Control.—"An 'updated' quality control program assures uniform quality products processed under a given product label," declares *Wilbur A. Gould,* professor and head of the Processing and Technology Division, Department of Horticulture, Ohio State University and Ohio Agricultural Experiment Station. In a paper presented at the Food Update Midwest Highlights—1963, he adequately answered a number of important questions concerning the development of such a program. The paper beginning on page 217 explains, for example, what quality is and various methods for determining it.

Information Center.—In an interesting article appearing on page 232, *George L. Saiger, M. D.,* describes the functions of the Food and Drug Administration Information Center on Adverse Reactions and Hazards. He declares that "the Center collects, screens, evaluates, stores, retrieves, re-evaluates and disseminates information on adverse reactions and hazards. There are recommendations for further study, precautionary labeling, a change in labeling, the issuance of a warning letter or withdrawal from use." Dr. Saiger, Director of the Division of Research and Reference, Bureau of Medicine, feels that there is room for improvement with respect to the development of international sources, but he believes that progress is being made in all directions.

Investigational Drugs.—The Assistant Commissioner of the Food and Drug Administration, *Winton B. Rankin,* discusses some of the more urgent questions that have arisen during the first year of administration of the Kefauver-Harris Drug Amendments, especially those relating to investigational drug procedures. In particular, he considers the investigational drug procedures that have been set forth in regulations first proposed under the old law, but put into effect under the new amendments. Mr. Rankin's paper begins on page 237.

Scientists' Forum.—*Bernard L. Oser,* Scientific Editor of the JOURNAL, discusses the use of chemical agents in agriculture and technology and the measures being taken to insure safety and protection of the public's health. The comments by Dr. Oser, who is president and director of Food and Drug Research Laboratories, Inc., appear on page 243.

Vol. 19, No. 4 April, 1964

Food·Drug·Cosmetic Law
Journal

The Wet Ham Controversy and New Concepts in Federal Food Regulation:

Armour v. Freeman

By KENNETH R. MYERS

The Author Is with the Law Firm of Ross, Hardies & O'Keefe in Chicago.

IT IS OFTEN STATED that Americans are the best-fed people on earth. Our populace is probably the most chronically overweight, the most conscientiously vitaminized, the quickest to respond to food fads and fancies, and the one with tastes for the most varied cuisine in the world. We are also the proprietors of an agriculture whose production outpaces demand more than that of any other nation. It is therefore not surprising that Congress has frequently undertaken to rationalize and simplify food marketing.

The present inquiry begins with a common staple: cooked, cured shoulder of pork, called smoked ham. The statutory scheme under examination is the Meat Inspection Act of 1907,[1] the initial significant attempt by the federal government to bring order and fair dealing

[1] 34 Stat. 1260 (1907) as amended, 21 U. S. C. 71, and following, Food Drug Cosmetic Law Reports ¶ 720.

to the food industry. The subtleties and complications that have attended the most recent application of this statute to sales in interstate commerce of smoked ham are the basis for this paper.

Because the outcome of the litigation between meat packers and the government places the validity of some regulatory techniques in doubt, inquiry must be made into alternative relief that Congress has provided through the Federal Food, Drug and Cosmetic Act. More important, however, is the effect of this case on the regulatory powers that have long been assumed to flow from the Meat Inspection Act.

ORIGINS OF THE HAM DISPUTE

Cooked ham is a popular staple, available in many forms. Raw shoulder of pork, refrigerated and sold in meat markets, is probably the most economical style of the meat. Purchased this way, the ham must be thoroughly cooked before serving and is subject to spoilation. Housewives may fear that a hazard of pork products, the trichina worm, makes the purchase of raw ham unwise. Whatever the reason, pork products are more frequently marketed in precooked forms than are other meats.

Precooked ham is sold in plastic bags in markets with natural fat and bone intact at a significant price premium over the raw product. Even higher on the cost scale is canned precooked ham, which keeps indefinitely and is available in a variety of cuts, styles, sizes and prices. Typically, the shank bone has been removed and an indeterminate amount of fat has been trimmed from the meat. The ham may be cooked, smoked or cured, the latter two processes being difficult to perform at home. These hams sell at two to three times the price of raw ham.

In 1955, a new method for smoking ham was introduced in the meat packing industry. Instead of lengthy pickling, the hams were given an "injection" of curing chemicals that created the same flavor and texture as the slower process, all in the short time required to boil the ham until cooked.

This instant process gained quick acceptance among meat packers. The packers discovered that by varying the strength of the curing solution, they could make the ham absorb large quantities of water while it was cooking or, alternatively, lose natural moisture in the process. Whether wet, dry or natural, the hams exhibited the same smoked taste and texture as the slowly cured product. The weight of

the cooked hams, however, could be increased up to 30 per cent or decreased slightly from the uncooked or "green" weight of hams before the processing. This weight variation represents retained and absorbed water content. Since the hams are sold by weight of the final product, the economic impact of this discovery was that water could be sold at the price of ham.

Of course, the protein content of a ten-pound ham cured from a nine-pound green weight product is one-tenth less than that of a cooked ten-pound green weight ham, and although most purchasers apparently cannot discern the presence of water by the appearance, taste or smell of the ham, long cooking may drive the added moisture from a wet ham. This leaves the unknowing purchaser with less than that for which he presumably bargained. However, the artificially added moisture constitutes a more healthful "natural" gravy than would result if a nine-pound ham had been cooked in a pint of water, according to nutritional experts representing the meat packers. Further, there is some basis for concluding that wet hams lose less nutrients in curing than hams returned to green weight.

Economic Questions Raised by Controversy

The substantive economic questions are therefore two: whether any deception of the purchaser occurs when the ham is sold, and whether the moisturized ham is inherently less healthly than its dry counterpart. The first issue will be referred to as the question of economic adulteration and the second, simply as the nutritional problem.

From 1955, when the new method of curing was first employed, until 1960, the capability of packers to enhance the weight of smoked hams posed no significant consumer problem. A pre-existing regulation [2] by the Secretary of Agriculture limited the weight of smoked hams to green weight, thus preventing the sale of wet hams in interstate commerce (which includes over 80 per cent of the meat market).

In late 1960, Secretary of Agriculture Ezra Taft Benson promulgated a new regulation [3] permitting meat packers to add up to 10 per cent moisture to smoked hams sold in interstate commerce. The Department of Agriculture justified this action on two grounds: that interstate packers were at a competitive disadvantage with respect to local packing houses, outside the jurisdiction of federal regulations,

[2] 17 *Federal Register* 4845, 9 CFR 17.8(c) (1952).

[3] 25 *Federal Register* 13952, 9 CFR 17.8(c) (1960).

who supposedly were adding 30 per cent moisture to the smoked hams they sold; and that consumer tastes created some demand for the moisturized meat, constituting a market from which interstate packers should not be excluded.[4]

Economic Adulteration Issue

The new regulation took effect on December 31, 1960. Before that date, Armour and Company, an interstate packer, had been selling smoked ham at a rate of about 55 million pounds per year, of which approximately 82 per cent was natural weight ham. The remaining 18 per cent of Armour's production contained 10 per cent added moisture and was labeled "Imitation Ham," in accordance with the regulation applicable to foods that do not comply with the Secretary's standards of content and have no independent established identity.[5] After Secretary Benson's regulation, Armour produced only wet hams, at a rate of 62 million pounds per year.[6] Although statistics are unavailable, it may be assumed that the packing industry as a whole experienced an equivalent transition and market growth.

The packers dispute whether the economic adulteration of smoked ham at this time resulted in an actual fraud upon buyers. Public hearings held by the Agriculture Department in 1961, if they did not prove affirmatively that moisturized ham was sold at proportionately lower prices than dry ham, at least failed to demonstrate that wet ham sold at the same prices as the dry product.[7] At any rate, in its complaint requesting injunctive relief against new regulations under the Meat Inspection Act, filed November 6, 1961, Armour undertook to prove the affirmative proposition that the price of the net protein remained constant.[8]

Economic analysis cannot prove that watered ham will generally command an increased price for the net protein content. In a market that is highly competitive, sale price is a function of cost. If smoked hams were sold under pure competition, a product containing 10 per cent diluent would necessarily sell at a 10 per cent lower price than the unadulterated ham, disregarding the costs of the diluent for

---

[4] *New York Times*, December 31, 1960, p. 10.

[5] 6 *Federal Register* 1142, 9 CFR 17.8(b) (1941).

[6] Brief for Appellant, p. 6, *Armour v. Freeman*, 304 F. 2d 404 (DC of D. C. 1962). (Suit for injunctive relief against Secretary Freeman's amendment of the Benson regulation.)

[7] See Brief for Appellant, cited at footnote 6, p. 7.

[8] Joint Appendix, p. 9a, pleading 19(2), *Armour v. Freeman*, cited at footnote 6.

simplicity. However, reasons exist for concluding that the premise of competition is not applicable to the entire ham market.

Buyer activity is the operative element that causes price to vary inversely with the extent of dilution of a product in a competitive market. Economic theory assumes that a buyer who must choose between 10 per cent wet ham and dry ham will choose dry ham until the price of wet ham descends to nine-tenths of the cost of the dry. But in fact, buyers may choose locally packed hams containing 30 per cent water, interstate hams with 10 per cent water, and even premium hams at dry weight. All of these products bear the same label, and their appearance and taste do not reveal the dilution. Therefore, the purchaser would tend to choose the least expensive product according to classical economic theory. If the market was purely competitive, based entirely on cost, that product would be the most highly adulterated (since ham costs more than water) and hence the 30 per cent diluted ham would set the market price for all packers. In fact, all varieties of ham are sold in the market daily, at widely varying prices, indicating that pure competition among all ham packers is not the proper model for the forces at work.[9]

Armour's contention that prices are reduced to compensate for the water content of smoked hams might be supported if all interstate packers of ham were in strong competition, even though they did not compete with local brands. If strong price competition prevailed among national meat packers, and all national packers added the same amount of moisture to their product, it would be anticipated that price reductions would shift to the consumer the cost savings from watering the product. However, current market data belies the existence of substantial price competition among the packers. On a recent market day in Cambridge, Massachusetts, one seller offered ten varieties of federally inspected canned cooked ham (all presumably containing 10 per cent moisture by weight). Prices per pound ranged from a minimum of 93 cents (Swift and Company) to a maximum of $1.33 for Armour smoked ham. The latter, although highest in price, is currently the most popular brand.[10]

[9] It might be theorized, alternatively, that cost savings based on high volume enable the interstate packers to sell 10 per cent wet ham competitively with local 30 per cent wet ham. The actual market condition is otherwise, however. Interstate ham generally sells at a premium, demonstrating that production efficiency is not responsible for the continued popularity of this product.

[10] This inversion from a competitive, price conscious market might be attributed to better cooking and dressing of Armour products. The writer suspects that it is probably related more closely to Armour's advertising activities, which outstrip all of its competitors'.

It must be concluded from this evidence that Armour is not in direct price competition with local or national packers. Further, Armour is able to dominate sales even when its interstate competitors reduce their prices significantly. Since Armour, for one, is not forced to meet the prices charged by other ham packers, there is little basis for the assertion that any correlation that may exist between market price and protein content in the sale of smoked hams is a result of market economics. If prices do vary with protein content, this might more reasonably be attributed to coincidence than to inexorable rules of market selling.

At present, no court has ruled upon the question of consumer fraud from the economic adulteration of ham. The Agriculture Department has taken the position that consumers are deceived by wet smoked hams,[11] although its theory does not appear to depend upon whether the moisture content increases the net cost of the ham.

Nutritional Problem Discussed

The nutritional problem is similarly unresolved. Secretary Benson argued that at least some consumers prefer wet hams; Secretary Freeman reported the results of a taste test of 500 persons, conducted by the Department of Agriculture, concluding that,

> [M]ost participants preferred ham cured at lower than the 120 per cent moisture level [20 per cent added water]. There was no significant difference in taste preference for hams at the 95 per cent, 100 per cent, and 110 per cent moisture levels, although those at the 95 per cent level were recognized as dry hams.[12]

Armour contends that wet hams are "every bit as wholesome and healthful" and that "consumers prefer these products."[13]

Both the taste tests and common experience suggest that consumers are totally unaware of the differences in ham, at least up to 10 per cent moisture content. However, the alteration in Armour's selling pattern after December 31, 1960 (in which wet ham rose from 18 per cent to 100 per cent of production) suggests that the label "Imitation Ham" is a serious drawback in the sale of the product.

Opposing claims by the Agriculture Department and the meat packers as to the food value of wet hams are probably conjectural. On the side of wet ham, it is suggested that the smoking process moisture aids the ham in retaining nutritional elements, improving

[11] Brief for Appellees, *Armour v. Freeman*, cited at footnote 6, p. 12.

[12] Brief for Appellees, cited at footnote 11, p. 9.

[13] Brief for Appellants, cited at footnote 6, p. 21.

wet hams over their dry counterparts. The packers do not claim that 10 per cent wet ham is 10 per cent more nutritious than natural weight ham or that consumers tend to serve heavier portions of the wet product than of the dry to compensate for the missing protein. A family that consumes a five-pound "ham" at a meal will probably continue to do so regardless of the moisture content; if this is true, the relevant nutritional comparison is not between a 4.5-pound ham cured to green weight and a 4.5-pound ham augmented to five pounds by moisture, but between a 10 per cent wetted 4.5-pound ham (net weight five pounds) and a five-pound ham cured to green weight. Therefore Armour's conclusions as to the superior nutritional values of wet ham, all based on comparisons of equal precooking weights, may not eliminate the question of food value.

THE SECRETARY'S ACTION

With this insight into the marketing of ham, it is apparent that Secretary Benson's midnight regulation of December 31, 1960 is subject to serious question.[14] In a regulatory area where minimum requirements tend to become maxima too, the Benson rule does not demand even a statement on the label of the ham revealing the added moisture (and no ham label has been found that alludes to water in any form).

The Secretary of Agriculture contends, and the district court made a preliminary finding that,

> The December 30, 1960 amendment resulted in heavy protest and vigorous opposition from consumer organizations and individuals.[15]

In all candor, this cannot be concluded.[16] Nonetheless, the ham situation may have required revision to increase the level of consumer

[14] The *New York Times,* July 30, 1961, p. 46, reports that the December 31, 1960 regulation "brought sharp criticism from some consumer groups and some of Mr. Benson's political foes. They contend he was giving the big packers a favor before he left office—allowing them to sell consumers water at ham prices."

[15] Findings of Fact and Conclusions of Law on plaintiff's motion for preliminary injunction, finding 10, Joint Appendix, cited at footnote 8, p. 102a (November 14, 1961).

[16] A search through periodical literature and the *New York Times* reveals no mention of the Benson regulation at all, except for an announcement of its promulgation (*New York Times,* December 31, 1960, p. 10). *After* Secretary Freeman called hearings to revise the Benson rule (March 17, 1961), public interest arose and a few articles appeared in *Consumer Reports* (see title "The Great Ham Robbery") decrying that existing regulation. By contrast, that March issue of *Consumer Reports* contains a long article on various forms of consumer fraud and deception in food marketing, but does not mention ham at all. Public interest in watered ham appears to have been nonexistent prior to March 17.

information and protection. Secretary Freeman may also have been influenced by a desire to bolster the pig market, which had just recovered from a lengthy recession. Agriculture Department figures released in June, 1961, but probably anticipated in March, indicated a 5 per cent increase in pig production entering the market in early 1962. The Secretary may have reasoned that housewives would continue to purchase the same weight hams regardless of water content. Thus, a return to the green weight rule would bolster raw pork demand significantly.

Secretary Freeman ordered hearings to investigate the operation of the Benson amendment and to consider its revision in March 1961. These hearings were held in April and May in eight cities across the nation. Written comments were accepted by the Department of Agriculture until June 10, 1961. In July, Secretary Freeman appointed a committee of three men to review the evidence adduced at the hearings and to make recommendations.[17]

No report by the hearing examiners or the committee was published by the Department of Agriculture.[18] On September 2, 1961, the Associated Press wires carried a statement that wet hams would be outlawed by the Agriculture Department within 30 days.[19]

The amended regulation appeared in the *Federal Register*[20] on October 18, 1961, to take effect on November 17, 1961. It prevents

---

[17] *New York Times,* July 30, 1961, p. 46.

[18] Armour later contended that the Secretary had violated Section 4(b) of the Administrative Procedure Act, 5 U. S. C. 1003(b), by reaching a decision before "consideration of all relevant matter presented" (Brief for Appellants, cited at footnote 6, p. 24). Armour also argued that the Secretary's regulation was invalid as lacking a statement of purpose required by the Administrative Procedure Act (Brief for Appellants, cited at footnote 6, p. 25) and that the Secretary violated his own ground rules by prejudging the case (Brief for Appellants, cited at footnote 6, p. 28). The court of appeals opinion ignores these contentions, presumably because a legislative ruling was involved, thus eliminating the argument of prejudgment, and the basis for the ruling was so apparent as to require no elucidation. As to violation by the Secretary of his own rules, the court may have determined not to raise the issue because under present law it is not susceptible of proof that the three-man committee did not submit its recommendations. Of these presumed silent rulings by the court, only the one dispensing with the "concise, general statement of their basis" that must accompany a ruling is significant. The discussion in the text above makes it clear that the Secretary may have based his ruling on any of a number of theories of monetary or nutritional deception of the public. Under the present amended rule without stated bases, Armour must disprove all theories in order to show that the Secretary's action was capricious.

[19] *New York Times,* September 2, 1961, p. 17.

[20] 26 *Federal Register* 9772.

federally inspected meat packers from attaching the label "ham" to any smoked product that exceeds green weight. Armour and the Department of Agriculture agree [21] that after the amendment goes into effect all wet hams are required to be labeled "imitation" by a pre-existing regulation.[22] The effect of the new regulation is therefore to return to the rules effective from 1952 to 1960.

Armour's Allegations

On November 6, 1961, Armour filed suit in District Court for the District of Columbia, seeking an injunction against any enforcement of the amended regulation and a declaratory judgment that the amendment is void.[23] Armour alleged that the Secretary had violated his own rules in calling a committee but not considering their report; that the Administrative Procedure Act was violated by the absence of findings or basis in the notice of amendment; that the amendment was contrary to the facts presented at the hearing and was arbitrary and capricious; and that Armour would be injured by the amendment because it could not sell its existing inventory of wet smoked hams at the existing market price after November 17, 1961. By supplemental affidavit, Armour raised an additional contention that the requirement that wet hams bear an "imitation" label was a violation of the Meat Inspection Act because it constituted false and deceptive labeling of the product.

After a hearing, the district court issued preliminary findings on November 14, 1961 denying Armour's request for a temporary injunction.[24] These findings state that there is a "genuine issue of material fact" as to whether the Secretary "acted arbitrarily and capriciously." [25] However, the court went on to find "substantial compliance" with all procedural requirements in the promulgation of the amendment to the rules.

The district court did not estimate the likelihood that Armour would prevail on the merits. Instead, it determined that there was no threat of irreparable injury to Armour sufficient to justify the issuance of an injunction and that the public interest would not be served by that action. The findings and conclusions of the district

[21] See Brief for Appellants, cited at footnote 6, p. 11; Brief for Appellees, cited at footnote 11, p. 4.

[22] 6 *Federal Register* 1142, 9 CFR 17.8(b) (1941).

[23] The Complaint is reproduced in the Joint Appendix prepared for the court of appeals, cited at footnote 8, p. 3a.

[24] Joint Appendix, cited at footnote 8, p. 100a.

[25] Joint Appendix, cited at footnote 8, p. 103a.

court do not discuss Armour's contention that the label "imitation" on wet ham is false and deceptive.

Armour appealed this preliminary decision, obtaining a reversal [26] in the court of appeals on February 8, 1962.

In a three-page opinion for a unanimous court, Chief Judge Miller determined that the amended regulation

> [I]s capricious and arbitrary on its face in requiring a packer to label a genuine ham as Imitation Ham, thus forcing him into violating the statute which forbids misbranding. . . .[27]

The court then clarified its position by stating that the choice of a label revealing "the nature and extent of the added moisture" would have "made this litigation unnecessary." The remainder of the opinion contains a finding that Armour would be irreparably injured by enforcement of the regulation because of "damage to its good name" from selling "grossly misbranded" meat products, and a short statement that the public interest is not harmed by the issuance of a temporary injunction.

Undoubtedly greatly surprised at this decision, the government filed a petition for rehearing *en banc,* supported by a longer brief than the original Brief for Appellees. On April 2, the court ruled that the petition (filed about four weeks after the decision was announced) was untimely under Rule 26, which provides 15 days for such action.[28] (Four of nine judges dissented from this ruling on the ground that a timely motion by the government to extend the time limit for the petition, although not granted, had not been denied. In a separate dissent,[29] they also expressed their opposition to the majority opinion on the merits, apparently without aid of oral argument or any reply to the government Petition for Rehearing from Armour.)

No trial of this case on the merits has been reported.

Statutes and Cases on Economic Adulteration

Secretary Freeman sought authority for his amendment to the ham regulations in the Meat Inspection Act of 1907, which includes the following general safeguard for consumers:

> When any meat or meat food product prepared for interstate or foreign commerce . . . shall be placed or packed in any can, pot, tin, canvas, or other receptacle or covering . . . the person, firm, or corporation preparing said product shall cause a label to be attached to said can, pot, tin, canvas, or other

[26] Case cited at footnote 6; cert. denied 82 S. Ct. 1559 (1962).
[27] Case cited at footnote 6, at p. 406.
[28] Case cited at footnote 6, at p.407.
[29] Case cited at footnote 6, at p. 414.

receptacle or covering, under the supervision of an inspector, which label shall state that the contents thereof have been "inspected and passed" . . . and no such meat or meat food products shall be sold or offered for sale by any person, firm, or corporation in interstate or foreign commerce under any false or deceptive name; but established trade name or names which are usual to such products and which are not false and deceptive and which shall be approved by the Secretary of Agriculture are permitted.[30]

This provision, clearly broader than an economic adulteration clause, has been interpreted to extend the false labeling approach to many types of food processing evils.

The "sister" statute of the Meat Inspection Act, the Agriculture Appropriation Act of 1906[31] (which applied to all foodstuffs not subject to the Meat Inspection Act[32]) specifically proscribes economic adulteration in a clause that has been retained in its successor legislation, the Federal Food, Drug and Cosmetic Act of 1938.

A food shall be deemed to be adulterated—(b)(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value that it is.[33]

Another section of the Federal Food, Drug and Cosmetic Act gives the Secretary of Health, Education and Welfare the power to seize and condemn adulterated food.[34]

The precision with which this statute pinpoints the substantive evil of economic adulteration is demonstrated by a typical application, *United States v. 88 Cases Bireley's Orange Beverage*.[35] The government condemned Bireley's orange drink, which was said by the court to contain "about 6 per cent orange juice, 2 per cent lemon juice, 87 per cent water, and small quantities of various other harmless substances."[36]

The court interpreted and applied Section 342(b)(4):

Undoubtedly, any percentage increase in the orange juice content with a corresponding decrease in water content would represent some improvement in food value. Hence, literally the product appears better than it is if it appears to the consumer to contain more than 6 per cent orange juice.[37]

---

[30] 21 U. S. C. A. 75, FOOD DRUG COSMETIC LAW REPORTS ¶ 725.

[31] C. 3913, 34 Stat. 674. The enforcement of this law, originally entrusted to the Department of Agriculture, has been transferred to the Secretary of Health, Education and Welfare by the 1953 Reorganization Plan, Sec. 5, 18 *Federal Register* 2053, 67 Stat. 631.

[32] 21 U. S. C. A. 392(a), FOOD DRUG COSMETIC LAW REPORTS ¶ 427.

[33] 21 U. S. C. A. 342, FOOD DRUG COSMETIC LAW REPORTS ¶ 122.

[34] 21 U. S. C. A. 334, FOOD DRUG COSMETIC LAW REPORTS ¶ 91.

[35] FOOD DRUG COSMETIC LAW REPORTS ¶ 50,091.05, 187 F. 2d 967 (CA-3 1951).

[36] Case cited at footnote 35, at p. 971.

[37] Case cited at footnote 35, at p. 971.

Margarine Case

The ease with which the court attained its formulation of the substantive violation in *Bireley's* has sometimes been matched in applications of the Meat Inspection Act to labeling cases. In the case of *Brougham v. Blanton,*[38] the Agriculture Department was called upon to defend its refusal to inspect and approve a margarine labelled "Creamo." The product contained animal fat, bringing it within the jurisdiction of the Meat Inspection Act. The Court upheld the Secretary's determination that the name "Creamo" deceived people by implying a significant butter or cream content in the product and also stated that

> [T]he power of determining whether a trade name is "false or deceptive" given by the law to the Secretary of Agriculture is, when exercised, conclusive of the falsity or deception of the name . . . the decision of the department, unless arbitrary, is conclusive.[39]

It should be noted at this juncture that false labeling and economic adulteration, although theoretically distinguishable, are in practice overlapping. "Creamo" was originally a margarine with significant dairy content; gradually, economic motives caused a reduction of the use of dairy ingredients until the label was no longer justified. The opinion of the Court employs a labeling approach, grounded on the possibility of misleading the public. The substance of a labeling violation would be that the product called "Creamo" was not really "Creamo," regardless of what it really was. Alternatively, if it could be shown that "Creamo" suggested to consumers significant dairy content that some margarines include, then the theory of economic adulteration would succeed because the current product held less than the common level of dairy nutrients "standard" in enriched margarine. This is, in fact, the theory of *Brougham v. Blanton,* for the Court found a danger of consumer fraud that is basically confusion of Creamo with a better product. Therefore, the distinction between false labeling and economic adulteration frequently disappears.

The Federal Food, Drug and Cosmetic Act includes both an economic adulteration clause, and a false labeling provision.[40] The statute also provides two basic remedies: seizure and condemnation of a product for relief from isolated marketing practices, and, for more general action, the "standard of identity" system. The latter empowers

---

[38] 249 U. S. 495 (1919).

[39] Case cited at footnote 38, at p. 499.

[40] "A food shall be deemed to be misbranded . . . If its labeling is false or misleading. . . . If it is an imitation of another food. . . ." etc. 21 U. S. C. A. 343, FOOD DRUG COSMETIC LAW REPORTS ¶ 131-¶ 144.

the Secretary of Health, Education and Welfare to establish a standard formula or process for a foodstuff, which standard is thereafter the only allowable content or method of manufacture for any product sold in interstate commerce under the chosen name.[41]

Scope of Meat Inspection Act

By contrast, the Meat Inspection Act has only the techniques and sanctions of the highly generalized false or deceptive formulation. However, it has been generally assumed that the scope of consumer protection under the Meat Inspection Act is approximately equivalent to that of the Federal Food, Drug and Cosmetic Act.[42] Differences in the structure and working of the two laws are explained by the belief that in meat processing the great hazards are perishability and palming, while in other agricultural produce in which processing is a more extensive activity, economic deception is a more significant danger. Therefore the Meat Inspection Act accentuates an inspection scheme with direct controls over the activities of packers, while the Federal Food, Drug and Cosmetic Act is largely addressed to the processors themselves to obtain compliance. This implies a need for more explicit standards in the latter statute. The Secretary also gains support for the thesis of equivalence from the jurisdictional provision,[43] which places a product subject to the Meat Inspection Act outside the regulation of the Federal Food, Drug and Cosmetic Act. The Meat Inspection Act extends to all foods containing meat or meat products, thus including processed foods with small amounts of animal fat content. It is unlikely that Congress expected this random factor that is entirely within the control of processors to affect the substantive protection afforded consumers by the food and drug laws. Therefore the parallelism in construction that the two very different statutory schemes do not in terms require is nevertheless generally conceded.

These statutes were not initially conceived as protecting consumer nutrition or buying habits. The House committee reporting out the Federal Food, Drug and Cosmetic Act of 1938 makes clear that aside from poisonous or filthy contents, the law has no concern to bar any produce from commerce if that produce is honestly labeled.[44] All that

---

[41] 21 U. S. C. A. 341, FOOD DRUG COSMETIC LAW REPORTS ¶ 107.

[42] Petition for Rehearing, pp. 15, 16.

[43] 21 U. S. C. A. 392(b), FOOD DRUG COSMETIC LAW REPORTS ¶ 428.

[44] Report on Food, Drug and Cosmetic Act of 1938, House Rept. 2139, 75th Cong., April 14, 1938. (Submitted by Mr. Lea for the Commerce Committee.)

is sought is a measure of fair dealing, so that buyers so inclined can determine the content of their purchases reliably. That content is not required to reflect any nutritional theories or precepts.

In operation, the food laws do tend to enforce nutritional theories. A variation of content from the normal recipe associated with a label name is not prosecuted unless the change violates some dietary practice or materially affects the food value of the product. Even more significant, when the administrator promulgates a standard of identity, in order to make that standard useful he must make it conform to the desires of consumers with respect to that product. Therefore the standards abound with vitamin additives and enhanced nutritive contents.[45]

Practice of Labeling "Imitation"

Reflecting the language of the statute,[46] the practice has developed of marketing all nonconforming products under a label "imitation" followed by the designation of a nearly equivalent standard of identity.[47] This procedure was endorsed most recently in *62 Cases of Jam v. United States,*[48] when the Supreme Court ruled that a product that failed to conform to the standard of identity for jam but was sold under the label "imitation jam" was not misbranded.

Consumers have exhibited a marked tolerance for the use of the term imitation, making it an ever smaller drawback in the sale of food. Until 1960, Armour marketed almost one-fifth of its smoked hams under the imitation label.[49] Nevertheless, as the ham litigation attests, a real competitive disadvantage is attached to that appellation. There has been some experience with the use of other words descrip-

---

[45] For example, see *Federal Security Administrator v. Quaker Oats,* Food Drug Cosmetic Law Reports 2623.55, 51,051.52, 318 U. S. 218 (1943) in which the standards for farina and other grains are discussed. This litigation determined that Quaker could not label as "farina" a product which contained more vitamin D than the standard of identity required, raising a question whether the administrator was adopting a theory even more esoteric than the vitamin enrichment concept: that excess vitamins are potentially harmful.

[46] 21 U. S. C. A. 343, Food Drug Cosmetic Law Reports ¶ 134 (see footnote 40).

[47] See, A. D. Herrick, *Food Regulation and Compliance,* Revere Publishing Company, New York (1947) pp. 850, and following.

[48] Food Drug Cosmetic Law Reports ¶ 50,125.46, 340 U. S. 593 (1951).

[49] See Appendix for reproduction of that label. The regulations require that the term imitation be placed prominently in the same type as the name of the standard product.

tive of a nonstandard product, such as "inferior" or "below standard," but imitation is the recurrent label in food packaging.[50]

Various cases have interpreted the powers of the Secretary to categorize products as standard or imitation under both the Meat Inspection Act and the Federal Food, Drug and Cosmetic Act. The leading case in meat processing is *Houston v. St. Louis Packing Company*.[51] That litigation was initiated by the packer to set aside a regulation by the Secretary of Agriculture establishing maxima of 2 per cent cereal and 3 per cent water in products labeled sausage. St. Louis Packing argued that its product, containing more cereal than the regulation permitted, was nonetheless wholesome. It also contended that long practice among packers tended to establish 10 per cent as the traditional additive level for sausage, demonstrating either that the Houston product was being sold under its "established trade name . . . usual to such products" [52] or that the Secretary's choice of 5 per cent additive level was arbitrary and capricious. The Secretary argued that the additive level chosen was the minimum adequate percentage that would assure a satisfactory texture in the finished product, and that additional cereal or water constituted economic adulteration.

The Supreme Court was in full agreement with the Secretary. Acknowledging that a wide range of ratios of meat to filler were used by packers on various occasions, the Court then applied the "substantial support in the evidence" test to determine that the regulation was valid, finding that the public might be deceived by a looser standard than the one chosen. Concurrently, the Court's opinion in *Brougham v. Blanton*, cited above, recited that the determination by the Secretary as to the falsity or deception of a practice is conclusive.

Other Case Law Delineating Administrative Power

Brougham and *Houston* together represent all the important case law concerning economic adulteration and false labeling under the Meat Inspection Act. However, subsequent cases involving applications of the Agriculture Appropriation Act and Federal Food, Drug and Cosmetic Act delineate the boundaries of the administrative power to categorize foods.

---

[50] See, *Nolan v. Morgan*, 69 F. 2d 471 (CA-7 1934), concerning a regulation that hard ripe peas be labeled "Below United States Standard Low Quality but Not Illegal." (Unripe, soft peas had been adopted as the standard of identity for the product.)

[51] 249 U. S. 479 (1919).

[52] 21 U. S. C. A. 75, FOOD DRUG COSMETIC LAW REPORTS ¶ 725.

Nolan v. Morgan applied the concept of arbitrariness to one administrative categorization. The regulation in question established soft, unripened peas as the standard of identity for all peas. Ripe peas, which are naturally hard and seed-like, were required to be labeled "Below United States Standard Low Quality but Not Illegal." Unripe peas are generally preferred over hard peas, but in order to secure just the former, fields must be harvested rapidly. Further, the soft peas are highly perishable while ripe peas can be stored indefinitely. The latter require long cooking to be suitably soft for consumption. The court held that the regulation was arbitrary, first noting that the two varieties of peas "are products as essentially different as if taken from radically different plants" [53] and concluding,

> We do not think that the statute contemplates, with respect to this product, that either immature peas or the dry peas shall be the generic product whereby the other is to be graded.[54]

The differences between the two varieties of peas were probably more economic than functional in 1934. Although hard peas are currently used only in composite foods such as soups and stews for which soft peas are unsuitable, it can be speculated that they were in competition with soft peas in 1934 for a wider range of uses. The unspoken instruction that the court may have intended is that the food laws must not be a vehicle for the intrusion of government authority into market competition between varying products, unless there is a sound nutritional basis for regulatory distinctions.

Ordinary and "Enriched" Farina

Relevant to this interpretation is the subsequent opinion in *Federal Security Administrator v. Quaker Oats Company* (cited at footnote 45). There the Supreme Court upheld an administrative standard differentiating two varieties of farina, ordinary and "enriched," from all other grains. Quaker's product was ordinary farina with added vitamin D, one of the contents of "enriched farina," but it lacked other additives required by the standard of identity for the latter product. With its long-standing recipe lying between the two newly established formulae and conforming to neither, Quaker chose to label its product "Farina Enriched with Vitamin D" and included a statement of the contents on each package. The Court considered the confusion which might result if every variety of farina plus additives that could be postulated was available in food markets and concluded that the only products that could bear a farina label were those that conformed

[53] Case cited at footnote 50, at p. 473. [54] Case cited at footnote 50, at p. 474.

specifically to the regulation standard of identity. This holding forced Quaker to choose either to change its recipe or to label its product "imitation."

This decision overruled an appeal court determination that the Quaker label fulfilled the requirements of "honesty and fair dealing" and therefore complied with the Federal Food, Drug and Cosmetic Act.[55] The opinion thereby established that the Secretary's regulations could be valid even though they sometimes have the effect of eliminating products from the market and are not always limited to the minimum requirements that would inform purchasers of the merits of the product.

If the assumption that *Nolan v. Morgan* survives alongside *Quaker Oats* is correct, then in the typical food regulation the administrator can act only to assure consumer information; but if a substantial nutritional issue exists (as in *Quaker Oats*, because one major market for farina is baby and child feeding), the powers conferred by the statute extend to devices referred to by Judge Prettyman in his *Armour* concurrence as "*in terrorem* labeling." [56] These devices are actually attempts to alter production and marketing patterns in foods rather than to merely establish honesty and fair dealing.

If this interpretation is correct, it provides a convenient explanation for the ham litigation. Here the major questions are primarily economic rather than nutritional, especially if Armour's contention that prices are diminished inversely with dilution was believed by the court.[57] Therefore, the Secretary's regulation must be measured by the narrower rule that permits only the minimum interference with production or marketing techniques required to assure honesty and fair dealing. Both the outcome and the preoccupation of the court with alternative modes of relief are thus made understandable.

Current commentary, however, raises a different basis for distinction between ham, jam and farina. The suggestion is that jam and farina are processed foods, for which any standard of ingredients is

[55] FOOD DRUG COSMETIC LAW REPORTS ¶ 2623.55, 129 F. 2d 76 (CA-7 1942).

[56] Case cited at footnote 6, at p. 413.

[57] The majority opinion does not include such a finding, although it does state that "At the hearing on the motions [for temporary injunctive relief] it was made to appear that [wet hams] are wholesome and healthful food having higher nutritional value than those to which the curing solution has not been added." (Case cited at footnote 6, at p. 406.) The writer considers this finding inadequate to protect the consumer interest (see above). In his concurrence Judge Prettyman assumed that the net price of protein remained stable for all varieties of ham (Case cited at footnote 6, at p. 412) because the government had not undertaken to prove otherwise.

necessarily an arbitrary choice from a continuum of alternatives, and that the administrator's judgment in such a situation must be measured more leniently than in the case of foods with more distinguishable identities.[58] This has been expressed as

> [A] distinction between foods which owe their essential characteristics to their natural state and recipe products which owe those characteristics to the manufacturing process.[59]

Clarifying the Term "Imitation"

In applying this distinction some scholarship has been set to the task of clarifying the term "imitation." *Houston* and *Quaker Oats* aid this quest only by indirection: each states that the determination of the falsity or deception of a label is the responsibility of the Secretary and his findings are conclusive. Because all nonconforming products are relegated to the use of "imitation" labels after a standard of identity is promulgated, it must be concluded that "imitation" is an expert word with a special meaning. The category of imitation foods is not defined by duplicity or any gross substitution of ingredients of synthetic origin, but is merely a result of an expert determination that a possibility of deception attends the sale of the included products. On the other hand, it is doubtful that the Secretary could at once concede superiority of a product and also demand that it be labeled "imitation" in disregard of the connotation of inferiority in that appellation. The *jam* case above confirms this theory of limited expertise. Stating first that "[N]othing can be legally 'jam' after the Administrator promulgated his regulation," [60] it then explains that,

> [T]he name "imitation jam" at once connotes precisely what the product is: a different, an inferior preserve, not meeting the defined specifications.[61]

Therefore the term "imitation," although technical and expert rather than colloquial, must be applied with understanding and deference for common usage.

This does not support the present outcome of the ham controversy, however. If there is a common-sense rule that the Secretary cannot label as imitation that which is in fact natural, obstacles to the application of this precept to cooked cured ham remain. Water in cooked ham is not demonstrably more common or commonly anticipated than cereal filler in sausage, as in the *Houston* case permitting imitation labeling. Further, as between ham and jam, purchasers

---

[58] 76 *Harvard Law Review* 846 (February, 1963).
[59] Cited at footnote 58.
[60] Case cited at footnote 48, at p. 599.
[61] Case cited at footnote 48, at p. 600.

must surely be more aware that nonfruit content is present in the latter than they are that the former contains large quantities of water.

Therefore, the vice of the natural food-processed food dichotomy is that it eliminates the power of the Secretary to exercise the most forceful available technique for distinguishing products, imitation labeling, with respect to those "natural" foods that consumers must generally assume are highly standardized and reliable. Good sense requires just the contrary result: when buyer understanding and market practice tend to group food products of variable content or value, the Secretary must be given the broadest power to alert buyers to differences that should influence their choice. That certain basic staples are improperly conceived as immutable should not be a reason for administrative restraint.

TECHNICAL REQUIREMENTS FOR PRELIMINARY INJUNCTION

The *Armour* case is notable for its treatment of the facts that a litigant must establish to sustain a motion for temporary relief against an agency regulation of widespread applicability. Courts have long understood that this form of relief, in staying the authority of the agency before a final determination of the merits of a regulation is reached, is potentially destructive of the attributes of speed and flexibility that administrative agencies are expected to maintain.

Court's Strong Negative Rule

Therefore, the federal courts have tended toward a strong negative rule controlling this remedy. The *Armour* court cited two cases applying the rule that has developed.[62] The *Virginia Petroleum* case states four criteria[63] for the issuance of a preliminary injunction: the individual party must be likely to win on the merits; he must be subject to "irreparable injury" that the injunction could eliminate; the interests of third parties must not be harmed by the issuance of an injunction; and there can be no substantial public interest contrary to that action.

Because all administrative actions are clothed with a presumption of regularity and legality, the burden of establishing the four requirements is necessarily upon the private party. It is obvious, however, that before trial no proposition can be established by the "real proof"

[62] Case cited at footnote 6, at p. 406, citing *Cox v. Democratic Central Committee*, 200 F. 2d 356 (1952) and *Virginia Petroleum Jobbers Association v. Federal Power Commission*, 259 F. 2d 921 (1958).

[63] Cited at footnote 62, at p. 925.

of testimonial evidence, and therefore these determinations turn largely on affidavits and hearsay sources.

A literal application of these rules to Armour's situation would probably disable it from obtaining preliminary relief. Assuming with the court that the regulation of cooked cured ham is arbitrary on its face,[64] the requirement of irreparable injury to Armour must still be met. The appellant presented "three categories" of losses to justify an injunction: losses from the disposal of its inventory of wet hams after November 17, 1961 under an imitation label; losses of sales to competing local packers who continue to prepare wet hams to satisfy the consumer preference that Armour claimed was prevalent; and injury to its reputation from labeling its wholesome product imitation and therefore implying that it is inferior.[65] The first of these losses, based on inventory that was disposed of under the new regulation, was withdrawn on appeal because it had "now been sustained."[66]

It should first be noted that the two remaining losses are alternative possibilities that cannot both occur. Either Armour is foreclosed from the wet ham market or it must suffer the stigma of the imitation label. If Armour chooses to remain in the wet ham market, this means that the profits from wet ham sales more than compensate for the injury from using an imitation label.

Against these claims of irreparable injury, the Secretary argued that the period before December, 1960 was profitable for federally inspected meat packers and the new regulations were merely a return to the practices of that period. This return could not cause an irreparable loss to Armour.[67] The final question, stated as favorably for Armour as reason will allow, might therefore be: does the difference between profits and higher profits constitute an irreparable injury sufficient to support a preliminary injunction?

The *Armour* court never reached such an inquiry, determining instead that the "damage [to] its good name" from the use of an imitation label on wet ham (Armour's third theory of loss) fulfilled the requirement of irreparable injury for a temporary injunction.[68]

It does not necessarily follow that loss of future profits will henceforth suffice to sustain preliminary injunctive relief. If this were the rule, the irreparable injury test would effectively be eliminated from all attacks on agency regulations affecting business activities.

---

[64] Case cited at footnote 6, at p. 406.
[65] Brief for Appellants, cited at footnote 6, p. 31.
[66] Cited at footnote 65.
[67] Brief for Appellees, cited at footnote 11, p. 8.
[68] Cited at footnote 6, at p. 406.

A more likely interpretation of the *Armour* case is that a great likelihood of success on the merits tends to reduce the vitality of the other criteria as obstacles to temporary relief. Certainly if success is conceded it is improper to deny the litigant his plea because the formality of final judgment is not complete.

The trial of the *Armour* case after the decision under discussion could fairly be termed a formality. The court established that the regulation is capricious and arbitrary on its face, a description that must mean that the regulation applies an improper remedy to any falsity or deception that may accompany the sale of wet ham under the same label as is prescribed for dry ham.

Under the interpretation of this holding that concludes that an imitation label is unsuited to differentiate natural food products (see above), the Secretary must demonstrate that ham is not conceived as standard or immutable by the public to prevail on trial. If the alternative theory of the decision is adopted, limiting the power of the Secretary except when substantial nutritional questions arise, the government must prove that wet ham is inferior to dry ham. Among the obstacles to the development of this theory are the contrary findings made by the Department of Agriculture at the time of Secretary Benson's regulation. Neither interpretation of the *Armour* opinion justifies a hopeful prognosis for the regulation under attack.

The effective elimination of part of the *Cox* rule for the issuance of temporary relief is therefore sensible in the light of a complete analysis.

CONCLUSION

It is of continuing importance and concern that the federal courts speak loudly and clearly when they address administrative agencies on subjects that are permanently, recurrently arising in the course of regulatory activities. This goal must not be abandoned, either at the height of judicial indignation or at the depth of its boredom.

The development of an adequate doctrine to guide the Departments of Agriculture and of Health, Education and Welfare in the regulation of food marketing could be a very helpful outcome of the temporary setback in the scheme of that regulation worked by the *Armour* case. On the other hand, if the portent of this decision is that the venerable techniques of these agencies must be revised from their foundations to accomplish less control over producers than has been exercised in the past, some adequate rationale for this conclusion must be found. This the record of the present litigation does not provide. **[The End]**

Why Quality Control?

By WILBUR A. GOULD

Wilbur A. Gould, Professor and Head of the Processing and Technology Division, Department of Horticulture, Ohio State University and Ohio Agricultural Experiment Station, Columbus, Ohio, Delivered This Address as Part of the Program of Food Update Midwest Highlights in Chicago, November 5, 1963.

IN THE DEVELOPMENT of a quality control program there are several questions that must be adequately answered. The more important of these are:

(1) What is quality, what are the standards for quality requirements and what are the methods for determining quality?

(2) Why should a processor have a quality control program?

(3) What are the basic fundamentals to be considered for a successful quality control program?

(4) What are the factors affecting quality?

Before answering these questions it should be pointed out that many large companies today have attained their enviable position by the control of the many products they process. They do not process a product that is lacking in uniformity or one that will "just get by," but rather a product that will continue to build their business. Perhaps more important than their success is the fact that management knows at all times what kind of quality is being packed. Thus, a quality control program serves the management of a company by keeping him fully informed of the quality and the condition of the products being packed, as well as keeping the management and his company in line with the industry trends.

What Is Quality?

Quality makes a product what it is. "It is the combination of attributes or characteristics of a product that have significance in determining the degree of acceptability of the product to a user." [1]

[1] United States Department of Agriculture, *Marketing Workshop Report*, 1951.

It is the combination of attributes or characteristics of a product that determines the value or worth of a product. As used by the industry, it is a concept involving degree: degree of purity, strength, flavor, color, size, maturity, workmanship, and condition or any other distinctive attribute or characteristic of the product. Thus, the term quality without being defined in terms of some standard means very little. On the other hand, the trade generally uses the term to mean the finest product attainable. Food processors have learned from years of experience that high quality products never fail to sell. This is due to the fact that Mrs. Consumer recognizes brands that maintain their quality at the standard set for that particular product. Repeat sales are, thus, the outgrowth of quality control practices.

What are the standards for quality evaluation? There are different ways of arriving at the many standards for product quality. However, the four that I like to use are:

(1) Legal Standards.—Legal standards are those commonly established by the federal, state or municipal agencies and generally are mandatory. These mandatory standards are set up by law or through regulation and represent the Federal Food, Drug and Cosmetic Act minimum standards of quality or the various state minimum standards of quality or the municipal minimum standards of quality. They are generally concerned with adulteration, that is, freedom from adulteration. This may involve insects, molds, yeasts, pesticides, etc. or they may be concerned with maximum limits of additives or establish specific conditions in process so that foods are not contaminated with extraneous materials. Examples of all legal standards that we concern ourselves with are available from the various agencies involved.

(2) Voluntary-Label Standards.—The voluntary or label standards represent the standards established by the various segments of the food industry. They generally are not detailed out to the consumer other than through consumer experience. The voluntary standards generally represent a consumer image and they may become a trademark or symbol of product quality. Generally speaking there are those used by private firms or supermarkets and tend to vary depending upon the particular requirements for any given label.

(3) Industry Standards.—The industry standards are those whereby an organized group attempts to establish given limits of quality for any given commodity. Normally these have become effective by marketing organizations or by specific commodity groups where legal

standards are not involved. Examples of these are cling peaches, peanut butter standards, and some of the frozen food standards.

(4) Consumer Standards.—The consumer standards represent the consumers, requirements of a product and generally are based on experience in use by the consumers. They are not too effective as a group, but individually they represent the day-to-day demands for any given product.

What Are the Methods for Determining Quality?

Organoleptic Evaluation or Subjective Methods.—This type of evaluating quality is based on the opinions of the investigators; usually it is a physiological reaction which is a result of past training, experience of the individual, influence of personal preference, powers of perception, etc. They are subjective because the individual is required to go through a mental process in giving his opinion as to qualitative and quantitative values of the characteristic or characteristics under study.

Objective Methods.—This method of evaluating quality is based on the observations from which the attitudes of the investigators are entirely excluded. They are based on recognized standard scientific tests and are applicable to any sample of the product or products without regard to its previous history or ultimate use. They represent the modern idea in quality control because the human element has been excluded. They can be dividend into these three general groups:

(1): Physical methods of measurements. This is perhaps the quickest method and the type requiring the least training of the three. They are concerned with such attributes of quality as size, texture, color, consistency, imperfections, etc. Usually instruments can be found or adapted for physical evaluation of product quality.

(2): Chemical methods of measurements. Standard food analysis methods are generally used (AOAC, Woodman, Winton, and Jacobs) for quantitative evaluation of nutritive values and quality levels in most cases. However, these types of chemical analysis are too long and tedious to say nothing of the expense involved in their determinations. As a result the industry and allied interested parties have developed methods that are termed "quick tests." In many cases these tests can be closely correlated with the longer procedures and accurate values are determined.

(3) Microscopic Methods. Microscopic methods have excellent application in a quality control program but usually require considerable training to properly interpret the results. They can be divided into these two general categories:

(a) Adulteration and Contamination: Here the examinations will indicate the presence of mold, insect fragments, insect excreta, foreign materials, etc. Each test is specific and the technologist must have the proper background to differentiate the various types of adulteration and contamination that might be present in the products. The new Food & Drug Technical Bulletin No. 1 should be in every food processor's library.

(b) Differentiation between cell types, tissue types, and microorganisms of various stored foods: Examples of their applications are found in tissue testing for deficiency of fertilizer materials, stored food in the tissues of plant materials, microorganisms causing spoilage and/or desirable fermentation changes.

Why Have a Quality Control Program?

Quality control may be thought of as the scientific control of production. The primary objective of a quality control program is to obtain adequate information on all the factors or characteristics of a product affecting the quality of that product. The intelligent interpretation of this information by the quality control technologist provides management with an index of the entire operation. This means that the quality control technologists' information constantly serves as a guide for management in regard to the exact quality that may be packed from a given quality of raw stock, or it may provide management with the necessary information needed in the processing of a product to pack a given quality. Thus, the quality control technologist serves as the "nerve center" for management and each of the separate departments.

Quality control will also open the door to research. Charles Kettering said, "Research is a high hat word that scares a lot of people, but it needn't as it is rather simple. Essentially, it is nothing but a state of mind—a friendly, welcoming attitude toward change. This change may involve people, facilities, materials, and equipment." Boss Kettering also said, "Research is something that if you don't do it 'till you have to, it's too late." In other words it is an investment in the future. Research, therefore, must delve into control activities.

In fact, quality control is the application of ideas and techniques derived from research and product development.

Some of the reasons for a quality control plan are: Control over raw materials through setting of specifications; Improvement of product quality; Improvement of processing methods with resulting savings in cost of production and greater profits; Standardization of the finished product according to label specifications; Increased order and better housekeeping or a sanitary plant; and Greater consumer confidence in the uniformly high quality of your product.

What Are the Basic Fundamentals for a Successful Quality Control Program?

There are six basic fundamentals that must be carefully considered and clearly worked out for the success of any quality control program. These are: Organization of the quality control department; The personnel; Sampling; Standards and Specifications; Measurement—Laboratory, Equipment, Procedures, Reports; and Interpretations.

The organization of a quality control program is the first fundamental that must be carefully considered. The program must be desired by top management. The quality control department should be directly responsible to top management—not under the raw products department, the factory operations or even under sales. Thus, the quality control technologist reports directly to management. Obviously, it is necessary for the quality control technologist to provide each of the other departments with specific information on the quality at the receiving platform, or on the line or even in the warehouse; but he is not responsible to these groups as such. Management must make the decision between quality and quantity and not any one of the several departments of the company. The quality control technologist should, however, have the authority from management to cooperate with production to maintain production operations such that the product being packed at all times maintains the desired standard or standards. Thus, it should be quite obvious that the careful organization of the quality control department is most important.

The personnel in the quality control department will vary with the products being packed, the size of the operation and the amount of control desired by management. The quality control technologist must have certain qualifications to fulfill the responsibilities necessary

for a successful quality control program. Some of the more important of these are:

(1) The quality control technologist must be adequately trained. This may mean an individual with considerable education in food technology or one with a basic education in food technology and good experience in the packing of food products. For seasonal operations advanced food technology students have been found to be quite satisfactory as the quality control technologist or as assistants to the quality control technologist.

(2) He must be truthful in his reports, in his decisions and above all in his analysis.

(3) He must have sales ability.

(4) He must be able to speak the language of the industry and write intelligently.

(5) He must be an excellent cooperator.

(6) He must always be alert and responsive to necessary changes.

(7) He must be well mannered and always neat in his appearance.

(8) He must always be on the job.

The need for quality control technologists is increasing annually. Because of interest shown by the industry, many of the colleges and universities have recognized this need and they have adopted courses in food technology with specific training in quality control and the preservation of foods. Quality control personnel, to do their job must, above all, be able to give instruction to production employees as to what is to be done, how it is to be done, and why it must be done. The personnel in a quality control department may be the deciding factor on the success of the program.

Samples and Sampling Plans

Probably the greatest limiting factor in the successful control of product quality is the sample for product evaluation. How many to use? and where to obtain same? Briefly stated, the sample must be representative of the lot of merchandise in question and selected at random. The United States Department of Agriculture has adopted a statistical sampling plan that should be followed when evaluating food product quality.

Standards and Specifications.—Quality control follows the establishment of product specifications. Remember, "Before you can control—

you must first be able to measure." With the newer information available on quality control methods and specific packing procedures for the different products, the management in cooperation with production, sales and quality control must draft specific process procedures, specifications or standards to be adhered to in the packing of a product. These standards or specifications and process procedures are developed for the primary purpose of providing information to production personnel in the packing of the desired quality. The quality control technologist's major function is to determine the product's deviation from these specifications and when necessary, he should make the needed changes to control the quality of the product at the desired level. Thus, management always knows what quality is being packed. Obviously, the personnel in the production department and the quality control department must cooperate to the utmost to produce a given quality product. In many cases the quality control personnel may be responsible for providing instruction for the cleaning of the factory and the general plant sanitation. This aspect is more the "insurance" program and should not be taken lightly. Sanitation includes: (1) Facilities, (2) Ingredients, (3) Packages, (4) Employees, (5) Water and (6) Waste Disposal.

Measurement.—The facilities for a quality control program will vary with the size of the operation, the number of products being packed and the different qualities being packed. It is not my intention to discuss these in detail, but only to emphasize the major factors to be considered in measurement of product quality:

(1) *Laboratory:* The old cutting room with some modifications becomes the laboratory. It need not be elaborate nor equipped with lots of fancy gadgets. It should, however, be close to the production lines, properly lighted, neat in appearance and adequately ventilated. It should be equipped with a grading table, an analytical bench and a taste panel table. Further the quality control manager should have a corner in the quality control laboratory for his files, desk, reference manuals, etc.

(2) *Equipment:* The equipment should include a can or package opener, vacuum or headspace gauge, grading scales, grading trays, sizing gauges, brine and syrup cylinders and hydrometers, thermometers and special equipment for the objective measurements of quality for each particular product. In some cases bacteriological equipment will be necessary as well as water and waste analysis equipment.

(3) *Procedures:* The specific procedures used to determine the quality of any product should be completely "spelled out." This means that any test used for a particular product must be standardized. Thus, the quality control manager must have a thorough knowledge of the many tests employed. With the quick tests of quality, the quality control technologist must follow these procedures as given, or small deviations may cause large errors in the results. Specific details are to be found in the United States Department of Agriculture, Grade Standards; Food and Drug Act, Minimum Standards of Quality, Fill and Identity; in the several research articles; and in the trade papers. The quality control technologist is expected to be thoroughly familiar with the Standard Methods of Analysis and the published literature on objective tests of quality. If methods are not available, he may have to develop techniques and procedures to meet his own specific set of conditions. At any rate, he should write out all procedures in complete detail. Thus he will always be using the same basic procedures until modified year after year.

(4) *Reports:* The complete write-up of the results is just as important as the analysis of the samples. The quality control technologist must complete report forms giving his findings and his recommendations. These should always be in writing with the original for management and copies to production, sales and the field operations when applicable. A copy, of course, should be retained for his files. The reports should give a complete history of his daily activities and recommendations where applicable.

Interpretation.—Statistical quality control is a most useful tool that can be of great value for all interpretation of reports. Many successful food firms today have established a SQC procedure as part of their QC program. They did not hire statisticians to do this, but relied on well-trained quality control personnel to develop the SQC procedures.

In understanding a statistical quality control program, we must first agree that variation is always present in the measured quality of manufactured products. This variation is composed of two components, that produced by "chance causes" and that produced by "assignable causes." Variation due to "chance causes" is inevitable. Variation due to "assignable causes" can usually be detected and corrected by appropriate methods.[2]

[2] D. H. Allan, *Statistical Quality Control,* Reinhold Publishing Corp. (1959).

SQC employs statistical principles and methods which have been developed to assess the magnitude of "chance cause variation" and to detect "assignable cause variation." "SQC will indicate the limits beyond which these variations in the product should not go without correction. The manner in which the SQC program determines the variations is based on the law of probability. Probability might be simply defined as the number of times an event occurs as to the total number possible. Thus, SQC is really a sampling of the product, determining the quality variation of the sample, and relating the findings to the entire lot under consideration." [3]

"The concept of the statistical control chart, very simply stated, is that if values which reflect the variation caused by 'chance causes' present in a process are plotted on a time basis, then statistical limits can be determined within which such values will lie. Values falling outside these statistical limits will indicate the occurrence of significant changes in the 'chance cause system,' usually because of the presence of an assignable cause." [4] On the $\overline{X}$ control chart these statistical limits are defined as the Upper Control Limit (UCL) and the Lower Control Limit (LCL). If a given attribute or characteristic exceeds the UCL, then that particular attribute is above its desired value or better than normal. Consequently, the packer in the case of net weight is giving the amount which exceeds the UCL to the consumer free of charge. In doing this his yield and profit is automatically minimized. However, if the net weight value falls below the LCL, this attribute is of a lower quality or value than the packer is seeking to maintain. The $\overline{X}$ (average or arithmetic mean) is a measurment of the central tendency. Half of the "chance causes," approximately, are located above it while the other half are located below it. It merely indicates the average value for the chance causes.

The Range (R) Chart is also a control chart. It indicates the difference between the highest and lowest value. Thus it indicates the variance present in a set of samples. The R Chart has an Upper Range Limit (URL). The height of the URL is determined by the "chance cause" variations and thus when a range exceeds this value it is usually due to an assignable cause.

It is necessary to use both the $\overline{X}$ and R chart in conjunction with each other because the $\overline{X}$ chart may indicate a consistent quality, but the range could vary from a minimum amount to a large extent.

---

[3] D. H. Allan, cited at footnote 2.
[4] D. H. Allan, cited at footnote 2.

The following example may clarify any misconceptions: Five samples were taken every hour for ten hours off a given production line. The average, $\bar{X}$, was computed as well as the range. The average of the five samples was plotted on an $\bar{X}$ chart and similarily the range plotted on a R chart. A glance at the R chart indicates that there was a wide range for the first two hours which narrowed down somewhat the third hour and widened the fourth hour and then gradually narrowed down to a narrow range the last three hours. The narrow range is indicative of greater uniformity. If the attribute of quality being evaluated has a narrow range which is within the UCL and LCL the operation is running under normal conditions. See SQC $\bar{X}$, R Chart on the following page.

"A flattening of the distribution attributable to material instability, operator carelessness, bearing wear in the machine, and innumerable other causes will be reflected by the appearance of a range of a sample above the URL. The process control chart thus provides certain and immediate information about the pattern of variation expected from the process, and affords prompt signals of trouble or of the absence of trouble." [5]

When developing an $\bar{X}$ and R chart one should first determine his objectives in using these charts. In most cases this will be to provide a basis for taking corrective action, that is, when the process is out of control. The next decision one must make is the selection of variables to be measured. Then one must select a method to measure these variables. The method and size of sample must be determined next. These samples should be selected so they are representative of the time interval covered. All methods, measurements, and procedures should be followed strictly since an alteration in any one of these factors may cause a significant change in the data being collected.

"When data are being recorded, any conditions that have changed since the last sample was taken should also be recorded. These include such items as changes in operators and machine settings. The chart is plotted originally without the benefit of control limits until sufficient data have been collected so that the control limits computed will be reasonably reliable." [6]

---

[5] *An Introduction to Statistical Quality Control,* Bureau of Ordnance, Department of the Navy.

[6] D. H. Allan, cited at footnote 2.

SAMPLE NO. OR OBSERVATION	FREQUENCY OF SAMPLE SETS — Hour, Line, etc.										
	1	2	3	4	5	6	7	8	9	10	$\bar{\bar{X}}$ $\bar{R}$
A	18.5	15.2	16.3	19.1	18.7	15.9	16.8	16.0	16.0	16.1	
B	17.0	15.3	14.8	18.4	18.3	15.2	15.8	16.1	16.2	16.0	
C	16.5	18.4	14.6	18.6	17.7	14.8	16.4	16.3	16.5	16.0	
D	16.8	15.0	15.1	16.1	16.2	14.1	15.8	16.0	16.1	16.1	
E	15.0	15.0	15.0	17.5	17.9	15.4	14.9	16.2	16.0	16.2	
TOTAL	83.8	78.9	75.8	89.7	88.8	75.4	79.7	80.6	80.8	80.4	
$\bar{X}$	16.8	15.8	15.2	17.9	17.8	15.1	15.9	16.1	16.2	16.1	16.29
R	3.5	3.4	1.7	3.0	2.5	1.8	1.9	0.3	0.5	0.2	1.88

$UCL_{\bar{X}}$ (Upper control limit for average) = $\bar{\bar{X}} + A_2 \bar{R}$

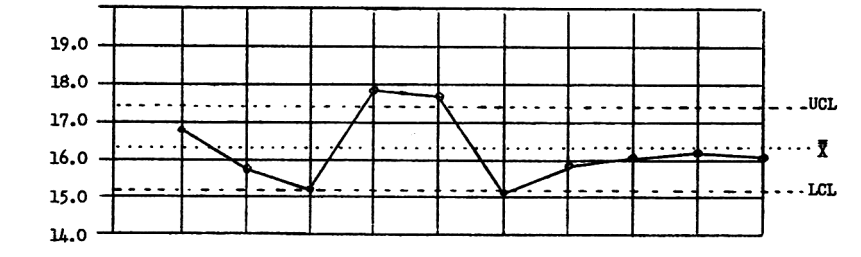
$LCL_{\bar{X}}$ (Lower control limit for average) = $\bar{\bar{X}} - A_2 \bar{R}$

UCL_R (Upper control limit for Range) = $D_4 \bar{R}$

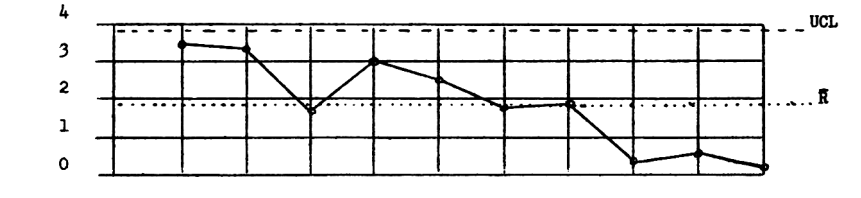
Note: A_2 for five (5) sample numbers in a set is equal to 0.58

D_4 for five (5) sample numbers in a set is equal to 2.11

$\bar{X}$ CHART



R CHART



In setting up a SQC program, one should start with one given attribute of quality and learn all there is to know about this before moving on to other attributes. Take an example such as a filler on a given line. One should evaluate each "pocket" by drawing five samples continuously from each pocket under normal running conditions. Thus, with a 16 pocket filler, 90 samples would be taken, each, of course, carefully coded as to pocket.

If a volume filler, determine actual volume of product and plot out on an $\bar{X}$, R chart with the 16 pockets versus five samples for each pocket. If any of these are out of order, adjustments are made accordingly. Then one would sample hourly, 5 samples at random and develop an $\bar{X}$, R chart for each hour of operation. This chart should be made up and mounted on a "clipboard" at the filler station for the operator to observe and make changes intelligently during the "run."

The $\bar{X}$ and R charts themselves will not correct a situation. They will only tell the operator where to look for the trouble. Once he has found the source of trouble, the operator must take appropriate action in order to control the particular unit operation within the established limits or specifications.

The filler is the simplest of all for the application of a SQC program. However, other attributes of quality can be established just as easily and in many cases be just as meaningful. As examples, concentration of detergents, chlorine, sugar, salt brine; sorting, trimming and coring efficiencies; seam formation; retort operations; etc.

The establishment and use of a SQC program is not just another tool to keep someone busy. It is a tool to force the operator of every unit operation in a food plant to pay strict attention to the process he is responsible for. It will result in more uniform products produced at reduced costs. Further, the SQC program has been proven to be an effective method of developing the responsibility of plant personnel for the good of a growing organization.

What Are the Factors Affecting Quality?

Quality of processed fruits and vegetables is affected by the following basic factors, either individually or in combination: variety, maturity, cultural practices, harvesting and handling practices, processing methods, storage of processed products, home preparation and use of the finished product.

The choice of the proper variety is perhaps the most important single factor when packing a quality product. Specific recommended varieties for one area of the country or even within the state may not apply to another section. Thus, the varieties of fruits and vegetables are specific for different growing areas, the intended use and the consumer's preferences. In the case of the growing area, specific recommendations are available upon request from the seed houses and the Experiment Station. In the case of the intended use, little work has been done along this line until very recently. Some examples are available upon request from the various Experiment Stations. As to the consumer's preference, very little has been done along this line, but considerable interest is being shown today in specific isolated areas.

The maturity of any vegetable is perhaps more important than the specific variety in many cases. Any recommended fruit or vegetable variety for processing should mature uniformly, should stand relatively long in the field and should be as resistant as possible to insects and diseases. The exact stage of maturity for harvest is dependent upon the intended quality contemplated at the factory. The maturity changes quite rapidly after harvest unless handled properly and promptly. The fieldman may have the crop harvested at its optimum condition, but if it is not processed promptly the quality may drop or go down into the next lower grade in a matter of a few hours.

Cultural practices from the standpoint of quality include such factors as organic matter, moisture, fertilizer, cultivation, pest control methods, etc. Anyone of the above factors may be the limiting factor in producing a quality product. Perhaps the best example of a limiting quality factor is the use of insecticides that give good control of the pests, but they may impart an off-flavor to the processed product or leave a residue. Considerable work has been done along the lines of evaluating the new insecticides from a flavor imparting angle, but there is room here for much more work and along the line of actual amounts of residues left in the finished product. With the constant battle between insecticide residues and insect contaminated products, the packer must always know the quality of his raw and finished products.

Harvesting and handling methods of fruits and vegetables for processing are factors that go hand in hand with maturity and other quality characteristics. The vegetable must be harvested at the

desired stage of maturity and promptly delivered to the processing plant for immediate processing to preserve all the quality. With the mechanical harvesters the processor has, in most cases, complete control of the harvesting of the crop and if he knows what quality he desires he should then get the crop harvested and handled according to specific schedules. Thus, he is able to gear the field operation to his factory operations and retain the maximum quality.

The actual processing methods are in-plant factors that may very adversely affect quality. The processor knows from many years of experience that he cannot improve upon the raw product maturity and other quality characteristics by processing the crop. On the other hand, he can very definitely lower the original raw product quality by using poor processing techniques. Consequently, the processor must exercise good in-plant quality control techniques to preserve the quality delivered to the plant. Some of the more important factors that must be carefully controlled are: efficiency of washing, trimming, cutting, inspecting and sorting; time and temperature of blanch or scald; fill in weights; brine characteristics; closing machine vacuums; can seam formation and processing (cooking and cooling) times and temperatures. Proper control of all these in-plant variables are necessary for quality retention.

The storage temperature and age of processed products have been reported to have effects on retention of the quality of the finished products. However, normal storage temperatures are not detrimental to quality of most processed products up to a year of storage. On the other hand, extreme high temperatures or fluctuating temperatures may be very detrimental in a short period of time.

The last factor that may affect the processed vegetable is the actual home preparation and cooking of the processed products. A perfect product can be grown, processed and properly stored, but very easily ruined by poor home preparation methods. Processors should be encouraged to inform the consumer of the best method of cooking their products. Informative, descriptive and grade labeling of canned products is a step in the right direction to improve consumer-processor relationships.[7]

[7] References: W. A. Gould, "The Best of Food Packer's Quality Control Clinic," and "Interpretation of Quality Control Data," published by Food Packer, 59 E. Monroe Street, Chicago 3, Illinois, 1955; Military Standard, Sampling Procedures and Tables for Inspection by Attributes, Mil-Std 105A, 1950 and 1955; A. Kramer and B. A. Twigg, *Fundamentals of Quality Control for the Food Industry*, The Avi Publishing Company, Westport, Connecticut, 1962.

Conclusion

In conclusion, a quality control program will assure product quality. The quality control technologist must know what to measure and how to measure product quality and its variation. He must be able to interpret his results in light of his company's specifications. Further, the best QC program means very little unless the results are applied to the production line. Management must give the "green-light" for the operation of a successful QC program. Thus, an "up-dated" quality control program assures uniform quality products processed under a given product label. **[The End]**

STUDY OF LUNG CANCER DEATH RATE OF FEMALE SMOKERS

A Public Health Service study of 683 women has shown a lung cancer death rate of 101.4 per 100,000 population, for female smokers. Earlier data for male smokers have established a lung cancer death rate of 392.8.

The present study also reveals that for female nonsmokers, the lung cancer death rate is 9.4, compared to 12.5 for male nonsmokers. This difference by sex is in line with that for most causes of death.

These and other findings were obtained in a survey of lung cancer mortality as related to residence and smoking histories conducted by Public Health Service scientists, and reported as Part II in the April issue of the "Journal of the National Cancer Institute." Part I of the study, on white males, was published in the April 1962 issue of the same magazine.

In the latest investigations, William M. Haenszel of the National Cancer Institute and his colleague, Karl E. Taeuber, now of the University of California, collected residence and smoking histories from relatives of a 10 per cent sample of white females who died of lung cancer in the United States during 1958-59.

In general, findings for females agree with the earlier ones for males. For example, the more women smoke, the greater their chance of developing lung cancer; and the risk is greatest for heavy smokers who move frequently and for the foreign-born settling in large cities. However, place of residence does not seem to play as important a role in determining lung cancer risk for women as for men smokers. There is no evidence that in females the effects of urban residence and excessive smoking and urban residence enhance one another. In men, the combined effect of excessive smoking and urban residence is greater than expected.

Future investigations are planned in which detailed information will be collected on such aspects of cigarette smoking as brand preference and age at which the habit was established. Mr. Haenszel and Mr. Taeuber believe that such information will make it possible to measure more precisely the degree of smoking exposure for each person studied.

The FDA Information Center on Adverse Reactions and Hazards

By GEORGE L. SAIGER, M. D.

Dr. Saiger Presented This Paper in Lexington, Kentucky on February 24, 1964, at a Special Conference on Drug Information Services Sponsored by the American Society of Hospital Pharmacists. The Author Is Director, Division of Research and Reference, Bureau of Medicine.

THE FOOD AND DRUG ADMINISTRATION Information Center on Adverse Reactions and Hazards is a function of the Division of Research and Reference in the Bureau of Medicine. It is concerned with: (1) Adverse reactions to drugs and therapeutic devices; (2) The hazards of chemicals used in the household and of cosmetics, pesticides and food additives; and (3) The accidental ingestion of drugs.

Definition of Terms

A *drug* can be defined as any chemical, and a *therapeutic device*, as any instrument, apparatus or contrivance, that is used in humans or other animals for the following or related purposes: (1) The prevention, diagnosis or treatment of disease, and (2) The prevention of pregnancy.

Foods are excluded when they are implied in the definition of a drug, and sports equipment is excluded when it is implied in the definition of a therapeutic device. Also, the term "disease" includes injury and it involves a consideration of sequelae, such as disability, defect and impairment.

Strictly speaking, an *adverse reaction* is any effect produced by a drug or therapeutic device which is neither preventive, diagnostic nor therapeutic and which occurs when that drug or therapeutic device is used according to the latest directions of the manufacturer. However, we also are interested in effects which are neither preventive, diagnostic nor therapeutic but which occur instead when a drug or therapeutic device is *not* used according to the latest directions of the

manufacturer. For those effects are subject to control measures as well. Furthermore, to know those effects is to have a better understanding of adverse reactions.

Chemicals other than drugs constitute a third category of interest, since they also are potentially dangerous to health. As you undoubtedly know, the chief mission of the FDA is to assist in protecting the public's health.

Development of Information Center

The Center has more than 45 sources of information relating to its areas of concern, among them the Hospital Reporting Program on Adverse Reactions to Drugs. Over 600 hospitals participate in that program, of which 60 are under contract.[1] Our plans are to have 100 hospitals under contract by the end of fiscal '64, 300 hospitals under contract by the end of fiscal '65 and 1,000 hospitals under contract by the end of fiscal '66. That should provide us with a good cross section of all hospitals in the United States on the basis of type of service rendered, size and geographic location.

The Hospital Reporting Program on Adverse Reactions to Drugs began as a pilot study in 1955 with five participating hospitals. Until recently, it was known as the Adverse Reaction Reporting Program. That important source of information served as a nucleus around which the Information Center was developed.

The organizations that cooperated with the FDA in planning the pilot study were the American Association of Medical Record Librarians, the American Society of Hospital Pharmacists, the American Hospital Association, the American Medical Association, the Pharmacy and Drug Therapeutics Committees of the five general hospitals that were to participate in the study and the United States Public Health Service. I might mention that Dr. George Archambault represented the American Society of Hospital Pharmacists as its President.

If there was one factor that created an awareness of the need for a reporting program, it was the experience gained in obtaining information on the relationship between the occurrence of blood dyscrasias and the use of the drug, chloramphenicol. That required 10,000 man-hours of inspectional work among hospitals and physicians and covered a period of three months. It was not until two and one-half years after

[1] The number of hospitals under contract increased to 70 on March 1, 1964.

the product was on the market that sufficient information had been gathered to warrant the investigation. It took that long, because we had to depend almost entirely on the literature.

It is conceivable that, at the present, we would have all the information needed with respect to chloramphenicol within a period of three months or less following its approval for marketing and with much less footwork on the part of our inspectional force. For today, we receive information through a continuous inflow from our many sources. Indeed, it is not unusual for us to learn of a serious reaction by means of a telephone call.

Briefly, the Center collects, screens, evaluates, stores, retrieves, re-evaluates and disseminates information on adverse reactions and hazards. There are recommendations for further study, precautionary labeling, a change in labeling, the issuance of a warning letter or withdrawal from use.

Investigational and Noninvestigational Drugs

There are two types of drugs that one must be concerned with in reporting adverse reactions: investigational drugs and noninvestigational drugs. An investigational drug is classified as such from a legal standpoint if there is no approved new drug application on file for it with the FDA or if it is being tested in a manner different from that for which it was approved; for example, at a higher dosage level, in a different dosage form or for the treatment of a different disease.

Every investigational drug must have a sponsor. Usually, the sponsor is the manufacturer.

Instructions for reporting adverse reactions to investigational drugs are established by regulation and are familiar to the sponsor at the time he files his IND or Form FD 1571 "Notice of Claimed Investigational Exemption for a New Drug." Those instructions require that the investigator report adverse reactions to the sponsor and that the sponsor, in turn, report them to the FDA. In addition, the investigator must complete and file with the sponsor Form FD 1572 "Statement of Investigator (Clinical Pharmacology)" or Form 1573 "Statement of Investigator." It should be noted that Form FD 1573 is concerned with clinical trials. Of course, the investigator can report directly to the Center, and he is encouraged to do so. But that cannot serve as a substitute for meeting the requirements of the law.

From an operational standpoint, the Center is supported by three branches and a medical reference library. These are located in the

Division of Research and Reference. The three branches are: (1) The Adverse Reaction Reporting Branch, (2) The Hazardous Substances Evaluation Branch, and (3) The Epidemiology and Medical Statistics Branch.

Evaluation of Information

Information on adverse reactions is evaluated by a staff of physicians in the Adverse Reaction Reporting Branch, and information on hazardous substances, by a staff of physicians and chemists in the Hazardous Substances Evaluation Branch. The Epidemiology and Medical Statistics Branch serves as the research arm of the Center. It was organized only recently, and in addition to epidemiologists and statisticians, its professional staff will include coders and programmers, for we shall be utilizing electronic data processing equipment in the not too distant future.

All of the medical specialties are well represented in the Division. We have found that in order to evaluate the information properly it is necessary to divide the professional personnel in the Adverse Reaction Reporting Branch and in the Hazardous Substances Evaluation Branch into panels and that those panels must be supported by a staff of consultants. It should be emphasized that evaluation is a careful procedure. We ask ourselves three questions: (1) Is this a *confirmed* or a *suspected* case? (2) Do we have similar cases on record? (3) How serious is it?

Our expertly staffed and well-stocked Medical Reference Library is responsible, among other things, for abstracting information in the literature. At the present, the Library scans 250 journals per month out of 750 received and it prepares 625 abstracts for the same period.

It can be stated that, in general, our staff is dedicated to the prevention of man-made disease.

It is estimated that, during all of fiscal '64, we shall have reviewed 7,500 reports in the literature and 58,000 reports from other sources. Our projected increase is 50,000 reports per year. An idea of an upper limit can be obtained by visualizing what the inflow would be if only 10 per cent of all cases of adverse reactions to drugs and therapeutic devices and of harmful exposure to chemicals other than drugs were reported. The figure would be astronomical.

Distribution and Exchange of Information

Information from the Center is disseminated by means of a monthly report issued by the Adverse Reaction Reporting Branch, a

monthly report issued by the Hazardous Substances Evaluation Branch and a weekly journal of literature abstracts issued by the Medical Reference Library. That material is distributed to all hospitals in the Hospital Reporting Program, to all organizations with which we exchange information and to other interested individuals and groups.

We are not satisfied alone in ascertaining the nature, and degree of severity, of adverse reactions to drugs. We also are involved in research projects which should provide us with reliable estimates of their incidence.

We feel that what is needed is a center to which information from all parts of the world can be channeled without delay. For that should bring to light, at the earliest possible moment, the rare, though serious, reactions and hazards. To a large extent, we are functioning in that capacity now, since we *do* exchange information on drugs with other countries through our State Department, and since we *do* have access to a world-wide literature. Furthermore, we believe that ours is the largest center of its kind in existence.

There still is room for improvement with respect to the development of international sources. We must be able to exchange information directly on a scientist-to-scientist basis, information that otherwise would appear in the literature must be made available much sooner than the date of publication and finally a standard reporting form must be developed. However, progress is being made in all of those directions.

Conclusion

Many independent efforts are being planned in this country. Each of them can be effective only to the extent to which there is an exchange of information. It would seem logical that all information on adverse reactions and hazards should be brought to the attention of the FDA, for with that organization lies the ultimate responsibility for regulatory action. Toward that end and others, we certainly are willing to share our broad experience. **[The End]**

Progress on Investigational Drugs

By WINTON B. RANKIN

The Author, Assistant Commissioner of the Food and Drug Administration, Presented This Paper at the Eastern Regional Pharmaceutical Manufacturers Association Meeting in New York City on December 10, 1963.

WHEN DR. SHEELEY INVITED US TO PARTICIPATE in this panel discussion we inquired about the purpose of the meeting. *Some* of the discussions that we have heard in recent weeks are in effect a continuation of the debate before Congressional committees last year as to whether the Kefauver-Harris Drug Amendments should be enacted. We doubt that much is to be gained by having the FDA participate at this time in further discussions of such nature. The law was enacted and the need today is for all of us to give our sincere thoughts and earnest efforts to putting it into effect smoothly. It may be that after it has been tried for a while, some of you will find that there are provisions with which you are not satisfied. It may be that we will find provisions that we believe should be amended. Then will be the time to talk about possible amendments. But now is the time to give this new law a fair trial and to do our best to make it a workable instrument.

Dr. Sheeley indicated that it was not the purpose of this meeting to provide a forum for continuation of the 1962 debate. And so we were most happy to accept the invitation to discuss some of the pressing questions that have arisen during the first year of administration of the new law.

In particular, I would like to consider the investigational drug procedures that have been set forth in regulations first proposed under the old law but put into effect under the new amendments.

The law and regulations essentially prescribe principles which have been recognized by the medical profession for many years, governing experimentation on man. Generally speaking, the requirements are that before a new drug may be shipped for clinical testing,

the government must be notified of the facts which convince the sponsor of the test that he is justified in trying a product on man. Among other things:

1. There must be an indication that adequate animal, chemical and other appropriate tests have been performed on the drug.

2. An indication of proper manufacturing controls in production.

3. A showing that a sound plan of investigation has been prepared and made available to the investigators together with other information which will enable them to reach their own conclusions as to the desirability of conducting the tests and the precautions which they should observe in conducting it.

4. The notice to the government should contain a showing that the sponsor has determined that the investigators selected to participate in the experiment are, in fact, qualified for their participation.

5. There is a requirement that investigators shall certify that they will obtain the consent of the subjects of the experiment or their representatives, except where this is deemed by the investigators not to be feasible or not in the best interest of the patient.

Patient Consent Requirement Clarified

This so-called patient consent requirement is perhaps the most misunderstood of any. There is a widespread belief among investigators that it is something new which has been added by the Kefauver-Harris Amendments—an exacting and perhaps frightening provision that in some way is going to make it much more difficult, if not impossible, to conduct clinical tests on new drugs in the future. But this is not the case at all. For the doctor to tell a patient that he would like to try a new drug and explain the proposed treatment does not add anything to the requirements under which physicians have operated for a great many years. Under common law the physician is not entitled to do anything to his patient or administer any drug, whether or not it is an approved drug, without obtaining the informed consent of the patient. Basically the same requirement has been set forth in various codes of medical ethics over a period of many years. There is nothing new in the patient consent requirement. If anything, it is less restrictive than the common law in that it gives the physician the opportunity, at least under the federal requirement, to decide when it is not feasible or not in the best interest of the patient to attempt to gain his consent.

Other Misconceptions About Procedures

It may be worthwhile to review briefly some of the other misconceptions about the investigational drug procedure. One is a big feeling of uneasiness that in some way the government under the new procedure is going to try to control all research in the United States, to dictate to clinicians what they should test and how they should test it. This also is not correct. Neither the law nor the regulations say, and we do not intend to try to make them say, that the government shall dictate the drug to be tested, the plan to be followed in testing or the investigators who will do the testing.

The sponsor will arrive at his own decision on these matters. It is quite true that he advises the government of his decisions before the test is undertaken. It is also true that if there is evidence of unreasonable hazard or a lack of reasonable testing to determine the probability of hazard, the government is obligated to block interstate shipment of the investigational drug. But this safeguard is a far cry from the domination of research.

It is not even the function of the government, as we visualize the requirements, to forbid the performance of a clinical test that is not particularly well designed scientifically, provided adequate preclinical examination is performed to reveal the possible hazards, investigators are properly advised, there are not obvious hazards which can and should be avoided, and the subjects of the experiment understand that they are undergoing an experimental procedure which necessarily may be understood to entail greater risks than an accepted one. Of course, when our scientists review a claim for exemption and offer comment to the sponsor, they will upon occasion offer suggestions as to modifications they believe would improve the experiment. Such suggestions have been requested by a number of firms. These are advisory and should not be construed as an indication that we intend to cancel an exemption merely because the test it covers is not the best one that could be devised.

Now whether the results of a poorly conceived study will serve to establish the safety and effectiveness of the drug to the point that that product can later be approved for general marketing is an entirely different matter. Our experts may well have to say to a manufacturer who relies upon inadequate experimentation: "We are sorry you do not have proof of safety and effectiveness which will justify commercialization of your new product. You need more and better investigations." That is not a new situation. It has prevailed for over

25 years with respect to safety studies on all new drugs, and for quite a number of years with respect to efficacy studies on certifiable drugs. But, the point is that the law does not establish the Food and Drug Administration as the dictator of drug research in this country.

A few researchers have been disturbed by the requirement that they report the results of their studies to the sponsor of an investigation. This is a basic part of the investigational process. If the results of an experiment are not disclosed then it contributes nothing to the development of a new drug and virtually nothing to science generally.

We do not see any prospect of relieving those who test new drugs from the reasonable requirement that the results be reported to the sponsor and then to public authority. Insofar as we know, only a small minority of the clinical investigators are disturbed about this provision.

There has been a tremendous amount of progress in the past year, and it is continuing at a steadily increasing rate. One of the noteworthy developments is the establishment of a practical system for handling and retrieving the mass of data that comes to FDA with regard to investigational drugs. At present five classes of basic information are recorded into punch cards. These include information about:

(1) Chemical structure and formulation,

(2) Drug manufacturer,

(3) Drug names,

(4) Pharmacology of the drug, and

(5) Route of administration and dosage.

Thus when our medical officers are considering a claim for exemption, they request a mechanical search of the recorded data to determine whether the same chemical—or a similar one—has been tested before and if so with what results. When this discloses the possibility of significant and serious ill effects not previously recognized by the sponsor of the new test, we will immediately advise him of the untoward results so that appropriate steps may be taken to avoid subjecting additional people to the same risk. The existence of such a reporting system should prove of great value not only to the subjects of clinical trials, but also to the firms that conduct them. Already the new system has paid dividends. It will be expanded to include information from other sources as soon as possible.

Advisory Committee on Investigational Drugs Commended

The FDA's Advisory Committee on Investigational Drugs under the chairmanship of Dr. Walter Modell has given invaluable assistance since it was formed. Some seem to feel less restraint in discussing their problems with the advisory committee members than in discussing them with the government, so we get a truer picture of the impact of the new procedure through the eyes of the advisory committee. Additionally, the committee members, who are distinguished investigators in their own right, bring their own skills and abilities to bear in suggesting solutions to troublesome problems.

Only recently the advisory committee has suggested methods of easing the amount of paper work required to make certain placebos and chemicals being used as research tools available to the scientific and medical community. We are in the process now of translating the committee's recommendations into proposed changes in the investigational drug regulations.

Other problems are under active study and discussion between the FDA and the advisory committee and unquestionably in the forthcoming months there will be revised procedures and perhaps additional revisions in the regulations, all designed to encourage the research effort without any sacrifice of consumer protection. We are greatly indebted to the members of the advisory committee for the major contributions they are making at considerable sacrifice. In our opinion the entire scientific community likewise owes these experts a sincere vote of thanks.

Drug Industry's Aid

The drug industry is helping significantly in implementing the new law and regulations. I was greatly impressed a few weeks ago by the very fine job that the medical services staff of Sandoz Pharmaceuticals had done in preparing a claim for exemption for an investigational drug. The information in the claim was set forth in a clear, concise manner which greatly facilitated our handling of the submission. I am advised that other claims by Sandoz have been prepared in a similar manner. I know also that Merck goes to great lengths to prepare its new drug applications so that they will present the necessary information in a most useable form. This again greatly facilitates our handling of the documents and expedites their processing to the advantage of all who submit new drug material for review. I

am advised that, among others, A. H. Robins and Winthrop have presented excellent documents to us.

Certainly there are many other firms who likewise have gone out of their way to see that their submission to the FDA are well-prepared scientific documents.

The law requires you who sponsor clinical tests to assure yourselves that the investigations are properly planned and conducted.

Industry can also be of assistance in explaining these requirements to the investigator in a fair and truthful manner. The investigator's opinion of the law and of the government is greatly influenced by what he hears from the drug industry.

The new requirements will save lives and raise the quality of medical research. When considered objectively, they are desirable. A number of manufacturers have told us that the investigational procedures are workable—that they can live with them. Are you willing to make the same statements to clinical investigators?

We in the FDA are bringing our best abilities to the administration of the investigational drug procedures. We intend to perform the job sincerely, honestly and with complete regard for the needs not only of the consumer public, but also of the industry and of the professions. It has been our observation that where government and all concerned with a regulatory statute approach a new law in this spirit it is possible to get it into operation smoothly and effectively. We will appreciate your continued cooperation during this transition period. **[The End]**

INTERSTATE SHIPMENT OF DRUG INGREDIENTS JUSTIFIES FEDERAL SEIZURE

The fact that a drug had been compounded and offered for sale only within the state of Michigan did not preclude its seizure under misbranding and mislabeling charges, since the components were drugs which had been shipped from outside the state, the United States Court of Appeals in Philadelphia has held. The compound was a drug held for sale after shipment in interstate commerce, within the meaning of Section 304(a) of the Federal Food, Drug and Cosmetic Act. The court noted that the ingredients, which were drugs that had not been misbranded when shipped, did not lose their identity as individual components of the seized compound. Also noted was the fact that the maunfacturer had stressed the value of various component drugs in his labeling.—*United States v. Detroit Vital Foods, Inc.*, FOOD DRUG COSMETIC LAW REPORTS ¶ 40,112.

The Scientists' Forum

Facts, Fears and Fallacies

By BERNARD L. OSER
President and Director, Food and Drug Research Laboratories, Inc.

Dr. Oser, This Magazine's Scientific Editor, Presented This Paper at the Annual Meeting of the American Public Health Association as Part of a Symposium on Pesticides, Food Additives and Public Health. The Meeting Was Held in Kansas City, Missouri, on November 11, 1963.

ONE OF THE STATED AIMS of the broad program of the American Public Health Association is to offer a forum for papers "providing authoritative material for use by science writers and the lay press in informing and educating large segments of the general public." The outpourings of popular writers have reflected a lack of sufficient appreciation or understanding of the chemical aspects of our modern environment. Public health policies should be based on a proper balance between the real benefits to be gained and the real, rather than hypothetical, risks that could result from the expanding uses of both old and new chemicals. Writers imbued with a crusading spirit have deliberately presented an exaggerated picture of potential destruction of human and animal life from the use of pesticidal agents and food additives. In best sellers, on the air, and in popular magazines ranging from the *Police Gazette* to the *Saturday Review,* these masters of the art of the conditional phrase and the rhetorical question, have confounded facts with suspicion and inculcated doubt and fear, instead of clarity and understanding. They have succeeded in spreading confusion throughout the land, and even abroad, and have instigated extensive legislative inquiries.

This symposium was planned with the intention of shedding some light on the use of chemical agents in agriculture and technology, and on the measures being taken to insure safety and protection to health. It is hoped thus to help restore equilibrium to an unduly alarmed public.

It is, of course, a fact that chemicals in general, and pesticides in particular, are capable of causing injury or death, but whether or not they are hazardous to man or beast depends on how they are applied. When research or experience establishes the capacity of a chemical agent to eradicate a disease-bearing or crop-destroying insect, a remote possibility of risk, such as may result from occasional misuse, should not stand in the way of its practical application.

It is theoretically impossible for toxicological research with laboratory animals to establish unequivocal and absolute proof of safety of a chemical for man or any other nontested animal, since species differences must inevitably leave a residue of uncertainty in translating results from animals to man. However, experience has shown that this transition has been affected with a high degree of assurance of safety. Several hundred new pesticides have undergone safety evaluation studies in animal tests over the past quarter century. Statistics of the United States Public Health Service show that the death rate from accidental poisonings by solids, liquids, gases and vapors have remained constant at about two per 100,000 during this period, and death from pesticides alone have accounted for only about one per million. In the light of this fact, one must conclude that these new pesticides are certainly no more hazardous in use than the previously known poisons.

Toxicological research, like all research, has no end-point. When sufficient data are accumluated to warrant a reasonable decision, action is justified. If progress were to depend on absolute proof of safety, thousands of lives would have been sacrificed to disease before we knew as much as we do about antibiotics or polio vaccines.

To say that the use of pesticides has caused a "chemical rain of death" or that it has made us no more than "guests of the Borgia" is a warped use of poetic license and a gross misrepresentation of the facts. Charges such as these do not deserve more attention because they are expressed in graceful literary language.

Legal tolerances for pesticide residues in food are based on animal studies in which the major objective is to find a dietary level which, upon daily ingestion throughout a lifetime, results in no adverse effect. Detailed physiological and pathological examinations are made to establish this safe dietary level for the test animals. The safe level in the human diet is then taken as a small fraction (generally 1/100) of this "no-effect" level. However legal tolerances for pesticides are considerably below these safe levels for two reasons: first,

because they apply to fruits, vegetables or other items of food which constitute only part of the whole diet; and secondly, because they are set at minimum levels necessary or unavoidable in achieving the intended effect. Because control tests show that actual residues of DDT are falling well below its present tolerance, there is a likelihood that the latter may be reduced by regulatory action.

In the face of these facts, the accusation that the "whole record of contamination and death" is being disregarded by industry and control officials alike, does them a serious injustice. Anyone who has had first-hand experience in dealing with government officials charged with the enforcement of pesticide and food additive regulations would recognize the unfairness of accusing these dedicated and zealous public servants of callous disregard of public interest, or of subservience to industry.

Statements designed to sow the seeds of doubt take many forms in the diatribes on this subject. A common one is the claim that investigations which establish the safety of individual substances tell us nothing about the possible effect of combinations. Granted that there is much to be learned about such interactions, with respect to both potentiation and inhibition, what we do know concerning pesticides is that potentiation is rare and is likely never to be observed, inasmuch as use levels are so far below the levels of demonstrable effect in animals. Moreover, there is evidence that the ingestion or administration of traces of foreign substances stimulates the production of drug metabolizing enzymes in the mammalian liver, some of which increase the tolerance to other drugs. This method of adaptation is only one of several defensive devices with which man and all animals is endowed.

Another weapon used in the attack against chemicals in our environment is to associate them with cancer. An etiological relationship between a chemical substance and the incidence of cancer is not proved by limited personal observation, nor by flimsy epidemiological observation. As the late Sir Jack Drummond once pointed out, "Almost every type of food and diet has at one time or another been held responsible for (cancer), it being a popular weakness to ascribe it to any innovation, such as tomatoes or bleached white flour, which may not at first meet with approval. None of these theories has survived even a superficial examination." To the examples cited by Professor Drummond may be added tea, canned foods, and currently, of course, tobacco and environmental chemicals.

Today the finger of suspicion is being pointed at pesticides and food additives, yet no class of substances has been as thoroughly investigated, prior to use, to establish their freedom from carcinogenic hazard. This is not to deny that more research is needed in the areas of methodology and diagnosis of experimental cancer, but the best available methods have been and are being used and it is the rare exception, rather than the rule, to discover carcinogenic potential in a pesticide or food additive.

Another fallacy is to suggest that the "deadliness" of an insecticide becomes progressively greater as its concentration increases in the fat of each successive species (as when birds eat earthworms, or fish eat plankton). The critical factors which must be taken into account are the total body burden, the rate of metabolism, the role of fat depots as a defense mechanism, and species resistance.

On the other hand it is indeed an unfortunate fact that in certain places, whether through carelessness or ignorance, needless loss of birds, fish, or other wildlife has occurred. But before assuming this to be a typical consequence of the use of pesticides, one might consider what proportion of the total tonnage of pesticides was involved in such episodes, and that the vast benefits that pesticides have brought in terms of the quality and quantity of food produced and protected from predators. The abolition of automotive transportation with its high accident toll would be unthinkable. Nor would it be suggested that a popular soap be prohibited because 0.56 per cent of its content is not claimed to be "pure."

Rather than decimating bird population, statistics appear to show an explosive increase during the period (though not by virtue of the fact) that modern pesticides have come into use. In many places, starlings and pigeons have become so numerous as to have reached the nuisance stage and have even caused loss of life through airplane accidents and the spreading of viral infection.

It is claimed that we have recklessly begun to upset the balance of nature. Without denying the existence of ecological cycles, it seems difficult to accept this rather mythical concept in the face of the fact that in the struggle for survival, all forms of animal life have from time immemorial been in a dynamic state. Even Miss Carson admitted that "The balance of nature has never been static; it is fluid, ever shifting, in a constant state of adjustment. Man himself is part of this balance." Man's attack on his predators, whether they be wild beasts, insects or disease germs, are neither recent nor different in principle

from that of any other species in its struggle for survival. What is new is the fact that Providence has afforded man the intelligence and the tools with which to wage the attack—and at a time when it is urgently needed to provide for his growing numbers.

The housewife whose domain is invaded by flies, roaches, termites, or bedbugs, whose pet dog has fleas or mites, or whose garden is infested with plant lice, aphids, or beetles, is not expected to concern herself about the balance of nature when she selects means of eradicating these pests from her home. Nor can the farmer worry about the balance of nature in his anxiety to protect his crops from the codling moth, cornborer, cutworm, fruit fly, or boll weevil, by the most efficient means at his disposal.

On the one hand we find a marine biologist, a Supreme Court Justice, a renowned dramatic critic, and assorted bird lovers and organic gardeners, applauding the attack on pesticides. On the other, are the scientists working in laboratories and in the field, including entomologists, toxicologists, food technologists, nutritionists, physicians and others, who deplore misrepresentations and distortions made in the interest of arousing public reaction. Fearmongering by means of threats of hidden hazards to health is contrary to public interest when it leads to repetitious investigations at public expense and to the adoption of excessively burdensome legislation. This must inevitably be reflected in the increased cost to consumers, in retarding technological progress, and in adverse effects on our international position.

Suggested Solutions

The real danger is the spread of chemiphobia and the failure of legislative and administrative agencies to counter-attack this trend with sufficient vigor. As a former scientific advisor to the President once put it, in a somewhat different context, "the hazard we face is that science will be so identified with destruction that its real significance will be lost, its ranks weakened, and its creativity diminished." Let us agree that more research is needed to promote the safe use of chemicals for better living, but let not unwarranted fear stop the clock. Let us agree that more education is needed to get the public to respect chemicals and drugs, to read, understand and obey labels; but let us not blame industry or government scientists for the carelessness, negligence, or illiteracy of consumers. Let us acknowledge that American agriculture has achieved miracles by utilizing modern

science and technology for the production of an abundance of food for our expanding population; but let us not thwart this trend by creating popular hysteria and surrounding technological progress with unnecessary restrictions. Let us support and strengthen our official guardians of public health and applaud their accomplishments, rather than impugn their motives and sow distrust of their diligence or competence. **[The End]**

GORDON RESEARCH CONFERENCES

The Gordon Research Conferences, international conferences on developments in the most active areas of basic research, will include 50 full-week sessions this summer. The program includes nine new research topics.

Scheduled to open June 15, the conferences will continue through September 4. The meetings, each devoted exclusively to a single subject and lasting a week, will be held at five New Hampshire locations: Colby Junior College, New London; New Hampton School, New Hampton; Kimball Union Academy, Meriden; Tilton School, Tilton; and Proctor Academy, Andover.

The conferences were established to stimulate research in universities, research foundations and industrial laboratories. This purpose is achieved by an informal type of meeting consisting of scheduled speakers and discussion groups. Sufficient time is available to stimulate informal discussion among the members of each conference. Meetings are held in the morning and in the evening, Monday through Friday, with the exception of Friday evening. The afternoons are available for recreation, reading or participation in discussion groups as the individual desires. This type of meeting is a valuable means of disseminating information and ideas to an extent that could not be achieved through the usual channels of publication and presentation at scientific meetings. In addition, scientists in related fields become acquainted, and valuable associations are formed that often result in collaboration and cooperative efforts between different laboratories.

Among the subjects scheduled for discussion at this year's conferences are: Hydrocarbon Chemistry; Nuclear Chemistry; Catalysis; Polymers, Textiles; Elastomers; Corrosion; Medicinal Chemistry; Food and Nutrition; Separation and Purification; Cancer; Nuclear Structure Physics; Environmental Sciences—Microchemical Contaminants in Water; Nucleic Acids; Theoretical Chemistry; Metals and Metal Binding in Biology; Statistics in Chemistry and Chemical Engineering; Scientific Information Problems in Research—Critical Tables; Radiation Chemistry; Steroids and Other Natural Products; Inorganic Chemistry; Analytical Chemistry; Chemistry of Heterocyclic Compounds; Adhesion; Lipid Metabolism; Solid State Studies in Ceramics; Cell Structure and Metabolism; Coenzymes and Metabolic Pathways; and Chemistry; Physiology and Structure of Bones and Teeth.

Further information, including a complete schedule of conferences and attendance application forms, may be obtained from Dr. W. George Parks, Director, Gordon Research Conferences, University of Rhode Island, Kingston, Rhode Island.

Get the Help of CCH's

Food Drug Cosmetic Law Reports with Products Liability

Focussed Reporting Designed to Meet Specialized Needs, Provide Protection on Food, Drug and Cosmetic Rules, Products Liability Claims

Toeing the mark on today's fast-changing food, drug and cosmetic rules while keeping in step with technological and processing advances combine to put a heavy burden on manufacturing executives and their legal and scientific advisers.

That's why we believe you'll welcome the help and guidance CCH's informative FOOD DRUG COSMETIC LAW REPORTS and PRODUCTS LIABILITY REPORTS provide on the application and interpretation of federal and state rules relating to food, drugs and cosmetics and products liability claims concerning them. Particularly valuable for executives, chemists, technologists and attorneys is the unique new "Index to Substances," which lists substances treated in federal laws, FDA regulations, and food and color additives petitions. Your subscription brings you up to date on today's effective rules administered through the Food and Drug Administration, plus essential federal and state requirements . . . keeps you continuingly informed on pertinent new developments . . . offers sound solutions to your everyday questions, special compliance problems.

For a complimentary copy of each REPORT, and further information on the problem-solving help they provide, fill in and mail the reply card attached.

COMMERCE CLEARING HOUSE, INC.

PUBLISHERS of TOPICAL LAW REPORTS

NEW YORK 17 420 LEXINGTON AVE. | CHICAGO 46 4025 W. PETERSON AVE. | WASHINGTON 4 425 13TH STREET, N. W.

FOOD DRUG COSMETIC
LAW JOURNAL
PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS
4025 W. PETERSON AVE., CHICAGO 46, ILL.
RETURN REQUESTED

SECOND CLASS POSTAGE
PAID AT CHICAGO, ILLINOIS

A COMMERCE CLEARING HOUSE PUBLICATION