VOL. 17, NO. 11 NOVEMBER 1962

Food Drug Cosmetic Law JOURNAL

Procedural Techniques in Food and Drug Administration

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: $20 per year. Single copies are $2 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

November, 1962
Volume 17 • Number 11

Second-class postage paid at Chicago, Illinois.

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Cosmetic Labeling and Packaging.—This topic is examined in an article by the Assistant Commissioner of the Food and Drug Administration, *W. B. Rankin,* which begins on page 747. He explains the activities of his department in investigating deceptive packaging and misleading labeling of cosmetics and enforcement procedures. The author believes that cosmetics should be properly tested before they are placed on the market. "From the data obtained by applicable procedures, it is possible to assess the local and systemic toxicity of substances applied to the skin and mucous membranes and to predict the amounts, the concentration and frequency of application that may be tolerated by man," he points out. Factory inspection authority must also be strengthened in order to allow access to certain information needed to evaluate procedures.

England's Public Analysts.—An address presented at Oxford, England, to the Association of Public Analysts by the Government Chemist, *D. T. Lewis,* is found at page 753. The author traces the history of the public analyst from the ancient times until the present, and discloses the important role he plays in the food and drug field. Mr. Lewis concludes that the future of the analyst, "be he a public analyst, a government analyst, an industrial or a pharmaceutical analyst, is well assured in the modern framework of a healthy society."

Vol. 17, No. 11 November, 1962

Food·Drug·Cosmetic Law
Journal

Procedural Techniques in Food and Drug Administration Proceedings

By BEN C. FISHER

The Author Is Chairman of the Committee on Food and Drugs, Administrative Law Section, American Bar Association. This Is a Report of That Committee to the Administrative Law Section.[a] This Article Is Reprinted From the Spring-Summer, 1962 Issue of *The Administrative Law Review* With Permission of the Editor-in-Chief, Victor G. Rosenblum.[b]

It is time for re-examination of the procedures by which the Food and Drug Administration (FDA), operating in the Department of Health, Education and Welfare, administers the Federal Food, Drug and Cosmetic Act (21 U. S. C. Section 301 and following, 52 Stat. 1040). The agency has recently been given vast new powers under the Food Additives Amendment of 1958 and the Color Additive Amendments of 1960. Other bills giving even more authority are now before Congress. The entire history of this agency, not unlike others, has been one of increasing regulatory activity. We need not decide whether this is good or bad. The fact that there is a substantial increase in the regulatory activities creates a need for clearly defined, fair and expeditious procedure.

Experience suggests that the increasing grant of substantive regulatory powers now requires an over-all re-examination of pro-

[a] Reports of Committees of the Section of the American Bar Association are NOT to be construed to represent the official policy of the American Bar Association or of the Section of Administrative Law. Reports reflect Section and Association policy ONLY as and when they are acted upon by the Section and by the House of Delegates.

[b] This article was written prior to the passage of P. L. 87-781 (S. 1552) which became law on October 10, 1962. Therefore, the reference to S. 1552 does not reflect the provisions contained in the bill as enacted.

cedural safeguards afforded by the FDA. Actually, there has been surprisingly little litigation or controversy over matters of basic procedure. Partly this is because manufacturers and producers who deal with the agency find it easier to comply with FDA demands than to participate in long drawn out, expensive litigation, liable to damage seriously the good will of the company. Partly this is because of the nature of the subject matter dealt with. Traditionally, where questions of public health are involved, as for example in connection with cancer, laymen and the courts have been most sympathetic to government regulation. And even though perhaps half of the substantive provisions of the Act deal *not* with safety or the public health but rather with economic deception and misbranding, the overtones of public health set the regulatory tenor.

Basic problems of procedures have been raised by the change in the thrust of administrative activities from the originally intended purpose of "policing" (using court technique of seizure, injunction and criminal prosecution) to "licensing" activities requiring prior approval before the sale or distribution of the product involved. Interestingly enough, the original justification for "premarketing" approval was the serious threat to health stemming from the marketing of a dangerous or poisonous substance. Now, however, the prior sanction requirement deals with all dangers covered by the Act, including economic deception, adulteration and misbranding.[1]

This shift of emphasis, as noted by leading lawyers in the field, is continuing and is increasingly affecting procedure.[2] Most of the contemplated procedure under the Federal Food, Drug and Cosmetic Act utilizes rule-making techniques rather than adjudication; however, with the increase in the "prior approval" type of regulation, much of the so-called rule-making is indistinguishable from adjudicatory licensing proceedings. And the new procedures, though more comprehensive than before, still suffer certain procedural weaknesses which are hangovers from rule-making theories and techniques.

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[1] Food Additives Amendment, Section 409(c)(3)(B); Color Additives Amendments, Section 706(b)(6). Even the new proposed legislation requiring a premarketing showing on safety of cosmetics makes no distinction between health and economic deception. See proposed new Section 605(d)(3) of H. R. 11582, introduced May 3, 1962, 87th Cong., 2d Sess. (Harris Bill).

[2] The so-called "Kefauver Bill," S. 1552, provides for prior licensing of producers of prescription drugs. See proposed Section 508(c) [a modified version, calling for registration only, was enacted in Sec. 510—CCH]. H. R. 11582, referred to in footnote 1, requires prior approval of both cosmetics and devices.

For example, one may request that a tolerance be established for a particular pesticide chemical which then enables the producer to market his product. These are considered regulations, but to all intents and purposes, the "regulation" is a license to that particular person to distribute his particular pesticide chemical under specifically prescribed circumstances. The same is true for a "new drug application" under Section 505 of the Act. If the Secretary approves it, the application becomes effective, and the owner of the drug has, in short, a license for its use. So also under the Color Additive and Food Additives Amendments,[3] a person may request the Secretary, by petition, to issue a regulation prescribing the conditions under which the additive may be used. The additive may be so common as to affect an entire industry or it may be of such a unique and specialized nature that only one manufacturer in the nation would normally benefit from the issuance of the regulation. All of these "licensing" activities would seem to require a full and fair adjudicatory-type proceeding, no matter what the label given to the function.

Another important aspect of this shift of emphasis to licensing is the shifting of the burden of proof to the individual to justify in advance his right to manufacture or market a particular food additive, new drug or color additive. No longer is the burden entirely upon the government to go into court to show the dangerous, unsafe, adulterated or otherwise improper condition of the marketed product. Now the burden is upon the manufacturer, or distributor in some cases, to prove in advance the safety of his product, or in other cases, the efficacy of his chemical, or that his claims are not deceptive or false. This, it is submitted, makes imperative the requirement that the FDA procedures be designed to process the license applications in an expeditious and fair manner, consistent with due process of law.

Nevertheless, as will appear from the later material, vestiges of rule-making attitudes and the assertion of broad discretionary powers remain. Partly this is because Congress continued to use rule-making terminology (where it never intended normal rule-making procedure);[4] partly because the agency is used to the broad discretion available to it in rule-making proceedings and thus, is reluctant to sacrifice such discretion to formalized adjudicatory hearing procedures.

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[3] Sections 706 (376) and 409 (348), the section cited in the parentheses is the citation to Title 21 of the U. S. Code.

[4] See for example, the Food Additives Section, 409(b) (348(b)); "Any person may . . . file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used."

It will be the purpose of this report to analyze in some detail the regulatory activities of the FDA and the procedures applicable to them. Where appropriate, tentative suggestions as to possible improvements or alternatives will be described.

REGULATORY ACTIVITIES

Adjudication

Both under the statute and in practice, there is little recognized adjudicatory activity under the Federal Food, Drug and Cosmetic Act. Section 404(a) (344(a)) of the Act provides for the issuance in certain cases of temporary permits to manufacturers of certain types of food which, by reason of contamination in the locality during manufacture, may be injurious to health. Section 404(b) of the Act authorizes the Secretary to suspend immediately on notice any temporary permit issued under this authority if it is found that the conditions of the permit have been violated. The holder is entitled to apply for the reinstatement of the permit and the Secretary is required to hold a hearing on the reinstatement request. This is considered adjudicatory by the agency, but there is no special procedural provision for the hearing under this section and so far as can be determined, a hearing has never been held.

Section 505 (355) of the Act, the new drug section, provides that no person shall introduce into interstate commerce any "new drug" unless he has filed an application therefor. Section 505(c) provides that the new drug application will become effective within 60 days unless prior to that time the Secretary, by written notice, postpones the effective date for a period of not more than 180 days. Section 505(d) provides that the Secretary shall refuse to permit the application to become effective if "after due notice to the applicant" and "opportunity for a hearing" he is not satisfied that certain standards having to do with the safety of the drug or the reliability of the methods of manufacture have been met. Section 505(e) also gives the Secretary the authority to suspend the effectiveness of an existing application "after due notice and opportunity for hearing" if the Secretary finds that new tests now show the drug to be unsafe or if there are untrue statements appearing in the application. Both of these activities are considered adjudicatory.

FDA recognizes as adjudicatory proceedings for suspension and revocation of a milk shipment permit under the Import Milk Act (21 U. S. C. 141, 143) and proceedings having to do with the shipment in interstate commerce of a dangerous caustic or corrosive substance

under Section 5(a) of the Federal Caustic Poison Act (15 U. S. C. 405(a)). So far as appears, no actual proceedings have been held under these provisions.

There are a few other matters which we believe to be adjudication, such as (1) an application for certification of a batch of harmless coal-tar colors for use in food under Section 406(b) (346(b)); (2) an application for certification of a batch of coal-tar colors for use in drugs, under Section 504 (354); (3) an application for certification of batches of drugs composed wholly or partly of insulin (Section 506 (356)); (4) an application for certification of a batch of drugs composed wholly or partly of specified antibiotics under Section 507(a) (357(a)); (5) an application for certification of a batch of coal-tar colors for use in cosmetics under Section 604 (364). The FDA apparently does not agree that this is adjudication and simply treats these as administrative actions. According to the agency, "If the analysis indicates compliance with the law and regulations, a certificate is granted. If not, the certificate is refused, and it is contrary to law to introduce such articles into interstate commerce." [5] Considering that the refusal to issue the certificate can destroy the economic value of that batch, the procedure is certainly cavalier. Apparently, in practice and with consent of the industry, this informal type of administrative action suffices. As a matter of procedure it leaves much to be desired.[6]

Rule-Making Activities

The rule-making functions of the FDA are extensive and complicated. First, the FDA issues general statements of policy and interpretive rulings defining in detail certain statutory language. There are also procedural and organizational rules adopted.

A second area of rule-making occurs in the establishment of substantive standards of safety, identity, labeling and packaging. For example, there is the food standards section, Section 401 (341); interpretive provisions on adulterated food under Section 402 (342); and mis-

[5] Survey and Study of Administrative Organization, Procedure and Practice in the Federal Agencies, Part 4, Department of Health, Education and Welfare, p. 439 (House of Representatives, 85th Cong. 1st Sess., 1957).

[6] The certification service can be suspended if petitioner is found to have defrauded the government, or misrepresented his records. 21 C. F. R. 9, 10, dealing with the suspension of certification of coal-tar colors provides for *no* procedure. Section 164.9 of 21 C. F. R. dealing with suspension of service for certifying drugs containing insulin, and Section 146.6 of 21 C. F. R. dealing with suspension of service for certification of antibiotic drugs, both provide for notice and hearing. Presumably, this would be adjudicatory.

branded food under Section 403 (343); regulations for the issuance of emergency permits to manufacturers who manufacture food, which may, by reason of contamination in the locality, be injurious to health under Section 404 (344); regulations prescribing the conditions under which a food additive may be safely used under Section 409 (348); the issuance of regulations prescribing appropriate tests and methods of assay for the purpose of determining the strength, quality and purity of certain drugs under Section 501(b) (351(b)); regulations setting forth the packaging and labeling requirements for certain drugs or devices under Section 502(b)(2) (352(b)(2)). Then there are other substantive rule-making activities under Section 502 (352), such as designating certain drugs as "habit forming," (subsection (d)), formulating exemptions from requirements of giving "adequate directions for use" (subsection (f)), or labeling drugs properly which are liable to deterioration (subsection (h)); finally, the establishing of regulations for listing certain color additives as safe for use in food, drugs or cosmetics under Section 706(a) and (b) (376(a)(b)).

These are examples of regulatory activities directed towards establishing substantive standards of safety, identity, labeling, packaging or directions for use. They constitute the heart of the FDA's regulatory activities.

Another major substantive area of rule-making under the Act is the establishment of "exemptions," that is, setting forth the numerous situations to which the general requirements will not apply. A few typical examples may be mentioned. Under the food misbranding situations, the Secretary may exempt certain foods from labeling requirements having to do with the naming of the ingredients where full labeling is "impracticable" (Section 403(i) (343(i))). Under Section 408(c) (346(c)) the Secretary can by regulation exempt from the necessity of obtaining a tolerance certain poisonous or deleterious pesticide chemicals "when such a tolerance is not necessary to protect the public health." By regulation, the Secretary may exempt certain small packages of drugs from the labeling provisions of Section 502(352) where compliance is not necessary for the protection of the public health.

Under Section 602 (362), dealing with misbranded cosmetics, exemptions can be established from some of the labeling requirements. All of these "exemption" cases follow most informal procedures.

Finally, the FDA is empowered to establish "tolerances." For example, Section 406 (346) provides that when certain poisonous or deleterious substances are added to food which cannot be avoided in

good manufacturing practice, the Secretary shall promulgate regulations limiting the quantity therein or thereon to the extent he finds this necessary for the protection of the public health. Also under Section 408 (346(a)) very extensive provisions set forth the establishment of tolerances for pesticide chemicals which may be used in or on raw agricultural commodities.

APPLICABLE PROCEDURES

Introduction

As can be seen from the above, the regulatory activities cover a wide variety of fields, and utilize varying regulatory techniques, such as requests for new drug applications, petition for issuance of food standards, certification of coal-tar batches, establishment of pesticide chemical tolerances, and regulations exempting certain products from general requirements. As might be expected, the procedure is as varied as the areas of regulation.

Some procedural requirements, as for example the processing of a new drug application, afford a thorough hearing. Other procedural requirements, such as for establishing exemptions, are minimal. The various applicable procedures are described below in order generally of decreasing complexity.

Hearings on New Drug Applications (Section 505)

Any person may file a new drug application. It shall become effective after 60 days unless the Secretary in writing postpones the date (for not more than 180 days). Section 505(d) (355(d)) provides that the Secretary shall refuse to permit the application to become effective, if after due notice and an opportunity for hearing, he makes one of four adverse findings. Also under Section 505(e) (355(e)), an existing new drug application may be suspended if, after due notice and an opportunity for hearing, the Secretary finds that new tests or experience show that the drug is unsafe or that the application contains any untrue statement of a material fact.

Under either section, the hearing examiner would have full hearing authority and would be appointed under Section 11 of the Administrative Procedure Act. A written record is kept and parties may file full written arguments. A "tentative order" with full findings of fact is issued by the Examiner, and then after exceptions, the Commissioner issues a final order based on the record. (See Section 130.14-130.28 of 21 C. F. R.)

Basically, this is a full hearing with all procedural rights reasonably well protected. As will be seen later, no other Section of the Act affords such full protection, or at least, not as interpreted by the FDA.

Hearings on Food Additive Petitions (Section 409)

Section 409(b) (348(b)) [7] provides that any person may file a petition for a food additive regulation, and the Secretary must, within 30 days, publish notice of the proposed regulation. After 90 days (or 180 if extended), the Secretary must either establish the regulation or deny the petition, giving reasons. Under Section 409(d), the Secretary may propose a food additive regulation on his own initiative, and after 30 days, may, by order, establish a regulation.

Within 30 days after issuance of the order, Section 409(f) (348(f)) provides that "any person adversely affected" may file "objections with the Secretary, specifying with particularity the provisions deemed objectionable, stating reasonable grounds therefor and requesting a public hearing." After notice and hearing, the Secretary shall issue an order based upon a "fair evaluation of the entire record" and shall set forth in detail his findings and conclusions.

These hearings are conducted by a Section 11 APA hearing examiner, who has extensive hearing powers (See Section 121.57-121.65 of 21 C. F. R.). He, however, does not issue a "tentative" order; rather he certifies the transcript to the Commissioner, who prepares a "proposed order." Then after exceptions and written argument, the Commissioner prepares the final order. Except for some general problems discussed under Section 701, below, this section appears to be reasonably complete so far as procedure is concerned. There is some question as to how valuable a hearing under subsection (f) would be if the Secretary simply denied the original petition. This is discussed generally, below under Section 701 procedure.

Proceedings on Establishing Tolerances for Pesticide Chemicals (Section 408)

The procedural requirements for the establishment of tolerances for pesticide chemicals used in or on raw agricultural commodities or the establishment of exemptions are very similar to the requirements for food additive regulations. Section 408(d) (346(a)(d)) [8]

[7] Section 409 was added to the Act by the Food Additives Amendments of 1958 (Public Law 929, 85th Cong., September 6, 1958).

[8] Section 408 was added to the Act by the Miller Pesticide Chemicals Amendment, Public Law 518, 83rd Cong., July 22, 1954.

limits more severely the class of persons who may file a petition requesting a tolerance or an exemption; and perhaps requires greater details and underlying data. However, once filed and once the Secretary of Agriculture certifies that the pesticide chemical is "useful" (a statutory prerequisite), the petition must be granted or referred to an "advisory committee." After a report from the advisory committee, the Secretary must establish a tolerance or exempt the chemical from the necessity of a tolerance.

Section 408(d)(5) (346a(d)(5)) provides that "any person adversely affected" by a regulation may file objections, and the petitioner has an opportunity to reply. The hearing will be similar to that afforded under Section 409, except that the report of the advisory committee becomes part of the record. Again a Section 11 APA hearing examiner is used, though he does not issue any "tentative" decision (See 120.24 of C. F. R.).

Section 408 proceedings appear to involve many indicia of adjudicatory proceedings. For example, the data submitted to the Secretary in support of a petition is considered "confidential" until publication of the regulation (Section 408(f) (346a(f)). This would normally suggest that the relief granted will probably benefit the petitioner mainly. This is reinforced by the requirement that petitioner submit an application with the Secretary of Agriculture to register the pesticide chemical as an economic poison. There is also interestingly enough the requirement that the Secretary of Agriculture, before he can *refuse* to issue a certificate of usefulness, must provide the petitioner a "prompt hearing" (Section 408(l) (346a(l))). Certainly all of these factors would suggest that the regulatory process involved is "private licensing."

Section 701 Procedures

The heart of the Act, procedurally, is Section 701 (371) where the general procedural requirements are found for many of the rule-making activities.[9] This section expressly applies to the following rule-making activities:[10]

[9] The language of Section 701(e) (371(e)) stems from the Hale Amendment of 1956, Public Law No. 905, 84th Cong. See also earlier procedure under Hale Amendment of 1954, Public Law 335, 83d Cong., which applied to Section 401 (341), the food standards section.

[10] Section 507(f) (357(f)), dealing with the certification of certain antibiotic drugs, has its own internal procedures, but they are almost identical to requirements of Section 701. So also procedure under 506(c) (356(c)), dealing with certification of drugs containing insulin, expressly applies the procedure of Section 701 in some cases.

(1) Section 401 (341), the fixing or establishing for any food a reasonable definition and standards of identity, quality and fill of container; (2) Section 403(j) (343(j)) labeling requirements for food for special dietary uses; (3) Section 404(a) (344(a)) issuance of temporary permits to manufacturers, processors, or packers of certain classes of food likely to be injurious to health; (4) Section 406 (346) the establishment of a tolerance necessary for the protection of public health in connection with poisonous or deleterious substances added to food; (5) Section 501 (351(b)), the prescribing of appropriate tests or methods of assay with which to determine the strength, quality or impurity of certain drugs; (6) Section 502(d) (352(d)), the finding that certain "habit forming" drugs are misbranded unless properly labeled; (7) Section 502(h) (352(h)), the finding that certain drugs, liable to deterioration, are misbranded unless properly labeled so as to show the precautions necessary for the protection of the public health; (8) Section 706(b) (376(b)), the listing of color additives for use in food, drugs and cosmetics; (9) Section 706(c) (376(c)), the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to 706(b).

For each of these rule-making activities Section 701 procedure applies. It is this section which needs most serious re-examination. There is little doubt that the activities generally defined are "rule-making." Section 701 requires that the rule be determined on the record after hearing. Thus, they are "formal" rule-making proceedings and fall under the requirements of Sections 7 and 8 of the Administrative Procedure Act. Moreover, many of the issues are hotly controverted and contested industry fights, for example, bread standards hearing, thus making even more essential a full and fair hearing.

An immediately difficult problem concerns the case where the Secretary either refuses to initiate rule-making requested by an "interested person" or by failing to act at all, accomplishes the same result. Section 701(e) (371(e)) provides that an action for the issuance, amendment, or repeal of a regulation shall be begun by a proposal of the Secretary himself "by petition of any interested person showing reasonable grounds therefor." The section provides that the Secretary "shall" publish the proposal and "shall afford all interested persons an opportunity to present their views thereon, orally or in writing."

In some cases, the Secretary has simply refused to act, thus frustrating the intended purpose of Section 701(e). While arbitrary

time limits should be reluctantly imposed, it may be advisable in this case to impose some time limit upon continued inactivity.

The Secretary has authority under the statute to refuse to publish the proposal if the grounds stated are not "reasonable." It is not clear how the public could proceed against the Secretary if he refused to act at all or if he denied the request to institute rule-making for whatever grounds he chose to give. The discretion of the Secretary is broad. One court has held that since discretion is involved, an action for mandamus or for declaratory relief would not lie in the courts.[11]

On the other hand, an abuse of the discretion should be reviewable probably in a federal district court. This might be based on continued refusal to act; or based on arbitrariness for refusal to publish a proposal that clearly stated "reasonable grounds." To permit an effective court review, the Act should be amended to require that if the Secretary determines not to institute the rule-making proceedings, he must issue an order incorporating therein a concise general statement of the basis for the conclusion but not simply quoting the statutory language.

The next procedural problem of 701 arises at the conclusion of the first stage in the proceedings. After all interested parties have a chance to present their views, the Secretary can either adopt the proposed regulation or deny the petition, giving his reasons. The Act nowhere states how detailed his denial must be. The Secretary may simply deny the petition paraphrasing the language of the statute.

Under Section 701(e)(2), a person "adversely affected" by the refusal to issue the order, as for example, the petitioner, could file objections to the order, specifying "with particularity" the provisions "deemed objectionable," "stating the grounds therefor, and requesting a public hearing upon such objections." This, however, could be a rather useless gesture. The issue in the objector's hearing would be the reasonableness of the Secretary's refusal to adopt or amend the rules. If, as would not be unlikely, the Secretary merely concluded that there was no "need" for, or general usefulness of, the proposed regulation, the burden upon the objector in the hearing would be almost impossible to bear.

Even if the Secretary does adopt a new or amended standard, there still are difficult procedural problems. Section 701(e)(2), as

[11] *Cook Chocolate Company v. Miller*, 72 F. Supp. 573 (D. D. C. 1947); See Levine, "The Cook Chocolate Case," 4 FOOD DRUG COSMETIC LAW QUARTERLY 172 (1949).

indicated above, gives a right to a hearing to any person adversely affected by the order. Recent case decisions cast some doubt as to how effective this right to hearing is. In a recent article by Vincent Kleinfeld, appearing in the FOOD, DRUG, COSMETIC LAW JOURNAL,[12] he discusses at some length the question of whether or not the Secretary has the discretion to refuse to hold hearings under Section 701(e)(2) after objections have been filed. Recent cases appear to support the administrator's discretion in refusing to hold hearings, at least where only questions of law are involved.[13]

Mr. Kleinfeld suggests that if any factual issue is raised in the objections, then there would have to be a full hearing. This seems crystal clear under the Act. What is unclear, however, is how far the discretion of the Secretary goes. Many issues phrased as factual questions can be interpreted by the Secretary as questions of law.

For example, there is currently pending a hearing under Section 701 concerning a standard for "whole fish flour." The proponents of the regulation want to legalize the marketing in the United States of a fish flour made by grinding and drying the entire fish, including heads, tails, fins, viscera and intestinal contents. Others, opposing this regulation, urged that the food standard should require that the flour be made from cleaned fish after discarding the portions found by some to be objectionable. After studying the comments, the FDA expressed the opinion that the portions of the fish, including heads, tails and intestinal contents would not "normally be regarded as acceptable for human food in the United States" and that the product was therefore "filthy" and adulterated under the provisions of the Act.[14]

The FDA thus proposed the adoption of a standard of identity for fish flour which required that it be made from cleaned fish. Objections were filed and the Commissioner has now ordered a hearing. Obviously, there are questions here as to what the public considers "acceptable for human food" and what is "filthy" under the Act. Many would consider these questions of fact. But the Secretary could have held that as a matter of law fish food composed of the whole fish

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[12] Kleinfeld, "The Hale Amendment —A Pyrrhic Victory?" 16 FOOD, DRUG, COSMETIC LAW JOURNAL 150 (1961).

[13] *Dyestuffs and Chemicals, Inc. v. Flemming,* 271 F. 2d 281 (CA-8 1959); Cf. *Certified Color Industry Committee v. Flemming,* 283 F. 2d 622 (CA-2 1960).

[14] In passing, it might be noted that the issue involved here seems purely one of aesthetics and not health and safety, nor misrepresentation. It seems to be conceded that the product would be completely safe and wholesome; as a matter of fact, it would provide a high source of protein available at a low price.

is "filthy" and thus adulterated under the Act. Using this technique, the right to a hearing under Section 701(e)(2) could be entirely frustrated, and any right of appeal would be in part nullified by a seriously deficient evidentiary record.

Other basic problems concern the hearing, itself. The first problem has to do with the appointment of a hearing examiner. Clearly Section 701 requires a formal rule-making proceeding with the rules to be made "on the record after opportunity for an agency hearing." Thus, according to Section 4 of the Administrative Procedure Act, the requirements of Sections 7 and 8 of that Act are precisely applicable. So that first question is who shall preside. Section 11 of the Administrative Procedure Act indicates that a hearing examiner should be used, one who is assigned to cases in rotation and one who "shall perform no duties inconsistent with their duties and responsibilities as examiners."

Cases under the Federal Food, Drug and Cosmetic Act are not exempted from requirements of Section 7 concerning the use of an independent hearing examiner,[15] but the practice, as a matter of fact, in hearings under Section 107(e) is to appoint as examiner a staff attorney in the Food and Drug Division of the General Counsel's Office of HEW, and have another attorney from the same division act as FDA counsel. Sometimes the FDA counsel who is supporting the proposed regulations, has a superior position in the Food and Drug Division to that of the examiner who presides. Thus, the hearing examiner, who has broad powers to accept or reject evidence and to govern the conduct of the case, is in a compromised position. Where the FDA and industry are in sharp disagreement, the inappropriateness of the potential dual role is obvious.

Interestingly enough, in hearings under Section 505(d) (355(d)), dealing with a new drug application, under Section 409(f) (348(f)), dealing with food additives, or proceedings under Section 408(d) (346(d)), regarding the establishment of a tolerance of a pesticide chemical, the agency rules provide that the hearing examiner shall be appointed pursuant to the provisions of Section 11 of the Administrative Procedure Act.[16] Concededly these activities have more of the

[15] Section 12 of the APA provides that no "subsequent legislation shall be held to supersede or modify the provisions of this Act except to the extent that such legislation shall do so expressly." Since almost all relevant FDA procedural provisions have been passed subsequent to the APA, without expressly modifying the APA, all sections of the APA are fully applicable to FDA proceedings.

[16] 21 C. F. R. 130.17, 121.57, 120.7.

elements of adjudication than do normal proceedings under Section 701. But the difference is one of degree. It is difficult to explain why policy as well as Sections 7, 8, and 11 of the APA do not dictate the need for an independent hearing examiner appointed pursuant to Section 11 of the APA. If not true in all cases, at least the need seems obvious where the controversy is sharp and the proceedings of not too general a character.

Except for proceedings under Section 505(b), dealing with new drug applications, the examiner never issues an "initial" or "tentative" decision in proceedings under these sections. Always he certifies the record to the Commissioner who issues a "proposed order," [17] which decision is subject to exceptions and written argument. Thus, another difficulty emerges: the problem of the institutional decision.

The decision, even though rule-making, is supposed to be made on the record. The Commissioner or the Secretary, as the case may be, is too busy to acquaint himself personally with the details of the record and the policy and legal arguments involved. He must, of necessity, rely upon his subordinates in the particular department or bureau involved to prepare for him summaries of the relevant evidence and arguments so that he can make the necessary judgment. Thus, the FDA divisions and bureaus and the FDA division in the General Counsel's Office play a great part in the formulation of the final rule as adopted by the Commissioner.

The problem, of course, is that the petitioners or private parties are never throughly aware of all the bases of decision, since they do not know all the points being urged by the staff upon the Commissioner. In general rule-making proceedings this is perhaps inevitable. In proceedings of limited scope or in what are really "licensing" proceedings, there is considerable doubt that such procedure is fair.

The case of *Willapoint Oysters, Inc. v. Ewing*, 174 F. 2d 676 (CA-9 1949) is generally conceded to support the flexible procedures used by the FDA under Section 701, though in fact most of the statutory language now applicable varies substantially from that applicable to the *Willapoint* case. According to that case (1) Section 701 proceedings are clearly rule-making; (2) there is nothing wrong in government counsel assisting in preparing portions of the findings and conclusions; (3) Section 8 of the APA does not require that there be an "initial decision" prepared by a hearing examiner; (4) the Ad-

[17] Section 408(d), 21 C. F. R. 120.27; Section 701(e), 21 C. F. R. 1.712; Section 409(b), 21 C. F. R. 121.70.

ministrator, who is charged with making the actual decision, can rely on the assistance and expertise of his subordinates.

It may well be that with the new statutory language of Section 701(e) and with the change in the statutory scheme to more "licensing-like" activities, all of the holdings of the *Willapoint* case are no longer entirely reliable authority.

Another problem of the 701(e) hearing is the determination of who has the burden of proof. It will be recalled that at the time of the 701(e) hearing, the Commissioner had already proposed the adoption, amendment or repeal of a particular regulation. He had presumably relied upon the substantive section of the Act which has certain statutory standards for the promulgation of rules.

Section 401 (341), for example, dealing with food standards, states that "whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations" fixing food standards. Under Section 406 (346), dealing with the establishment of tolerances for poisonous ingredients in food, the Secretary shall promulgate regulations limiting the amount of poisonous substances to the extent "he finds necessary for the protection of the public health" and only when such substance is required in production or cannot be avoided in good manufacturing practice. Under Section 706(b) (376(b)), the Secretary shall by regulation provide for the listing of color additives for use in or on food, drugs or cosmetics "if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations."

These general standards are the tests by which the Secretary determines whether or not to adopt finally a particular regulation despite the objections of the parties seeking the hearing. As a basic matter, it would seem clear that the burden of proof to support the regulation proposed to be adopted would fall upon the proponent of the rule—perhaps the original petitioner if his proposal was accepted, or the FDA, itself, if it proposed the regulation or the changes adopted. The objectors, of course, are dissatisfied with the proposed regulations, either because the regulation should not have been adopted at all, that is, there was no need for it, or because the actual proposal should have been changed or amended. Yet, in practice, unless the objectors go forward with their evidence as to why the regulation is improper, there will be no record upon which to determine the validity of the objections and the regulation will stand.

This shifting of the burden to the objectors can constitute a most serious problem. Perhaps an appropriate procedure in these hearings would be to require in cases where the agency's staff has itself helped to develop the testing and studies leading to the formulation of the proposed rule, that the government witnesses appear and testify in support of the proposed regulation. This would help complete the record. But perhaps, more important, it would help to alleviate some of the difficulties of the institutional decision.

We have already touched upon the difficulties facing the objectors when the FDA has failed under Section 701(e)(1) to propose a rule at all the negative burden of proof is almost insurmountable.

These, in summary, are a number of the hearing problems under Section 701. The procedure, it is submitted, though basically fair for general rule-making proceedings of broad scope, breaks down under the heavy work load of ever-increasing substantive grants of authority. Failure to act at all, delays, diffused and ambiguous authority and apparent arbitrariness can be the result.

Miscellaneous Rule-Making Procedures

A substantial amount of rule-making activity in the FDA has no specific procedures set forth in the Act. Accordingly, there is only the most informal and limited type of rule-making participation permitted. Typical examples include the general statements of policy or interpretive rules. The FDA may hold informal conferences with the public or interested parties and may even invite written comments after notice in the *Federal Register*. But then again, the agency may afford none of these types of participation. The courts have generally held that interpretive rulings require no hearing, evidence or findings.[18] The basis given is the fact that the interpretation given is simply the agency's understanding of the law and can easily be reviewed in court when an actual controversy arises.

Without extended comment on the risks of this "gun to the head approach" where as here criminal sanctions are available to the FDA, it is obvious that many statutory interpretations could benefit from the accumulated insight and experience of the public. Thus, public comments, even if not absolutely required, would normally serve a useful purpose and could in many cases, prevent agency arbitrariness.

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[18] *United States v. 353 Cases . . . Mountain Valley Mineral Water,* 247 F. 2d 473 (CA-8 1957). See also Section 4 of the APA.

Beyond these general policy regulations, there are a myriad of other grants of express rule-making authority. Express regulations authorized by the Act for which there is no stated procedure include the following. Section 403(e) (343(e)), requires a food in package form contain, among other things, an accurate statement of the quantity of the contents; provided the Secretary shall permit reasonable variations, however, and "exemptions as to small packages shall be established by regulations." Section 403(i) (343(i)) requires that the food label bear the common or usual name of the food, if any, and if made from two or more ingredients, the names of each ingredient. If compliance with Section 403(i)(2) (343(i)(2)) is impracticable or results in deception, or unfair competition, exemptions shall be established by regulations. Section 403(k) (343(k)) requires labeling if the food contains any artificial flavoring, coloring or chemical preservative. There is a proviso that if the requirements of this paragraph are impracticable "exemptions shall be established by regulations."

Section 405 (345) authorizes the Secretary to promulgate regulations exempting from any labeling requirements (1) "small open containers of fresh fruits and fresh vegetables" and (2) food which is, in accordance with the practice of the trade, "to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed."

Section 502(b) (352 (b)) requires that a drug will be deemed misbranded if in package form unless it bears a label with certain information on it, with the proviso that reasonable variations shall be permitted and exemptions as to small packages shall be established by regulations. Section 502(e) (352(e)) requires that a drug have a label giving the common name of the drug or its ingredients. There is again a proviso that if the compliance with these requirements is impracticable, exemptions shall be established by regulations. Section 502(f) (352(f)) requires that a drug have labeling bearing adequate directions for use and warnings against uses which may be dangerous to health. The labeling as to directions for use can be eliminated where not necessary for the protection of the public health, upon regulations of the Secretary exempting the particular drug.[19]

Section 503(353) expressly provides for the promulgation of regulations exempting from labeling or packaging requirements drugs and

[19] Interestingly enough Section 502(d) (352(d)) and 502(h) (352(h)) are expressly covered by Section 701, though Sections 502(b)(e) and (f) are not. The reason for the difference in procedure is apparently based on the importance of the regulatory activity.

devices which are to be processed, labeled or repacked in substantial quantities in establishments other than those where originally processed or packed. Section 505(i)(355(i)) dealing with new drugs provides that the Secretary may promulgate regulations for exempting from the operation of that section "drugs intended solely for investigational use by experts."

Part of the rule-making activities of Sections 506(356) and 507 (357) have no specific procedure set forth. Section 602(b)(2)(362(b)(2)) provides that a cosmetic in package form is misbranded unless its label contains an accurate statement of quantity. However, there is the proviso that reasonable variations will be permitted and exemptions as to small packages may be established by regulation. Section 603(363) authorizes the Secretary to promulgate regulations exempting from labeling requirements of the Act, cosmetics which are to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed.

None of these provisions have any specified procedure. There appears to be little reason or logic why such significant lack of procedures are permitted under the Act. Section 4 of the APA defining the rule-making responsibilities of agencies generally is certainly applicable. Notice of the proposed rule-making published in the *Federal Register,* an opportunity to participate through submission of written data, views or arguments (without necessarily the right to oral argument), a consideration of relevant material presented and "a concise general statement" of the basis and purpose of the rules actually adopted is clearly required under Section 4.

It appears that the Secretary does not always comply with these general requirements. The need, of course, for informality, private conferences and speed is obvious. Apparently many industrial representatives and members of the bar prefer the totally informal *ad hoc* procedures presently in vogue at the agency in these areas where specific procedures are not provided. And this is fine so long as the results are satisfactory to the informal participants. What happens, though, when the FDA acts in an arbitrary or illegal fashion? What relief is there when there has been no established procedure?

Suppose, for example, under Section 403(i) a particular food processor seeks an exemption from the requirement that the label of the food bear the names of each of the ingredients on the grounds that to require the labeling will result in "deception or unfair competition." Under present procedure, he would informally request an

exemption and confer informally with the staff. The Secretary might refuse to act at all or he might deny the request in a generalized, uninformative letter of denial. Similarly Section 502(f) provides that a drug or device should be deemed misbranded unless its labeling bears adequate directions for use. If the labeling isn't necessary for the protection of the public health, the Secretary can, by regulation exempt such drug or device. Under present procedure, upon a request for exemption, the Secretary can simply refuse to act on the request or could deny it by a simple letter of denial. Furthermore, under neither of these examples would the public necessarily know the exemption proceedings were even pending.

Thus, even in these informal rule-making proceedings for which the Act sets no procedure, some re-examination is in order. Probably a public notice of the request for rule-making should be required. Further, if the FDA refuses to grant the request, there should be a reasonably complete order explaining why. This would permit judicial review of at least basic questions of interpretation and policy.

MISCELLANEOUS PROBLEMS OF PROCEDURE

The Food Additive Act and the Delaney Clause

The Food Additives Act of 1958 has raised several procedural problems of consequence. Delay has been one of the most troublesome, but with the passage of time and with experience, some progress should be made on this score.

One particularly troublesome section has been the so-called Delaney Clause. Section 409(c)(3)(A)(348(c)(3)(A)).[20] This provides that no food additive shall be deemed safe:

> If it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the saftey or the product, to induce cancer in man or animal.

The 1958 law also included a grandfather clause which exempted from the term "food additive," "any substance used in accordance with a sanction or approval granted prior to the enactment" of the 1958 Act. (Section 201(s)(4)).

At first reading, this would not seem so severe a sanction, particularly in light of the obvious seriousness of cancer. However, as administratively interpreted, this section has been construed to require an absolute prohibition of the use of a substance likely to induce

[20] The same clause, though in somewhat better form, has been added to the Color Additives Act of 1960, Section 706(b)(5)(B)(C).

cancer under any circumstances, no matter how unrealistic or unrelated to the substance and use contemplated.

It is true that there is some support for the claim that if the substance can induce cancer under *any* circumstances, it can be administratively banned under *all* circumstances no matter how safe; this authority is sometimes necessary because the state of the art won't permit the establishment of a safe level of use.[21] This, however, is an extreme position, and one not properly the situation in the case of the Delaney Amendment.

Really, two basic questions are involved: (1) Is the substance carcinogenic? (2) Can a safe threshold tolerance or dosage be determined even for an established carcinogen? The Administrator has interpreted the Delaney Clause as forbidding the establishment of a tolerance under this second question, though the weight of scientific opinion is that in many cases a safe dosage is possible, and even under the first question, he has prevented the use of substances only suspected of being carcinogenic.

Another surprising interpretation of the FDA is that a feed additive which is likely to induce cancer in some animals thereby makes the meat of all animals which have been given the food additive unfit for human consumption, even though there is no evidence that the particular animal will be adversely affected or that the meat when consumed by humans is likely to induce cancer. This has occurred in connection with the use of diethylstilbestrol (DES) in animal feed. DES is a known carcinogen; however, it has been estimated that it is used in beef feed supplements in about 75 per cent of all beef cattle feeding. The use of this drug in animal feed, primarily beef and for poultry, had long been approved and at the time of the adoption of the Delaney Clause in 1958, there were outstanding hundreds of new drug applications expressly authorizing the use of DES as a feed supplement. Thus, the "grandfather" clause of Section 201(s) applied.

However, in a general policy statement on veterinary drugs issued May 30, 1959 (Section 3.37 of 21 C. F. R., 24 F. R. 4376) without benefit of any full rule-making procedures, the FDA rules that no further new drug applications would be granted for the use of DES in animal feed, and that prior sanctions already in existence for the

[21] Cf. *Flemming v. Florida Citrus Exchange,* 358 U. S. 153 (1958), where the court held the secretary properly revoked the certification of a particular coal-tar color, even though no evidence that level of ingestion in human consumption was harmful. The court very carefully relied upon the particular language and history of Section 406 (346) to support the decision.

use of this drug would be continued, though they could not be amended or supplemented.

In connection with poultry, recent tests indicated the presence of a harmful residue in the edible portions of the treated poultry, and administrative action has been taken to revoke existing new drug applications granted many firms. But in connection with beef cattle, the evidence shows that DES is not harmful to cattle and no residues remain in the edible portion of the beef. Yet the FDA will issue no new or supplemental drug applications.

This has created the anomalous and unwarranted situation that one manufacturer who received authority to use DES prior to 1958 can continue to use it as a feed supplement, whereas his competitor next door cannot. Obviously, this has nothing to do with safety. All that it means is that the cattle growers will use the competitor who has the existing authorization.

This is an entirely too narrow an administrative interpretation of Section 201(s)(4), the grandfather provision. Congress was exempting from the requirements of a food additive regulation a "substance" "used in accordance with a prior approval." It was the use of the drug, not the manufacturer, which had the sanction.

Even the Secretary, recognizing the unfairness of his position, had suggested to Congress in connection with the Color Additive Amendments (and has since proposed it for other legislation) [22] that the provisions of the Delaney Clause should be amended so as not to apply to drugs used in animal feeds, where it can be shown that the drug would do no harm to the animal, and where under prescribed conditions of use, no residue of the carcinogen remains in the edible tissue of the treated animal. In other words, the Secretary was willing to exempt, by statute, the use of the carcinogenic chemicals where it could be established that they would be safe for human consumption where used in annimal feeds. Yet he was not willing to do this by administrative interpretation. This, it is believed, is clearly a mistake. His willingness to accomplish this by statute only heightens the arbitrariness of the agency's intransigence.

Excessive Publicity of Proposed Agency Actions

A difficult problem in the administration of the Act has to do with the question of publicity, and the part agency publicity regarding

[22] H. R. 11582, 87th Cong., 2d Sess., introduced May 3, 1962. Section 302.

pending cases or investigation properly plays in the over-all regulatory activity. The determination of whether a particular food or drug was detrimental to the health of the nation should normally be determined in the hearing room after a full and fair hearing. But the Secretary, by the issuance of a series of press releases and news stories condemning the food or drug, can effectively destroy the marketability of a product without the need of a hearing at all. Trial by press release can be most unfair and improper.

Section 705(375) of the Act authorizes the Secretary to disseminate information regarding food, drugs and cosmetics "in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer." It seems clear that Congress intended to set a standard for the Secretary to apply in determining whether to call a press conference. Obviously if there is, in the language of the statute "an imminent danger to health" the Secretary has to be able to move quickly. Evidence to date indicated, however, that this discretion has been abused.

Press releases have been used in the food field, regarding the efficacy and health value of a variety of vitamins, minerals, food supplements and other "natural" food promotions. The issue in these cases is clearrly not whether there is an imminent danger to health, but whether the public is being deceived by claims that certain vitamins, minerals or food supplements have greater therapeutic values than in fact they have. Here, excessive publicity is certainly not required. The mere announcement of formal administrative action should suffice.

It should be noted that the Bar Association's Administrative Procedure bill, which has been introduced in the second session of the Eighty-seventh Congress, as H. R. 9926 (also S. 1887), expressly deals with this subject; the bill proposes that agency publicity which was intended to discredit or disparage a person under investigation, or a party to an agency proceeding, may be held to be a prejudicial prejudging of the issues, and the reviewing court may set aside the agency action. We would strongly support this bill. But beyond this, we suggest that perhaps Section 705 should, itself, be amended to make clear that except for emergency situations, legitimate publicity on specific cases extends only to the issuance of notices of hearings, decisions in hearing cases and issuances of rule-making or policy statements.

The Section 305 Hearing

Section 305(335) requires that before any violation of the Act is reported to a United States Attorney for criminal prosecution, the defendant shall be given "appropriate notice and an opportunity to present his views." However, this "hearing" is not a prerequisite to prosecution.[23] The FDA affords this type of hearing only when it wishes to do so, and apparently the industry has not seen fit to question this unlimited discretion. However, complaints have been registered against the use by the FDA of a 305 proceeding to scare a manufacturer into compliance with an agency borderline ruling regarding labeling, packaging, or other similar restrictions—a situation where the agency is not sure its position is entirely sound. Clearly the use of Section 305 should be invoked, only where there is a serious violation of law and actual intent to prosecute, rather than to situations where no serious violation is involved and the FDA is using the 305 technique to secure compliance with an unusually strict interpretation.

Conclusions

The various procedural questions discussed above are not intended to be all-inclusive, nor are the suggestions for change or improvement necessarily the correct answers. Like Topsy, many of the procedural techniques just "grew"—and "grew" without relation to other sections of the Act and their procedures. In light of the increasing complexity of the agency's functions, and in light of the continuing shift of responsibility to securing prior approval before manufacturing or marketing a product, a re-examination and probable overhaul of the procedures are in order. Certainly, this Committee is convinced that present procedures do not reflect the high standard of fair and expeditious treatment to which persons dealing with the agency are entitled.

[The End]

[23] *United States v. Dotterweich,* 320 U. S. 277 (1943), rehearing denied, 320 U. S. 815.

Cosmetic Labeling and Packaging

By W. B. RANKIN

Mr. Rankin Presented This Paper at the National Association of Direct Selling Companies Meeting in Washington on June 11, 1962. He Is Assistant Commissioner of the Food and Drug Administration.

IT WAS INDEED A PLEASURE to receive your invitation to participate in your forty-eighth annual convention. Not only do we in the Food and Drug Administration enjoy the opportunity of meeting with representatives from industry, but also we are convinced that through such contacts as this meeting today both of us have an opportunity to become acquainted with each others problems and to work out solutions to joint problems while they are small.

We in the Food and Drug Administration firmly believe in the advantage of a cooperative approach with consumers and industry to achieve a fair administration of the Food, Drug and Cosmetic Act. While the time probably is not yet at hand when such an approach will be a complete substitute for formal legal actions, it will unquestionably accomplish much and greatly reduce the instances in which we have to go to court. And if this results in sound consumer protection, as it can, then everyone benefits.

Stephen Reville and Fuller Holloway have told me that you are interested in a number of aspects of our work, among other things, the packaging and labeling of cosmetics, the trend of our enforcement activities, and perhaps some general comments about the testing that we believe is needed for cosmetics. Additionally, if there is time I would like to mention very briefly the President's food and drug legislative program which is now before the Congress and will have a bearing on the activities of cosmetic manufacturers.

As you know, there is widespread interest in packaging and labeling of consumer commodities. Senator Kefauver's hearings on drugs and Senator Hart's hearings on food packaging have shown this. In

addition, we in the Food and Drug Administration have a continuing flow of inquiries from consumers which show a growing concern with the labeling, the packaging, and the safety of cosmetics as well as foods and drugs.

FDA's Function

Before getting into the details of cosmetic labeling and packaging, I will take a moment to outline the function of the Food and Drug Administration. We administer the Federal Food, Drug and Cosmetic Act which requires foods, drugs and cosmetics in interstate commerce to meet certain minimum requirements of purity, safety and labeling.

In general our work is divided into three categories. First comes the health problems. If a food contains organisms that are capable of causing food poisoning, if a drug is marketed under the wrong label so that it constitutes a hazard to health, or if a cosmetic is on the market which causes injuries, we devote as much of our resources as is required to detecting and determining the trouble. Health problems always have first call on our time.

Sanitation Problems

Closely related and sometimes indistinguishable from the health problems are problems of sanitation, particularly in food plants. These have second call on our time. If a food is not prepared and handled in a sanitary manner, it is unsuitable for distribution to consumers, and appropriate measures must be taken to deal with it. It is very seldom that we encounter serious insanitation in cosmetic factories.

When we have dealt with health and sanitation problems, we then turn to the third category—problems involving primarily the consumers' pocketbook, such as sale of oleomargarine as butter, horse meat as beef, or sale of cosmetics in packages that are misleading in size or labeling.

In the early 1950's we discontinued attention to this third category almost entirely. Our staff had been cut. Problems of safety were growing because of modern technological developments. We had all we could do to keep up with health and sanitation matters. For several years now the President has been requesting and the Congress has been appropriating additional funds to enable us to carry forward more fully the obligations placed upon us by law. We are now able to begin to give attention once more to the cheats that hit the customer's pocketbook.

Four-Point Program of Consumer Rights

The requirements of federal law for cosmetics in this labeling and packaging area are relatively simple. As a matter of fact, they were well summarized by President Kennedy in his Consumer Protection Message to the Congress last March. You will recall that the President stated a four-point program of consumer rights. He identified these rights as (1) the right to safety, (2) the right to be informed, (3) the right to choose, (4) the right to be heard.

Certainly your interests and ours are identical with respect to these consumer rights. You don't want to injure your customers with bad products. You know that the firm that gives consumers full information upon which he can make an informed choice is the firm that has the best chance of staying in business. And I know from discussions with Mr. Reville and Mr. Holloway that you share the desire of other consumers to be heard in the formulation of government policy and to be given fair and expeditious treatment in the administrative tribunals of the government.

I hope that during our roundtable discussion this afternoon and at other times, you will exercise your right to be heard and will let us know of any FDA programs or policy that you believe should be changed in the interest of the consumer.

Facts Consumer Must Know

Let us take a look for a moment at the consumers' right to be informed and to be given the facts he needs to make an informed choice. In order for him to exercise this right in the cosmetic field, the law requires that (1) the cosmetic label be truthful in all respects; (2) the cosmetic label show the name and place of business of the manufacturer, packer or distributor; (3) the cosmetic label bear an accurate statement of the quantity of contents of the package; (4) required label information be placed prominently on the package with such conspicuousness and in such terms as to render it to be read and understood by the ordinary individual under customary conditions of purchase and use; and (5) the container be so made, formed, or filled that it is not misleading.

Examples Shown

Recently we have had occasion to look at a number of the cosmetics on the market. We have observed some products that need

to be changed to meet fully the labeling and packaging requirements of the law. Perhaps the best way to illustrate the possibilities for improvement would be to exhibit some examples of products that could benefit by changing labeling or changing packaging.

I am not going to call the names of the products. They are not important to the discussion.

Here are a hair shampoo and four deodorants with labeling of small size embossed in the plastic containers. The embossed letters have the same color as the rest of the package. This labeling is not conspicuous. In two cases, the name and address of the manufacturer and the statement of net weight are embossed on the bottom of the package rather than on the main panel.

Here is a green shampoo whose color tends to obscure the statement of contents and name and address of the manufacturer that appear on the reverse side of the bottle label. Here is a green deodorant with labeling printed in green directly on the glass bottle. The lettering on the glass is difficult to read.

Here are three products whose containers are enclosed in additional packaging which tends to hide or completely obscures required label information on the original container. In one instance the declaration of net weight is printed on the inside of the carton where it is completely obscured by the ointment jar contained in the carton.

It would not be difficult to place the required labeling on the front panel of the label of each of these cosmetics in a type that is legible and that contrasts with the background. The front panel is the panel that is displayed to the customer at time of sale.

Deceptive Packaging

Now what about deceptive packaging? This hair pomade jar was sent in by a consumer who felt offended. From the outside the plastic jar looks like it would easily hold two ounces of pomade. However, it has hollow sides and bottom. It holds only one ounce. The consumer who signed his letter "A disgusted buyer" wrote: "Enclosed is a gyp jar I thought you would like to see. . . . This replaces a solid white glass jar which contained more. The price was the same."

Here is another example of the same thing. This plastic jar looks from the outside like it would hold four ounces of cream. Because of the hollow sides and bottom it will hold only two.

And here is a bottle of cologne packed in a carton considerably larger than is needed to hold the bottle.

These examples are not cited as representative of the practices of all firms. Many cosmetic houses do use conspicuous labeling and nondeceptive packages.

Steps to Take in Changing Labeling or Packaging

What should you do if you have a cosmetic on the market whose labeling or packaging needs to be changed? Of course, the obvious answer is, "Change it." But there is an additional step you can take—come in and tell us that you are changing it, and let us know that you are moving promptly.

Three manufacturers have done just that recently. Each of them was marketing a cosmetic labeled "economy size" that was not as economical as a larger size the firm produced. Each of these firms has outlined to us the steps it is taking to correct the situation. While we have not given any guarantee that their products will escape legal action, we hope the changeover to proper labeling takes place promptly so that this matter can be handled without court actions. We have no desire to bring court actions just for the sake of litigating. Our goal is to see that consumer rights are safeguarded as the law requires.

Mr. Reville suggested that while you gentlemen are not the ones who have final responsibility in your companies for making safety tests, you would be interested in having a general picture of the testing we consider proper.

General Picture of Proper Testing

Cosmetics should be tested before marketing to see what effect they will have when applied to the body. Test procedures are available and should be used to determine, among other things, whether a product will be irritating to skin or mucous membrane and if so, in what concentration.

They should be tested to see whether they are absorbed into the body. Where absorption occurs, the product should be tested to determine whether it has adverse systemic effects.

Recognized procedures should be used to screen out compounds that are severe sensitizers. Where appropriate, other tests should be

made, for example, the effect of the compounds on the eye if there is any likelihood that the preparation will enter the eye during use, and the inhalation toxicity of aerosol preparations. Where a cosmetic may be ingested, lipstick for example, the ingestion hazard should be evaluated.

From the data obtained by applicable procedures, it is possible to assess the local and systemic toxicity of substances applied to the skin and mucous membranes and to predict the amounts, the concentration and frequency of application that may be tolerated by man.

We know that many cosmetic manufacturers routinely subject their products to safety testing before placing them on the market. There are some who either don't test their products for safety or do not apply adequate tests with the result that some harmful cosmetics have reached the market.

We recommended that manufacturers test each cosmetic for safety before it is marketed.

President's Message on Consumer Protection

In his consumer protection message to the Congress last March, President Kennedy asked for legislation to require cosmetics to be tested and proved safe before they are marketed, and bills are now pending in the House of Representatives which would require such safety testing. Hearings were scheduled on one of them to start on June 19.

The President has also recommended that the factory inspection section of the Food, Drug and Cosmetic Act be strengthened. This would permit our inspectors to make complete inspections when they are in factories. At present some firms decline to allow inspectors access to certain information needed to make a sound evaluation of the legality of their practices. This interferes with adequate consumer protection and should be corrected as recommended by the President. Hearings were also started on June 19 on a bill to amend the inspection section of the law. **[The End]**

Public Analysts – Ancient and Modern

By D. T. LEWIS

This Address Is Reprinted from the July, 1962 "Monthly Report" of the British Association of Public Analysts. It Was Presented to the Association of Public Analysts by the Government Chemist, D. T. Lewis, on the Occasion of Their Annual General Meeting at Oxford, England on May 12, 1962.

INITIALLY may I thank you all most sincerely for the great honour you have paid me in inviting me to be your guest speaker at this annual function. I have, in preparation for this task, endeavoured by diligent reading to acquaint myself most fully with the historical background of the Association of Public Analysts and I have found the history of my laboratory and of your association greatly intertwined. The library of the Government Laboratory has several documents of interest dating from 1842 onwards, in particular a very rare and almost unobtainable history of the Somerset House Laboratory, written in 1902 by a revenue officer, John St.-Clair Cholomondeley. Of particular interest to me also was the excellent history of the Society of Public Analysts and other Analytical Chemists, as it then was, which was so ably and beautifully written by Dr. Bernard Dyer and Dr. Ainsworth-Mitchell 30 years ago.

From these various sources I have learned of the Adulteration Act of 1860 which permitted in the counties the appointment of analysts by the Courts of Quarter Sessions, or by the Commissioners of Sewers in the City of London, or by the Vestries and District Boards of the Metropolis generally. From this womb of ostentatious, but far-sighted officialdom was your organisation conceived over a century ago.

Later, because of certain difficulties associated with the administration of this earlier act, the more embracing Act of 1872 extended the right of appointing public analysts to boroughs possessing separate

police establishments, and, following the creation by the government of a Select Committee, the celebrated "Sale of Food and Drugs Act" of 1875 brought somewhat more exact and comprehensive legislation to control wilful adulteration.

This nineteenth century era appears to have been rather a hectic period both for the public analysts and for the chemists of Somerset House and I note from the historical documents that when your president, Dr. Theophilus Redwood, called a meeting of your predecessors at the London, City Terminus Hotel on 7th August, 1874, two of the main resolutions which were heatedly discussed were:

Firstly:—Regarding the training and qualifications to be possessed by public analysts, and

Secondly:—A strong depreciation of the official proposal that the Government Chemist of the Revenue Laboratory should act as referee in disputed cases of analysis.

Two Main Protagonists

The two main protagonists in the analytical field at this time were both skilled microscopists. One was that eminent pioneer in food analysis, Dr. Arthur Hill Hassall, and the other was the first Principal of the Government Revenue Laboratory, George Phillips (1842-74). I notice from the records of the laboratory that there were indeed, frequent cases of dispute between the public analysts and the chemists of the Government Laboratory. Surveying these disputes in retrospect, we can deduce the causes and judge both sides with wisdom and compassion. The science of food chemistry was in its infancy. Standard, agreed, analytical procedures were few and of dubious accuracy. There was little or no consultation between the opposing sides. The methods of referee analysis used by the Government Laboratory were not published or known by the public analysts of that period. Suspicion and distrust were, therefore, natural consequences and grievances were magnified by a complete lack of cooperation. It is small wonder, that, when writing at this time, Dr. Hassall, exasperated beyond measure by some analytical results produced by the Government Laboratory, made an offer to the government of his day to check tobacco adulteration himself with more accuracy than the Excise "with its seventy chemists and 4,000 inspectors." Perhaps I should, in fairness to George Phillips, point out that his total Somerset House staff at that time (as given by our historical records) consisted of four assistants recruited from the Excise Service.

Contributions to Public Welfare

Despite these bitter differences between Hassall and Phillips, there can be little doubt that both men in their separate spheres contributed largely to the public welfare, and both waged a highly successful and devastating war on those unscrupulous traders who sold adulterated commodities.

Hassall's published investigations for the Lancet Sanitary Committee on the tremendous hazards to public health resulting from the then widespread use of dangerous additives in food, undoubtedly triggered off those Parliamentary reactions which led to the introduction of the first protective legislation affecting foods and drugs.

Similarly the work of George Phillips and his co-workers protected the public from those who sought to profit by adding worthless vegetation to tobacco. He was also responsible for one of the earliest chemical studies on the brewing of beer, (Parliamentary Paper, 1847) and he devized with Dobson the original gravity method for beer which is still in use. Methylated spirit was introduced by him in 1855, so that manufacturers could purchase denatured duty-free spirit for use as solvents in the various industries. This availability of cheap spirit soon produced those racketeers who adulterated whisky with methylated spirit. One of your celebrated members, Dr. Dupre has a paper in "The Analyst" of March 31, 1876 relating to the detection of such adulteration.

The Government Laboratory, in its earlier years, paid much attention to the determination of alcohol by the hydrometric method and the work of Sikes and the compilation of the Proof Spirit Tables belong to this era. It has always intrigued me that the man who carried out the standard work on equating 100° proof spirit as determined by the classical ignition of gunpowder test, with the 57.10 per cent of alcohol by volume at 60° F standard which we use today, should possess the rather teetotal name of "Drinkwater!" I can hardly believe that he lived up to this lugubrious appellation during his promotion of this most fascinating piece of investigation.

Early Leaders

In 1874, after 32 years' service with the Somerset House Laboratories, George Phillips retired on a generous Treasury allowance of £750 per annum and was succeeded by Dr. James Bell. It was a splendid gesture by Sir Charles Cameron, your president in 1893, that, at the first dinner of your society to which any public or official guest

was invited, he selected Dr. James Bell. History records that in a charming speech, Dr. Bell prophesied an era of peace and goodwill between the chemists of his department and the Public Analysts. Peace, of course, did not break out immediately, but with the continually increasing friendly relations between our two organizations over the past 50 years, I think we would today accept Dr. Bell's remarks as being singularly prophetic. Members of the Government Laboratory and of your society now sit in amity on some of the most important committees of the United Kingdom, and, as Dr. Bell's lineal successor, may I repeat his sentiments most warmly and sincerely on this parallel occasion. From an academic standpoint, I was most interested to observe that at that self-same dinner of 1893 sat one of your vice presidents, John Newlands, chemist, philosopher and raconteur, originator of the new celebrated Law of Octaves which was a true precursor of the Electronic Octet theory of valency and anticipated the Periodic Table (1869) of Mendeleef. Derided by the Chemical Society, his paper was not even published in the *Journal of the Chemical Society* for 1863, but the Royal Society acknowledged Newland's prescience by the belated award of the Davy Medal. Newland's papers were, of course, published in *Chemical News* of that time but there is no record of whether or not they were known to Mendeleef.

One cannot consider the Periodic Table without reflecting on the fact that the public analyst of today is becoming concerned with almost every element of every major group because of some impact on public health problems. Thus considering Group VII, we have fluorine associated with the fluoridation of water: chlorine has eliminated the scourge of typhoid from our reservoirs: bromine is the base of our bromide sedatives: iodine features in thyroxin and the food colouring matter erythrosin and even manganese is a trace element of nutrient value. Indeed, nearly a century ago one of your leading members, Dr. Wigner, showed that manganese was consistently found in the leaves of the tea plant regardless of its geographical origin.

The more exotic elements technetium (Masurium), rhenium and astatine are so far of little interest to the public analyst, but having regard to the anticorrosive influences now being studied, in the case of technetium it is probable that the analyst of the next decade might find this element employed in the development of tins for canned food.

"The Analyst" Published in 1875

One of the events of enormous consequence in the professional field was the publication by your association of "The Analyst" in

1875, an event which revolutionized the entire structure and practice of chemistry.

In recent years I need only mention the wonderful work on the standardization of methods of analysis for all food, drugs, fertilizers and feedingstuffs and so forth, which has been carried out by the specialist committees and panels of the Analytical Methods Trust. Many eminent men have served on these bodies and the contribution they have made to the practice of analysis not only in the United Kingdom but internationally, has been a magnificent achievement.

Continuing with our review of the past it will be appreciated that the main instruments available to the public analyst of a century ago consisted of the chemical balance, Biot's polarimeter, the microscope, various forms of hydrometers and some calibrated glass ware. A crude form of the chemical balance is believed to have originated in ancient Egypt about 5,000 B. C. When I suggested to your president that the title of my address would be "Public Analysts—Ancient and Modern," I had in mind the fact that those duties relating to public welfare which the members of your honoured profession so zealously undertake, were probably of origins far older than the Adulteration Act of 1860.

Indeed those food tasters, or should we call them "Public Alchemists" of the Twentieth Dynasty of Rameses III, were undoubtedly carrying out a very hazardous personal bioassay in order to inform their royal clients that the food supplied contained no additives which might render it injurious to health and that it really was of the nature, substance and quality demanded and not to the prejudice of the purchaser. In elaborating on this theme of the great antiquity of your profession, we must include reference to the Greek philosopher Archimedes, for did he not develop the concept of specific gravity and demonstrate to King Hieron of Syracuse that his royal crown was made of adulterated gold. However much Archimedes failed to conform with your high standards of professional dignity because he ran naked through the streets shouting "Eureka," we must feel fascinated by the thought that the technique he developed is still one of the main weapons in our analytical armoury even after 2,000 years.

The last 50 years have, of course, been unparalleled in the speed of development of instrumental methods and in the elaboration of microanalytical techniques. The levels of adulteration now capable of positive identification now lie in the parts per million range or less. The skilled, professional chemist of today has a knowledge of a be-

wildering complex of sensitive techniques and instrumentation; of paper, columnar and gas chromatography, of emission, atomic absorption, infrared and ultraviolet spectroscopy and spectrophotometry, of mass spectrometry, of electron probes, X-ray diffraction and X-ray fluorescence analysis, of coulometry and polarography, of microbiological assessment and of bioassay.

Economics of Analysis

Unfortunately some of these instrumental advantages are largely negatived from the point of view of the professional analyst by the question of cost. The economics of analysis is a question of the most fundamental importance to any individual, to any industrial concern, and to any country which wishes a fair return for its expenditure. I am always reminded of the "chymical discussion" the great diarist, Samuel Pepys, had with a friend called Dr. Allen. Pepys wrote of Allen, "A compound of gold, aurum fulminans or azide, a grain of which put into a silver spoon and fired, will give a blow like a musket and strike a hole through the silver spoon downwards." Pepys then makes the devastating comment "A cheaper experiment can be made with an iron spoon prepared." No wonder he won fame by bringing to order the financial affairs of the "King's Navee."

One of the crying needs in professional analysis today is to develop cheap simple methods for exact microchemical determinations. Sometimes attention to the concentration factor will help towards economy. A sample containing 0.01 parts per million of adulterant and requiring a £4,000 square wave polarograph for its detection could be analyzed on a polarograph costing £200 if the sample could be concentrated a hundredfold.

Indeed, we may have to take steps, as practising analysts, to protect ourselves from this superfluity of sensitive instrumentation which can measure submicrogram quantities. The question of "sampling" too is not unimportant in this context because, if we only take a decigram for a complete analysis, to what extent does that one decigram represent the average composition of a pound of bread or a pint of milk?

It is fortunate that simple techniques such as Schoniger flask combustion or titrimetric E. D. T. A. determinations do compete in routine analysis with the more exotic instrumental methods.

A megaton bomb may be a rapid means of excavating huge maritime harbours, but no one would employ such an atomic device to dig a

hole in a road. Similarly, a double beam recording spectrophotometer may be completely unnecessary to conduct a routine analysis which can be performed accurately and efficiently using the classical colorimeter tube to give results within the limits demanded by statutory legislation. Both the analyst and his client will profit by the employment of the cheaper method and by the elimination of expensive techniques.

Fluoridation of Water Example

In this connection I will illustrate this point by mentioning that my laboratory has been concerned with those tests being carried out by the Ministry of Health on the fluoridation of waters in the Anglesey, Watford and Kilmarnock areas. Sodium fluoride or sodium fluorosilicate are used to dose the waters to a 1 p.p.m. level which is the recommended concentration necessary for the prevention of the incidence of dental caries. In the very exact analysis of fluoride we invariably use a spectrophotometric method employing the well known cerium alizarin complexan reagent developed by Professor Belcher. However, the classical zirconium alizarin "bleaching" method recently described as modified by Lim in "The Analyst" gives very good results using the simple colorimetric tube method.

Paper chromatography also remains an inexpensive and elegant tool and this method is daily employed by analysts to examine the 30 dyestuffs permitted by the United Kingdom (Colouring matter in Food Regulations (1957)).

These regulations refer to dyestuffs in food and not necessarily in drugs although it would obviously be wiser for a manufacturer to use in drugs those colouring matters regarded as acceptable for consumption in foods. It may always be argued that medicinals are consumed very infrequently and there is also the obvious case where a dyestuff is employed because of its therapeutic effect and under this heading it should probably be considered as a drug.

The tasks and responsibilities of the public analyst have complicated enormously in the last decade, and, should we enter the Common Market, they will become yet more complex. Of the 30 food dyestuffs I have already mentioned, very few are acceptable to West Germany, Italy, France, Belgium, Luxemborg or the Netherlands and there must obviously be an extensive programme for the harmonization of the food legislation of the member states before any Common Market comes, in an absolute sense, into existence.

Toxic Chemical Residues in Agricultural Products

Similar remarks apply to the presence of toxic chemical residues in agricultural products. The United Kingdom has, at the moment, no statutory legislation controlling the permitted amounts of residues of D. D. T., dieldrin, heptachlor, parathion, and other pesticides in various foodstuffs, indigenous or imported, although there is a growing tendency in many countries to introduce such legislation. In Australia, Canada, New Zealand and the United States, pesticide legislation is most strictly enforced and this enforcement presents their public analysts with major problems of chemical identification and estimation. There can be little doubt that this field of analysis will engage your attention for many years to come.

Over the past two years, numerous questions have been raised in Parliament regarding the effect of agricultural pesticides on wild life and of the steps being taken to prevent the adulteration of foods and crops by toxic residues.

In our laboratory we have carried out an extensive survey of the content of specific pesticides in the viscera of pigeons, foxes, and so forth. You will know that the manufacturers of pesticides have agreed with the Ministry of Agriculture, Fisheries and Food not to use dieldrin, aldrin and heptachlor as dressings for spring sown grain.

I had the privilege of being one of the 12 members of the Research Study Group on Toxic Chemicals in Agriculture and Food Storage under the Chairmanship of Professor H. G. Sanders, Chief Scientist to the Ministry of Agriculture, whose report was published at the end of 1961. Evidence was taken by the Committee from 28 organizations, including your own, and from 28 specialist scientific observers, and dealt with hazards to workers, consumers, farm livestock and the effect of pesticides on wild life, honeybees, soil, water supplies, and so forth. In this official Sanders Report, details are given of the measures being taken to safeguard the public. Under the "Notification of Pesticides Scheme" the Scientific Subcommittee of the Advisory Committee on Poisonous Substances and Food Storage considers the data supplied by a pesticide manufacturer regarding a new product, and makes recommendations to the main advisory committee, of which Dr. Hamence is an independent member. When *new* toxic pesticides have been cleared under the notification scheme they may be submitted for official approval to the Plant Pathology Laboratory, Harpenden, where provision is made, if necessary, for independent biological testing. I need not enlarge on the contentious point that biological tests

must, of necessity, be carried out on animals, although the results must be interpreted to clinical standards affecting human tolerances. In practice, the control of pesticide residues in agricultural foods in this country remains largely voluntary, the Ministry advising on (1) the appropriate chemical to use on a specified crop, (2) the maximum dose per acre per season, and (3) the interval between the last application and the harvesting of the crop. Our entry into the Common Market may have far reaching effects on such a voluntary scheme.

No cases of consumer food poisoning due to the uses of pesticide in agriculture have occurred in the United Kingdom, although there have been a few instances of accidental poisonings. The most notable occurred at Pontardawe in May, 1956, when the Ministry of Health sought our assistance in tracing the cause of the outbreak.

Fifty-nine people were medically treated for nausea, dizziness and convulsions following the contamination of flour used in bread-making. The sacks of flour had been transported in a railway wagon previously used for a consignment of the insecticide endrin in a xylene solution which had leaked from the containers. Mixed melting point tests on the crystalline compound separated from the flour, together with ancillary infrared and ultraviolet examinations provided overwhelming evidence of the presence of the identified pesticide "endrin."

In our laboratories we have had considerable success using paper chromatography and gas-liquid-chromatography for the chlorinated pesticides, but the phosphorus toxic derivatives are not so readily estimated and we are at present imposing the infrared techniques.

Additives Discussed

Additives in food supplies and in water supplies, be they permitted additives or adulterants, must always attract the interest and criticism of the general public who naturally object to any system of compulsory medication. Some modern additives are certainly malign and probably the most modern instance of these are the fission products, such as Strontium 90 and Caesium 137. The Government Laboratory acts for the Ministry of Housing and local government in assessing the fission product concentration in reservoir and effluent waters in the United Kingdom; Sr^{90}(28y) and Cs^{137}(30y) being the main radionuclides examined. The contribution of drinking waters to the body concentration of Sr^{90} is small (1 per cent), the main contributor being the milk-cream food chain, which contributes about 5 picocuries of Sr^{90} per day to the diet and has been extensively studied by Dr. Scott-

Russell and his colleagues at the Wantage Laboratories of the Agricultural Research Council. The average concentration of Sr^{90} in milk ranges from 10 to 40 picocuries/litre for various agricultural areas of the United Kingdom.

The bone structure, although mainly $Ca_3(PO_4)_2$, may contain from 200 to 400 micrograms of natural strontium, per gram of calcium, and when fission products are ingested, a certain amount of Sr^{90} remains in the bone. Figures published by the Medical Research Council in 1961 show that children in the 0 to 5 year range have 3 S. U., in the 5 to 20 year range 1.1 S. U. and in the older people the average range is 0.3 S. U. (1 sunshine unit represents 1 picocurie of Sr^{90} per gram of calcium). These figures are of course well below the M. R. C. tolerance, but there is an upward trend with every successive weapons test. Figures for the bones of herbage eating animals may be 100 times as great as for people. Following a nuclear pile disaster or an atomic weapon explosion, the shortlived (8 day) I^{131} becomes of consequence in the milk chain, but fortunately decays completely in about two months from the time of the incident.

At the time of the 1961 Russian tests, the M. R. C. regarded as acceptable a tolerance of 130 pc/litre for milk over a 12 month period. These are, however, all malign additives which may come to the attention of the public analyst, but about which he can do very little. In addition, the public analyst is confronted with a vast array of permitted additives such as flavorings, preservatives, dyestuffs, antioxidants, emulsifiers, stabilizers and so on, which have been approved by the Food Standards Committee following a detailed consideration of the biological, toxicological and carcinogenic tests to which the additives have been submitted. Quantitative maximum permissible levels are quoted for many additives, but this does not appear to be true of coloring matters which are usually expected to be present in "reasonable" amounts. Similar remarks apply to the antibiotic "Nisin" for use with heat processed foods in hermetically sealed containers, there being no statutory limit. Most analysts, would, I believe, prefer to see a fixed maximum level stated in the legal recommendations. Internationally there is no common practice regarding the use of antibiotics, such as aureomycin or terramycin in flesh foods of animal, fowl or fish.

Antibiotic Usage

In the United Kingdom two separate Acts control the usages of antibiotics, because apart from the normal foods legislation, the Thera-

peutic Substances Act (1956) of the Ministry of Health also controls the use and distribution of some 13 antibiotics, excluding Nisin. Of these, only three antibiotics with growth stimulating properties, penicillin, chlorotetracycline and aureomycin (or oxytetra cycline) are permitted by law as, under strictly defined conditions, additives to feeding stuffs. Supplements usually contain a few grams per pound and are incorporated at a level of a few pounds per ton into the feeding stuff so that the over-all concentration of the antibiotic should be relatively small. It is of course possible for the farmer to feed stock so generously with supplement that the effect becomes curative or therapeutic and here one could encounter the vexing question of significant residues of antibiotics in meats, milk, and so forth. Milk-producing cows with mastitis are, of course, normally treated via the udder with antibiotics, particularly penicillin, and although continuous milking ultimately eliminates the antibiotic, the possibility of some residues entering the public milk supply is an ever-present contingency unless the recommended precautions are taken.

United States legislation permits up to 4 p.p.m. of tetracycline in raw poultry, because trials have suggested that this is wholly destroyed by cooking. Similarly the Canadian Authorities accept up to 5 p.p.m. of the same antibiotic in fish preservation provided treated foods are clearly labelled to this effect. There appears to be some dubiety among experts as to whether antibiotic residues in fish are destroyed by normal cooking, and if they are not, then they will obviously pass on to the consumer.

Use of Antibiotics as Preservation Forbidden

In the United Kingdom the use of antibiotics as preservatives is of course strictly forbidden by the Food and Drugs Act of 1955.

These international differences in food legislation present a confused pattern to the analysts of the various countries who are engaged on the examination of imported materials coming into their respective countries. Moreover the diversity and number of benign or malign additives which any public analyst may encounter in his day to day investigations, now presents a rather frightening picture. We have travelled very far from the days of Dr. Hassall and Mr. Phillips, when the determination of alum in bread or chicory in coffee were regarded as problems of the first magnitude. Other considerations complicate the modern picture yet further. We are all aware of the fact that physics has intruded strongly into the realm of chemistry

and most analysts today must possess a fairly extensive knowledge of both subjects. The millimicron is now as familiar a term as the milligram; the coulomb is well on the way to becoming the volumetric standard of the future, since current and time can now be measured with inconceivable accuracy. In the last decade, the curie unit of 3.7×10^{10} disintegrations per second has become yet another of those analytical terms which the analyst is beginning to accept with a resigned nonchalance. Similar remarks apply to the health physics energy unit—"the Rad." Geiger counters, photomultiplier tubes and gamma spectrometers are no longer academic curiosities but have become work-a-day instruments in many laboratories.

An "Analytical Renaissance"

We are thus faced with an analytical renaissance. On the one hand, we have a multitudinous variety of additives and adulterants to detect and determine in the most minute quantities. On the other hand, scientists have produced a variegated complex of the most delicate instruments whereby these analyses may be competently achieved. Only the economic factor remains unsolved. This is one of the greatest problems confronting the individual professional analyst or small groups of analysts today and the solution is, to say the least, obscure. Suggestions have been made regarding the setting up of Regional Laboratories by local authorities, but these have not been enthusiastically received. We are caught up in a maelstrom of chemical advances; discoveries and developments succeeding each other in such a rapid stream that we have little time to become scientifically acclimatized and reorganized in order that we may enjoy the advantages of our new knowledge and our new equipment.

Some of these newer methods not only permit us to assess quantitatively the amounts of certain elements or compounds present, but also enable us to develop ideas regarding what R. C. Chirnside in his S. A. C. presidential address of 1960 called "its composition, its properties, its qualities," that is, the real nature of the entity under examination, the phases involved, the molecular structures of the main components, the lattice positionings of impurities, and so on.

I may say that public analysts from the early days have always appreciated this difference between "analysis" and any numerical assessment of constituent ingredients. Your classical phrase of "nature, substance and quality demanded" has far-reaching implications when interpreted from the analytical standpoint. Indeed, even if you deter-

mine in your laboratories the nature and substance of a material submitted to you for analysis, how are you able to express "quality" unless it has been defined in some statutory fashion. Food Standard Orders exist for very few commodities—coffee, soft drinks, ice-cream and so on. With the complexities of modern manufacturing processes there undoubtedly exists a need for more precise legislation to assist the public analyst in the defining of that all-important term "quality." Here again the Analytical Methods Committees of the Society for Analytical Chemistry, with their representatives drawn from the Pharmaceutical Society, industry, governmental laboratories and from your association, are undoubtedly engaged on exploratory scientific and administrative work which must ultimately prove of the greatest importance in the field of food and drugs legislation.

Your association has always been extremely active in these fields, and there can be no doubt that the vigilance of public analysts has contributed greatly to the introduction of wise, protective legislation, the concomitant suppression of adulteration, the truthful labelling of commodities and so on. When the Institute of Chemistry in 1884 held a conference on "Food Adulteration and Analysis," it was one of your presidents, Dr. Augustus Voelcher, who proposed that the law against the adulteration of foods could be profitably extended to cover cattle foods. Although they were not introduced within his lifetime, the later passing of the Fertilizers and Feeding Stuffs Acts of 1893 and 1906 and 1926, were undoubtedly not uninfluenced by those recommendations of the Symposium of 1884.

The appointment of Official Agricultural Analysts was a logical consequence and the pioneering scientific work of Dr. Bernard Dyer in this field is well worthy of special mention. He lectured for many years throughout the country on agricultural matters and his work on soil analysis and soil phosphate determination is internationally known. As you are well aware, the laboratory of your president, Dr. Hamence, still bears Dr. Dyer's distinguished name and its members are still active in those fields of public service to which he devoted most of his life. I know from personal observation the tremendous amount of his own personal time which Dr. Hamence devotes to the progress and development of the profession of Analytical Chemistry. He is Treasurer and Secretary of the Analytical Methods Trust and gives freely of his time and mature experience both to the affairs of your association and the many committees of the Society for Analytical Chemistry and the Society for Chemical Industry.

It is a fortunate country which can lay claim to the possession of a continuing stream of dedicated chemists of this type; who carry on the exalted traditions of their scientific forebears and predecessors, who embellish the status of the professional chemist and who contribute materially to the general welfare of all humanity. Analytical chemistry is no longer a Cinderella, even in the academic world. We have all welcomed the appointments of professors of analytical chemistry at the Universities of Birmingham and Belfast and we are well aware of the increasing interest being taken in this field by other universities and technical colleges. During the present year, we in the Government Laboratory have been privileged in having both Professors Belcher and Wilson to lecture to our staff on special advances in analytical chemistry and we welcome this academic liaison with our laboratory, which must be one of the oldest professional analytical laboratories in the world.

New Duties

It was inevitable that the government chemist should acquire various statutory analytical duties under various acts of Parliament. For example, he is a member of the Home Office Poisons Board; he acts as the Chief Agricultural Analyst under the original Fertilizers and Feeding Stuffs Act. One of the most recent duties is that of Referee Analyst under the Drug Testing Scheme of the National Health Service Act of 1946, where the Executive Councils Analysts' certificate is disputed. Our referee duties at the laboratory of the Government Chemist are carried out with considerable impartiality and we examine critically any official methods of analysis which do not, in our experience give complete reliability. When dubious methods are encountered, the British Pharmaceutical Codex Committee are informed and we generally examine and suggest alternative procedures. Our chemists carry out considerable work on the development of testing of new analytical procedures of all kinds.

The use of alternative procedures is in any case well worthwhile and, for corroborative analysis, microchemical techniques frequently permit an economical use of sample which is not possible with many of the official assay methods. The number of drug samples referred to the laboratory do not now number more than four or five dozen per annum, and this small number is undoubtedly due to the availability of good, standard methods of analysis. A frequent source of trouble is undoubtedly due to the incomplete mixing of correctly

dispensed drug mixtures so that samples of the same batch yield differing analytical data. Occasionally, however, there is trouble with the method itself. For example, we have found the original method for thyroxin is not particularly reliable, whilst it is well known that the standard method for Chloral Hydrate/KBr calls for exact attention to experimental detail. Whenever, in the exercise of our referee function, we are dubious of any analytical factor, we use all the physical and specialised instrumental techniques at our disposal in order to determine the cause of the trouble. The important factors of "time" and "cost" of a particular investigation must be of secondary importance in our laboratory when compared with our primary referee objective of determining the cause of the disputed analysis. It is a splendid tribute to the competence of modern professional analysts that the number of samples forwarded to our laboratories are now so few in number compared with the tens of thousands which are examined every year by professional analysts in the United Kingdom.

In this modern age, the growth and complexity of food materials is only rivalled by the growth and complexity of drugs. Dr. Frank Hartley, in a recent address to the Royal Society of Arts, suggested that probably 5,000 to 6,000 are being used in medicine today. The galenicals of Dr. Hassall's time now include antibiotics, steroids, tranquillizers, antihistamines, hormones, and so on. Indeed, so complicated is the present picture, that Dr. Garratt, Chairman of the 1961 Pharmaceutical Conference, has suggested that "drugs" be removed from the demesne of the "Food and Drugs Act" and incorporated in a newer form of "Medical Substances legislation." Drugs, Dr. Garratt suggests, would be tested in regional laboratories responsible to the Ministry of Health and a "notification scheme" was also recommended whereby new drugs would require a certificate of official approval before issue. Dr. Garratt's remarks are symptomatic of our twentieth century society; of our ever increasing acquisitions in foods, in drugs and in all material things: increases which are so vast and so revolutionary that there is a feeling that the age-old protective structures are insufficiently strong to support the responsibilities of a new age.

The entire subject of food and drugs is now of so complex a character that even in a generic address of this nature, I am conscious of the fact that there are major fields I have not even mentioned. No word has been said of hormones, vitamins, or bacterial spoilage; nor of the history of food preservation ranging from Appert's hermetically sealed glass jar of 1810, Durand's tinplate can of the same period,

to the dehydrated foods, plastic packings and radiation sterilization experiments of today. Truly a vast and complicated field covering many disciplines.

Conclusion

Whether we agree or disagree with Dr. Garratt's contention, it is certain that the responsibility for the control of all those numerous commodities defined as foods, drugs, fertilizers, and the like, will always fall within the field of the analyst, regardless of how he may be defined. The future of the analyst, be he a public analyst, a governmental analyst, an industrial or a pharmaceutical analyst, is well assured in the modern framework of a healthy society. It, however, behooves us to remember that the various disciplines of analytical chemistry, and indeed of all the sciences, are now so interwoven that we are all increasingly dependent on each other. In this context, may I conclude my address with a quotation of Roger Bacon's dating from 1267—

> All the sciences are connected: they lend each other material aid as parts of one great whole. Each does its own work, not for itself alone but for the other parts. No part can attain its proper result separately, since all are parts of one and the same complete wisdom. **[The End]**

STATEMENT REQUIRED BY THE ACT OF AUGUST 24, 1912, AS AMENDED BY THE ACTS OF MARCH 3, 1933, JULY 2, 1946 AND JUNE 11, 1960 (74 STAT. 208) SHOWING THE OWNERSHIP, MANAGEMENT, AND CIRCULATION OF

FOOD DRUG COSMETIC LAW JOURNAL published monthly at Chicago, Illinois, for October 1, 1962.

1. The names and addresses of the publisher, editor, managing editor, and business managers are:

Publisher: Commerce Clearing House, Inc., Chicago 46, Illinois.

Editor: Henry L. Stewart, Chicago 46, Illinois.

Managing Editor: George H. Harris, Chicago 46, Illinois.

Business Manager: James L. Jones, Chicago 46, Illinois.

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5. The average number of copies of each issue of this publication sold or distributed, through the mails or otherwise, to paid subscribers during the 12 months preceding the date shown above was: (This information is required by the act of June 11, 1960 to be included in all statements regardless of frequency of issue.) 1,096.

Henry L. Stewart
(Signature of editor, publisher, business manager, or owner)

Sworn to and subscribed before me this 28th day of September, 1962.

[Seal] Seymour Matin
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