The Role of the American Medical Association in Product Evaluation

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Abstract

In the area of soap bacteriostats the concern of the American Medical Association is with safety. Manufacturers who contemplate market tests of consumer products are encouraged to share the scientific information about these products with the appropriate AMA department.

THE ROLE OF THE AMERICAN MEDICAL ASSOCIATION in product evaluation is, to many, a rather nebulous area. This arises in part from an unfamiliarity with the organizational structure of the AMA and, to a considerable degree, from the changes which have taken place over the years in the role of the AMA in product evaluation.

The AMA is a federation of 54 state and territorial medical associations with a membership of 214,000 medical doctors out of a total physician population of 301,000. Its policy-making body is the House of Delegates, the members of which are elected on a representative basis by each state association. The House of Delegates also elects the officers, as well as the Board of Trustees, of the national association. The Board of Trustees is responsible for the operation of the AMA between meetings of the House. To assist in discharging their responsibilities, the House and the Board have established a number of councils and committees, each with a fairly well-defined role and responsibility. These councils and committees make recommendations to the Board and to the House, and only when these recommendations are approved do they become the policy of the AMA.

The AMA occasionally issues policy statements about drugs and cosmetics; these are prepared most often in connection with AMA testimony on proposed legislation. The AMA has never issued a policy statement on soap bacteriostats, however.

The AMA publishes 11 scientific periodicals, and it has become customary to attribute to the AMA the positions expressed by individual persons whose papers have been accepted for publication in these journals. Nothing could be farther from the truth. All editors publish papers which do not necessarily agree with the current scientific concepts of their editorial boards and reviewers; such papers often lead to a dialogue between researchers interested in this field, and this dialogue can, of course, spread to other journals and even to symposia. The AMA, as a scientific organization, not only favors such dialogues but also encourages them since, in this manner, scientific knowledge is most rapidly advanced. Of current interest are the evaluation of the efficacy of antibacterial soaps and the problem of photosensitization reactions to some of the available bacteriostats.

In an editorial in the July 4, 1966, issue of the Journal of the American Medical Association entitled "The Bane of Body Odor" the attention of physicians was directed to two current reports on photo-allergic contact dermatitis. The editorial advised "practitioners to be constantly alert to the possibility of contact photodermatitis from soaps and other toilet articles even though the patient has not changed brands for years. Recent additions of tribromosalicylanilide or bithionol to established products can be a source of confusion in diagnosis and therapy."

On July 8 the New York Times, beginning with a reference to the editorial and slightly misquoting it, ran an interview with the authors of the two papers referred to in the editorial. In the interview one of the authors explained that the diagnostic difficulties arose because "the rash resembles poison ivy and a host of other allergy reactions." Apparently the headlines were larger than the actual reactions reported.

Both of these articles were referred to in the announcement of this AOCS session on soap bacteriostats which appeared in the September 1966 issue of Detergent Age. Not only did the Detergent Age author coin a new word "photosynthesizers," but he also synthesized the following unsupportable statement, "An editorial in the AMA Journal criticizing the industry for failing to label soaps containing germicides. . ." The AMA is a democratic institution and, as such, is accustomed to criticism of its actions from within and without; enthusiasm for criticism of the AMA should not however lead to distorted comments. The stories in the New York Times and in Detergent Age proved disturbing, to their credit, to those industry representatives who were familiar with the problem of photosensitization, the recent dialogue, and the AMA editorial.

As to product evaluation, this role of the AMA may well have begun with the organization of the Council on Pharmacy and Chemistry (now known as the Council on Drugs) in 1905. From its inception until 1955 the Council engaged in a program of product "acceptance," based upon the voluntary compliance of commercial outlets with "rules" chiefly designed to encourage the proper labeling of drug products and to restrict promotional claims to scientifically established uses. Only products marketed in conformity with the "rules" were described in The Journal of the AMA and annually in book form in New and Nonofficial Remedies. A "seal of acceptance" was introduced in 1930 for use on packages and in advertising of accepted products. The "rules" were partially revised in 1946 to meet changing conditions and the influence of the 1938 Federal Food, Drug, and Cosmetic Act upon the commercial distribution of pharmaceuticals. After World War II the Council was faced with the problem of considering a greatly increased number of new drugs as well as requests for acceptance of brands competing with old drugs.

By 1950 it was apparent that the acceptance program, which fostered the consideration of multiple brands of older drugs, left the Council little time for the consideration and the early publication of information on new drugs which was desired by physicians. Under the acceptance procedure the Council also could not describe a new drug in its annual publication unless or until there was conclusive evi-

dence to establish its clinical usefulness and safety. Accordingly, after careful consideration of these problems and by authorization of the Board of Trustees, the Council terminated its seal-acceptance procedure on February 15, 1955 (JAMA *157*, 664–665, 1955) and notified all manufacturers and distributors of previously accepted drug products that they were allowed a period of six months in which to discontinue use of the seal and all other references to Council acceptance.

Current product evaluations by the Council on Drugs, primarily on single-entity drugs, are intended to provide authoritative information, pro and con. Individual product monographs usually appear in the Journal of the American Medical Association and subsequently are incorporated in the Council's annual publication New Drugs, which contains individual monographs primarily on single-entity drugs introduced during the past 10 years. It also provides comparative reviews of older drugs in a particular therapeutic group. Hexachlorophene is the only soap bacteriostat which has been the subject of such a monograph. The inclusion of a drug in New Drugs does not imply that the Council accepts, endorses, recommends, or guarantees any individual brand or preparation of this evaluated drug.

It should be pointed out that the American Medical Association does not conduct any laboratory or clinical evaluations of any products. Therefore the information upon which the councils and committees of the AMA act must come from other sources. During the past 60 years the Council on Drugs has received an increasing degree of cooperation from pharmaceutical manufacturers, and a major amount of the information available to the Council and staff is derived from the manufacturer. The Department of Drugs, which staffs the Council, also maintains a Section on Documentation, which scans the domestic and foreign literature for reports on new drugs or new actions, favorable or unfavorable, on older products.

The outstanding resource of the AMA however resides in its ability to reach within its own membership many of the specialists who have been involved in the preclinical and clinical investigation of any product. The value of this cooperation freely obtained from these consultants cannot be readily estimated. The consultants, as a rule, provide extensive evaluations of their own experience with a given product, and these evaluations serve as the basic foundation on which Council monographs, that is, drug evaluations, are developed.

When new products approach the test market stage, particularly if the products incorporate new active agents, it is very useful if the firm shares its scientific information with the appropriate AMA department. Needless to say, this information is handled on a confidential basis. In cosmetics, or in the grey areas of medicated cosmetics and antibacterial soaps, the Committee on Cutaneous Health and Cosmetics is concerned with any problems which affect health that may result from the use of these products. Should any health problems arise, it is only natural for the public, physicians, and the reporters to seek further information and enlightenment from the AMA. It is therefore desirable that the proper AMA department has the information at hand so as to be able to evaluate it more adequately.

For example, reports on photosensitization which results from the use of soap bacteriostats are of current interest. It is known that tetrachlorosalicylanilide is a potent photosensitizer and can be relied upon to produce reactions in a panel of test subjects. Also it is known that tetrachlorosalicylanilide is not being used in any product on the United States market. The published dialogue indicates that the number of persons who exhibit sensitivity to other currently popular soap bacteriostats is quite low, that many of the patch tests are conducted with artificially high concentrations of reagents, and that even the test areas on the subjects differ from the areas of ordinary use and exposure. Nevertheless reactions do occur, both under patch test conditions and conditions of normal use. A balanced interpretation of all this information is required. At this time the author would tend to agree with the views of Stephen Epstein, as expressed in the March 7, 1966, issue of The Journal of the AMA, viz., a) at present TBS should not be condemned as an antiseptic in soaps, and b) the occurrence of photocontact allergy to TBS is frequent enough to warrant that physicians should be alerted to this source of photo-allergy.

Another problem is that the introduction of a new ingredient into an established product can make it more difficult for a physician to detect the source of an allergic reaction. It seems logical that all physiologically active ingredients should be identified on the product label, preferably by a United States Adopted Name.

It is appropriate to repeat, at this point, the significant role of the AMA scientific publications relative to product evaluation. Of particular significance to the audience today are the Journal of the American Medical Association and the Archives of Dermatology, both recognized as outstanding publications in their respective fields. As a result of the efforts of the editorial boards and the editorial staffs of these publications it is generally recognized that articles appearing in them have met the criteria of scientific merit. Some of these articles may be in the form of reports of an AMA council or committee, and, in those cases only, may such a report be construed as an evaluation of a product by the AMA. Yet these journals print many articles, some recognized as being controversial or provocative, which represents only the findings and opinions of the authors and are never to be construed as equivalent to evaluation of the product by the AMA. The full responsibility for the statements within such articles lies with the author, and the editors of the journals have merely deemed the article worthy of publication without expressing any position of the AMA with respect to the product or products referred to in the article. The editor of the AMA scientific publications, John H. Talbott, welcomes papers on medically oriented studies, particularly if they help resolve outstanding controversies.

Acceptance of product advertising for AMA journals or for an exhibit at an AMA meeting is likewise not to be equated with product acceptance or evaluation by the AMA. It simply means that the product and the advertising claims have been judged to conform to the advertising policies that currently exist in these spheres of AMA activity.

Since the health problems associated with soap bacteriostats appear to be minor at this time, the principal AMA evaluation of these products or, more precisely, of the claims made for these products, occurs when a proposed advertisement or exhibit is

evaluated for possible acceptance by the Department of Advertising Evaluation and its consultants. This is an autonomous department, which utilizes the information produced by other AMA organizational units but relies on the opinions of its own *ad hoc* consultants. Advertising claims are sometimes based on evidence or sometimes on belief, are almost always enhanced by puffery, and can occasionally be controversial.

Most copy for either journal advertisements or product exhibits is rejected in the form in which it is first submitted to the AMA Department of Advertising Evaluation; of course, the reasons for the rejection are given as well as suggestions for revision. The copy that ultimately results is frequently better substantiated by the evidence and is, occasionally, more effective. Scientists concerned with the development of these products should be aware that advertising evaluation policies, such as those of the AMA, enhance the prestige and contributions of the industrial scientists who have been close to the testing and evaluating of a product. Therefore should management refer advertising copy back to the scientific staff, it should be recognized that, as with the preparation of a paper for publication or a scientific symposium, this added burden puts responsibility, but also recognition, where it belongs.

In respect to soap bacteriostats the ultimate concern of the American Medical Association is safety; manufacturers and the public share this same concern.