

Modifying Order

101 F.T.C.

IN THE MATTER OF

AHC PHARMACAL, INC., ET AL.

MODIFYING ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SECS. 5
AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3017. Consent Order, April 28, 1980—Modifying Order, Feb. 8, 1983*

This order reopens the proceeding and modifies the Commission's order issued on April 28, 1980 (95 F.T.C. 528), by relieving respondent of the obligation of disseminating corrective advertisements which state that "no product can cure acne" prior to disseminating advertisements for "AHC Gel" or any acne product or regimen. In addition to the two well-controlled, double-blind clinical studies previously required for all superiority claims, the modified order now permits respondents to rely on FDA Panel recommendations as a reasonable basis for substantiating superiority claims.

ORDER REOPENING THE PROCEEDING AND MODIFYING
CEASE AND DESIST ORDER

AHC Pharmacal, Inc., and James E. Fulton, M.D., (hereinafter "Petitioners") have filed, pursuant to Rule 2.51 of the Commission's Rules of Practice, a Request for Modification of Order, including a request to vacate (hereinafter "Petition").

Petitioners seek the modification or elimination of two provisions of the Commission's Order of April 28, 1980. Petitioners also ask that the action be dismissed and the Order vacated.

The Order concerns Petitioners' representations as advertisers of an acne product and a regimen, and requires them to disseminate corrective advertisements that "no product can cure acne" before engaging in any advertising.

The initial request of July 7, 1982, seeks the modification of the Order in two respects: (1) Petitioners seek to change the format and the media of the corrective advertising required under the Order, and (2) presumably as an alternative, they allege that the basis of the Commission's Complaint is now moot in view of a recent report by a panel of FDA experts and argue that the Commission action should be dismissed and the Order vacated.

Additional issues raised by Petitioners' letter of August 27, 1982, include (3) a charge that their constitutional rights of due process and equal protection are being violated by the Order requirement of double-blind clinical studies to support efficacy claims, and (4) an allegation that a new acne product on the market may, in fact, cure acne, which renders the requirement of the corrective message "no product can cure acne" factually and legally erroneous.

The first issue raised by Petitioners concerns the breadth and frequency of the corrective advertising and the advertising media to be used. Petitioners seek to change the requirement of the Order to disseminate corrective advertising in Sunday newspaper supplements and on radio and to substitute therefor a brochure soliciting mail orders to be sent to at least 20,000 consumers who are potential purchasers of the product.

In support of this portion of the request Petitioners have shown that changed financial conditions of the corporate respondent now prevent it from being able to pay for the cost of such advertising. They further submit that the direct mailing of a less expensive brochure bearing the corrective message to the very consumers who may have been previously exposed to the now prohibited advertising would be more in keeping with the spirit of the Order.

However, Petitioners also argue that the passage of time supports their contention that the corrective advertising requirement be eliminated. There is no evidence before us as to what, if anything, the public recalls of the original advertising, and whether the public perception of the product is still tainted by the claims of "cure" and "superiority." Respondents argue that during the four years when they chose not to advertise at all whatever "lingering effect" the previous claims may have had was dissipated and, therefore, lessened the need for corrective advertising.

Additionally, an argument is made by the Petitioners that a new drug, Accutane, recently approved by FDA for acne treatment, "may, in fact, cure acne." Therefore, the argument continues, the Commission should no longer require the respondents to disseminate a statement ("no product can cure acne") that may be "factually and legally erroneous."

The Commission is persuaded by the evidence of changed financial circumstances and the argument about the passage of time that modification of the Order is warranted. Moreover, without reaching the question as to whether any product may, in fact, cure acne, the Commission is of the opinion that under the facts of this case it will not be against the public interest to relieve Petitioners from the requirement of the corrective message. 15 U.S.C. 45(b) and 16 C.F.R. 2.51.

The second issue raised by Petitioners is the publication by the Food and Drug Administration ("FDA") of advance notice of proposed rule-making for Topical Acne Drug Products for Over-the-Counter Human Use, 47 FR 12430, (March 23, 1982) (to be codified at 21 C.F.R. 333), and the recommendation of an Advisory Review Panel contained therein. Petitioners assert that since certain labeling representations regarding products containing benzoyl are now acceptable to the Pan-

el, and since benzoyl is the active ingredient of Petitioners' products, the basis for the Commission's original Complaint is now moot and that consideration should be given to dismissal of the action and the vacating of the Order.

The Panel report referred to by the Petitioners is a part of a proposed rulemaking by the Food and Drug Administration that would establish conditions under which over-the-counter (OTC) acne drug products are generally recognized as safe and effective and not misbranded. FDA published an advance notice of the proposed rulemaking on March 23, 1982. The notice is based on the recommendations of the Advisory Review Panel on OTC Antimicrobial (II) Drug Products.

The Panel has reviewed the literature and data submissions and has listened to testimony of interested persons. Numerous manufacturers of acne preparations submitted their products. AHC Pharmaceutical submitted "bp Gel Medication" and "bp Gel Medication Strong."

The Panel recommends three category conditions. Category I Conditions are those under which OTC acne drug products are generally recognized as safe and effective and are not misbranded. Category II Conditions are those under which OTC acne drug products are *not* generally recognized as safe and effective or are misbranded. Category III encompasses products for which insufficient data precludes final classification at this time.

The Panel concluded that benzoyl peroxide in concentrations of 2.5 to 10 percent is one of the two active ingredients that are generally recognized as safe and effective (Category I) in treatment and prevention of acne.

The Panel recommends numerous acceptable phrases to be used in labeling for products effective in the treatment of acne, in the prevention of new acne lesions, and in antibacterial claims.

The Commission finds insufficient basis in the Panel's report to support Petitioners' contention that the basis for the Commission's original action is now moot and that the Order should be vacated.

The gravamen of the Commission's Complaint is the allegation concerning the unqualified claim for the effectiveness of Petitioners' product and regimen. The Complaint alleges that the advertisements claim, directly or by implication, that the respondents' product or regimen will cure acne and is superior to other products on the market.

The Panel's recommendations of acceptable language are carefully drawn. Absolute claims are not recommended. The Panel's recommendations do not support the Petitioners' contention that "the basis of the Commission's original complaint is now moot. . . ." The Panel's recommendations do not directly contradict Parts I.A. and B.1. of the

Order that clearly prohibit "cure" claims by Petitioners. Given the claims alleged in the Complaint, the Commission believes the Panel's recommendations provide no basis to support Petitioners' argument that the Order should be vacated.

The Commission is willing to vacate an order upon a showing that changes in fact or law or the public interest make the continuation of an order unnecessary. Petitioners have failed to show such changes in the instant case. For example, they have not demonstrated that the Commission would interpret their advertisements any differently today than when the order was issued, nor have they provided copy tests or other extrinsic evidence demonstrating that the advertisements do not make the claims the Commission prohibited. Moreover, the Commission finds no basis in the public interest for vacating this order.

Petitioners finally argue that the requirement of the double-blind clinical studies for claims that the product results in a skin free of pimples, blackheads, etc., is a violation of "due process and equal protection" since the Panel concluded that products containing benzoyl peroxide "can be represented . . . without any testing whatsoever."

None of the recommended representations in the Panel's list permits a sweeping, unqualified claim of "skin free of pimples, blackheads, etc." The Panel recommends as acceptable such qualified labeling claims as "Clears up most acne pimples", "Clears up most acne blackheads", and similar qualified representations if descriptive of products effective in the treatment or prevention of acne.

Moreover, having signed the Consent Order in this matter, Petitioners waived any right to seek judicial review or otherwise to challenge or contest the validity of the order. 16 C.F.R. 2.32. Accordingly, we do not reach the argument of the denial of due process and equal protection, advanced by the Petitioners.

Nevertheless, it is in the public interest that Petitioners should be permitted to make claims about their products that their competitors may make, if supported by a reasonable basis; including superiority claims, if properly supported by such an authority as the recommendation of the Panel. For example, whatever implications of superiority there may be in a claim that benzoyl peroxide has been found safe and effective by the Panel while an ingredient classified by the Panel as Category II has been found unsafe or ineffective, those implications are adequately substantiated by the findings and conclusions of the Panel. The Order will be modified accordingly. In continuing to require two well controlled double-blind clinical studies for all superiority claims not supported by the FDA or its Panel, the Commission, of course, expresses no view on the broader question of whether that

level of substantiation would be an appropriate requirement for all comparative claims for all drugs or other products.

Petitioners have failed to show other changes in fact to warrant any other modification of the Order.

It is therefore ordered, That the proceeding is hereby reopened and the Decision and Order issued April 28, 1980, in Docket No. C-3017 is hereby modified to read as follows:

ORDER

I

It is ordered, That respondents AHC Pharmacal, Inc., a corporation, and James E. Fulton, individually and as a corporate officer, their successors and assigns, either jointly or individually, and the corporate respondent's officers, agents, representatives, and employees, directly or through any corporation, division or other device, in connection with the advertising, offering for sale, sale or distribution of all products do forthwith cease and desist from:

A. Disseminating or causing the dissemination of any advertisement by means of the United States mail or by any means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, which directly or indirectly:

1. Represents that use of a product variously known as AHC Gel, AHC Pharmacal's benzoyl peroxide gel medication and b.p. gel medication (hereinafter "AHC Gel") either alone or as part of "Dr. Fulton's Acne Control Regimen" (hereinafter "the Acne Control Regimen") or any other acne product or regimen will cure acne or any skin condition associated with acne;

2. Misrepresents the extent to which any product has been tested or the results of any such test(s);

B. Disseminating or causing the dissemination of any advertisement by means of the United States mail or by any means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, which directly or indirectly:

1. Represents that use of "AHC Gel", either alone or as part of "the Acne Control Regimen", or use of any other acne product or regimen by persons with acne, will result in skin free of pimples, blackheads, whiteheads, other acne blemishes, or scarring;

2. Represents that "AHC Gel", either alone or as part of "the Acne Control Regimen", or any other acne product or regimen, is superior to other over-the-counter acne preparations for the treat-

ment of acne, including but not limited to other benzoyl peroxide products,

unless, at the time of each dissemination of such representation(s) respondents possess and rely upon competent and reliable scientific or medical evidence as a reasonable basis for such representation(s). ("Competent and reliable scientific or medical evidence" shall be defined as evidence in the form of at least two well-controlled double-blind clinical studies which are conducted by different persons, independently of each other. Such persons shall be dermatologists who are qualified by scientific training and experience to treat acne and conduct the aforementioned studies. *Provided, however,* That the findings and conclusions of the FDA Advisory Review Panel on OTC Antimicrobial (II) drugs as published in 47 FR 12430 *et seq.* (March 23, 1982), unless and until any such finding or conclusion shall be modified by the FDA, and in that event, such finding or conclusion as modified, shall also constitute "competent and reliable scientific or medical evidence.");

C. Disseminating or causing the dissemination of any advertisement by means of the United States mail or by any means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, which directly or indirectly makes representations referring or relating to the performance or efficacy of any product or refers or relates to any characteristic, property or result of the use of any product, unless, at the time of each dissemination of such representation(s) respondents possess and rely upon a reasonable basis for such representation(s).

II.

It is further ordered, That respondents shall forthwith distribute a copy of this order to each of their operating divisions.

III.

It is further ordered, That each respondent notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of this order.

IV.

It is further ordered, That such respondent shall, within sixty (60) days after this order becomes final, and annually thereafter for three (3) years, file with the Commission a report, in writing, signed by respondent, setting forth in detail the manner and form of its compliance with this order.

V.

It is further ordered, That each respondent shall maintain files and records of all substantiation related to the requirements of Parts IB and IC of this order for a period of three (3) years after the dissemination of any advertisement which relates to that portion of the order. Additionally, such materials shall be made available to the Federal Trade Commission or its staff within fifteen (15) days of a written request for such materials.

Petitioners' request for other modification of the Order and for dismissal of the action and vacating of the Order is hereby denied.

It is further ordered, That the foregoing modification shall become effective upon service of this Order.

Commissioners Pertschuk and Bailey voted in the negative.

SEPARATE STATEMENT OF COMMISSIONER DAVID A. CLANTON ON ORDER
MODIFICATION IN AHC PHARMACAL, INC.

The Commission today issued an order modifying the corrective advertising and substantiation requirements of a 1980 Consent Order entered into with AHC Pharmacal, Inc. In a separate statement, Commissioner Pertschuk expresses concern that the newly modified order might give the respondent room to make claims for which there is little or no scientific basis.

In point of fact, the modified order does no such thing. As Commissioner Pertschuk's statement might suggest to the respondent that it is free to make certain claims that are still prohibited, I have taken this opportunity to correct that misimpression.

The original order, entered in 1980, prohibited the respondent from making certain claims unless they were supported by "competent and reliable scientific or medical evidence." No FDA panel had examined the efficacy of acne remedies at that time, so scientific or medical evidence was defined to require two well-controlled clinical studies.

Recently, however, an FDA Advisory Review Panel concluded an investigation and published its findings on the safety and efficacy of various acne remedies. The sole effect of our order modification is to

provide that those findings would also be considered "competent and reliable scientific or medical evidence." The FDA panel was composed of leading experts in the field of antimicrobial drugs, and there has been no suggestion anywhere in these proceedings that the panel's findings were incompetent or unreliable. Thus, the respondent may now make a claim if it is supported either by two well-controlled clinical studies *or* by the findings of the FDA panel.

However, it is important to point out that claims which are *not* supported by such evidence are still prohibited. The order should not be read as providing the respondent with a "zone of play," permitting any claim which even looks as though it might be supported by the panel's findings, any more than the original order would have permitted a claim which only looked as though it might be supported by two clinical tests. Unless a claim is in fact confirmed, either by the conclusions of the FDA panel or by two independent clinical tests, that claim is still prohibited.

Thus, I cannot share Commissioner Pertschuk's concern (at p. 2 of his statement) about advertisements which might imply that a 10% benzoyl peroxide solution was generally more effective than a product containing only a 2.5% solution. As Commissioner Pertschuk correctly points out, the FDA panel did *not* find that a 10% solution was more effective than a 2.5% solution for most acne sufferers, so any implied claim to the contrary would not be supported by the panel's findings. Accordingly, any advertisement which made such an implied claim would still violate the order.

The same answer applies to the concern (again at p. 2) that the respondent could argue that the panel's findings would support a claim that the product would result in a skin "free of pimples." The truth is that nothing in the panel's conclusions would support such an unqualified claim. Indeed, this was one of the claims involved in the original complaint, and the Commission's modifying order explicitly states that "the panel's recommendations do *not* support the petitioner's contention" that such a claim would now be permissible. (Order at p. 4; emphasis added). If this were not clear enough, the modifying order later repeats that "none of the recommended representations in the panel's list permits a sweeping, unqualified claim of 'skin free of pimples, blackheads, etc.'" (*Id.*) There thus is no basis for even suggesting that such claims would now be permitted under the modified order.

In short, Commissioner Pertschuk is simply incorrect to the extent that he implies that the modified order might permit any claims, express or implied, that were not directly supported by the panel's findings and conclusions (or by two clinical tests). The petitioner would be well advised not to place any reliance on such suggestions.

DISSENTING STATEMENT OF COMMISSIONER MICHAEL PERTSCHUK ON
ORDER MODIFICATION IN AHC PHARMACAL

The modified order adopted today by the Commission ostensibly retains the order's provision requiring the petitioner to have clinical tests to prove claims that its product would give buyers a "skin free of blemishes" or that its product is superior to other OTC acne medications. But the Commission now has introduced a large area of uncertainty about which claims require clinical testing by AHC and which claims do not.

Under the proposed modification, petitioner can make any superiority claim which is based on the "findings and conclusions" of the FDA panel. Instead of limiting therapeutic superiority claims to a narrow class of claims which are adequately supported by scientific proof, this order modification threatens to enlarge the "zone of play" in which a seller can make a spurious claim and effectively protect itself from prosecution by cloaking itself in the protective mantle of the FDA panel's findings. It allows advertisers to lift the FDA panel's "findings" out of the narrow specific context in which they were made and use them to make comparisons between products—comparisons which the FDA itself does not allow.

Let me just provide one example. When the FDA finishes its OTC acne drug review, only those products which are found by FDA to be "safe and effective" can be sold. How then is the poor marketer to convince consumers to buy its product rather than its competitors? Based on the history of OTC drug advertising, I confidently predict that advertisers will resort to spurious differentiations, all of which will imply that their products are actually better than the others. The proposed modification will certainly invite such claims. Take, for example, the following cautiously phrased "finding" of the FDA panel:

The Panel recognizes that acne represents a spectrum of severity . . . The Panel feels that higher concentrations of benzoyl peroxide may be suitable for severe acne or for mila [*sic*] acne lesions that have not responded to lower concentrations. [2]

What kinds of superiority claims does that "finding" support? How about:

Forget those sissy 2.5% benzoyl peroxide solutions! When you're really *serious* about acne, try "Big 10"—the acne medication with more than 3 times as much benzoyl peroxide as the best seller!

Most sufferers of acne would clearly interpret that to mean that the 10% solution is much more effective than a 2.5% solution. Yet the

studies reviewed by the FDA panel found that for most acne sufferers, the 2.5% solution of benzoyl peroxide was *just as effective* as the 10% solution, while causing less severe and less frequent side effects. But is the claim also supported by the FDA panel's "findings" cited above?

Nor is this concern altogether theoretical. The petition itself states that the requirement to conduct clinical tests to support claims that its product will result "in a skin free of pimples, blackheads, etc, is totally out of touch with the FDA's expert panel's conclusion that benzoyl peroxide containing products can be represented for such results without any testing whatsoever," and "it appears that the very advertising which the Commission complained of in 1978 is now acceptable labeling claims to the FDA's expert panel."

I would support a modification which spells out exactly the types of claims which are supported by the FDA panel's findings. For example, the FDA panel's findings do provide a scientific basis for petitioner—or any other OTC acne drug seller—to claim that products with benzoyl peroxide or sulfur (the only two ingredients found by the FDA to be safe and effective) are therapeutically superior to products with only those ingredients found by the FDA generally not to be safe and effective. The principal deficiency in the Commission's modification is its failure to make clear which claims are supported by the FDA panel and which claims are not. The result is to invite the spurious differentiations discussed above, or, at the least, to leave ourselves open to future disputes which can only be resolved by enforcement proceedings.

In my view, the Commission, in adopting this modification, simply begins to unravel what has been a useful, understandable, and justifiable standard for substantiation of OTC drug comparison claims.

Complaint

101 F.T.C.

IN THE MATTER OF

CONAGRA, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF SEC. 5 OF
THE FEDERAL TRADE COMMISSION ACT AND SEC. 7 OF THE CLAYTON ACT

Docket C-3103. Complaint, Feb. 16, 1983—Decision, Feb. 16, 1983

This consent order requires an Omaha, Neb. manufacturer and seller of bakery and hard wheat flour, among other things, to timely divest seven specified flour production facilities to a Commission-approved buyer(s), capable of maintaining the facilities as competitive entities. Additionally, the order prohibits the company from acquiring, for a period of ten years, any interest in any flour milling plant in eleven western states without prior Commission approval.

Appearances

For the Commission: *John Peterson.*

For the respondent: *Bertram M. Kantor, Wachtell, Lipton, Rosen & Katz, New York City.*

COMPLAINT

The Federal Trade Commission, having reason to believe that the above-named Respondent, subject to the jurisdiction of the Commission, has acquired stock and assets of Peavey Company in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45; and that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, pursuant to Section 11 of the Clayton Act, 15 U.S.C. 21, and Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), stating its charges as follows:

Definitions

For purposes of this complaint the following definitions shall apply:

Bakery Flour means hard wheat flour, soft wheat flour and whole wheat flour sold generally to bakeries and institutional users.

Hard Wheat Bakery Flour means flour milled from hard wheat, which is sold generally to bakeries and institutional users to make white pan bread.