

1970-1971

Complaint

rules and regulations promulgated under the Fur Products Labeling Act, are based.

It is further ordered, That respondents notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondent, Pizitz, Inc., 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 the order.

It is further ordered, That the respondent corporation, Pizitz, Inc., shall forthwith distribute a copy of the order to each of its operating divisions.

It is further ordered, That respondents herein shall, within sixty (60) days after service upon them of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

IN THE MATTER OF
PFIZER INC.
ORDER, OPINION, ETC., IN REGARD TO THE ALLEGED VIOLATION OF SECTION 5
OF THE FEDERAL TRADE COMMISSION ACT

Docket 8819. Complaint, July 6, 1970—Decision, July 11, 1972.

Order affirming the hearing examiner's initial decision dismissing the complaint against a New York City manufacturer of a nonprescription product recommended for use on minor burns and sunburn.

Opinion of the Commission resolves the general issue that the failure to possess a reasonable basis for affirmative product claims constitutes an unfair practice in violation of the Federal Trade Commission Act.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Pfizer Inc., a corporation, hereinafter referred to as respondent, has violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Respondent Pfizer Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal office and place of business located

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at 235 East 42nd Street, in the city of New York, State of New York.

PAR. 2. Respondent is now, and for some time past has been engaged in the manufacturing, advertising, offering for sale, sale and distribution of a preparation for sunburn treatment called "Un-Burn" and other proprietary drugs and products to retailers for resale to the public.

PAR. 3. In the course and conduct of its business as aforesaid, respondent now causes, and for some time past has caused, its said products, when sold, to be shipped from its plants and facilities to purchasers thereof located in various states other than the state of origination, and maintains, and at all times mentioned herein has maintained, a substantial course of trade in said products in commerce, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 4. In the course and conduct of its business as aforesaid, respondent has made and continues to make in print advertisements, including product packages and labels, and other promotional material and in television and radio broadcasts transmitted by television and radio stations located in various States of the United States and in the District of Columbia having sufficient power to carry such broadcasts across the state lines, numerous statements and representations respecting the pain relieving properties of said product when used by persons suffering from sunburn.

Typical and illustrative of said statements and representations, but not all inclusive thereof, are the following:

In radio and television broadcasts:

1. New Un-Burn actually anesthetizes *nerves* in sensitive sunburned skin.
2. Un-Burn relieves pain *fast*. Actually *anesthetizes nerves* in sensitive sunburned skin.
3. Sensitive skin * * * Sunburned skin is sensitive skin. Sensitive sunburned skin needs * * * UN-BURN. New UN-BURN contains the same local anesthetic doctors often use. * * * Actually anesthetizes nerves in sensitive sunburned skin. I'll tell you what I like about UN-BURN. It's the best friend a blonde ever had! * * * I'm a blonde * * * and I know what it means to have sensitive skin. Why, I'm half afraid of moon burn! That's why I'm mad about UN-BURN. It stops sunburn pain in * * * less time than it takes me to slip out of my bikini. That's awfully nice to know when you're the sensitive type. * * *

On labels: "UN-BURN" comprehensive treatment for "sunburn" * * * relieves pain * * * anesthetic. * * *

PAR. 5. By making the above-quoted statements, and others similar thereto, but not expressly set forth herein, respondent represents, and has represented, directly or by implication, that each of the statements respecting the pain relieving properties of the said product has been substantiated by respondent by adequate and well-controlled scientific studies or tests prior to the making of such statements.

PAR. 6. In truth and in fact, the aforesaid statements respecting the said product, "Un-Burn," have not been substantiated by respondent by adequate and well-controlled scientific studies or tests prior to the making of such statements.

Therefore, the representation as set forth in Paragraph Five hereof was and is false, misleading and deceptive.

PAR. 7. The making of any statement or representation, directly or by implication, that Un-Burn will actually anesthetize nerves in sensitive sunburned skin, or any other statement or representation regarding the performance or effectiveness of such product, when such statement or representation is not supported by prior, fully documented, adequate and well-controlled scientific studies or tests is in itself an unfair practice.

PAR. 8. Respondent at all times mentioned herein has been and now is in substantial competition in commerce with individuals, firms and corporations engaged in the sale and distribution of sunburn remedies of the same general kind and nature as that sold by respondent.

PAR. 9. The use by respondent of the aforesaid misleading and deceptive statements, representations and practices has had, and now has, the capacity and tendency to mislead members of the purchasing public into the purchase of substantial quantities of respondent's product. As a result thereof, substantial trade has been and is being unfairly diverted to respondent from its competitors.

PAR. 10. The aforesaid acts and practices of respondent, as herein alleged, were and are all to the prejudice and injury of the public and of respondent's competitors and constituted, and now constitute, unfair methods of competition in commerce and unfair and deceptive acts and practices in commerce in violation of Section 5 of the Federal Trade Commission Act.

Mr. Edward F. Downs and *Mr. Stuart Lee Friedel* supporting the complaint.

Mr. Roy L. Reardon, Mr. William J. Manning, Mr. Melvyn L. Cantor, Mr. Charles E. Koob, of Simpson Thacher & Bartlett, New York, New York, and Mr. Charles F. Hagen for respondent.

INITIAL DECISION BY WALTER K. BENNETT, HEARING EXAMINER

APRIL 16, 1971

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PRELIMINARY STATEMENT

This proceeding brought by the Federal Trade Commission by complaint filed July 15, 1970, charges respondent Pfizer Inc., with violation of Section 5 of the Federal Trade Commission Act.¹

The alleged factual basis for the charge is two-fold: (1) that respondent has advertised and sold its sunburn remedy "Un-Burn" in commerce without having made adequate and well-controlled tests prior to such advertising to determine the efficacy of the product to support the claim that it anesthetizes nerves in sensitive sunburned skin and stops pain fast and (2) that it falsely implied by its advertisements that it had conducted such adequate and well-controlled tests.

On August 5, 1970, the hearing examiner scheduled a prehearing conference for August 18, 1970, setting up the requirements that motions should be made returnable at such conference.

Prior to answer and by motion papers filed August 13, 1970, respondent sought a cancellation of the prehearing, a postponement of the time to answer and a motion to dismiss and to certify to the Commission.

Argument on the motions, initially scheduled for August 25, 1970, was held September 21, 1970, and they were disposed of by written

¹ 15 U.S.C. 45.

order filed the same day and not appealed. Among other matters, the order held that there was merely a matter of law involved, which should not be certified, and that the allegations of the complaint were adequate to require a full evidentiary hearing before the matter could be determined.

Respondent's answer filed October 6, 1970, admitted that it was incorporated and did business as alleged and had advertised the product "Un-Burn" as charged although it denied that such advertising was typical or continuing. It denied its advertisements made the implications alleged and that it has knowledge or information that the claims had not been substantiated by adequate and well-controlled scientific studies or tests. Respondent admitted it was in competition with others but denied any violation of law or that its action had the effect of misleading the public. Then, the answer asserted six affirmative defenses in effect alleging: that respondent had not acted recklessly and in disregard of human health and safety; nor unreasonably; that the complaint was defective because it had not alleged the untruthfulness of respondent's advertising; that the claims were true; that the Commission had no authority to impose a requirement beyond the requirements of the Commissioner of the Food & Drug Administration; and that there was no public interest in continuing the proceeding because respondent had submitted an adequate and well-controlled test demonstrating that its claims for "Un-Burn" were true.

On October 9, 1970, there was a prehearing conference primarily regarding the scheduling of proposed discovery and possible simplification of issues. The conference culminated in an order dictated on the record (Tr. 116-121).²

On November 16, 1970, respondents filed a motion under Rule 3.36 (b) for the issuance of a subpoena to the Commission. This was denied by order dated November 25, 1970. In the meantime, the parties had been attempting to define certain of the issues and by December 1, 1970, had reached an impasse on the issue of the meaning of "adequate and well controlled scientific tests." On December 1, 1970, respondents filed a motion to: (1) require complaint counsel to define "adequate and well controlled;" (2) secure reconsideration of the orders denying issuance of a subpoena to the Commission; (3) postpone trial.

² The following abbreviations will sometimes be used:

C. Complaint	RX Respondent's Exhibit
A. Answer	CPF Complaint Counsel's Proposed Findings
Tr. Transcript	
CX Complaint Counsel's Exhibit	RPF Respondent's Proposed Findings

(In citing proposed findings the references therein are deemed to be included)

A second prehearing conference was held December 3, 1970, to hear respondent's motion, it having proved impossible to meet the schedule proposed following the October 9, 1970, conference.

At the December 3rd conference, the meaning of adequate and well-controlled scientific tests was canvassed as well as the necessity for additional discovery. It was decided that the formal hearings would have to be postponed and respondent was given an opportunity to submit a new motion for a subpoena.

On December 14, 1970, following the submission of a new motion for a subpoena to the Commission, the undersigned issued an order calling for limited production of Commission documents at the formal hearings.

Further motions were made regarding scheduling due to the unavailability of the professional witnesses. A hearing in Miami, Florida and a postponement of a few days was accordingly ordered. (Orders dated January 13, 1971 and January 15, 1971.) In addition respondent made an informal suggestion concerning the order of proof, *i.e.*, that the issues of the implications from the advertising be first determined. This was rejected on the basis of complaint counsel's objection.

Hearings commenced January 20, 1971, in Washington, D.C. and concluded February 22, 1971. One witness was heard in Miami, Florida by consent of both parties and because of his inability to be present in Washington, D.C. There were also brief adjournments of the sort customary in judicial proceedings to meet the convenience of the expert professional witnesses taken by consent.

Counsel were most cooperative in production and authentication of documents, in the prelisting of witnesses and in the submission in advance of *curricula vitae* of the experts. Four expert witnesses were called by counsel supporting the complaint and over 70 exhibits were offered. Respondents called three officials and six experts and marked over 100 exhibits. Complaint counsel recalled one expert on rebuttal.

After the conclusion of complaint counsel's case-in-chief respondent moved to dismiss.³ The hearing examiner then reserved decision (Tr. 809, 814-826). Respondent's motion to dismiss at the conclusion of complaint counsel's case is now denied because at the time of that motion all inferences favorable to complaint counsel had to be drawn and the evidence offered by respondent had to be disregarded.

³ Tr. 809 For convenience of the witnesses, three of respondent's witnesses were called prior to the argument of the motion. Their testimony accordingly is disregarded in denying the motion.

BASIS OF DECISION

This decision is based on the entire record, including the proposed findings and conclusions of the parties. All findings of fact not expressly, or in substance, adopted are denied as erroneous, immaterial or irrelevant. In accordance with Rule 3.51(b), references are made to the specific pages of the principal supporting items of evidence in the record. The citations to the principal supporting portions of the record, however, are not intended to exclude other portions of the record, all of which have been carefully considered in light of the demeanor of the witnesses and their consistency or inconsistency with contemporaneously written documents.

We now set forth our findings of facts, conclusions and proposed order. In the interest of convenience, we first dispose of those findings which are admitted by answer before proceeding to contested ones.

FINDINGS OF FACT

The following findings are based on admissions in the answer.

A. *Admitted Findings*

1. Respondent Pfizer Inc. (sometimes referred to herein as Pfizer), is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware with its principal office and place of business located at 235 East 42nd Street, in the city of New York, State of New York (C1, A1; CPF 1; RPF 1.2).

2. Respondent is now, and for some time past, has been engaged in the manufacturing, advertising, offering for sale, sale and distribution of "Un-Burn," which is recommended for use in connection with minor burns, including sunburn, and further has been engaged in the manufacturing, advertising, offering for sale, sale and distribution of other proprietary drugs and products to retailers for resale to the public (C2, A2; see CPF 2).

3. In the course and conduct of its business as aforesaid, respondent now causes, and for some time past has caused, its said products, when sold, to be shipped from its plants and facilities to purchasers thereof located in various states other than the state of origination, and maintains, and at all times mentioned herein has maintained, a substantial course of trade in said products in commerce, as "commerce" is defined in the Federal Trade Commission Act (C3, A3; CPF 3; see RPF 1.3).

4. In the course and conduct of its business as aforesaid, respondent has made in print advertisements, including product packages and labels, and other promotional material and in television and radio

broadcasts transmitted by television and radio stations located in various States of the United States and in the District of Columbia having sufficient power to carry such broadcasts across the state lines, numerous statements and representations respecting the pain relieving properties of said product when used by persons suffering from sunburn.

Some of said statements and representations, but not all inclusive thereof, are the following:

In radio and television broadcasts:

- a. New Un-Burn actually anesthetizes *nerves* in sensitive sunburned skin.
- b. Un-Burn relieves pain *fast*. Actually *anesthetizes nerves* in sensitive sunburned skin.
- c. Sensitive skin * * * Sunburned skin is sensitive skin. Sensitive sunburned skin needs * * * UN-BURN. New UN-BURN contains the same local anesthetic doctors often use. * * * Actually anesthetizes nerves in sensitive sunburned skin. I'll tell you what I like about UN-BURN. It's the best friend a blonde ever had! * * * I'm a blonde * * * and I know what it means to have sensitive skin. Why, I'm half afraid of moon burn! That's why I'm mad about UN-BURN. It stops sunburn pain in * * * less time than it takes me to slip out of my bikini. That's awfully nice to know when you're the sensitive type * * *

On labels: ["UN-BURN" comprehensive treatment for] * "sunburn" * * * relieves pain * * * anesthetic. * * * (C4, A4; see CPF 4).

5. Respondent at all times mentioned herein has been and now is in substantial competition in commerce with individuals, firms and corporations engaged in the sale and distribution of sunburn remedies of the same general kind and nature as that sold by respondent (C8, A8; CPF 10).

B. *Contested Findings*

The following findings are based on the hearing examiner's evaluation of the evidence:

No Implication of Tests from Advertising

6. On the basis of all of the evidence offered with respect to the advertising of the product Un-Burn and having carefully observed the pictures and sound reproduced from T.V. advertising (CX 1-13) it has not been established to the satisfaction of the hearing examiner that respondent has represented directly or by implication, that each of the statements respecting the pain relieving properties of the said product had been substantiated by respondent by adequate and well-controlled scientific studies or tests prior to the making of such statements. While

* After the conclusion of their case counsel supporting the complaint conceded that the words in brackets should be out of the case (Tr. 811).

It should be noted that both records and T.V. sound tape are available in evidence and it is respectfully suggested to any reviewing authority that the actual tape projection rather than the foregoing quotations be observed in order that proper inferences may be drawn (see Tr. 211-212).

the hearing examiner does not consider himself bound in any way by the expert testimony of Dr. Joseph G. Smith, a psychologist called by respondent, Dr. Smith's analysis (see Tr. 752 *et seq.*) was both lucid and convincing on the issue of the lack of implication from the advertising matter that "adequate and well-controlled scientific tests" had been conducted prior to issuance of the advertising material (Tr. 729-798, particularly 752-762, 795-796, 797-798). Moreover, quite apart from Dr. Smith's testimony, the hearing examiner perceived no such representations or implications from the advertising materials either viewed one by one or considered as a whole. In addition Mr. Ross the (CX 1-13) president of the Leeming Division of Pfizer said he had reviewed consumer reaction and there was none to that effect (Tr. 615-617; see RPF III). The most the advertising implied was that the product could work as represented.

Development of Un-Burn

7. As described by Henry L. Ross, Jr., president of the Leeming Division of Pfizer, the concept of the product Un-Burn was first presented to Pfizer by an advertising agency in the form of a package with a design and the name "Un-Burn" (Tr. 597). Thereafter, a decision was made to develop a product in the sunburn remedy field that would use the name and design suggested (Tr. 598). The company took a careful look at the products on the market in that category and particularly the product Solarcaine (Tr. 599). The company decided to go ahead because a profitable product seemed feasible and it would fulfill a need for a product to be sold principally during the summer which was a slack season for Pfizer (Tr. 599). Mr. Ross approved the use of the topical anesthetics benzocaine and menthol after receiving assurances from the medical people that the advertising claims could be supported by these two active ingredients at the level selected to put into the product (which was patterned closely after Solarcaine the market leader (Tr. 600)), and that all available literature had been thoroughly reviewed and favorable conclusions had been reached on their efficacy as a topical anesthetic (Tr. 600-601).

8. The parties have stipulated that if appropriate named individuals were called from named competing companies they would testify that the following products containing benzocaine had been on the market since the date set opposite the name and that the product was recommended for the treatment also set opposite the name.

Name	Date on market	Recommended for
Burtone.....	1955	Minor burns and sunburn.
Solarcaine.....	1949	Sunburn, other minor burns and other ailments.
Derma Medicone Ointment.....	1948	Not stated.
Burn-A-Lay.....	1935	Burn treatment.
Morusan.....	1946	Temporary relief of discomfort due to minor burns.
Americaine.....	1948	Relief of sunburn, other burns, cuts and scratches.

(Stipulation 2/10/71; Tr. 1136-1138; RPF 2.8.)

9. James W. Jenkins, vice president in charge of the research and development sections of Pfizer-Leeming/Pacquin Divisions, (Tr. 647) testified concerning the formulation of the product Un-Burn by his division and the extent of research and testing done (Tr. 644-727). One of the first things done was to make a drugstore survey of the products already on the market (Tr. 648). These included: Dermoplast, Surfacaine, Pontocaine, Mediquik, Bactine, Lanacane, Campho Phenique, Johnson and Johnson First Aid Spray, Johnson and Johnson First Aid Cream, Safeguard, Solarcaine Spray, Solarcaine Lotion, Unguentine Spray, Unguentine Ointment and Nupercainal (Tr. 649; RPF 2.9). He found that benzocaine and menthol were prominently used in these products and that the marketing people regarded Solarcaine as the market leader (Tr. 649). Initially Pfizer had contemplated producing a "cosmetically elegant" product to compete with Johnson's First Aid Cream and Noxzema. This contained benzol alcohol and menthol as active ingredients for the anesthetic effect (Tr. 650). A cream using these ingredients was developed in the spring of 1966 and tested in a very small test on the beach that summer (Tr. 651). In the fall of 1966, however, the marketing group determined that an aerosol caine product should be produced with benzocaine and menthol as the active ingredients (Tr. 651). These active ingredients were later incorporated in the cream and in a lotion so that by the time in the summer of 1969 that the product was distributed nationally, benzocaine and menthol were the active ingredients in all Un-Burn products (Tr. 653). Benzocaine was selected because of the drugstore survey and because of a literature search that "told us that it was an effective and safe and esthetic ingredient to be used in this type of product." Further it was discussed with Dr. Carlozzi of the Pfizer medical staff (Tr. 652). Menthol, also used, was chosen because it was reported in medical literature as a local anesthetic and antipruritic (a product to stop itching (Tr. 652)).

Tests Conducted on Un-Burn Prior to Marketing

10. Marketing tests to determine acceptability by consumers were made in 1967, in the fall of 1968, and in the winter of 1968-69 in Florida (Tr. 653-654). In addition under Dr. Jenkins' supervision considerable safety testing was done on animals, a prophetic patch test was done on humans and there was testing with human serum of the antiseptic qualities of the product. A test was also conducted by injecting guinea pigs to determine whether any ingredient of the Un-Burn base interfered with the anesthetic action of the benzocaine (Tr. 655; CX 16-67.) Tests were conducted on the formulations leading up to the final product as well as on the final formulation (Tr. 656). Those on the final formulation included: a report on tests by an independent laboratory as to the anti-bacterial effectiveness of the lotion, aerosol and cream with human serum (Tr. 651-659; CX 48, 51, 61); two reports of guinea pig wheal tests on the aerosol and lotion (Tr. 657; CX 40, 50); three skin irritation tests on rabbits for the lotion, aerosol and cream (CX 52, 53, 67; Tr. 662-663); Draize Eye irritation tests conducted on rabbits with the aerosol (CX 54), the lotion (CX 55) and the cream (CX 66; Tr. 657); and prophetic patch tests on 100 human subjects to determine whether the ingredients were capable of producing primary irritation or sensitivity of the skin (CX 56; Tr. 657, 666-667). After describing the tests Dr. Jenkins (Tr. 659-667) testified that in his opinion they were adequate and well-controlled scientific tests demonstrating that there was no safety hazard in the use of the product and that it would support the claim of antibacterial activity (Tr. 668; RPF 4.8). With respect to the efficacy of the ingredients benzocaine and menthol, Dr. Jenkins said he caused a survey to be made of the Pfizer library on references to benzocaine and menthol, that he reviewed the literature surveyed, discussed the matter with the medical director of Pfizer, and reached the conclusion that the tests made and historical information reviewed establish the safety and efficacy of the product (Tr. 672-673). Dr. Michael Carlozzi, the medical director of Pfizer, corroborated Dr. Jenkins and expressed the opinion that the literature reviewed and the clinical experience of the medical profession justified Pfizer's reliance upon such sources for the efficacy of benzocaine and menthol rather than conducting unnecessary efficacy tests (Tr. 1097-1099, 1125-1126). He also pointed out that as part of the guidelines for panels on drug efficacy (RX 110; Tr. 1106-1108) the experience and informed judgment of the members of the panel were part of the criteria to be considered (Tr. 1108-1109, 1119-1122).

Government Criticism of Adequacy of Pfizer Tests

11. Counsel supporting the complaint as part of their case offered all of the tests performed by Pfizer (CX 16-69) and also the advertising and labeling used (CX 1-16). Then they attacked the adequacy of the testing for efficacy by calling their 4 expert witnesses.

12. The first Commission witness, Dr. Harry M. Robinson, Jr. (Tr. 223-285) is a practicing physician in Baltimore and a professor of dermatology with thirty years experience in the field.⁵ He is also an expert in testing drugs and evaluating tests (Tr. 225, 238). He had not however done specialized research in the field of topical anesthetics or sunburn (Tr. 230) and had done no adequate and well-controlled scientific studies on benzocaine or menthol or any other sunburn preparation (Tr. 236).

13. Over objection by counsel for respondent Dr. Robinson testified that he had examined the tests done by Pfizer (CX 16 thru 68) and that in his opinion the tests conducted were not adequate to prove that: Un-Burn anesthetizes nerves in sensitive sunburned skin; relieves sunburn fast; stops sunburn pain; is a comprehensive treatment for sunburn; is an anesthetic when used on sunburned skin; is so effective in relieving sunburn pain that persons with sensitive skin such as a fair-skinned blonde girl need not fear or worry about being exposed to the sun (Tr. 240-241).

14. Dr. Robinson was then asked (Tr. 241-270) concerning each of the tests (CX 16-68) made by respondent (despite the objection that some were on earlier formulations (Tr. 242-245)). As to each, he responded that they were not adequate to establish that Un-Burn anesthetized nerves in sensitive sunburned skin but (except for the consumer research study (CX 68)) were all safety tests. The consumer research study was not adequate because it was not controlled (Tr. 269-270). As clarified on cross examination the tests were of five types: skin irritation, eye irritation, antibacterial, prophetic patch and guinea pig wheal tests (Tr. 271). They were largely safety tests to determine whether the product to be marketed is safe (Tr. 273) and the testing done was sound (Tr. 273) and adequate for the purpose of showing that there was no hypersensitivity produced in humans, and no eye irritation or skin irritation in animals (Tr. 271-278). One type of test to determine anesthesia in animals was inadequate because not topically applied but injected (Tr. 250, 255, 259, 265-266). Another type of test having to do with consumer reaction (Tr. 269) Dr. Robinson dismissed as inadequate because pain is subjective and mere yes and no answer was insufficient to determine the anesthetic quality of

⁵ His *curriculum vitae* was received as Exhibit 70 (Tr. 223).

anything (Tr. 269-270). He suggested a polygraph test might be required (Tr. 270) but on cross examination he stated he had never seen a polygraph used on tests regarding sunburn (Tr. 279). He also indicated that a single blind study was worthless (Tr. 280).

15. On the basis of Dr. Robinson's testimony and before the next witness took the stand, the parties stipulated (Tr. 288) that the witness's testimony would be that the tests described in the following exhibits were not designed to prove that Un-Burn anesthetizes nerves or relieves the pain of sunburn (CX 16-23, 25-38, 41-49, 51-56, 59-69, all numbers being inclusive) and that accordingly these exhibits did not establish those facts.⁶ Identical stipulations were made as to the other two witnesses called by counsel supporting the complaint (Tr. 318, 501).⁷

16. The second Commission witness, Dr. John Adriani, (Tr. 289-313) is a specialist in surgery, anesthesiology, and pharmacology. He is chief of the anesthesia services of Charity Hospital in New Orleans, Louisiana, and is also professor in both Tulane University School of Medicine and Louisiana State School of Medicine (Tr. 290-291). He was for four years Chairman of the Advisory Committee of the United States Food and Drug Administration on Anesthetics and Respiratory Drugs (Tr. 292) and was also a member of the Committee of the Secretary of the United States Department of Health, Education and Welfare on the Evaluation of the Task Force Report on Prescription Drugs (Tr. 292-293). He does laboratory testing in the pharmacology department laboratory at Louisiana State University and performs clinical pharmacology testing at Charity Hospital (Tr. 291). He acts as consultant to the Food and Drug Administration's Bureau of Medicine. And, he has done extensive editing and publication of medical journal articles and texts (Tr. 294).⁸ Dr. Adriani has been testing drugs including local anesthetics for some 35 years (Tr. 296).

17. Dr. Adriani said he was familiar with the ingredients in Un-Burn and that he had tested products which had some or all of such ingredients (Tr. 295-298). He said animal tests would have to be followed by tests on humans because animal studies in relief of sunburn were not adequate (Tr. 298). He stated he had examined Commission Exhibits 24, 39, 40, 50, 57 and 58 (Tr. 300, 301). He was shown the T.V. program CX 4 (Tr. 303-304) via projector equipped with sound and

⁶ At Tr. 288 line 18, the numbers CX 25-38 are omitted but they were inserted the following day by stipulation (Tr. 318).

⁷ By direction and in the interests of expedition the transcript of January 26, 1971, starts with p. 500 rather than 375 because the last page number was not available to the reporter at Miami.

⁸ His complete *curriculum vitae* is marked CX 71.

testified that the testing "positively" did not support the claims in the advertising (Tr. 308) because the product was sprayed on the subject in the movie and injected in the tests (Tr. 308) and that the injection has no "correlation at all" with the topical (sprayed on) application (Tr. 310). He then testified as to each test that it did not substantiate the claims (Tr. 311-312). Moreover, none was reasonably designed to prove and did not prove that Un-Burn when used topically will anesthetize nerves in sunburned skin or relieve sunburn pain (Tr. 312). There was no cross examination (Tr. 313).

18. The Commission's third witness was Dr. William Thomas Beaver (Tr. 318-373). Dr. Beaver is a Clinical Pharmacologist, and as such specializes in the effects of drugs in living systems (Tr. 319). He is also a Doctor of Medicine and is Associate Professor in Georgetown University where he teaches medical students and staff and does research. His major area of interest is pain-relieving drugs and the design of experiments demonstrating the efficacy of drugs in man (Tr. 320).⁹ From 1963 to 1967 he was a research associate at Sloan-Kettering Institute for Cancer Research and was almost exclusively involved in doing drug studies in analgesics. He was also a member of the National Academy of Science, National Research Council panel on relief of pain, drug efficacy study (Tr. 320) which was one of those engaged in the review of drugs for efficacy under the auspices of the Food and Drug Administration (Tr. 320-323). He acts also as consultant to the Food and Drug Administration (Tr. 324) and has had experience in designing and reviewing protocols for tests (Tr. 325).

19. Dr. Beaver after reading the T.V. storyboard (CX 11) was asked concerning the tests described in CX 25, 39, 40, 50, 57, and 58. Before testifying on these he was subjected to an extensive voir dire examination attempting to determine just what standards he used in evaluating the tests *i.e.*, those of the F.D.A. or those of the dictionary definition of adequate and well-controlled (Tr. 328-341). He was guided according to his testimony by general principles accepted by the community of clinical pharmacologists that at the moment coincided with the F.D.A. principles (Tr. 330). Dr. Beaver then testified that the tests did not substantiate the claims in the advertising because: (1) the study was on animals and could not be extrapolated with any degree of confidence to human beings; (2) the study deals with interdermal injection and could have a totally different result from topical application; (3) he could not be sure of the identity of the material tested with Un-Burn (Tr. 343-345). He then described what in his opinion would be an adequate test (Tr. 351-356). This included:

⁹ Dr. Beaver's *curriculum vitae* is Exhibit 72 (Tr. 320).

(1) use of human subjects; (2) production of the sunburned condition; (3) comparison with a placebo of essentially the same formulation without the anesthetic, applied at random; (4) development of a standard for the amount of sunburn; (5) use of double blind approach so that neither the subject or the tester could identify which was the active product and which the placebo; (6) reading on the pain on stimulation or at rest over a time period; (7) adequate number of subjects; (8) calculation to determine that differences in recorded scores was not due to chance (Tr. 351-356). A motion was made to strike this testimony because it was based on the FDA standard. This was denied on the basis of a voir dire examination (Tr. 356-367). On cross examination Dr. Beaver testified that on panels of National Academy of Sciences and the National Research Council, some panels accepted the informed judgment of the panel members as to the effectiveness of drugs (Tr. 372). On the panel on which he served, the panel members insisted upon studies although in some cases they assumed the adequacy of the test reported when the documentation was not entirely clear (Tr. 369-371). A motion to strike Dr. Beaver's testimony was denied because in the hearing examiner's opinion Dr. Beaver's description of the tests required came within the dictionary definition of adequate and well-controlled (Tr. 374).

20. Dr. Harvey Blank was the final expert called by the Commission. He is a Doctor of Medicine and specializes in dermatology (Tr. 502-592). He is a professor and chairman of the department of dermatology of the University of Miami School of Medicine (Tr. 502).¹⁰ Previously he had been associate medical director of Squibb Institute of Medical Research and it was his duty to help in the development of products, to set up and evaluate tests, and to advise Squibb Pharmaceutical Company (Tr. 503-504). He is experienced in testing drugs and evaluating tests and has tested preparations recommended for sunburn pain (Tr. 505). He was chairman of the panel of the drug efficacy study of the National Research Council for the Food and Drug Administration to evaluate drugs for use on the skin (Tr. 506).

He described preliminarily the types of tests, agreed that testing on human beings was necessary because of the difference between animal skin and human skin and indicated that in skin preparations for the relief of itching, for example, many ingredients had a soothing effect and care must be taken to determine whether the active or anesthetic ingredients do more than the product without the active ingredients (Tr. 509, 510).

21. Dr. Blank then compared the claims made by the TV commercial

¹⁰ His *curriculum vitae* is marked Exhibit 73 (Tr. 503).

(CX 10) with the tests described in Commission Exhibit 24. After an extensive voir dire examination (Tr. 511-522) in which Dr. Blank indicated he utilized the FDA standard plus some other considerations in making his evaluation, he testified that the test described in CX 24 did not substantiate the TV claims because of the following principal reasons: first, the product was injected and not administered topically and second, you cannot transfer studies on a guinea pig to man without confirmation. He also said the same objections applied to the tests described in CX 24, 39, 40, 50, 57, and 58 (Tr. 522-523). With regard to the reason why there is a difference between injection and topical application Dr. Blank explained that the skin was a barrier that most agents do not penetrate in any substantial amount and therefore in testing drugs to be applied to the skin you have to know whether the product will go through the skin (Tr. 524-526).

22. On cross examination Dr. Blank refused to state whether the panel he chaired had exercised the right to rely on the experience of the panel members in approving drugs for efficacy because the panel report had not been released (Tr. 530). The hearing examiner upheld this refusal (Tr. 537, 548). The doctor said that in preliminary discussions the panel chairmen were informed they had that right to utilize previous experience rather than insisting upon adequate and well-controlled scientific tests (Tr. 535). There was also an attempt to have the report of the panel produced. The hearing examiner ruled that this must be done by motion for a subpoena to the Department of Health, Education and Welfare (Tr. 555). It was then brought out that the witness had refused to talk with counsel for respondent because he was given very short notice at an inconvenient time (Tr. 558). His folder of papers to which he referred during his direct testimony was examined by the hearing examiner and ordered produced (with the exception of one document which dealt with another company and with enzymes (Tr. 559-562)). After examining the file respondent offered a report submitted in April 1959 under the witness' administrative supervision (Tr. 563). This is marked RX 99A-K and is an unpublished report to Plough Inc., regarding the product Solarcaine with correspondence relating thereto. The University of Miami was paid a fee for the study (Tr. 568). The documents were received in evidence (Tr. 570). It was established that in 1959, Dr. Blank approved a letter and report attesting to the efficacy of Solarcaine, a Benzocaine product (RX 99F). (It will be recalled that Solarcaine was one of the products Un-Burn was developed to compete with and to emulate (Tr. 599)).

23. On redirect examination Dr. Blank indicated that he thought the results which had been obtained were from the use of an occlusive patch (Tr. 575) placed over the lotion because of lack of action without it (Tr. 573).

24. On recross, although Dr. Blank reiterated that a patch had to be used to get the anesthesia (Tr. 576), he said he did not tell Plough Inc., that they were going to have to tell people to use patches on top of the lotion when they used it (Tr. 576) and he admitted that he had written Plough that their product "had a distinct pain relief, cooling and soothing properties which relieved the discomfort of minor sunburn and other minor burns and such localized sensations as itching, tingling, and so on" (Tr. 577). He also admitted there was nothing in his letter which told Plough the product had to be applied with the aid of a patch (Tr. 577-578) and further admitted that the test he used (RX 99 A-E) was not adequate by present standards (Tr. 579). He testified, however, that the test had no relevance to Un-Burn (Tr. 580). He then testified that he and his associates had tested Un-Burn spray and cream in the past four or five months but that he had not published the result of the test or reduced it to writing in any form (Tr. 580). With regard to the Plough product (Solarcaine) he found "down [sic] at that time" that the product "containing benzocaine was effective on normal skin and produced an effect in fifteen minutes" and advised Plough "that the products worked" knowing that Plough was going to sell the product to the public (Tr. 581-582). On further redirect examination, Dr. Blank said that he and his associates had tested Un-Burn by techniques now used for anesthesia of the skin, *i.e.*, instead of pricking the skin with a needle which allowed the lotion to penetrate the skin barrier they were now using a hot beam of light to determine whether or not anesthesia is produced (Tr. 583). On tests he conducted on Un-Burn he testified "that even after one hour of application it was impossible to detect any anesthesia with Un-Burn" (Tr. 585). On recross, Dr. Blank admitted that he had known he was to testify (Tr. 585) and had told counsel supporting the complaint about the tests which had been conducted on associates (Tr. 586-587). He further admitted that the test was preliminary and that he did not consider it to be an adequate and well-controlled scientific study and test of the efficacy of Un-Burn (Tr. 588). The test was made only on three people repeated many times but "we got no effect so we didn't go on" (Tr. 589). The three subjects performed the test on themselves (Tr. 590) and there was no written protocol or written result (Tr. 591). Dr. Blank did not tell Plough Inc., at any time that he had modified his

conclusions expressed in the report sent to it (Tr. 592). Although invited to make a further statement the witness indicated that he did not feel it necessary to do so (Tr. 592).

Summary Finding on Evidence Introduced in Complaint Counsel's
Case-in-Chief

25. At the conclusion of complaint counsel's case-in-chief it had been established that respondent Pfizer Inc., had advertised, on TV and in other media with interstate coverage, that Un-Burn anesthetizes nerves in sensitive sunburned skin and relieves pain fast. It was also established *prima facie* from the testimony of the experts called that the tests conducted by Pfizer prior to marketing were not adequate to determine the efficacy of the product on human beings but merely determined its safety and its efficacy as an antibacterial agent.

There was inconclusive evidence concerning the efficacy of the product apart from the adequacy of the tests. And, evidence that on undamaged skin a topical anesthetic would not penetrate to the nerve endings.

It was conceded that the product was sold in interstate commerce and that it was in competition with other products produced by others.

Findings Relating to Respondent's Affirmative Defenses

We shall now consider the facts relating to respondent's six affirmative defenses under the following three headings: *No Recklessness or Disregard of Safety; Truth of Respondent's Advertising Claims; Propriety of Reliance on Historical and Clinical Experience.*

No Recklessness or Disregard of Safety

26. As heretofore described in Finding number 10 hereof, respondent made elaborate test on both animals and humans at all stages of the development of the product to insure that it was safe to use and would not cause undue irritation or sensitivity. Complaint counsel's first expert witness, Dr. Harry M. Robinson, Jr., made this very clear after his detailed analysis of the tests that were conducted by Pfizer Inc. (Tr. 241-278). So, there is really no contest in that regard. Respondent's officials in charge of development also testified that Pfizer had conducted tests to insure the safety of the product and described them in detail (Tr. 668). There was no proof offered that cast any doubt on the safety of the product in normal usage.

Truth of Respondent's Advertising Claims

27. Respondent bases its claim that its product Un-Burn anesthetizes nerves and stops pain fast on three types of proof: first, its review of the medical and pharmaceutical literature concerning the active ingredients benzocaine and menthol; second, the clinical experience of its experts and their knowledge of the history of the acceptability of these drugs as topical anesthetics; and, third, a test conducted after the commencement of this proceeding. We deal with each of these separately under ensuing subheadings.

Review of the Medical Literature

28. Henry L. Ross, Jr., the president of Leeming Division of Pfizer, who was director of marketing at the time of the development of Un-Burn (Tr. 597) testified that he was assured by Pfizer's medical people that the claims it planned to use could be supported by the two active ingredients at the level selected to be put into Un-Burn, which was patterned closely to Solarcaine, and he was further assured that all available literature or information on the two active ingredients had been thoroughly reviewed and favorable conclusions reached as to the efficacy of the ingredients as topical anesthetics (Tr. 600-601; see also 605). He reiterated this position on cross examination and added that they had found products which had made these same claims with the same active ingredients for many, many years (Tr. 618-620). He specifically claimed that as to active ingredients, Un-Burn was the same as Solarcaine, the leader in the field (Tr. 620). He also took the position that in the case of these well known ingredients a review of the literature was equivalent to testing and that if he put out a product containing ingredients listed in the literature it works (Tr. 629-630).

29. James W. Jenkins, a doctor of philosophy in chemistry, who was vice president of Research and Development of Pfizer's Leeming/Pacquin Divisions (Tr. 647) and responsible for quality control and testing, corroborated Mr. Ross (Tr. 652) and said he had discussed the problem with Dr. Carlozzi of the medical staff and that the literature search "told us it was an effective and safe and esthetic ingredient" (Tr. 652). Dr. Jenkins ordered a survey at the library at the Parsippany laboratory to be made, got a list of references and reviewed them himself adding an additional reference (Tr. 670). The references pertaining to benzocaine and menthol included:

Grollman, Pharmacology and Therapeutics;
The Merck Index;
Goodman and Gillman;

Remington's Practice of Pharmacy;
Journal of Pharmacology and Experimental Therapy, Harry;
Principles and Practice of Modern Cosmetics;
Greenberg & Lester "Handbook of Cosmetic Materials";
Journal of American Pharmaceutical Associates—an article;
Abbott Laboratories—Technical Bulletin on Benzocaine;
The Dispensatory of the United States of America. (Tr. 671).

As a result of the safety and other tests, his review of the literature and his discussions with Dr. Carlozzi, the medical director of Pfizer, Dr. Jenkins gave his opinion that the testing done was sufficient to establish the safety and efficacy of Un-Burn (Tr. 672-673).

On cross examination Dr. Jenkins testified that the literature examined had no test data just simple statements (Tr. 705) and admitted that he was a specialist in neither dermatology or anesthesiology (Tr. 710). He also said he had read one article (CX 96) that indicated in part that no clinical studies had been made of the relative suitability of many of the established local anesthetics for use on burns (Tr. 713) but it did not change his opinion about Un-Burn (Tr. 714).

30. Dr. Michael Carlozzi, the medical director of Pfizer (Tr. 1090-1134), a graduate of Long Island College of Medicine, obtained experience as a medical officer during World War II and has had extensive experience in the medical departments of several pharmaceutical companies (Tr. 1091).¹¹ He testified that he had advised Pfizer that Un-Burn would be effective in alleviating sunburn pain, based on the facts: that they were incorporating benzocaine and menthol agents which had been available for decades and had been in widespread use as topical anesthetic agents; that they were accepted as such by standard textbooks and by the clinical experience of the medical profession (Tr. 1097). The fact that other such products were on the market also had an influence in his decision (Tr. 1097, see also Tr. 1098). He consulted Dr. George Clinton Andrews' work on dermatology (RX 87) and several other standard textbooks (Tr. 1128).

31. Dr. William Beaver who was called by complaint counsel on rebuttal attested to the fact that the National Formulary and the U.S. Pharmacopoeia, United States Dispensatory, Goodman and Gillman, and Merck Index were standard reference works used by doctors and pharmacists (Tr. 1274-1279).

Clinical Experience of Respondent's Experts

32. Dr. Norman Orentreich who conducted a post-complaint test on Un-Burn and whose qualifications are later described, testified with re-

¹¹ His *curriculum vitae* is RX 106 (Tr. 1091).

gargard to his use of benzocaine in his personal practice (Tr. 848) and by other dermatologists (Tr. 847). He said that it had been in use as a local topical anesthetic since at least the turn of the century (Tr. 848) and that it was his opinion that it works by interfering with the conducting of impulses along the nerves or anesthetizes them (Tr. 848). He said that the opinion that benzocaine was an effective topical anesthetic was taught in medical school as early as 1948 (Tr. 850). He gave similar testimony regarding menthol (Tr. 853-854).

33. Dr. Norman Kanoff (Tr. 1037-1087), whose qualifications are also later described, testified that he used benzocaine in his practice and it was recognized as a topical local anesthetic by him and by other doctors for at least 50 years (Tr. 1043-1044). He explained what sunburn was (Tr. 1040) and its effect on the permeability of the skin (Tr. 1040-1043) and expressed the opinion that benzocaine acted on the nerve endings themselves to interfere with the conduct of nerve impulses and anesthetized them (Tr. 1043) and he would recommend it to relieve skin pain (Tr. 1044). He said he was also familiar with menthol and that it was recognized as an antipruritic and mild anesthetic and used by him and by other doctors (Tr. 1044). He admitted on cross examination that some accepted drugs had later been proved ineffectual (Tr. 1065). He also admitted he could not be certain his patients did what he recommended (Tr. 1060-1061) and that mild sunburn was self-limiting and would get better if not treated at all (Tr. 1082).

34. Dr. Robert A. Berger (Tr. 1142-1171), a specialist in dermatology;¹² has been in practice since 1959. He is assistant professor at Mount Sinai Hospital and was formerly associated with teaching at University Hospital of New York and Bellevue Hospital (Tr. 1144). He sees some 12,000 patients in private practice and another 3,000 in the hospitals (Tr. 1145). He described what sunburn is and stated his opinion that sunburned skin was damaged skin (Tr. 1146). He also said that the pain of sunburn was irritation of nerves and nerve endings in the upper layers of skin (Tr. 1147). He described benzocaine as a topical anesthetic agent used in creams, sprays and ointments and recognized as such in his speciality (Tr. 1147). It has been in use for over 50 years (Tr. 1198). He also described menthol as an antipruritic agent and also to a degree an anesthetic agent (Tr. 1148). Both benzocaine and menthol are used by doctors (Tr. 1148-1149). Dr. Berger has used benzocaine and menthol in his practice and often advised patients by telephone on first aid for sunburn to use an over-the-counter product with benzocaine (Tr. 1150). He said it was his opinion that it penetrated the skin (Tr. 1151). On cross examination Dr. Berger

¹² His curriculum vitae is Exhibit 107 (Tr. 1143).

said he had not conducted blood tests to determine whether menthol or benzocaine penetrated the skin and were present in the blood stream (Tr. 1156). Dr. Berger also admitted he did not know that patients followed his advice but thought it was reasonable to assume they did (Tr. 1158, 1159, see also 1169-1171). He agreed that there were drugs which had been used and gained acceptance which were later found to be ineffective (Tr. 1164). On redirect examination he reiterated that in his opinion there was adequate medical support for Pfizer's claims regarding Un-Burn in May 1969 (Tr. 1168-1169).

35. Dr. James W. Burks (Tr. 1174-1202), a practicing dermatologist and clinical professor of dermatology at Tulane University Medical School,¹³ testified that he saw 80-100 patients with sunburn in his office each year but that most of his sunburn practice was over the telephone (Tr. 1177, 1179). In his practice as a whole he sees some 20,000 patients a year (Tr. 1179). He said sunburned skin was damaged skin that was no longer intact and that this was caused by chemical damage to the small cells of the skin (Tr. 1177-1178).

Dr. Burks said benzocaine had been used by doctors since the 1800's and was one of the first anesthetics used by dermatologists and it is used today for the treatment of topical skin problems particularly those that itch (*i.e.*, a form of nerve irritation) (Tr. 1180). He prescribes benzocaine both for those who call at his office and those who call on the phone, particularly the latter because they can get one of the caines, Solarcaine, or Un-Burn without a prescription at 2:00 a.m. (Tr. 1181). Dr. Burks also gave a similar opinion concerning menthol and its uses as a mild anesthetic and antipruritic agent (Tr. 1181). It is also used by doctors and by Dr. Burks for relief of itching, burning, stinging or discomfort of the skin because of its cooling or anesthetic effect (Tr. 1182). In the armed forces during the doctor's experience in New Guinea in World War II, benzocaine lotion was one of the two topical remedies that the army supplied. It was of great service (Tr. 1183).

The Post-Complaint Tests and Criticism Thereof

36. Dr. James W. Jenkins, vice president of Pfizer's Leeming/Pacquiu Division, identified a test (RX 84) which was run by Dr. Orentreich in October and November 1970 (some three months after issuance of the complaint) (Tr. 674), based on a test plan or a protocol in the preparation of which he had collaborated with Dr. Orentreich (Tr. 674). Dr. Jenkins testified that in his opinion the study was both adequate and well-controlled and explained his reasons (Tr. 676). The

¹³ His *curriculum vitae* is Exhibit 104 (Tr. 1176).

product to be tested and the placebo were coded. Dr. Jenkins retained the code until after the study was completed, then caused it to be handwritten on the first page of the report (Tr. 677). The placebo was the same as the active product with the benzocaine and the menthol removed (Tr. 679). Dr. Jenkins calculated the results arithmetically and determined that taking all subjects in each case the active ingredient was more effective than the placebo (Tr. 680). In the case of particular individuals tested on the aerosol:

17 found the active more effective

1 found no difference

1 favored the placebo over the active (Tr. 680).

In the case of the lotion:

19 found the active more effective

2 favored the placebo over the active (Tr. 680).

Dr. Jenkins also calculated the results by test intervals and reached a comparable conclusion (Tr. 681). He summarized the results by saying that "Un-Burn aerosol and Un-Burn lotion proved to be effective in relief of pain from sunburn" (Tr. 682). In his cross examination, he indicated he was relying on Dr. Orentreich's experience in testing (Tr. 716) and he could not supply detailed information concerning the number of subjects or just how the tests were conducted (Tr. 716-718).

37. Dr. Norman Orentreich who was responsible for the post-complaint study on Un-Burn testified with respect to it (Tr 855 *et seq.*). Dr. Orentreich is an associate professor of Clinical Dermatology in New York University College of Medicine.¹⁴ He has been active in medical societies and has written numerous articles. He is director of the Orentreich Medical Group consisting of four qualified dermatologists. It handles some 40,000 patients a year of which he sees some 20,000. He described in technical terms what sunburn was and how it damaged the skin (Tr. 838-843). He also indicated that it diminished the barrier function of the skin (Tr. 843-847) so that it became more permeable. He stated that in his opinion benzocaine was capable of penetrating the skin and anesthetized the nerves (Tr. 848). He also stated that menthol was a standard topical antipruritic agent and had a coolant as well as a direct anesthetic action (Tr. 853).

Testifying with regard to the test identified by Dr. Jenkins, Dr. Orentreich said it had been conducted under his supervision with coded products so neither he nor any of his staff knew which were active products and which placebo (Tr. 856). The 22 subjects selected were from within the doctor's medical group with a broad spectrum of caucasian skin types who were able to discriminate and be objective

¹⁴ His *curriculum vitae* is in evidence RX 105 (Tr. 833-834).

about their subjective responses (Tr. 856-858). A tested and specially designed lamp was used to closely resemble sunlight and inflict a small area of sunburn at a constant distance. Subjects were each given the same 2-minute exposure (which had been predetermined to cause a substantial first degree sunburn on all types) on five different approximately 1 x 1 inch square areas on their backs, sufficiently separated so there was no leakage of effect from one site to another (Tr. 858-861). Four of the sunburned areas each got an application from one of the four coded products. The fifth area was left as a control (Tr. 862). Then each area was stroked from the unburned skin over the burned area and the reaction was compared with the control. There was also random cross checking. The control area was rated 4 and the response from the other areas 4 if no change. The response from treated area was rated 3 if there was mild discomfort; 2 if moderate diminution of discomfort; 1 if marked diminution of discomfort; and 0 if there was no discomfort at all (Tr. 863). This testing was done a sufficient number of times, trying to fool the individual, to get reproducible data. The data was tabulated and submitted in the report (Tr. 863). After the code was broken Dr. Orentreich said the conclusion he reached was that the active ingredients were more effective than the placebo. This verified what he already knew, that the product would be effective for sunburn discomfort (Tr. 864). In the doctor's opinion the test was an adequate and well-controlled scientific test which substantiates the claim that Un-Burn actually anesthetizes nerves in sensitive sunburned skin (Tr. 864-865).

37a. On cross examination of Dr. Orentreich it was brought out that he knew that there was a question about the advertising claim for Un-Burn and that he was to design a test to determine whether the product would stop pain and anesthetize nerves (Tr. 874). He indicated that Mr. Edwards of his organization probably submitted an outline of the technique of testing (Tr. 875); but, that he himself was involved in setting up the procedure (Tr. 876). The number of subjects was determined by Pfizer's willingness to pay (Tr. 876-879) and Dr. Orentreich assumed that was on the basis of the statistical evaluation by Pfizer (Tr. 877) because there were three series of tests (Tr. 877). Dr. Orentreich said he thought there were 15 different subjects and that some had participated in more than one series of tests (Tr. 878). He averred that neither the subjects or the testers whom he identified knew which was the placebo and which the active product though of course they knew which was aerosol and which lotion (Tr. 882). The actual tests were conducted by two nurses under Mr. Edwards supervision and the results were recorded by Miss Con-

nor (Tr. 882-883). Dr. Orentreich maintained general supervision (Tr. 883). The subjects were all female; two-thirds were nurses, others were laboratory technicians or medical secretaries; and they received extra compensation for their participation (Tr. 886). Their age range was 21-40 (Tr. 887) and about $\frac{2}{3}$ were fair and light skinned, $\frac{1}{3}$ on the dark side (Tr. 887). He also described the details of how exposure was made, how far apart the areas of exposure were, how the lamp was constructed and operated and how it had been pretested (Tr. 888-890). He described the pain produced by the lamp and the reasons for testing after a 16-hour period (Tr. 890-894). He expressly stated that the burn caused was above-minimum and a discomforting advanced first-degree burn just short of blister formation (Tr. 895-896). He explained how the products were applied or randomized (Tr. 896) and that a mask was used to insure that the aerosol spray was localized. The lotion was applied in a constant fashion (Tr. 897). He did not think the menthol and its removal caused the placebo to smell differently from the active product (Tr. 898). He testified that he was satisfied that the subjects had no preconceived notions of which product was applied to each site (Tr. 899). He indicated that the tests were made within a 16-18 hour range after the injury was inflicted and justified that time period and interval (Tr. 900-1002).¹⁵ Dr. Orentreich also described in detail how the subjects were stroked with an orange stick to cause pain and how the subjects responded and were cross checked by additional strokings (Tr. 1003-1007). He said there was no measuring instrument on the stroking and no study of each of the subject's tolerance to pain but that in his opinion the technique used was sufficiently standard to create meaningful data (Tr. 1008). The cross examination then drew attention to a number of responses by subjects where the response was slight or was the opposite of the study as a whole (Tr. 1009-1016). The doctor explained that there was an effect from the aerosol spray but that it was a fleeting effect so that an active ingredient was necessary (Tr. 1017). He said no blood samples were taken to determine whether the benzocaine was in the blood stream (Tr. 1017). He explained however, that he was of the opinion that the test established that Un-Burn anesthetized nerve ends (Tr. 1019) and gave a technical explanation of why this was so (Tr. 1020-1021). He further explained that while benzocaine did not penetrate the skin rapidly placing it on the surface has a prolonged reservoir effect (Tr. 1022). He said that the percentage of benzocaine was $\frac{1}{2}$ percent in the lotion and almost 1 percent in the spray but that

¹⁵ In the transcript the number 900-1000 was used on one page presumably for the convenience of the typists.

when the spray equilibrated with the skin surface there was a concentration of about 12 percent and 3 percent in the lotion (Tr. 1022). Dr. Orentreich explained that the placebos gave some relief because they prevented exposure to the air or had a cooling effect; but, that the study showed the active ingredients had an additional positive effect (Tr. 1024). Dr. Orentreich said he had not written an article because the test had just been done and was not done for that purpose (Tr. 1025-1026). He said he might sit down with a statistician and see if the latter thought it was statistically adequate. He did not, however, do the test for that purpose and was told it was statistically significant (Tr. 1026).

38. On redirect examination, Dr. Orentreich testified that no one knew of the identity of any of the coded products (Tr. 1027-1028); that the tests for a subjective response were recognized tests (Tr. 1028) that the placebo effect here was due in part to the properties of the base as well as to the psychological effect (Tr. 1029-1030); and, that the cost of a visit to a dermatologist to get a prescription drug was sufficiently high so that most persons with sunburn used an over-the-counter preparation (Tr. 1031-1032). Mr. Cantor, of counsel for respondent, during the re-cross examination stated that he had written the code equivalents on the face of RX 84 on December 17, 1970, and that was the first time the code was broken (Tr. 1033). The witness testified that he had not gone over the details of the test with Pfizer but that during his conference with Dr. Jenkins there were discussions on how one could design a test that would show that the active agent worked (Tr. 1034). On questions by the examiner, the witness stated that there was a single application of the medication and testing for responses after certain periods of time (Tr. 1035).

39. Dr. Norman Kanoff testified that he thought Dr. Orentreich's test established that Un-Burn relieved sunburn pain (Tr. 1055, 1084). He said, however, that he could not ascertain certain factors from the report itself (Tr. 1066-1069) but placed reliance on the test because Dr. Orentreich, who had been his colleague at New York University for 15 years, had done the testing (Tr. 1086).

40. Dr. Robert A. Berger testified that Dr. Orentreich's study indicated that benzocaine penetrated sunburned skin while in his opinion it would not penetrate normal skin (Tr. 1151).

41. Dr. James W. Burks testified that he thought the testing done by Dr. Orentreich (Exhibit 84) was adequate to substantiate that benzocaine will penetrate sunburned skin and anesthetize nerves (Tr. 1188).

42. Dr. David Salsburg, a Doctor of Philosophy from the University of Connecticut¹⁶ and an expert statistician employed by Pfizer Pharmaceuticals, testified regarding the statistical significance of Dr. Orentreich's tests (RX 84). Using an arbitrary determination of the onset of activity (Tr. 1210) and the Paired T test, he determined that there was considerably less than a five percent chance that the results found by the study were due to chance (Tr. 1214). From his calculations he reached the conclusion "in lay language—that the Orentreich study provides statistically significant evidence that the Un-Burn formulation will do better than its carrier alone, in both lotion and aerosol, in terms of speed of action, of anesthetizing effect, and duration of activity." (Tr. 1215).

43. On cross examination, Dr. Salsburg testified that he was a probabilist in that he did not believe that anything proved anything but that the study "provided strong evidence that the Un-Burn formulation does work." (Tr. 1216). He said his arbitrary selection of a point for the onset of activity was done in accordance with standard statistical procedure (Tr. 1223-1224). He also testified regarding the results shown on particular subjects. On redirect examination, Dr. Salsburg indicated that in his opinion there was a statistical probability that the observations were done in a truly random fashion (Tr. 1227). On re-cross, Dr. Salsburg stated that according to his calculations there was only a 1/2 percent chance that his conclusion was in error (Tr. 1229) and that in all probability another experienced statistician would have chosen the same figure for the onset of activity (Tr. 1230). On examination by the undersigned, Dr. Salsburg said he could not tell whether or not the subjects were an adequate sample of the entire population (Tr. 1231) but that question was seldom asked in clinical research (Tr. 1232). He said he could tell that there were a sufficient number of subjects because there were significant results (Tr. 1232). He also said that the chances of getting a result of 16 subjects finding a preference for Un-Burn by pure chance was 0.2 percent (Tr. 1234).

44. Dr. William Beaver was recalled by counsel supporting the complaint on rebuttal (Tr. 1242-1313). He testified he had formed an opinion concerning the adequacy of Dr. Orentreich's test (RX 84; Tr. 1243). On voir dire examination, it was made clear that his opinion was based on the test paper alone as he had neither read nor heard about Dr. Orentreich's testimony concerning the study (Tr. 1243-1244).

It was his opinion that he could not tell whether the study was adequate to demonstrate whether the inclusion of benzocaine in the

¹⁶ His *curriculum vitae* is Exhibit 103 (Tr. 1204-1205).

formulation enhanced the efficacy of the product because the description of the methods used was not adequate (Tr. 1246). The specific criticisms and answers which would have been found if Dr. Orentreich's and others' testimony had been considered were:

1. There was no description of the exact nature of the placebo and the active product so that he could be assured that the study was double-blind (Tr. 1247). Dr. Orentreich testified that the study was double-blind and Dr. Jenkins concerning the placebo).

2. The exact nature of the coding of the medications is not shown. Were the same containers used over and over or did each individual have his own set (Tr. 1248). (Dr. Orentreich made it clear that neither subject nor testers knew what was placebo and what active and in any event Dr. Beaver did not regard this defect as fatal (Tr. 1248).

3. The nature of the test preparation. It is not clear whether it produced a condition comparable to naturally occurring sunburn (Tr. 1249). (Dr. Orentreich testified that they had pretested the lamp and that the burn given was just under 2nd degree).

4. How were the test squares laid out (Tr. 1249). (Dr. Orentreich testified in detail concerning this).

5. How were the test medications assigned to various areas. Were they truly on random fashion (Tr. 1249). (Dr. Orentreich testified as to this and Dr. Salsburg testified that the results indicated statistically that the application was made in a random fashion).

6. How were the test areas compared against the control area and what were the criteria for response (Tr. 1250). (Dr. Orentreich testified with respect to this at some length).

7. There was no statistical analysis (Tr. 1251). (Both Dr. Salsburg and Dr. Jenkins testified with respect to the statistical results).

8. There was no description of how the measured effect was elicited (Tr. 1251). (Dr. Orentreich covered this thoroughly on both direct and cross examination).

45. In light of the fact that the criticisms made of Dr. Orentreich's study were all covered by the latter's testimony or other testimony introduced in the case, Dr. Beaver's testimony based solely on the test paper itself simply did not rebut the other testimony concerning the adequacy of the test. Accordingly, Dr. Orentreich's test must be regarded as adequate to establish that Un-Burn anesthetizes nerves in sunburned skin and relieves sunburn pain.

Propriety of Reliance on Historical Data and Clinical Experience

46. In regard to the drug efficacy studies conducted for the Food and Drug Administration, expert witnesses for both counsel support-

ing the complaint and counsel for respondent were in agreement that the judgment of the physicians on the panel could be considered in evaluating the efficacy of drugs (Dr. Carlozzi—Tr. 1101-1108; RX 110; Dr. Blank—Tr. 532-534; Dr. Beaver—Tr. 371-372, Tr. 1281).

47. Dr. Norman Orentreich, who had conducted the post-complaint test (CX 84), expressed the opinion that it was reasonable for Pfizer to make the claim that Un-Burn anesthetizes nerves in sensitive sun-burned skin on the basis of the safety and other tests it had conducted and on the state of medical learning as of May 1969 (Tr. 866). Among the reasons given were that "benzocaine has for seventy years, at least, been considered an effective topical anesthetic. I think that for a time students were taught it was the only effective topical anesthetic" (Tr. 867). He then analyzed the testing done and stated "you had every reason to believe that it was reasonable that you had a safe and effective preparation" (Tr. 867-868).

48. Dr. Norman Kanoff, who had conducted the prophetic patch test (CX 56; Tr. 1045) which is one of the safety tests relied on by respondent, is a specialist in dermatology, a graduate of Georgetown School of Medicine and an associate professor of dermatology at New York University¹⁷ and director of Dermatology in New York Polyclinic Hospital (Tr. 1037-1039). He stated that the test he conducted was adequate and well-controlled and described how it was conducted (Tr. 1045) and that the other tests conducted (CX 40, 48, 50, 51, 52, 53, 54, 55, 56, 65, 66 and 67) were adequate for the purpose for which they were conducted (Tr. 1045) and that based on the tests and the state of medical learning in May 1969, it was reasonable for Pfizer Inc., to make the claims it did in its advertising (Tr. 1047-1049). One of the reasons was there was "generally accepted medical knowledge concerning the active ingredients" (Tr. 1049). He also testified that the clinical experience of practitioners is the ultimate test (Tr. 1049).

49. After reviewing the tests made by Pfizer, Dr. Robert A. Berger expressed the opinion that it was not necessary to run efficacy tests to make the claims made by Pfizer because the tests made showed safety, lack of irritation and sensitivity to allergic reaction and because the active ingredients have been in existence for many years, are present in many competitive formulations, and there is reference to them in the literature and much clinical experience as to their efficacy (Tr. 1153). He said that clinical experience in his opinion was what counted because the goal is to achieve a clinical result (Tr. 1154).

50. Dr. James W. Burks testified that the tests made by the Pfizer Company were adequate for the purpose for which they were con-

¹⁷ His *curriculum vitae* was received as RX 108 (Tr. 1037).

ducted (Tr. 1182) and that in his opinion based on a review of the tests and the state of medical learning in May of 1969 it was reasonable for Pfizer to claim that Un-Burn would anesthetize nerves in sensitive sunburned skin (Tr. 1183-1184). He said that he thought the tests were enough, if not more than enough, to establish the safety and lack of complications (Tr. 1084). He said he believed that clinical experience was the final test of the value of a drug and that investigative findings were purely supportive (Tr. 1185). He said in the case of these topical anesthetics the doctors and the patients know they work (Tr. 1185).

On cross examination Dr. Burks said he based his opinion on the state of medical learning on the first training he had and on the books he had studied. Benzocaine was listed as one of the most useful anesthetics of the skin (Tr. 1190). He also reiterated that if a drug was used for 50 to 70 or 100 years and was not found to be dangerous but highly effective it would make it unnecessary to do any investigative work (Tr. 1193). He also acknowledged the placebo effect (Tr. 1194) and said it gave relief in "direct proportion to the enthusiasm of the one that gives it" (Tr. 1194). If you believe in the product you are prescribing it rubs off on the patient (Tr. 1195). While acknowledging he could not control the patient he assumes that when he tells a patient at 2:00 a.m. to get a certain preparation that indicates the patient gets it, puts it on and if he doesn't call back the doctor assumes the product worked (Tr. 1197). He also distinguished between the topical anesthetic benzocaine which was useful to ease reliably mild discomfort in sunburn and an anesthetic to prevent any feeling in an operation (Tr. 1199). With regard to the concentration, 1 or 2 percent is effective to permit the patient to get enough dulling effect to be able to sleep (Tr. 1200-1201).

51. Dr. William Beaver was recalled by counsel supporting the complaint on rebuttal and was asked concerning the efficacy of clinical experience. He testified that clinical experience alone in his opinion was not medically acceptable evidence of a drug's ability to stop sunburn pain unless the medication dramatically, immediately and invariably stopped the pain (Tr. 1258). Having previously testified that he could not tell from reading the responses whether they were dramatic enough or not he was not permitted to testify whether or not the responses were sufficiently dramatic in the case of Un-Burn (Tr. 1264-1266).

Summary Finding on Respondent's Defenses

52. At the conclusion of respondent's case it was established that:

a. There was no implication from the advertising that adequate and well-controlled tests had been made.

b. Sunburned skin is not undamaged skin and has greater permeability than undamaged skin.

c. Recognized medical literature and the medical practice of dermatologists for between 50 and 70 years regarded the active ingredients in Un-Burn as efficacious for the relief of sunburn pain.

d. It was reasonable for respondent to rely on such clinical experience and medical literature for the efficacy of Un-Burn without making adequate and well-controlled scientific tests to determine its efficacy, since there had been adequate and well-controlled scientific tests to determine its safety.

e. Following the issuance of the complaint, respondent caused a test to be made by Dr. Orentreich's organization that conforms to the requirements for adequate and well-controlled testing. This test showed that it was much more probable than not that Un-Burn was more effective than its base materials in relieving sunburn pain.

Summary Finding on Complaint Counsel's Rebuttal

53. The testimony offered on rebuttal was inadequate to counter the proof offered by respondent.

REASONS FOR DECISION

As pointed out in the order declining to dismiss the complaint or to certify the question to the Federal Trade Commission,¹⁸ it is very clear that the Commission not only possesses the authority to determine what facts constitute an unfair trade practice but that it is its duty to maintain a vigilant watch over commerce to prevent new types of corrosive practices that impede fair competition.

Accordingly, nothing in this decision denigrates the Commission's power to declare that it is an unfair trade practice for a pharmaceutical company to advertise that its product has a particular effect unless the company has made certain by a reasonable¹⁹ investigation made prior to the issuance of the advertising that such an effect can reasonably be expected to be produced.

Unlike the usual case of false advertising, there is no charge here that the claims made in the advertising are not wholly accurate. The

¹⁸ Order dated September 21, 1970. See particularly p. 3 citing *FTC v. Brown Shoe Company*, 384 U.S. 316, 321 (1966) and *FTC v. Tezaco*, 393 U.S. 223, 225 (1968).

¹⁹ See order of September 21, 1970, p. 2, 3 and the cases there cited.

charge is: (1) that the advertisement implies that adequate and well-controlled scientific tests were made prior to the advertising and (2) that it is an unfair practice to advertise the product without having made adequate and well-controlled scientific tests as to its efficacy.

Having viewed the T.V. presentation with a projector and listened to the simultaneous sound recording device several times, as well as having studied the texts in evidence, the hearing examiner failed to observe anything that would reasonably ²⁰ imply that prior adequate and well-controlled scientific tests were conducted to determine the effectiveness of the product Un-Burn as charged in the complaint. Dr. Smith, the expert called by the respondent, reinforced the hearing examiner's judgment by a careful and logical analysis. There was no rebuttal evidence offered. We now consider the second charge that it is an unfair practice to advertise a product like Un-Burn unless prior to the advertising, adequate and well-controlled scientific tests were conducted to determine the product's efficacy to anesthetize nerves and stop sunburn pain.

In the opinion of the undersigned, the practice in this instance should not be held to be an unfair practice because the active ingredients of Un-Burn, benzocaine and menthol, have for a great many years been recognized as effective topical local anesthetics in medical and pharmaceutical literature and have been in continuous use by doctors specializing in dermatology for the topical relief of sunburn pain for many years. There was no reckless disregard of the safety of the users, because carefully controlled tests were made first on animals and then on humans to determine that the product was safe, non-irritating and non-sensitizing. It was also established by an animal test that the base into which the active ingredients were compounded did not inhibit the anesthetic effect of the active ingredients.

Clearly, no prior adequate and well-controlled scientific test was made on human beings to determine whether the product was efficacious in human beings. Thus, the allegations of the complaint in this regard were established. And, if it were not for the fact that for between 50 and 70 years the medical profession and particularly those doctors who specialized in dermatology had been successfully using the active ingredients in Un-Burn, benzocaine and menthol, to relieve sunburn pain, clearly an order should properly be issued because to advertise an untried remedy without adequate testing would be as the Commission charged an unfair trade practice.

However, to take the position that a particular type of test must be made, wholly disregards the value of the clinical experience of a

²⁰ The implication clearly must be within the bounds of reason, *FTC v. Colgate-Palmolive Co., et al.*, 380 U.S. 374 (1965).

number of experts in the dermatology field of medicine such as those called by respondent. Moreover, such a position would appear to repudiate clinical experience entirely and to insist that laboratory testing be substituted in all instances where advertising is involved. This would submerge the art of medicine in a sea of laboratory tests. There was no dispute that the ingredients were used by doctors for the purpose claimed. Accordingly, it does not seem reasonable to suppose that the Federal Trade Commission would deliberately take a position disregarding clinical experience particularly since that position would be contrary to the position taken by the Food and Drug Administration in the adequacy testing of drugs (See RX 110). It would seem, therefore, that the Federal Trade Commission under its announced policies would defer to the agency that is specifically charged by Congress with determining the adequacy and safety of drug products.²¹ We assume that knowledge of the clinical use of the product by dermatologists was not brought to the attention of the Commission at the time of the issuance of this complaint.

Of the utmost significance is the fact also that the evidence introduced demonstrated that the product is in all probability quite effective to relieve sunburn pain. So, it would be an exercise in futility to prevent claims being made without proof when now such proof has been made.

Only one doctor called by counsel supporting the complaint claimed that on test (which was concededly preliminary), he found Un-Burn ineffective. The same doctor some years before (using a method of testing which he now criticizes) had told one of respondent's principal competitors in this field that its product Solarcaine was effective. He has not withdrawn such advice. Respondent's product was designed to emulate Solarcaine and used much the same ingredients.

After the complaint was issued by the Commission, moreover, respondent caused a test to be conducted that in the opinion of the undersigned was adequate to establish that the product was probably effective to relieve sunburn pain by anesthetizing nerves. The only criticism of the test completely disregarded the testimony given by the doctor who had conducted the test and by the statistician who attested to its statistical validity. The criticism was founded solely on the text of the unpublished report.

On the basis of the evidence as a whole, therefore, particularly the evidence of clinical use which presumably was not before the Com-

²¹ It will be recalled that in the matter of *National Association of Women's and Children's Apparel Salesmen*, Docket 8691 [76 F.T.C. 1082], the Commission deferred to the decision of NLRB under similar conditions.

Initial Decision

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mission when it issued the complaint, and on the basis of the post-complaint testing we are of the opinion that the public interest would not be served by the entry of a cease and desist order in this case.

CONCLUSIONS

1. The Commission has jurisdiction over the person of respondent and over the subject matter of this proceeding.
2. The evidence failed to establish that the advertising reasonably implied that adequate and well-controlled scientific tests had been made prior to the issuance of the advertising.
3. The evidence failed to establish that the product was not effective to produce relief from sunburn pain.
4. While the evidence established that no adequate and well-controlled scientific tests were conducted to determine the efficacy of the product prior to the issuance of the advertising, the medical literature and well-recognized clinical experience demonstrated that the ingredients in the product had been considered efficacious by specialists in the field of dermatology for between 50 and 70 years and it was reasonable for the respondent in those special circumstances to make claims based on such historical and clinical proof and to test only for safety. The safety tests were adequate and well-controlled.
5. It would thus in the opinion of the hearing examiner not be in the public interest under the peculiar facts established in this proceeding, particularly those developed after the complaint was filed, to issue a cease and desist order.
6. The following order should be issued.

ORDER

It is ordered, That the complaint herein be and the same is hereby dismissed.

OPINION OF THE COMMISSION

By KIRKPATRICK, *Commissioner*:

I THE PROCEEDINGS

On July 15, 1970, the Federal Trade Commission issued its complaint alleging that Pfizer, Inc., had violated Section 5 of the Federal Trade Commission Act. Respondent Pfizer contested the allegations of this complaint and the matter was assigned to a hearing examiner for a hearing. The hearing examiner decided that the Commission's staff counsel had failed to establish that an order to cease and desist

should issue. Counsel supporting the complaint have appealed the examiner's decision to the Commission. Upon consideration of the record of the proceedings before the hearing examiner, the examiner's initial decision, and the briefs and arguments of the parties, the Commission has decided that the decision of the hearing examiner should be affirmed.

II THE COMPLAINT

The Commission's staff counsel, who have the burden of proving the allegations of the complaint, challenge certain advertising by Pfizer for the product "UN-BURN," a nonprescription product recommended for use on minor burns and sunburn. The complaint cited the following radio and television advertising for Un-Burn as typical and representative:

New Un-Burn actually anesthetizes *nerves* in sensitive sunburned skin.

Un-Burn relieves pain *fast*. Actually *anesthetizes nerves* in sensitive sunburned skin.

Sensitive skin * * * Sunburned skin is sensitive skin * * * Sensitive sunburned skin needs * * * UN-BURN. New UN-BURN contains the same local anesthetic doctors often use * * * Actually anesthetizes nerves in sensitive sunburned skin. I'll tell you what I like about UN-BURN. It's the best friend a blonde ever had! * * * I'm a blonde * * * and I know what it means to have sensitive skin. Why I'm half afraid of moon burn! That's why I'm mad about UN-BURN. It stops sunburn pain in * * * less time than it takes me to slip out of my bikini. That's awfully nice to know when you're the sensitive type * * *¹

The complaint alleges that the foregoing advertising claims were not substantiated by Pfizer by "adequate and well-controlled scientific studies or tests prior to the making of such statements."

Based on these facts, complaint counsel set forth charges alleging two separate and distinct violations of Section 5 of the Federal Trade Commission Act—first, a charge of unlawful deception, and second, a charge of unlawful unfairness. The deception charge alleged that Pfizer's advertising constituted a *deceptive practice* in representing to consumers that "each of the statements respecting the pain-relieving properties of the said product has been substantiated by respondent by adequate and well-controlled scientific studies or tests prior to the making of such statements." The unfairness charge rests upon the proposition that it is an *unfair practice* to make advertising claims of this nature lacking adequate and well-controlled studies or tests.

¹ As recommended by the hearing examiner in his initial decision, during the oral argument before it the Commission observed the TV commercials being challenged, and listened to the radio tapes. (See I.D., pp. 6-7 [p. 30 herein]. CX 4, 5, 6, 7.) These advertisements for Un-Burn contain two primary representations: (1) Un-Burn will actually anesthetize nerves in sunburned skin; (2) Un-Burn will stop sunburn pain fast.

III. DECEPTION

Section 5 of the Federal Trade Commission Act provides that deceptive acts or practices in commerce are unlawful. In Section 5 advertising cases, the requisite "acts or practices" have usually taken one of three forms: (1) advertising containing direct representations; (2) advertising containing representations which reasonably may be said to be implied by the advertising, or (3) advertising which fails to disclose material facts. The Commission may utilize its accumulated "expertise" in analyzing the facts of each case to determine what direct and implied representations are contained in advertising.² Its expertise is also utilized in evaluating what facts are material to consumers, and thereby to determine the situations in which material facts have not been disclosed. A sufficient showing of deception is made if there exists a "capacity to deceive."³ In evaluating the capacity of an advertisement to deceive, the net impression of the advertisement, evaluated from the perspective of the audience to whom the advertising is directed, is controlling.

It is against the foregoing regulatory framework that the deception charge in this case must be viewed.

While there were many direct representations contained in the Un-Burn advertising, they are not being challenged. Thus, unlike most deceptive advertising cases, the truth or falsity, or deceptiveness, of advertising claims such as "New Un-Burn," or "actually anesthetizes nerves," or "relieves pain fast" is *not* an issue in this proceeding. The complaint does charge, however, that respondent's advertising, both directly and by implication, represented that each of the statements respecting the pain-relieving properties of Un-Burn *has been substantiated* by respondent by adequate and well-controlled scientific studies or tests *prior* to the making of such statements.

Complaint counsel have not undertaken to prove explicit deception, but rather are relying solely upon the Commission's expertise to find that the implied representation is reasonably contained in the advertising, and that it has the capacity to deceive consumers.⁴ Complaint

² *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374 (1965).

³ See Gellhorn, *Proof of Consumer Deception Before the Federal Trade Commission*, 17 Kansas L. Rev. 559 (1969).

⁴ (O.A. Tr. p. 4). Complaint counsel frame their argument in the following terms:

"[I]t is obvious that (1) because respondent's advertising clearly represented that Un-Burn is a drug that will stop sunburn pain fast (Tr. 779), (2) because the public believes that an advertiser cannot make false claims about his product (Tr. 774, 776, 778), (3) because the public expects a product to work (Tr. 778, 779), and (4) because the public expects a manufacturer to have evidence that his product will work as claimed (Tr. 778, 779, 780, 781), respondent did in fact represent in its advertising that each of the statements respecting the pain relieving properties claimed for Un-Burn had been substantiated by respondent with adequate and reliable evidence and that this evidence was obtained prior to the making of such statements." (Complaint counsel's appeal brief, pp. 5 & 6.)

counsel argue that Un-Burn's advertising *implied* that—each statement in advertising—respecting pain-relieving properties—has been substantiated—by respondent—by adequate—and well-controlled—scientific tests—or studies—conducted *prior* to the making of such statements. Thus, we are urged, for example, to make the following distinctions: (1) between “pain-relieving properties,” and other claims of product efficacy, content, speed and method of operation; (2) between substantiation “by respondent,” and substantiation which may have been “by” someone else (competitors, doctors, consumers, independent laboratories, etc.); (3) between a very precise type of substantiation (“adequate and well-controlled scientific studies or tests”), and other possible standards of substantiation (*e.g.*, adequate substantiation, usual and customary steps, reasonable basis, reliable, comprehensive, etc.); (4) between “scientific studies or tests” and other possible bases for substantiation, such as medical literature, clinical experience, consumer experience; and (5) between “prior” testing and a reasonable basis for belief, or subsequent tests.

Complaint counsel argue that respondent's advertising represented to consumers that Un-Burn is a drug which actually anesthetizes nerves in sensitive sunburned skin, and which will provide fast and total relief of sunburn pain. Complaint counsel cite the phrase “anesthetizes nerves fast” and the advertising references to doctors as statements which consumers will associate with scientific proof of the product's efficacy and as implying medical approbation of Un-Burn. In response, respondent argues that the total setting of the ad, the frivolous nature of the dialogue, the use of a bikinied model, and the general “aura of sexiness” prevent the ad, taken as a whole, from carrying the scientific overtones argued by complaint counsel.

Complaint counsel's sixth proposed finding of fact would hold that respondent represented by implication that the statements that Un-Burn anesthetizes nerves in sensitive skin and stops sunburn pain fast have been substantiated by respondent by “adequate evidence” prior to the making of such statements. Complaint counsel's seventh proposed finding of fact, on the other hand, goes further. It is there argued that by representing that they had “adequate evidence” to substantiate their advertising claims, respondent thereby impliedly represented that they possessed adequate and well-controlled scientific studies or tests which substantiated such claims. The Commission does not believe that such an implied representation can reasonably be found in respondent's advertising.

IV. UNFAIRNESS

The Commission's jurisdiction to proscribe "unfair" commercial practices has been utilized frequently as an independent basis for Commission action.⁵ Most often the term is coupled, perhaps in an effort to add direction and content, either to the deceptive or to the restrictive aspects of the practice in question.⁶ The Commission, of course, has been delegated the power by Congress to give definition and content to the term "unfair practices."⁷ The 1938 Wheeler-Lea Amendment made it clear that this jurisdiction extends to the protection of consumers:

* * * this amendment makes the consumer, who may be injured by an unfair trade practice, of equal concern, before the law, with the merchant or manufacturer injured by the unfair methods of a dishonest competitor.⁸

The Commission's responsibilities with regard to unfair trade practices were analyzed in its 1969 *All-State Industries* opinion:⁹

[T]he responsibility of the Commission in this respect is a dynamic one: it is charged not only with preventing well-understood, clearly defined, unlawful conduct but with utilizing its broad powers of investigation and its accumulated knowledge and experience in the field of trade regulation to investigate, identify, and define those practices which should be forbidden as unfair because contrary to the public policy declared in the Act. The Commission, in short, is expected to proceed not only against practices forbidden by statute or common law, but also against practices not previously considered unlawful, and thus to create a new body of law—a law of unfair trade practices adapted to the diverse and changing needs of a complex and evolving competitive system.

The recent *S & H* case sets forth a succinct confirmation of the Commission's jurisdiction over unfair practices:

[T]he Federal Trade Commission does not arrogate excessive power to itself if, in measuring a practice against the elusive, but congressionally mandated standard of fairness, it, like a court of equity, considers public values beyond simply those enshrined in the letter or encompassed in the spirit of the antitrust laws.¹⁰

⁵ Cf. *All-State Industries, et al.*, Docket No. 8738 (April 1, 1969), 423 F.2d 423 (1970), cert. denied, 400 U.S. 828 (1970); *FTC v. R. F. Keppel & Bros., Inc.*, 291 U.S. 304 (1934); *Wolf v. FTC*, 135 F.2d 564 (7th Cir. (1943)); *First Buckingham Community, Inc.*, Docket 8750 (May 20, 1968) [73 F.T.C. 938]; *Chemway Corporation*, Docket C-1945 (June 14, 1971) [78 F.T.C. 1250].

⁶ See, e.g., *Topper Corporation, et al.*, Docket C-2073 (November 1, 1971) [79 F.T.C. 681].

⁷ *FTC v. Sperry & Hutchinson*, Docket 8671 (June 1968), rev'd, 432 F.2d 146 (5th Cir. 1970), rev'd, 405 U.S. 233 (March 1, 1973).

⁸ H.R. Rep. No. 163, 75th Cong. 1st Session, p. 3 (1937).

⁹ Slip opinion at p. 11.

¹⁰ *Federal Trade Commission v. Sperry & Hutchinson Co.*, supra.

In footnoting this statement, the court said:

The Commission has described the factors it considers in determining whether a practice which is neither in violation of the antitrust laws nor deceptive is nonetheless unfair:

(1) whether the practices, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law, or otherwise—whether, in other words, it is within at least the penumbra of some common law, statutory, or other established concept of unfairness; (2) whether it is immoral, unethical, oppressive or unscrupulous, (3) whether it causes substantial injury to consumers (or competitors or other businessmen). "Statement of Basis and Purposes of Trade Regulation Rule 408 [Unfair or Deceptive Advertising and Labelling of Cigarettes in Relation to the Health Hazards of Smoking]." 29 Fed. Reg. 8324, 8355 (1964).

An unfairness analysis will take into account many basic economic facts and considerations, and will permit a broad focus in the examination of marketing practices. Unfairness is potentially a dynamic analytical tool capable of a progressive, evolving application which can keep pace with a rapidly changing economy.¹¹ Thus as consumers products and marketing practices change in number, complexity, variety, and function, standards of fairness to the consumer may also change.

Generally, the individual consumer is at a distinct disadvantage compared to the producer or distributor of goods in reaching conclusions concerning the reliability of product claims. Very often the price of a consumer product is sufficiently low that the cost to the consumer of obtaining relevant product information exceeds the benefits resulting from the increased satisfaction achieved thereby. In other cases, the complexity of a consumer product, and accordingly the large amount of detailed product information necessary to an informed decision, makes the costs of obtaining product information prohibitive. This problem is further magnified by the large number of competing products on the market.¹² Thus, with the development and proliferation of highly complex and technical products, there is often no practical way for consumers to ascertain the truthfulness of affirmative product claims prior to buying and using the product. When faced with a vast selection of products to choose from, the typical family unit is not sufficiently large enough, and its requirements are too

¹¹ See *FTC v. Standard Education Society*, 86 F. 2d 692, 696 (2d Cir. 1936), *rev'd on other grounds*, 302 U.S. 112 (1937) (Hand, J.):

"[The Commission's] powers are not confined to such practices as would be unlawful before it acted; they are more than procedural; its duty in part at any rate, is to discover and make explicit those unexpressed standards of fair dealing which the conscience of the community may progressively develop."

¹² In the over-the-counter drug field, for example, it has been estimated that there are between 100,000 and 200,000 products available. (Statement of Dr. Charles C. Edwards, Commissioner, Food and Drug Administration, in Hearings Before the Subcommittee on Monopoly of the Select Committee on Small Business, 92d Congress, 1st Session, May 25, 1971, Part 1.)

varied, to allow detailed investigation of the goods to be purchased. The consumer simply cannot make the necessary tests or investigations to determine whether the direct and affirmative claims made for a product are true.

Given the imbalance of knowledge and resources between a business enterprise and each of its customers, economically it is more rational, and imposes far less cost on society, to require a manufacturer to confirm his affirmative product claims rather than impose a burden upon each individual consumer to test, investigate, or experiment for himself. The manufacturer has the ability, the knowhow, the equipment, the time and the resources to undertake such information by testing or otherwise—the consumer usually does not.

Turning to that part of the complaint which challenges respondent's marketing practices as unfair, the Commission is of the view that it is an unfair practice in violation of the Federal Trade Commission Act to make an affirmative product claim without a reasonable basis for making that claim. Fairness to the consumer, as well as fairness to competitors, dictates this conclusion. Absent a reasonable basis for a vendor's affirmative product claims, a consumer's ability to make an economically rational product choice, and a competitor's ability to compete on the basis of price, quality, service or convenience, are materially impaired and impeded. The balance of this opinion will concern itself with an analysis of the reasonable basis standard in relation to the record before us.

The consumer is entitled, as a matter of marketplace fairness, to rely upon the manufacturer to have a "reasonable basis" for making performance claims. A consumer should not be compelled to enter into an economic gamble to determine whether a product will or will not perform as represented. The economic gamble involved in a consumer's reliance upon affirmative product claims is created by the vendors' activities, and cannot be easily avoided by consumers. Taking a different and analytical perspective and weighing the minimal cost and burden on vendors by requiring that there be a reasonable basis for affirmative product claims, against economic losses to consumers which can fairly be ascribed to advertising claims lacking such reasonable basis (losses which are, in a practical sense, unavoidable for the consumer), it is likewise clear that economic fairness requires that this obligation be imposed on vendors.¹³ The record reflects the fact that

¹³ Compare Fletcher, *Fairness and Utility in Tort Theory*, 85 Harv. L. Rev. 537, 542 (1972).

"Reasonableness is determined by a straightforward balancing of costs and benefits. If the risk yields a net social utility (benefit), the victim is not entitled to recover from the risk-creator; if the risk yields a net social disutility (cost), the victim is entitled

the cost to a consumer of a visit to a dermatologist to obtain a prescription drug is sufficiently high that most persons with sunburn utilize an over-the-counter commercial preparation (Tr. 1031-1032). Thus, the consumer is to a great degree dependent on the manufacturer for information concerning products of this type.

In addition, fairness to competitors requires that the vendor have a reasonable basis for his affirmative product claims. A sale made as a result of an unsupported advertising claim deprives competitors of the opportunity to have made that sale for themselves.

This view finds direct support in the recent decision in *Leon A. Tashof v. F.T.C.*¹⁴ There, the Commission found that a retailer falsely advertised that his products were available at discount prices. The Commission in effect ordered the respondent to stop advertising that he sold any product at a discount price unless he had a reasonable basis for such a claim. In view of this retailer's past history, the Commission prescribed a specific type of "reasonable basis"—the Commission ordered that the respondent, before advertising that he sells at discount prices, must take a statistically significant survey to demonstrate that prevailing market prices are substantially above respondent's prices. In affirming the Commission's decision, the Court expressly noted that this order subjected the respondent to civil penalties if the respondent advertises discount prices without having taken the survey, *even if the advertisement is true*. The unfairness analysis in the Commission's *All-State Industries*¹⁵ case is also directly on point.

*When a seller knows, but the buyer does not know, that the debt contracted by the buyer in making a credit purchase will be assigned to a third party, the buyer may be entering into a transaction quite different in its characteristics from the one the buyer imagines he is entering. * * ** In this circumstance, we find it palpably unfair for a seller who routinely assigns instruments of indebtedness executed by his purchasers to third parties to fail to disclose to his purchasers that such transfer is contemplated and may result in a substantial alteration of the buyer's rights and liabilities. (Emphasis added.)

to recover. The premises of this paradigm are that reasonableness provides a test of activities that ought to be encouraged and that tort judgments are an appropriate medium for encouraging them."

This balance admittedly gives more consideration to the producers' interests than does the test suggested by Adam Smith: "[T]he interest of the producer ought to be attended to only so far as it may be necessary for promoting that of the consumer." Smith, *An Inquiry Into The Nature and Causes of the Wealth of Nations*, 625 (Modern Library Edition, 1937).

¹⁴ 437 F.2d 707 (D. C. Cir. 1970).

¹⁵ *All-State Industries*, Docket No. 8738 (slip opinion, pp. 13-14), *aff'd*, 423 F.2d 423 (1970), *cert. denied*, 400 U.S. 828 (1970).

In summary, the Commission concludes that the making of an affirmative product claim in advertising¹⁶ is unfair to consumers unless there is a reasonable basis for making that claim.

This standard, it should be noted, focuses in large part on the adequacy of the underlying evidence, and is not solely a "reasonable man" test. It thus rounds out the *Kirchner* case, which suggested that an advertiser "* * * should have in his possession such information as would satisfy a reasonable and prudent businessman, acting in good faith, that such representation was true." This test evaluates both the reasonableness of an advertiser's actions and the adequacy of the evidence upon which such actions were based.

The question of what constitutes a reasonable basis is essentially a factual issue which will be affected by the interplay of overlapping considerations such as (1) the type and specificity of the claim made—e.g., safety, efficacy, dietary, health, medical; (2) the type of product—e.g., food, drug, potentially hazardous consumer product, other consumer product; (3) the possible consequences of a false claim—e.g., personal injury, property damage; (4) the degree of reliance by consumers on the claims; (5) the type, and accessibility, of evidence adequate to form a reasonable basis for making the particular claims. More specifically, there may be some types of claims for some types of products for which the only reasonable basis, in fairness and in the expectations of consumers, would be a valid scientific or medical basis. The precise formulation of the "reasonable basis" standard, however, is an issue to be determined at this time on a case-by-case basis. This standard is determined by the circumstances at the time the claim was made, and further depends on both those facts known to the advertiser, and those which a reasonable prudent advertiser should have discovered. Such facts should be possessed *before* the claim is made.

In like manner, the criteria listed above will serve as a touchstone for evaluating those instances in which the Commission is unlikely to proceed against advertisers for failure to have support for an advertisement. In the past, the Commission has recognized that there is a category of advertising themes, in the nature of puffing or other hyperbole, which do not amount to the type of affirmative product claims for which either the Commission or the consumer would expect documentation. In *Kirchner*,¹⁷ we held that advertising an inflatable swimming aid as "invisible" is harmless hyperbole.

¹⁶ This standard pertains only to advertising representations, and does not deal with the question of whether the mere fact of marketing a product implies or requires that certain standards of safety and health must be met. Cf. *Chemway Corporation*, Docket C-1945 (June 14, 1971) [78 F.T.C. 1250]; *H. W. Kirchner*, 63 F.T.C. 1282 (1963).

¹⁷ 63 F.T.C. at 1290.

True, as has been reiterated many times, the Commission's responsibility is to prevent deception of the gullible and credulous, as well as the cautious and knowledgeable (see *e.g.*, *Charles of the Ritz Dist. Corp. v. F.T.C.*, 143 F.2d 676 (2d Cir. 1944)). This principle loses its validity, however, if it is applied uncritically or pushed to an absurd extreme in respect of every conceivable misconception, however outlandish, to which his representations might be subject among the foolish or feeble-minded. Some people, because of ignorance or incomprehension, may be misled by even a scrupulously honest claim. Perhaps a few misguided souls believe, for example, that all "Danish pastry" is made in Denmark. Is it, therefore, an actionable deception to advertise "Danish pastry" when it is made in this country? Of course not. A representation does not become "false and deceptive" merely because it will be unreasonably misunderstood by an insignificant and unrepresentative segment of the class of persons to whom the representation is addressed. If, however, advertising is aimed at a specially susceptible group of people (*e.g.*, *children*), its truthfulness must be measured by the impact it will make on them, not other to whom it is primarily directed.

In this case, complaint counsel is apparently challenging the reasonableness of the basis for two specific affirmative product claims made for Un-Burn: (1) Un-Burn actually anesthetizes nerves in sunburned skin,¹⁸ and (2) Un-Burn stops pain fast.¹⁹

The Standard of Reasonableness

Complaint counsel's unfairness charge basically urges that the only reasonable basis for performance or effectiveness representations for a drug or medical product would be fully documented, adequate and well-controlled scientific studies or tests. Complaint counsel deny that a reasonable basis could be found in the medical literature, clinical experience, or general medical knowledge. Respondent, on the other hand, argues that it possessed a reasonable basis to support its affirmative product claims, and therefore did not need to take the additional step of obtaining controlled scientific tests. Respondent rested its defense on the proposition that the complaint set forth too narrow a view of the type of support required to make affirmative product claims, and contended that there was in fact a reasonable basis for making the questioned claims for Un-Burn.

On appeal, complaint counsel argue that courts have held that the only form of evidence which is adequate and reliable to sustain claims for a drug such as Un-Burn is adequate and well-controlled studies or tests. In support of this proposition, complaint counsel cite cases which hold, based upon a reading of statutory language and the pertinent legislative history, that the Food and Drug Administration validly issued administrative regulations establishing criteria for adequate

¹⁸ Complaint, Paragraph 4.

¹⁹ CX 4-7; Complaint, Paragraph 4.

and well-controlled clinical investigations for determining drug efficacy.²⁰ Having disclaimed at trial any relationship between FDA standards of drug efficacy and the definition of "adequate and well-controlled scientific studies or tests" as set forth in their complaint, however, complaint counsel cannot now attempt to rely, directly or indirectly, on those FDA standards. Complaint counsel have rested their case squarely on the "ordinary dictionary definitions" of the words "adequate and well-controlled scientific studies or tests"—it is, accordingly, on this basis that the Commission must evaluate their argument and the record evidence.²¹

Adequate and Well-Controlled Scientific Studies or Tests

Complaint counsel argue that the only reasonable basis for making efficacy and performance claims for a drug such as Un-Burn would be adequate and well-controlled scientific studies or tests conducted prior to the marketing of the product. Thus, a primary issue at trial was the existence or non-existence of such studies or tests. It is clear that Pfizer's *safety* testing was not designed to, and did not in fact, support the affirmative *efficacy* representations made for the product (I.D., pp. 9-10 [p. 33 herein]). Respondent's pre-marketing tests consisting of *injections* of benzocaine could not indicate the probable anesthetic effect of a *topical* application of this substance (Tr. 259, 308, 344, 522). The tests for the product's *antiseptic* effects do not lend any support to the *anesthetic* effects claimed (Tr. 288, 311). Nor were the tests on guinea pigs sufficient to substantiate the efficacy of the product on human beings (Tr. 726). The hearing examiner found, and the record amply supports his determination, that Pfizer did not conduct adequate and well-controlled scientific studies or tests *prior* to marketing Un-Burn to substantiate the efficacy claims for Un-Burn (I.D., pp. 17, 35 [pp. 40, 54 herein]).

More generally, the record in this matter is clear that for a test, standing alone, to provide a reasonable basis for an affirmative product claim, the test should be an adequate and well-controlled scientific test (I.D., pp. 10-17 [pp. 33-40 herein]; Tr. 330-331, 351-356). Such a test should be conducted on human beings, not on animals (Tr. 298, 343, 351, 509, 522). A pre-existing test protocol is usually essential to an adequate test (Tr. 296, 345, 1065). The record also indicated the strong desirability of double-blind scientific tests (Tr. 280, 370).

²⁰ *PMA v. Richardson* (D. Del. 1970). *Upjohn Co. v. Finch*, 422 F.2d 944 (6th Cir. 1970).

²¹ This precludes consideration, in connection with this particular case, of the FDA's activities in defining the scientific content of "adequate and well-controlled clinical investigations." See HX-1; 35 Fed. Reg. 3073 (February 17, 1970), 35 Fed. Reg. 7250 (May 8, 1970).

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Some time *after* the present proceeding was instituted, respondent did undertake to conduct an adequate and well-controlled test of Un-Burn's efficacy (Tr. 676). This was the test conducted by Dr. Orentreich (Tr. 647; I.D. 30 [p. 51 herein]). While there was some argument as to whether this test actually met the standards of an adequate and well-controlled scientific test (O.A. 14-15)²² it seems clear that it was designed to be such (Tr. 674-676, 864-865). The Orentreich test stands in marked comparison to the tests undertaken by respondents prior to marketing, and graphically demonstrates the insufficiency of such premarketing tests to support the efficacy claims made for the product (Tr. 716, 863, 1116, 1188, 1215, 1226). Even assuming that the Orentreich test did establish that Un-Burn actually anesthetizes nerves,²³ the fact that this test was not conducted *prior* to making the affirmative product claims for Un-Burn precludes it from being considered as a defense to the violation charged in this complaint. In order to have had a reasonable basis, the tests must have been conducted prior to, and actually relied upon in connection with, the marketing of the product in question. Nor does the fact that the product subsequently performed as advertised indicate that there is a lack of public interest in the matter.²⁴ The fundamental unfairness results from imposing on the consumer the unavoidable economic risk that the product may not perform as advertised; that is, at the time of sale, neither the consumer nor the vendor have a reasonable basis for belief in the affirmative product claims.

It is thus clear that the tests conducted by Pfizer did not provide a reasonable basis for the making of these performance claims. The tests were not adequate and well-controlled scientific tests conducted prior to the making of the efficacy representations.

[T]o take the position that a particular type of test must be made, wholly disregards the value of the clinical experience of a number of experts in the dermatology field of medicine such as those called by respondent. Moreover,

²² The nature and intricacy of the debate on the adequacy of this test leads to the view that the Commission's role should simply be one of attempting to determine the existence and general quality of the tests and a threshold determination as to the reasonableness of reliance thereon, rather than an attempt to conclusively determine the adequacy of the tests.

²³ One definite obstacle to such a finding is the fact that this test undertook to compare the effectiveness of Un-Burn with the noneffectiveness of a placebo, rather than to compare Un-Burn's effectiveness with the level of effectiveness claimed by Pfizer's advertising (See, Tr. 680-682, 1215).

²⁴ Compare *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 388 (1965). A false representation violates Section 5 even if the misstatement in no way affects the qualities of the product. The concern is "with methods designed to get a consumer to purchase a product, not with whether the product, when purchased, will perform up to expectations." In short, the focus is upon the method of marketing. See also, *Philip Morris, Inc.*, Docket 8838 (March 12, 1971) (marketing practices which allegedly constitute safety hazards are challenged as allegedly unfair); *FTC v. Algoma Lumber Co.*, 291 U.S. 67 (1934).

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such a position would appear to repudiate clinical experience entirely and to insist that laboratory testing be substituted in all instances where advertising is involved.²⁵

As a question of fact, based on the evidence in this record, the Commission finds that complaint counsel have failed to demonstrate that the only reasonable basis for these affirmative product claims would be adequate and well-controlled scientific studies or tests. It is accordingly necessary to consider, as a matter of fact, the other bases put forth by respondent in support of their "reasonable basis" defense.

Composition of Competing Products

As one of the factors in the argument that there existed a reasonable basis for the product claims in question, respondent alleges that it surveyed competing products on the market to determine (1) the ingredients in such products, and (2) the advertising claims which were being made for such products. Respondent apparently reasons that since the ingredients in Un-Burn are substantially identical to those competing products,²⁶ it is permissible to make the same advertising claims as are made for such competing products—or at least those which have not been challenged as false by a government agency (Tr. 1116, 1130, 1162). The restatement of this argument is sufficient to refute it. The Commission clearly can give no weight to this type of argument in evaluating whether there was a reasonable basis for respondent's claims.

The fact that apparently there did exist a valid efficacy test for a competing product of similar composition which was known to and verified by respondent, however, might have provided a reasonable basis for similar efficacy claims for Un-Burn (CX 99; Tr. 562-573; O.A. 24).²⁷ The evidence with regard to this particular test, however, falls substantially short of constituting an adequate test for the particular anesthetic claims made for Un-Burn. Nor is there sufficient evidence that Pfizer knew of, and relied upon, this test in marketing Un-Burn.

Medical Literature

Respondent urges that its search of the medical literature contained in Pfizer's library, prior to marketing Un-Burn, provided a reasonable basis for the Un-Burn efficacy representations. While complaint coun-

²⁵ I.D., p. 35 [67 herein].

²⁶ This argument is weakened by the fact that apparently no scientific analysis was made to determine whether the competing products had the same formula as Un-Burn (Tr. 703).

²⁷ Such claims, of course, cannot imply that respondent's product is unique or different from the competing product in question.

sel do not meet this argument directly, their argument that the *only* reasonable basis would be scientific studies or tests encompasses this point. In oral argument, however, complaint counsel did concede that medical literature containing reports on adequate and well-controlled tests might be sufficient.

The record evidence is sufficient to demonstrate to the Commission that medical literature might, in some instances, be sufficient basis for making affirmative product claims (Tr. 671, 704, 713, 1054, 1108, 1118, 1128).

Closely allied with medical literature as a reasonable basis, would be the general state of medical knowledge at the time the claims were made, regardless of how that knowledge is ascertained (Tr. 1049, 1097, 1134; I.D. 20-23 [pp. 42-45 herein], 30-32 [pp. 51-52 herein]). Thus, the examiner found that:

Recognized medical literature and the medical practice of dermatologists for between 50 and 70 years regarded the active ingredients in Un-Burn as efficacious for the relief of sunburn pain. (I.D. 32 [53 herein].)

Persuasive in this regard is the fact that the NAS-NRC panels utilized by the Food and Drug Administration were permitted to recognize as probative reports on studies contained in the medical and scientific literature (RX 110, p. 5; HX 1; Tr. 369, 371, 535).

The guidelines for these NAS-NRC panels²⁸ set forth the following basis for judgments as to drug efficacy:

The judgments of the Panels will be based on the following criteria: (1) factual information that is freely available in the scientific literature, (2) factual information that is available from the FDA, from the manufacturer or other sources, or (3) on the experience and informed judgment of the members of the Panels. (See also, Tr. 535.)

These guidelines later discuss one instance where scientific literature alone could provide the basis for a judgment as to effectiveness:

It is anticipated that substantial evidence for the effectiveness of many of the drugs assigned to a Panel will be found to be well-documented in the scientific literature familiar to the members of the Panel. In these cases, the Panel may be prepared to make its recommendations and to support them by citations from the scientific literature alone.

In a later section, the guidelines discuss other types of evidence of effectiveness:

IX. *Some Special Considerations*

In the deliberations of the Panels, issues will almost certainly arise as to considerations, other than factual evidence, that should be weighed in arriving

²⁸ Guidelines for the Drug Efficacy Study of the National Academy of Sciences-National Research Council, August 1966 (RX 110; I.D., p. 30 [pp. 50-51 herein]).

at judgments on effectiveness. The significance of many of these factors will vary widely in different classes of drugs and of the indications. No general guidelines for these can be offered. As these questions arise, however, Panel chairmen are invited to present them to the Policy Advisory Committee together with any suggestions as to the manner in which they might be resolved.

A few general issues can, however, be anticipated.

D. Wide Usage

There will likely be cases in which a Panel is in doubt as to the sufficiency of evidence of effectiveness of a drug that has gained repute among practicing physicians or that has been in wide use for a period of years. It will be quite in order for the Panel to draw attention to these facts in recording its judgment as to effectiveness.

F. Subjective Evaluations

The informed judgment and experience of the members of the Panels in valid evidence contributory to the final decision on the efficacy of a drug for the indications presented. In justifying its decision, however, the Panel is expected to delineate the extent to which it is supported by the substantive evidence available for its review.

Complaint counsel's burden in this proceeding is that of demonstrating that respondent's actions in reliance upon the medical literature did not provide a reasonable basis for the affirmative product claims. Complaint counsel for example, could have offered evidence or argument that: (1) respondent's search of the medical literature was of such a limited scope that it was unreasonable, or (2) the conclusions drawn by respondent from the medical literature actually reviewed were unreasonable, or (3) the "testimonial" quality of the medical literature was not sufficient basis for the product claims.²⁹ Complaint counsel's insistence that the medical literature specifically report on actual tests fails to address itself to, or satisfy, their burden in this regard.³⁰ Complaint counsel's primary evidence on this point was the rebuttal testimony of Dr. Beaver, who basically showed a possible conflict in the medical literature. This does not satisfy the burden of proof resting on complaint counsel on this issue.

²⁹ Complaint counsel's argument was misdirected to some degree, to any medical literature which a witness may have reviewed (Tr. 1312; CCRB 2; Compare I.D., p. 19 [pp. 41-42 herein]).

³⁰ Thus, we do not reach several significant issues pertinent to this point, e.g., did the medical literature deal with the Un-Burn ingredients in the same combination and amounts as they appear in the final formulation of Un-Burn (O.A., 4, 18); is chemical equivalence sufficiently indicative of therapeutical equivalence (Tr. 1081, 1116, 1117, O.A. 12); are authors' opinions and conclusions sufficient, or must the actual underlying tests be described; or whether the medical literature will ever be capable of supporting product claims which relate to a condition which varies so widely among the people it affects as does sunburn.

Clinical Experience

Respondent's final argument is that the clinical experience of the medical profession in itself provides a reasonable basis for making efficacy claims for Un-Burn. Again, in view of complaint counsel's primary focus on the necessity for scientific tests, the Commission is not in a position to definitely evaluate whether clinical experience as to benzocaine and menthol would provide a reasonable basis for assuming its efficacy. It was clear from the evidence of record, however, the "clinical experience" covers a wide range of circumstances and must be carefully analyzed and evaluated, including consideration of the type of ailment being treated. Accordingly, the reasonableness of clinical experience must be evaluated as a factual issue in each case (Tr. 1083, 1097, 1108, 1122, 1185, 1253, 1258, 1263, 1300). In this regard, the relevant inquiry is into a respondent's knowledge of, and reliance upon, clinical experience *prior* to making the product claims in question. Thus, Pfizer's witness as to clinical experience, who were contacted by Pfizer only in preparation for trial, are irrelevant to the issue (*See I.D.*, pp. 20-23 [pp. 42-44 herein]).

Respondent's Efforts to Provide A Reasonable Basis for Affirmative

Pfizer's director of Marketing testified that he took three measures to satisfy himself as to the efficacy of the product Un-Burn. First, he received "complete assurance" from Pfizer's medical people that the claims he planned to use for Un-Burn could be supported by the two active ingredients in the quantities in which they were to be used in the product. He was assured that the way a topical anesthetic works is to anesthetize nerves and thereby stop pain (Tr. 605). He was also assured by the "medical people" that the product was patterned very closely after the market leader, Solarcaine. Secondly, he was assured that all available literature or information on these two active ingredients had been thoroughly reviewed and favorable conclusions derived from this review as to the efficacy of the ingredients as topical anesthetics. Finally, he personally reviewed all competitive advertising to satisfy himself that Pfizer would not be claiming anything more than other products with the same active ingredients. The director of marketing testified that Pfizer did not conduct tests on humans to determine whether the efficacy claims could be supported, but consciously "accepted another method of satisfying" themselves by going over the history of the ingredients. No specific tests were conducted on human beings to prove that Un-Burn anesthetizes nerve ends (*I.D.*, pp. 10, 19 [pp. 33, 41 herein]; Tr. 623-624).

The Pfizer medical official responsible for testing all new Pfizer products, testified that two efficacy tests were run on Un-Burn:

1. Testing with regard to the antibacterial properties of the product, and
2. The guinea pig wheal tests.

These latter tests involved the injection of Un-Burn into guinea pigs. His conclusions as to the results of Pfizer's testing on Un-Burn were as follows:

[The products passed the safety and efficacy tests. The tests demonstrated that there were no safety hazards pertaining to the products, and that the antibacterial activity of the product would support the antiseptic claim, and finally, the guinea wheal test demonstrated to us that the active ingredient, one of the active ingredients, benzocaine, was not inactivated by anything in the formulations. (Tr. 668).

As a result of the safety and other tests, his review of the literature, and his discussions with Dr. Carlozzi, the medical director of Pfizer, Dr. Jenkins gave his opinion that the testing done was sufficient to establish the safety and efficacy of Un-Burn (*I.D.*, p. 20 [p. 42 herein]; Tr. 672-673).

Inasmuch as complaint counsel's argument did not go directly to the reasonableness of these actions, we lack a sufficient basis for a finding in this regard. In future cases, we would be interested in both the qualifications of the medical and scientific advisors, and some showing that their judgments were rendered on an informed and unbiased basis. Also properly considered here would be the issue of whether reliance upon medical literature and clinical evidence as to the separate ingredients in Un-Burn is appropriate, or whether additional consideration must be given to (1) the combination of ingredients as they appear in the final product, and (2) the various conditions of use to which the product can reasonably be expected to be subjected, including variations as to skin types and degrees of sunburn. The Commission is not, moreover, convinced of the reasonableness of respondent's attempts to rely upon clinical experience as to the efficacy of benzocaine and menthol in general, to support the specific degree of efficacy ("anesthetizes" nerves, "stops" sunburn) claimed for Un-Burn.³¹

Evidently respondent made no written report setting forth the actions which were taken to support the existence of a reasonable basis for its advertising claims. Such a report, if made in good faith prior to

³¹ The Orentreich test evaluated the efficacy of Un-Burn only in comparison to a placebo—it did not attempt to determine whether nerves were "actually anesthetized" or sunburn pain had in fact "stopped." (CCRB 3-4.)

marketing, if reasonable in scope and approach,³² and if reasonably clear as to the evidentiary basis for the specific claims in question (be they scientific tests, specified medical references, or specific clinical evidence), would certainly have, in itself, gone a considerable distance in demonstrating the existence of a reasonable basis for their affirmative product claims.

V REMAINING ISSUES

Respondent raises a number of collateral arguments which should be noted. First, respondent argues that "fairness" is an unconstitutionally vague standard upon which to base a Commission order. Second, a holding based on fairness would violate the First Amendment to the Constitution. Third, the Food, Drug, and Cosmetic Act implicitly limits the Commission's Section 5 jurisdiction in certain circumstances. Fourth, the "focusing of Congressional attention" on this proceeding was inconsistent with the Fifth Amendment. The Commission finds none of these arguments persuasive.

VI CONCLUSION

Having reviewed the record, initial decision, briefs and argument in this proceeding, the Commission has determined that the hearing examiner's dismissal of the complaint should be affirmed. The divergent approaches of complaint counsel and counsel for respondent, both to the appropriate legal standard and to the facts of this case, resulted in the issue simply not being satisfactorily joined.

While the Commission finds that respondent failed in its attempt to demonstrate affirmatively the existence of a reasonable basis for its Un-Burn advertising, the evidence is not sufficient to prove that respondent in fact *lacked* a reasonable basis for its advertising claims. The record evidence is simply inconclusive with regard to the adequacy of the medical literature and clinical experience relied upon by respondent, and with regard to the reasonableness of such reliance.

While this failure of proof might be cured by a remand, the Commission does not believe further proceedings are warranted in the public interest. The reformulation of the legal standard from "adequate and well-controlled scientific studies or tests" to "reasonable basis" might warrant an extensive trial *de novo*, and the advertising in question has already long been discontinued. The significance of this particular case lies, therefore, not so much in the entry of a cease and desist order against this individual respondent, but in the resolution of the general issue of whether the failure to possess a reasonable basis

³² The issue of whether an advertisement has appropriately formulated the standard of what constitutes a "reasonable basis" remains a separate question of fact. See discussion at pp. 16-17 [pp. 66-67 herein], *supra*.

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for affirmative product claims constitutes an unfair practice in violation of the Federal Trade Commission Act. As to that issue, the foregoing opinion expresses the views of the Commission. In view of these circumstances, the Commission has determined to affirm the order and initial decision of the hearing examiner except to the extent inconsistent with this opinion.

Commissioner MacIntyre concurs as to the result reached by the majority.

Commissioner Jones concurs in the statement of law applicable to this case as laid out in the opinion, but in light of the opinion and the record in this matter, dissents to the disposition of the case since it deprives respondent of an opportunity to seek a court review of the issues involved.

FINAL ORDER

This matter having been heard by the Commission upon the appeal of counsel supporting the complaint from the hearing examiner's initial decision, and upon briefs and oral argument in support thereof and in opposition thereto, and the Commission, for the reasons stated in the accompanying opinion, having denied the appeal:

It is ordered, That the order of the hearing examiner be affirmed, and that, except to the extent inconsistent with the accompanying opinion, the examiner's initial decision be, and it hereby is, adopted as the decision of the Commission.

It is further ordered, That the complaint be, and it hereby is, dismissed.

Commissioner MacIntyre concurs as to the result reached by the majority. Commissioner Jones concurs in the statement of law applicable to this case as laid out in the opinion, but in light of the opinion and the record in this matter, dissents to the disposition of the case since it deprives respondent of an opportunity to seek a court review of the issues involved.

IN THE MATTER OF

BABY PRODUCTS, INCORPORATED, ET AL.

CONSENT ORDER, ETC., IN REGARD TO THE ALLEGED VIOLATION OF THE
FEDERAL TRADE COMMISSION ACT