

Complaint

95 F.T.C.

IN THE MATTER OF

AHC PHARMACAL, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3017. Complaint, April 28, 1980 — Decision, April 28, 1980

This consent order requires, among other things, a Miami, Fla. firm and its corporate president, engaged in the marketing and advertising of health related products, to cease disseminating advertisements which represent that the use of AHC Gel or any similar preparation, alone or as part of an acne control regimen, cures acne and results in a blemish-free skin; or that any such preparation is superior to other over-the-counter acne products. Respondents are required to have a reasonable basis for advertising representations relating to product performance, efficacy and results and prohibited from misrepresenting the extent or results of product testing. Respondents are further prohibited from disseminating advertisements for acne products without first disseminating prescribed corrective advertising as specified in the order. Additionally, ad substantiation must be maintained for a period of three years.

Appearances

For the Commission: *Steven Newborn.*

For the respondents: *Pro se.*

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 AHC Pharmacal, Inc. (hereinafter "AHC Pharmacal"), a corporation, and James E. Fulton, M.D. (hereinafter "Fulton"), as an individual and corporate officer, hereinafter at times referred to as respondents, having 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. "AHC Pharmacal" is a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida with its office and principal place of business located at 1609 N.W. 14th St., Miami, Florida.

PAR. 2. "Fulton" is an individual and corporate president of "AHC Pharmacal." He formulates, directs and controls the acts and practices "AHC Pharmacal," including the acts and practices described

herein, and he is the principal beneficiary of the corporation's business. "Fulton's" business address is 1609 N.W. 14th St., Miami, Florida.

PAR. 3. Respondent "AHC Pharmacal" is a privately held corporation which was organized and is maintained for the purpose of promoting and conducting the business interests of "Fulton." "AHC Pharmacal" and "Fulton" have been and now are marketing and advertising health related products, including but not limited to a product variously known as AHC Gel, AHC Pharmacal's benzoyl peroxide gel medication and b.p. gel medication (hereinafter "AHC Gel"), a product advertised for the treatment of acne. The respondents, in connection with the manufacture and marketing of said product, have disseminated, published and distributed, and now disseminate, publish and distribute advertisements and promotional material for the purpose of promoting the sale of "AHC Gel" for human use. "AHC Gel" is marketed by the respondents, both separately and as part of a program for the treatment of acne known as "Dr. Fulton's Acne Control Regimen" (hereinafter "the Acne Control Regimen"). This product, as advertised, is a "drug" within the meaning of Section 12 of the Federal Trade Commission Act.

PAR. 4. In the course and conduct of their said businesses, the respondents have disseminated and caused the dissemination of certain advertisements concerning "AHC Gel" and "the Acne Control Regimen" through the United States mail and by various means in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, including, but not limited to, the insertion of advertisements in magazines with national circulations, and advertisements in the form of a booklet, entitled "Acne: A Treatable Disease" which was, and is, sent through the United States mail, for the purpose of inducing and which was likely to induce, directly or indirectly, the purchase of the product "AHC Gel," and have disseminated and caused the dissemination of advertisements concerning said product by various means, including but not limited to the aforesaid media, for the purpose of inducing and which are likely to induce, directly or indirectly, the purchase of said products in commerce.

PAR. 5. Typical of the statements and representations in said advertisements disseminated as previously described, but not necessarily inclusive thereof, are the following:

Complaint

Is the ACNE Problem Finally OVER?



Acne sufferer, now specialist, has developed a new treatment* for acne control that offers young adults their first real hope for clear complexions.

"My acne started at sixteen. I tried everything from oral antibiotics to x-ray treatment, even ultraviolet light. Nothing worked. I became a Dermatologist and Ph.D. in Biochemistry in an attempt to find a cure for acne."

"After seven years of research, I discovered benzoyl peroxide (bp) gel*, a topical medication that has revolutionized the treatment and control of acne."

"Since 1973, my Acne Health Care Centers throughout the United States have treated tens of thousands of acne sufferers using my benzoyl peroxide medications. The results: over 65% of our patients (even the cystic variety) are dramatically improved within eight weeks."

"Unfortunately, our clinics can only treat a very small percentage of those that really need help."

"In an effort to reach the many acne sufferers that are often given false hope about their problem and are continually disillusioned by over-the-counter acne remedies, we have developed a very exciting ACNE CONTROL REGIMEN."

"If we are giving the opportunity to reach you, the acne sufferer early, we can bring the condition under control and eliminate the possibility of facial scarring that may result from continued acne breakouts."

"I consider this acne control program to be the finest available today for the control of acne — next to being treated at one of my Acne Health Care Centers."

James E. Fulton, Jr.

James E. Fulton, Jr., M.D., Ph.D.
Founder of Acne Health Care Centers
Founder of Acne Research Institute
Dermatologist, American Board of Dermatology
Fellow, American Academy of Dermatology



Before Treatment

How Dr. Fulton's regimen* works

Acne is genetic.
Normally, dead skin cells are flushed up the pores of oil glands by sebum (surface oil) and washed away.

In genetically defective skin, these cells stick — the pores become impacted — acne develops.

These impactions (whiteheads, blackheads), later pustules, which could result in permanent scarring, exist beneath the surface of the skin.

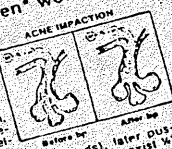
Special soaps and most over-the-counter preparations attempt to dry up oil only at the surface level. This will never help the acne problem.

Dr. Fulton's "Acne Control Regimen" actually penetrates into the pores and treats the genetic problem in two ways:

1. Kills the C-acnes bacteria which produce irritating acids in the pores and accelerate the clogging process.
2. Reduces the cohesiveness of dead skin cells, thus loosening and clearing up acne impactions.

THE RESULT: An opportunity now exists for the acne sufferer to find dramatic improvement.

*Dr. Fulton's unique gel of ultrafine stabilized benzoyl peroxide — BPAL applied topically. Part Fulton, J.E., Studies on mechanism of action of benzoyl peroxide. J. Invest. Dermatol. 51:151, 1974.



AHC PHARMACAL, INC. 1351 N.W. 16th St.
Miami, Florida 33125

Please rush — complete program(s) of Dr. Fulton's ACNE CONTROL REGIMEN

Which includes: (1) A 1 oz. bottle of P.E. Benzoyl Peroxide Gel (2) Dr. Fulton's Manual (3) Dr. Fulton's Treatable Diagram — ACNE: A Treatable Disease

Enclosed is \$12.95 (which includes postage & handling for each program)

☐ VISA ☐ Check or Money Order ☐ Master Charge Bank Am.

Credit Card # _____ Exp. Date _____

Name _____ Address _____ State _____ Zip _____

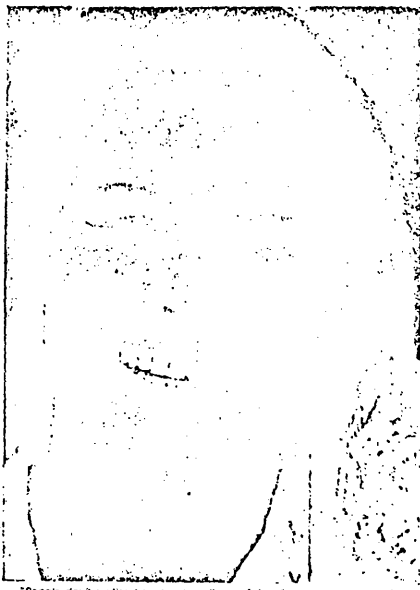
City _____

Signature _____

IF YOU DO NOT WANT TO RUSH, PLEASE RETURN THE COUPON TO THE FOLLOWING ADDRESS:

MAIL YOUR BACK GUARANTEE: If your program does not improve your skin, return the empty containers for a full refund.

The ACNE Problem is Finally OVER



"People don't realize how emotionally painful and frustrating acne can be. For seven years my days started and ended with depression. Dr. Fulton's Acne Control Regimen has given me new hope."

Before Treatment

Acne sufferer, now specialist, has developed a new treatment* for acne control that offers young adults their first real hope for clear complexions.

"My acne started at sixteen. I tried everything from oral antibiotics to x-ray treatment, even ultraviolet light. Nothing worked."

"I became a Dermatologist and Ph.D. in Biochemistry in an attempt to find a cure for acne."

"After seven years of research, I discovered benzoyl peroxide (bn) gel*, a topical medication that has revolutionized the treatment and control of acne."

"Since 1973, my Acne Health Care Centers throughout the United States have treated tens of thousands of acne sufferers using my benzoyl peroxide medications. The results: over 85% of our patients (even the cystic variety) showed dramatic improvement within eight weeks."

"Unfortunately, our clinics can only treat a very small percentage of those that really need help."

"In an effort to reach the many acne sufferers that are often given false hope about their problem and are continually disillusioned by over-the-counter acne remedies, we have developed a very exacting 'ACNE CONTROL REGIMEN.'"

"If we are given the opportunity to reach you, the acne sufferer early, we can, in most cases, bring the condition under control and eliminate the possibility of facial scarring that may result from continued acne breakouts."

"I consider this acne control program to be the finest available today for the control of acne — next to being treated at one of my Acne Health Care Centers."



James E. Fulton, Jr., M.D.

James E. Fulton, Jr., M.D., Ph.D.
Founder of Acne Health Care Centers
Founder of Acne Research Institute
Diplomat, American Board of Dermatology
Fellow, American Academy of Dermatology

How Dr. Fulton's regimen* works

Acne is genetic.

Acne is clogged pores.

Normally, dead skin cells are flushed up the pores of oil glands by sebum (surface oil) and washed away.

In genetically defective skin, these cells stick — the pores become impacted — acne develops.

These impactions (whiteheads, blackheads), later pustules, which could result in permanent scarring, exist beneath the surface of the skin.

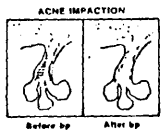
Special soaps and most over-the-counter preparations attempt to dry up oil only at the surface level. This will never help the acne problem.

Dr. Fulton's "Acne Control Regimen" actually penetrates into the pores and treats the genetic problem in two ways:

1. Kills the *C. acnes* bacteria which produce irritating acids in the pores and accelerate the clogging process.

2. Reduces the cohesiveness of dead skin cells, thus loosening and clearing up acne impactions.

THE RESULT: An opportunity now exists for the acne sufferer to find dramatic improvement.



*Dr. Fulton's unique gel of glycerin stabilized benzoyl peroxide — not applied for. Ref. Fulton, J.E., Studies on mechanism of action of benzoyl peroxide. J. Cutaneous Med. 9, 1973, 1976.

AHC PHARMACAL, INC. 1351 N.W. 16th St.
Miami, Florida 33125

Please rush — complete program(s) of Dr. Fulton's ACNE CONTROL REGIMEN

Which includes: (1) A 3 oz. bottle of b.p. Medicated Soap
(2) A 1 oz. bottle of b.p. Gel Medication
(3) Dr. Fulton's Manual
"ACNE: A Treatable Disorder"

Enclosed is \$12.95 (which includes postage & handling for each program).

☐ VISA ☐ Check or Money Order ☐ Master Charge ☐ Bank No. _____

Credit Card # _____ Exp. Date _____

Name _____ Apt. # _____

Address _____

City _____ State _____ Zip _____

Signature _____ (M-478)

MONEY BACK GUARANTEE: If your improvement does not satisfy you, just return the empty containers for a full refund.

PAR. 6. Through the use of said advertisements and others referred to in Paragraphs Four and Five, respondents represented, and now represent, directly or by implication that use of "AHC Gel," either alone or as part of "the Acne Control Regimen," will cure acne regardless of the severity of the condition.

PAR. 7. In truth and in fact, use of "AHC Gel," either alone or as part of "the Acne Control Regimen," will not cure acne. Therefore, the advertisements referred to in Paragraphs Four and Five were and are misleading in material respects and constituted, and now constitute, false advertisements, and the statement and representation set forth in Paragraph Five was, and is false, misleading and deceptive.

PAR. 8. Furthermore, through the use of the advertisements referred to in Paragraphs Four and Five, respondents represented, and now represent that:

a. Use of "AHC Gel," either alone or as part of "the Acne Control Regimen," by persons with acne will result in skin free of pimples, blackheads, whiteheads, other acne blemishes, and scarring.

b. Use of "AHC Gel," either alone or as part of "the Acne Control Regimen," by persons with acne will help control pimples, blackheads, whiteheads, other acne blemishes, and scarring, regardless of the severity of the disease.

c. "AHC Gel," either alone or as part of "the Acne Control Regimen," is superior to all other over-the-counter acne preparations for the treatment of acne, including but not limited to other benzoyl peroxide products.

PAR. 9. In truth and in fact there existed at the time of the first dissemination of the representations referred to in Paragraph Eight no reasonable basis for the making of these representations, in that respondents lacked competent and reliable scientific evidence to support said representations. Therefore, the making and dissemination of said representations as alleged constituted, and now constitute, unfair or deceptive acts or practices in or affecting commerce.

PAR. 10. In the course and conduct its aforesaid business, and at all times mentioned herein, the respondents have been, and now are, in substantial competition in or affecting commerce with corporations, firms and individuals representing or engaged in the over-the-counter and prescription drug industries.

PAR. 11. The use by respondents of the aforesaid unfair or deceptive representations and the dissemination of the aforesaid false advertisements has had, and now has, the capacity and tendency to mislead members of the consuming public into the erroneous and mistaken belief that said representations were and are true.

PAR. 12. The aforesaid acts and practices of respondents, as herein alleged, including the dissemination of the aforesaid false advertisements, were and are all to the prejudice and injury of the public and of respondents' competitors, and constituted, and now constitute, unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, in violation of Sections 5 and 12 of the Federal Trade Commission Act.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the bureau proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violations of the Federal Trade Commission Act; and

The respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of such agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, and waivers and other provisions as required by the Commission's rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent AHC Pharmacal, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida with its office and principal place of business located at 1609 N.W. 14th St., Miami, Florida.
2. Respondent James E. Fulton, M.D. is an individual and corporate officer of AHC Pharmacal, Inc. and maintains an office at 1609 N.W. 14th St., Miami, Florida.
3. The Federal Trade Commission has jurisdiction of the subject

matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

I

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

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

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

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

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

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

2. Represents that "AHC Gel", either alone or as part of "the Acne Control Regimen", or any other acne product or regimen, is superior to other over-the-counter acne preparations for the treatment of acne, including but not limited to other benzoyl peroxide products,

unless, at the time of each dissemination of such representation(s) respondents possess and rely upon competent and reliable scientific or medical evidence as a reasonable basis for such representation(s). "Competent and reliable scientific or medical evidence" shall be

defined as evidence in the form of at least two well-controlled double-blind clinical studies which are conducted by different persons, independently of each other. Such persons shall be dermatologists who are qualified by scientific training and experience to treat acne and conduct the aforementioned studies.

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

II

It is further ordered, That within sixty (60) days of the acceptance of this order, respondents shall cease and desist from disseminating or causing the dissemination of advertisements for "AHC Gel", "the Acne Control Regimen", and/or any other acne product or regimen, unless respondents first disseminate corrective advertisements for the Acne Control Regimen (including AHC Gel) in Sunday newspaper supplements and on radio.

A. All such Sunday newspaper supplement corrective advertisements shall clearly and conspicuously disclose, in the headline with boldface type no smaller than 48 points (one-half inch) in height, that "no product can cure acne." Nothing in the headline, or any part of the advertisement, shall in any way obscure or contradict the clear meaning of the disclosure. Furthermore, no language in said advertisement shall appear in a type size equal to or larger than the headline type size.

Said Sunday newspaper supplement corrective advertisements shall be disseminated in the following cities: Boston, MA; Atlanta, GA; Cleveland, OH; Philadelphia, PA; Pittsburgh, PA; and San Francisco, CA. Respondents may substitute cities of reasonable demographic and geographic similarity, provided that said cities are substituted on a one-for-one basis. Said corrective advertisements shall be run at least one full-page advertisement per month for a time period of three consecutive months, provided that said advertisements shall not be disseminated during the months of June, July, or August.

Respondents may elect to run two half-page corrective advertisements in the place of each and every full-page corrective advertise-

ment to satisfy their corrective advertising obligations under this part of the order. *Provided, however*, that all such corrective advertisements must be run in different weekly issues of the aforementioned newspaper supplements for any given locale, and other requirements of this order (*e.g.*, headline type size, dissemination schedule, etc.) are fully complied with.

B. All corrective advertisements which are required for dissemination by radio shall be at least thirty seconds in duration and shall begin with the unobscured announcement that "no product can cure acne." Nothing else in the advertisement shall in any way obscure or contradict the clear meaning of this statement. Said radio corrective advertisements shall be disseminated as non-consecutive spots over major radio stations (as defined below) in the following urban areas: Chicago, IL; Los Angeles, CA; Miami, FL. Said radio corrective advertisements shall be disseminated at least twice each month during the same three months as the Sunday newspaper supplement corrective advertisements, referred to in IIA, are disseminated.

For purposes of this order a "major radio station" shall be defined as a radio station which (a) has a broadcast power of at least 6,000 watts horizontal and 6,000 watts vertical, and (b) is described in its own promotional materials as being targeted at teenagers or young adult audiences and/or primarily playing rock, disco or contemporary hit music.

C. The obligation to run corrective advertisements shall not in any way alleviate other order obligations. Furthermore, such advertisements shall not represent, directly or indirectly, that the Federal Trade Commission approves, recommends or in any manner endorses the advertised product or product's advertising.

III

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

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

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

respondent, setting forth in detail the manner and form of its compliance with this order.

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

Complaint

95 F.T.C.

IN THE MATTER OF
ELI LILLY AND COMPANY

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

Docket C-3021. Complaint, April 29, 1980 — Decision, April 29, 1980

This consent order requires, among other things, an Indianapolis, Indiana manufacturer and seller of pharmaceuticals and other chemical substances, to cease engaging in several anticompetitive practices involving the United States finished insulin industry. Additionally the order requires Eli Lilly and Co. to grant certain licenses covering its existing and future insulin-related technology to existing and prospective competitors.

Appearances

For the Commission: *William C. Holmes.*

For the respondent: *Charles E. Buffon, Covington & Burling,*
Washington, D.C.

COMPLAINT

The Federal Trade Commission, having reason to believe that Eli Lilly and Company, hereinafter referred to as "Lilly" or "respondent", has violated Section 5 of the Federal Trade Commission Act, as amended, (15 U.S.C. 45), and Section 7 of the Clayton Act, as amended, (15 U.S.C. 18), and that a proceeding in respect thereof would be in the public interest, hereby issues this complaint, stating its charges as follows:

I. RESPONDENT

PARAGRAPH 1. Lilly is a corporation organized and existing under and by virtue of the laws of the State of Indiana, with its principal executive offices located at 307 East McCarty St., Indianapolis, Indiana.

PAR. 2. Lilly's principal business is the manufacture and sale of chemical compounds and substances for use by or on living organisms — human, plant and animal. This business accounted for approximately 89% of the consolidated net sales of Lilly and its subsidiaries during the years 1972 through 1976.

PAR. 3. In 1976, Lilly's consolidated net sales were approximately \$1.34 billion, consolidated net income after taxes was approximately