UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

In the Matter of)
SCHERING-PLOUGH HEALTHCARE)
PRODUCTS, INC.,)
a corporation.)

File No. 942-3341

AGREEMENT CONTAINING CONSENT ORDER TO CEASE AND DESIST

The Federal Trade Commission, having initiated an investigation of certain acts and practices of Schering-Plough Healthcare Products, Inc., a corporation, and it now appearing that Schering-Plough Healthcare Products, Inc., a corporation, hereinafter sometimes referred to as proposed respondent, is willing to enter into an agreement containing an order to cease and desist from the use of the acts and practices being investigated,

IT IS HEREBY AGREED by and between Schering-Plough Healthcare Products, Inc., by its duly authorized officer, and its attorney, and counsel for the Federal Trade Commission that:

1. Proposed respondent Schering-Plough Healthcare Products, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 3030 Jackson Avenue, Memphis, Tennessee 38151.

2. Proposed respondent admits all the jurisdictional facts set forth in the draft of complaint here attached.

- 3. Proposed respondent waives:
 - (a) Any further procedural steps;
 - (b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and
 - (c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it,

together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft of complaint here attached, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding and (2) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to proposed respondent's address as stated in this agreement shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the proposed complaint and order contemplated hereby. Proposed respondent understands that once the order has been issued, it will be required to file one or more compliance reports showing that it has fully complied with the order. Proposed respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

ORDER

For the purpose of this Order, the following definitions shall apply:

A. "Sun protection product" shall mean any product intended for, or promoted as, providing users with protection against the harmful effects of sun exposure or ultraviolet radiation, including but not limited to products containing a sunscreen ingredient.

B. "Children's sun protection product" shall mean any sun protection product that uses the word "babies," "children," "kids," or words of similar import in the name or promotion of the product, or that is advertised or promoted for use primarily by children under the age of twelve (12).

C. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

I.

IT IS ORDERED that respondent, Schering-Plough Healthcare Products, Inc., a corporation, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Coppertone Kids or any other children's sun protection product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication:

- A. The length of time that a single application of the product will provide protection from the sun for individuals engaged in sustained vigorous activity in and out of the water; or
- B. The efficacy of such product in providing protection against any harmful effect of sun exposure or ultraviolet radiation,

unless, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

IT IS FURTHER ORDERED that respondent, Schering-Plough Healthcare Products, Inc., a corporation, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any sun protection product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting, in any manner, directly or by implication, the existence, contents, validity, results, conclusions or interpretations of any test or study.

III.

Nothing in this Order shall prohibit respondent from making any representation for any sun protection product that is specifically permitted in labeling for any such product under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

IV.

IT IS FURTHER ORDERED that respondent shall design, produce and print a color brochure concerning the importance of sunscreen usage by children, which contains all of the following messages or themes:

- A. The importance of sunscreens in preventing skin damage, including skin cancer, sunburn and premature skin aging;
- B. Regular use of a high SPF sunscreen during childhood can significantly reduce the risk of certain types of skin cancers later in life;
- C. A single bad sunburn during childhood can significantly increase a child's risk of developing skin cancer later in life;
- D. The importance of proper application of sunscreens;
- E. The need to reapply sunscreens after toweling or sustained vigorous activity; and
- F. The need to use sunscreens during outdoor activities -- not only in connection with water activities.

Respondent shall submit a draft of the brochure, and a draft plan for its dissemination, no later than sixty (60) days after the date of service of this Order, to the Associate Director of the Commission's Division of Advertising Practices for review and approval. No later than sixty (60) days after the Associate Director's approval of the brochure and the dissemination plan, respondent shall disseminate 150,000 copies of the brochure to parents or organizations with access to parents or others who work with or care for children under the age of 12.

v.

IT IS FURTHER ORDERED that, for five (5) years after the last date of dissemination of any representation covered by this Order, respondent, or its successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All materials that were relied upon in disseminating any such representation; and
- B. All tests, reports, studies, surveys, demonstrations or other evidence in its possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers or governmental organizations.

VI.

IT IS FURTHER ORDERED that the provisions of this Order shall not apply to any label or labeling printed prior to the date of service of this Order and shipped by respondents to purchasers for resale prior to one hundred (100) days after service of this Order.

VII.

IT IS FURTHER ORDERED that respondent, its successors and assigns, shall:

- A. Within thirty (30) days after the date of service of this Order, provide a copy of this Order to each of respondent's current principals, officers, and directors, and to all personnel, managers, agents, and representatives having sales, advertising, or policy responsibility with respect to the subject matter of this Order; and
- B. For a period of five (5) years from the date of service of this Order, provide a copy of this Order to each of respondent's principals, officers, and directors, and to all personnel, managers, agents, and representatives having sales, advertising, or

policy responsibility with respect to the subject matter of this Order within three (3) days after the person assumes his or her position.

VIII.

IT IS FURTHER ORDERED that respondent shall notify the Commission at least thirty (30) days prior to any proposed change in its corporate structure, 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 under this Order.

IX.

THIS ORDER will terminate twenty years from the date of its issuance, or twenty years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; **provided**, **however**, that the filing of such a complaint will not affect the duration of:

- A. Any paragraph in this Order that terminates in less than twenty years;
- B. This Order's application to any respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this paragraph as though the complaint was never filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

X.

IT IS FURTHER ORDERED that respondent shall, within sixty (60) days after service of this Order, and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this Order.

Signed this ______ day of ______, 19_____

SCHERING-PLOUGH HEALTHCARE PRODUCTS, INC., a corporation

BY:

President

MORGAN M. W. WEBER Senior Counsel

NANCY L. BUC Buc & Beardsley 919 18th Street, N.W., Suite 600 Washington, D.C. 20006 Attorney for proposed respondent TOBY MILGROM LEVIN Counsel for the Federal Trade Commission

MAMIE KRESSES Counsel for the Federal Trade Commission

APPROVED:

C. LEE PEELER Associate Director Division of Advertising Practices

JOAN Z. BERNSTEIN Director Bureau of Consumer Protection

UNITED STATES OF AMERICA BEFORE FEDERAL TRADE COMMISSION

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In the Matter of SCHERING-PLOUGH HEALTHCARE PRODUCTS, INC., a corporation.

DOCKET NO.

COMPLAINT

The Federal Trade Commission, having reason to believe that Schering-Plough Healthcare Products, Inc., a corporation, ("respondent"), has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH ONE: Respondent Schering-Plough Healthcare Products, Inc. is a Delaware corporation, with its principal office or place of business at 3030 Jackson Avenue, Memphis, Tennessee 38151.

PARAGRAPH TWO: Respondent has manufactured, advertised, labeled, promoted, offered for sale, sold, and distributed over-the-counter health care products, including "Coppertone Kids" sunblock lotion, to consumers. Coppertone Kids is a "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

PARAGRAPH THREE: The acts and practices of respondent alleged in this complaint have been in or affecting commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

PARAGRAPH FOUR: Respondent has disseminated or has caused to be disseminated advertisements and promotional materials for Coppertone Kids, including but not necessarily limited to the attached Exhibits A through H. These advertisements and promotional materials contain the following statements and depictions:

A. (Depiction: child performing cannonball dive off of diving board)

Coppertone Kids sunblock lasts through 32 back flips, 64 cannonballs and 52 belly flops.

Introducing new Coppertone Kids 6-Hour Waterproof Sunblock. It goes on. And goes on protecting.In and out of the water, all day long.Because it's the sunblock that keeps kids protected from the sun, and waterproof for a full six hours.As proven by kids themselves in test after test. Coppertone Kids 6-Hour Waterproof Sunblock.It goes on. And stays on.

Read and follow label directions

(Exhibit A)(magazine ad)

B. (Depiction: child performing cannonball dive off of diving board)

Coppertone KIDS sunblock lasts through 32 back flips, 64 cannonballs and 52 belly flops.

Coppertone KIDS 6-Hour Waterproof Sunblock goes on and stays on. In and out of the water. All day long. Because it's the waterproof sunblock that keeps kids protected from the sun for a full six hours. As proven by kids themselves in test after test. Coppertone KIDS 6-Hour Waterproof Sunblock. It goes on and stays on.

Read and follow label directions

(Exhibit B)(magazine ad)

C. (Sound effects: kids playing in pool)

... Kids can last in the water for hours...But all sunblocks can't. That's why there's Coppertone Kids Waterproof Sunblock. It lasts 6 full hours, in and out of the water, so you don't have to reapply it as often. Which means your kids get great protection, and you get peace of mind...Coppertone Kids 6-Hour Waterproof Sunblock. It goes on and stays on. Use as directed.

(Exhibit C) (radio ad)

D. (Sound effects: kids playing in pool; mother repeating herself)

Billy, time for more sunblock. ...time for more sunblock. ...time for more sunblock...

Coppertone Kids waterproof sunblock is made to last a full 6 hours, in and out of the water, so you won't have to reapply it as often. That means your kids get great protection, and you can stop repeating yourself...Coppertone Kids 6 hour waterproof sunblock. It goes on. And stays on.

(Exhibit D) (radio ad)

E. (Depiction: Three mothers fishing at the ocean. One mother reels in her son from the water, applies sunscreen on the child, and then cuts the fishing line holding him)

...Mom's gotta keep a line on her kids... 'cause she's gotta keep re-applying that sunblock every time they come out of the water. But now there's new Coppertone Kids 6 Hour Waterproof Sunblock. (super: USE ONLY AS DIRECTED) It keeps a kid protected from the sun, and waterproof for a full six hours. So Mom puts it on...and cuts them loose... New Coppertone Kids 6 Hour Waterproof Sunblock. It goes on and stays on. (Super: It goes on. And stays on.)

(Exhibit E) (tv ad)

F. Coppertone Kids sunblock is uniquely formulated to provide long-lasting waterproof protection. This waterproof formula lasts for a full **6 HOURS** in and out of the water, and keeps kids protected from the sun's burning UVA and UVB rays.

6-HOUR WATERPROOF - Ideal for water active kids. **LONG LASTING** - Kid tested to go on and stay on...

(Exhibits F & G) (label and promotion sample)

G. Dear Doctor:

Coppertone, the most trusted name in suncare, now provides a complete line of sunblocks specially formulated for children...Coppertone KIDS offers 6-hour waterproof protection.

...

Coppertone KIDS

- Waterproof for a full 6 hours
- Long-lasting protection...
- Available in SPF 15 and 30

All Coppertone Children's Sunblocks are clinically tested on children, so you can be confident your patients are getting safe, effective sun protection.

(Exhibit H) (promotional letter to doctors)

PARAGRAPH FIVE: Through the use of the statements and depictions contained in the advertisements and promotional materials referred to in PARAGRAPH FOUR, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A through H, respondent has represented, directly or by implication, that a single application of Coppertone Kids provides six hours of protection from the sun for children engaged in sustained vigorous activity in and out of the water.

PARAGRAPH SIX: Through the use of the statements and depictions contained in the advertisements and promotional materials referred to in PARAGRAPH FOUR, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A through H, respondent has represented, directly or by implication, that at the time it made the representation set forth in PARAGRAPH FIVE, respondent possessed and relied upon a reasonable basis that substantiated such representation.

PARAGRAPH SEVEN: In truth and in fact, at the time it made the representation set forth in PARAGRAPH FIVE, respondent did not possess and rely upon a reasonable basis that substantiated such representation. Therefore, the representation set forth in PARAGRAPH SIX was, and is, false and misleading.

PARAGRAPH EIGHT: Through the use of statements contained in the advertisements and promotional materials referred to in PARAGRAPH FOUR, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A,B,F, G and H, respondent has represented, directly or by implication, that it has conducted tests demonstrating that a single application of Coppertone Kids provides six hours of protection from the sun for children engaged in sustained vigorous activity in and out of the water.

PARAGRAPH NINE: In truth and in fact, respondent has not conducted tests demonstrating that a single application of Coppertone Kids provides six hours of protection from the sun for children engaged in sustained vigorous activity in and out of the water. Among other reasons, none of the tests relied upon by respondent evaluated a single application of the product under the advertised conditions of use, <u>i.e.</u>, sustained vigorous activity in and out of the water. Therefore, the representation set forth in PARAGRAPH EIGHT was, and is, false and misleading.

PARAGRAPH TEN: The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this _____ day of _____, 19____, has issued this complaint against respondent.

By the Commission.

Donald S. Clark Secretary

SEAL:

[Exhibits A-H attached to paper copies of complaint, but not available in electronic form.]

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted an agreement to a proposed consent order from Schering-Plough Healthcare Products, Inc. ("Schering-Plough Healthcare"). Schering-Plough Healthcare, a wholly-owned subsidiary of the Schering-Plough Corporation, is a manufacturer and distributor of health care products, including sunscreens.

The proposed consent order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves alleged deceptive representations made in advertising for Coppertone Kids, a sunscreen product promoted for use on children. According to the FTC complaint, Schering-Plough Healthcare represented, without adequate substantiation, that a single application of Coppertone Kids provides six hours of protection from the sun, at the advertised SPF level, for children engaged in sustained vigorous activity in and out of the water. The complaint also alleges that Schering-Plough Healthcare falsely represented that it had conducted tests demonstrating that the product provides such protection. According to the complaint, among other things, the company's tests did not evaluate a single application of the product under the advertised conditions of use (sustained vigorous activity).

The consent order contains provisions designed to remedy the violations charged and to prevent Schering-Plough Healthcare from engaging in similar acts and practices in the future.

Part I of the proposed order prohibits Schering-Plough Healthcare from representing: (a) the length of time that Coppertone Kids or any other children's sun protection product will provide protection from the sun for persons engaged in sustained vigorous activity in and out of the water; or (b) the efficacy of any children's sun protection product in providing protection against any harmful effect of sun exposure or ultraviolet radiation, unless the company has scientific substantiation for the representation.

The order defines a "children's sun protection product" as any sun protection product that uses the word "babies," "children," "kids," or other similar words in the name or promotion of the product, or that is advertised or promoted for use primarily on children under the age of twelve.

Part II of the proposed order prohibits Schering-Plough Healthcare from misrepresenting the existence, contents, validity, or conclusions of any test or study concerning any sun protection product. Part III of the order allows Schering-Plough Healthcare to make any representation for a sun protection product that is specifically permitted in labeling for that product under any tentative final or final Food and Drug Administration standard or under any new drug application approved by the Food and Drug Administration.

Part IV of the proposed order requires Schering-Plough Healthcare to produce and disseminate a consumer brochure addressing the importance of sunscreen usage to children and the health benefits associated with it, and promoting the proper use and application of sunscreens on children. The brochure, which is subject to FTC approval, will be disseminated by Schering-Plough Healthcare to organizations with direct access to parents or organizations with access to parents or others who work with or care for children under the age of 12.

Parts V, VII, IX, and X of the proposed order require Schering-Plough Healthcare to keep copies of all materials relied upon in making any representations covered by Parts I and II of the order; to provide copies of the order to certain of the company's personnel; to notify the Commission of any change in corporate structure; and to file compliance reports with the Commission. Part VI permits respondent to use existing labeling for 100 days after the date of service of the order. Part VIII provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

SEPARATE STATEMENT OF COMMISSIONER MARY L. AZCUENAGA CONCURRING IN PART AND DISSENTING IN PART in <u>Schering-Plough Healthcare</u>, File No. 942 3341

Today, the Commission accepts for public comment a proposed consent agreement resolving allegations about certain claims in the advertising of Coppertone Kids 6-Hour Waterproof Sunblock. I concur except with respect to Part IV of the proposed order, which requires the respondent to develop and disseminate a consumer education brochure addressing the dangers of unprotected exposure to the sun. Consumer education brochures are an integral part of the Commission's consumer protection program, but they are not necessarily defensible adjuncts to Commission orders.

A fencing-in provision will be sustained by the courts as long as it is "reasonably related" to the violation found. ¹ Fencing-in relief properly may include requirements beyond simply prohibiting the challenged conduct that are designed to "close all roads to the prohibited goal, so that [the Commission's] order may not be by-passed with impunity." ² The allegedly

¹ FTC v. Colgate-Palmolive Co., 380 U.S. 374, 394-95 (1965); FTC v. National Lead Co., 352 U.S. 419, 428 (1957).

² FTC v. Ruberoid Co., 343 U.S. 470, 473 (1952).

deceptive claim is that the respondent's sunblock for children would remain effective for six hours even if the children engaged in "sustained vigorous activities in and out of the water," such as playing in sand, taking off and putting on clothes and toweling off after swimming. Complaint ¶ 5. The proposed order expressly enjoins the respondents from making the challenged claim, either directly or indirectly, for the product at issue as well as for "any other children's sun protection product." Order ¶ I.

In addition, the proposed order requires the respondent to develop and distribute 150,000 copies of a color brochure concerning the importance of sunscreen usage by children. The order requires that the brochure contain six messages or themes only one of which addresses the issue in this case, the need to reapply so-called water-proof or water-resistant sunblock after vigorous activity or after toweling off. Order ¶ IV-E.

The brochure requirement, even the message that relates most closely to the challenged claim, is not focused on preventing the respondent from making the challenged claim or otherwise from avoiding compliance with the order. The brochure would help educate consumers regarding an important health issue, and, presumably, make them less likely to be misled by the kind of implied claims challenged in this action. ³ There is no reason to think that it would enhance the deterrent effect of the order on Schering.

Presumably, the brochure requirement will not be unduly burdensome or costly for Schering because it will promote the use

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³ The product label already contains the statement, "Reapply after toweling."

of its product, and the brochure is undoubtedly commendable as a public health initiative. Nevertheless, under the circumstances, it is an overly broad order requirement as measured against the current standard for ordering relief. ⁴ There is a value to the Commission in maintaining the integrity of the standard for imposing a fencing-in remedy.

I respectfully dissent from Part IV of the order.

⁴ It would be even more difficult to justify Part IV of the order as corrective advertising, because it is unlikely that the implied claim challenged in the complaint would linger in the minds of consumers long after it ceased being made. <u>See</u> Warner-Lambert Co. v. FTC, 562 F.2d 749, 762 (D.C. Cir. 1977), <u>cert</u>. <u>denied</u>, 435 U.S. 950 (1978).

Statement of Commissioner Roscoe B. Starek, III Concurring in Part and Dissenting in Part in Schering-Plough Healthcare Products, Inc. File No. 942-3341

I have voted to accept for public comment the consent agreement with Schering-Plough Healthcare Products, Inc. ("Schering"), because I have reason to believe that the challenged advertisements are deceptive and I find that the proposed order, for the most part, provides appropriate relief. I do not, however, support the requirement that Schering produce and distribute a consumer education brochure that includes numerous specified "messages or themes." As set forth in the proposed order, this consumer education remedy is overbroad and in any event is unlikely to assist in the prevention of the violations alleged in the complaint. Although I am an advocate of a strong Commission consumer education program, and we can be proud of the valuable work done by the Bureau of Consumer Protection's Office of Consumer and Business Education, this remedy is a well-meaning but not legally justifiable effort to fund a general consumer education campaign.

The Commission enjoys extensive authority to fashion fencing-in relief for deceptive practices so long as the remedy has a reasonable relation to the violations alleged in the complaint. See, e.g., FTC v. Colgate-Palmolive Co., 380 U.S. 374, 394-95 (1965); FTC v. National Lead Co., 352 U.S. 419, 428-29 (1957). With such authority, however, comes the responsibility to exercise it judiciously. In my view, the consumer education remedy mandated by this proposed order bears no reasonable relationship to the violations alleged in the complaint. The proposed complaint alleges that Schering lacked a reasonable basis for the claim that a single application of Coppertone Kids provides six hours of protection from the sun for children engaged in sustained vigorous activity in and out of the water.¹ The order addresses this allegation by requiring scientific substantiation for claims about the efficacy of any children's sun protection product in providing protection against any harmful effect of sun exposure or ultraviolet radiation, or about the length of time that any such product will provide sun protection for individuals engaged in sustained vigorous activity in and out of the water.

In addition, however, the order would require Schering to design, produce and print a brochure -- subject to the approval of the Associate Director of the Division of Advertising Practices ("DAP") in the Commission's Bureau of Consumer Protection -- about the importance of sunscreen usage by children. The order mandates that the brochure include *all* of the following "messages or themes":

- (A) The importance of sunscreens in preventing skin damage, including skin cancer, sunburn, and premature skin aging;
- (B) Regular use of a high SPF sunscreen during childhood can significantly reduce the risk of certain types of skin cancers later in life;
- (C) A single bad sunburn during childhood can significantly increase a child's risk of developing skin cancer later in life;
- (D) The importance of proper application of sunscreens;

¹ The proposed complaint challenges as false the claim that Schering has conducted tests demonstrating that a single application of Coppertone Kids provides six hours of protection from the sun for children engaged in sustained vigorous activity in and out of the water. The proposed order broadly prohibits false establishment claims for any sun protection product.

- (E) The need to reapply sunscreens after toweling or sustained vigorous activity; and
- (F) The need to use sunscreens during outdoor activities -- not only in connection with water activities.

Order ¶ IV. The respondent must disseminate 150,000 copies of this brochure to parents or to organizations with access to parents or others who work with or care for children under age twelve. 2

Of the six required messages, only statement (E) seems likely to assist in the prevention of future deception like or related to that alleged in the complaint. Yet by including this key reapplication information in an extensive list of other facts about sunscreen, the order makes it less likely that consumers will see the reapplication information. In my view, it is highly unlikely that a parent who receives and reviews whatever brochure is approved will recall the one piece of information related to the complaint allegation when the parent makes a sunscreen purchase. Because the scope of the information to be included in

² Like the brochure, the dissemination plan is subject to the approval of the Associate Director in charge of DAP.

the brochure is so broad, the consumer education remedy is not reasonably related to the violations alleged in the proposed complaint. 3

It is also troubling that if the Commission issues this order, it essentially will be ordering the respondent to advertise that persons should buy and use more of the respondent's products. Schering already has every incentive to communicate the required messages to consumers. In fact, the consumer education remedy is advertising ("use more sunscreen") that the company might wish to do in any event since the conduct provisions of the order may prevent it from continuing to distinguish its children's sun protection product from others by claiming that it requires fewer applications. The deterrence value of this remedy is minimal at best.

Finally, if this relief were sought in litigation, rather than obtained through a consent agreement, it would not withstand scrutiny under the First Amendment. For purposes of First Amendment analysis, there is no difference between compelled

³ The consumer education remedy here stands in contrast to a fencing-in provision contained in a consent order issued by the See Blenheim Expositions, Inc., Docket No. Commission last year. C-3633 (Jan. 18, 1996) (requiring a franchise show promoter to undertake a limited distribution of an FTC consumer education brochure to customers attending its franchise shows). The respondent in Blenheim allegedly made unsubstantiated claims regarding the earnings and success of franchise owners and false claims regarding a poll of franchise owners. The brochure specifically identified FTC requirements with which franchisors must comply, including consumers' right to receive an earnings claims document, and it provided instructions on how to evaluate earnings claims. It thus contained information likely to assist the respondent's customers to detect and protect themselves from possible future misrepresentations of earnings like those alleged in the complaint. Although the brochure also addressed other issues related to the purchase of a franchise, all of the advice in the brochure at least arguably would help prospective franchisees avoid becoming victims of future violations by the respondent.

speech and restrictions on speech. Riley v. National Fed'n of the Blind, 487 U.S. 781, 796-97 (1988). A valid restriction on commercial speech must be no more extensive than necessary to serve the substantial governmental interest directly advanced by the restriction. Rubin v. Coors Brewing Co., 115 S. Ct. 1585, 1591 (1995) (discussing Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980)). Thus, disclosures compelled by the FTC can be no broader than necessary to prevent future deception or to correct the effects of past deception. See, e.g., National Comm'n on Egg Nutrition v. FTC, 570 F.2d 157, 164 (7th Cir. 1977), cert. denied, 439 U.S. 821 (1978). Additionally, the government bears the burden of showing that a speech restriction will advance its interest "to a material degree." 44 Liquormart, Inc. v. Rhode Island, 116 S. Ct. 1495, 1509 (1996) (plurality opinion of Justice Stevens) (citing *Edenfield v. Fane*, 507 U.S. 761, 771 (1993)). A commercial speech restriction that "provides only ineffective or remote support for the government's purpose" does not pass this test. 44 Liquormart, 116 S. Ct. at 1509 (citing Central Hudson, 447 U.S. at 564).

The dubious efficacy of the proposed consumer education remedy makes it unlikely that it will directly advance the

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asserted governmental interest in preventing future deception by the respondent. In addition, I doubt that a credible argument can be made that the information that the order specifically requires be included in the brochure is no more extensive than necessary to prevent future violations by Schering. Certainly Schering has waived any First Amendment objections to this relief by entering into the consent agreement. Nonetheless, when a remedy implicates First Amendment rights, the Commission should be particularly reluctant to obtain through negotiation relief that it lacks at least a colorable chance to obtain in litigation.

In my view, it would be better to have no consumer information remedy in the consent order if the only alternative is an overbroad remedy of doubtful efficacy that raises First Amendment concerns.