

IN THE MATTER OF

JOHNSON & JOHNSON CONSUMER PRODUCTS, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3636. Complaint, Jan. 18, 1996--Decision, Jan. 18, 1996*

This consent order prohibits, among other things, a New Jersey-based personal health-care products company and its parent corporation from misrepresenting the results or conclusions of any test or study concerning any over-the-counter products with a use relating to human reproduction, reproductive organs or sexually transmitted diseases ("STDs"). It requires the respondent to have competent and reliable scientific evidence for any claims regarding the efficacy of over-the-counter contraceptives or products to protect against STDs. In addition, the respondent must have competent and reliable scientific evidence to substantiate the advertising claims of any personal lubricant and/or spermicide.

Appearances

For the Commission: *Linda K. Badger, Matthew D. Gold, and Jeffrey Klurfeld.*

For the respondent: *Clayton Patterson*, in-house counsel, New Brunswick, N.J.

COMPLAINT

The Federal Trade Commission, having reason to believe that Johnson & Johnson Consumer Products, Inc., ("respondent"), a corporation, 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 1. Respondent Johnson & Johnson Consumer Products, Inc., a wholly-owned subsidiary of Johnson & Johnson, is a New Jersey corporation with its offices and principal place of business at 1999 Grandview Road, Skillman, New Jersey.

PAR. 2. Respondent has manufactured, advertised, labeled, offered for sale, sold, and distributed K-Y Plus Nonoxynol-9

Spermicidal Lubricant ("K-Y Plus"), and other products to consumers. K-Y Plus is a "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

PAR. 3. 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.

PAR. 4. Respondent has disseminated or has caused to be disseminated advertisements for K-Y Plus, including but not necessarily limited to the attached Exhibits A-C. These advertisements contain the following statements:

A. "K-Y Plus, because one out of every six condoms develops tiny holes during use. Holes invisible to the naked eye, but big enough for sperm, HIV and other viruses to pass through. K-Y Plus Brand Spermicidal Lubricant with Nonoxynol-9 provides double protection. First, the natural-feeling lubrication guards your condom against friction that can cause holes. Second, it contains a highly effective spermicide, doctor-recommended Nonoxynol-9, to give you peace of mind in case your condom fails. Ask your doctor about K-Y Plus. For your own protection.

Condom Insurance. The safer choice."

[Exhibit A (Print: "Condom Insurance")]

B. "New K-Y Plus, because one out of six condoms fails. Anyone can make a mistake, or a condom can develop tiny holes during use - invisible to the eye, but big enough for sperm, HIV and other viruses to pass through. So new K-Y Plus Brand with Nonoxynol-9 just makes good sense for personal lubrication. It provides double protection.

First, the clean-rinsing and natural-feeling lubrication of K-Y Plus guards your condom against friction that can cause invisible holes. Second, it contains a highly effective spermicide, doctor-recommended Nonoxynol-9, to give you peace of mind in case your condom fails.

Introducing condom insurance. The safer choice."

[Exhibit B (Print: "Introducing Condom Insurance.")]

C. "Studies show that up to 18.5% of condoms will fail - leaving patients vulnerable to pregnancy and STDs.

...

Like regular K-Y BRAND Jelly - available as always - new K-Y PLUS is crystal clear and provides safe water-soluble lubrication to guard against friction and condom breakage. New K-Y PLUS also contains proven nonoxynol-9 for extra protection against unplanned pregnancy.

NEW K-Y PLUS Spermicidal Lubricant An extra layer of protection."

[Exhibit C (Print: "Protect the Protector")]

PAR. 5. Through the use of the statements contained in the advertisements referred to in paragraph four, including but not necessarily limited to the advertisement attached as Exhibit C,

respondent has represented, directly or by implication, that scientific tests or studies show that up to eighteen and one half percent of condoms will fail; leaving users vulnerable to pregnancy and sexually transmitted diseases.

PAR. 6. In truth and in fact, scientific tests or studies do not show that eighteen and one half percent of condoms will fail, leaving users vulnerable to pregnancy and sexually transmitted diseases. Therefore, the representation set forth in paragraph five was, and is, false and misleading.

PAR. 7. Through the use of the statements contained in the advertisements referred to in paragraph four, including but not necessarily limited to the advertisements attached as Exhibits A-C, respondent has represented, directly or by implication, that:

A. One out of six condoms develops tiny holes during use which are big enough for sperm, HIV and other viruses to pass through.

B. One out of six condoms fails due to mistakes in using condoms or through the development of tiny holes during use.

C. K-Y Plus provides protection against the development of tiny holes in condoms during use.

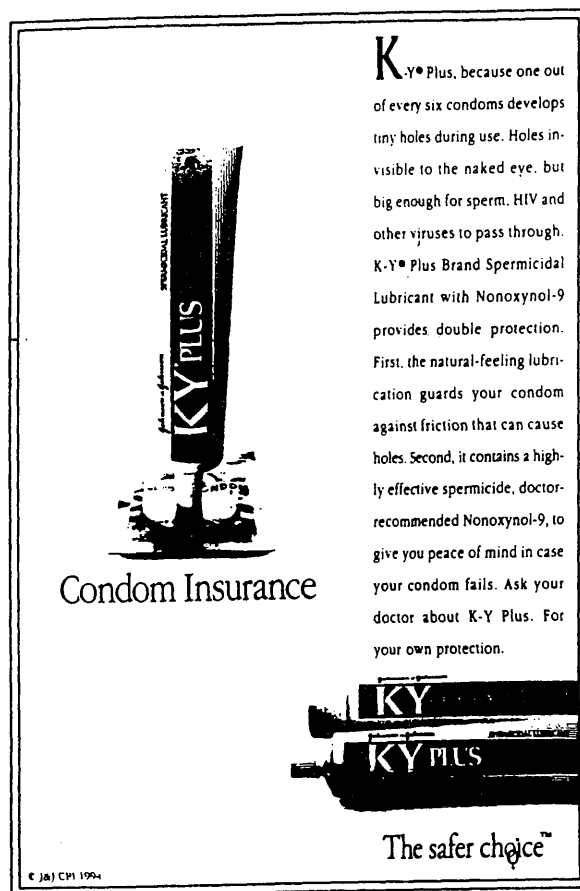
D. K-Y Plus provides protection against HIV and other viruses.

PAR. 8. Through the use of the statements contained in the advertisements referred to in paragraph four, including but not necessarily limited to the advertisements attached as Exhibits A-C, respondent has represented, directly or by implication, that at the time it made the representations set forth in paragraphs five and seven, respondent possessed and relied upon a reasonable basis that substantiated such representations.

PAR. 9. In truth and in fact, at the time it made the representations set forth in paragraphs five and seven, respondent did not possess and rely upon a reasonable basis that substantiated such representations. Therefore, the representation set forth in paragraph eight was, and is, false and misleading.

PAR. 10. 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.

EXHIBIT A



The advertisement is enclosed in a rectangular border. On the left, a tube of KY Plus lubricant is shown vertically, with its cap removed and the applicator tip pointing downwards. Below the tube, the words "Condom Insurance" are printed in a serif font. To the right of the tube, a block of text is arranged in a column. At the bottom right, two more tubes of KY Plus are shown horizontally, one above the other. Below them, the phrase "The safer choice™" is written in a script font. In the bottom left corner of the advertisement, there is a small copyright notice.

K-Y® Plus, because one out of every six condoms develops tiny holes during use. Holes invisible to the naked eye, but big enough for sperm. HIV and other viruses to pass through. K-Y® Plus Brand Spermicidal Lubricant with Nonoxynol-9 provides double protection. First, the natural-feeling lubrication guards your condom against friction that can cause holes. Second, it contains a highly effective spermicide, doctor-recommended Nonoxynol-9, to give you peace of mind in case your condom fails. Ask your doctor about K-Y Plus. For your own protection.

Condom Insurance

KY PLUS

KY PLUS

The safer choice™

© 1994 J&J CP

This advertisement created by:

LINTAS:NEW YORK

Ad No: P4-1129

Client: Johnson & John

Title: Condom Insurance.

EXHIBIT A

Complaint

121 F.T.C.

EXHIBIT B



Introducing
condom insurance.

New K-Y[®] Plus, because one out of six condoms fails. Anyone can make a mistake, or a condom can develop tiny holes during use — invisible to the eye, but big enough for sperm, HIV and other viruses to pass through. So new K-Y[®] Plus Brand with Nonoxynol-9 just makes good sense for personal lubrication. It provides double protection.

First, the clean-rinsing and natural-feeling lubrication of K-Y[®] Plus guards your condom against friction that can cause invisible holes. Second, it contains a highly effective spermicide, doctor-recommended Nonoxynol-9, to give you peace of mind in case your condom fails. And if you don't need a spermicide, regular K-Y[®] Brand Jelly is the water-based lubricant that won't erode latex condoms like petroleum jelly and other oil-based products can. Ask your doctor about regular K-Y[®] Jelly and new K-Y[®] Plus.



The safer choice

EXHIBIT B

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EXHIBIT C

EXHIBIT C

NOW

Protect the Protector

It's a risky world out there for some of your sexually active patients. That's why you recommend the condom. But the condom can also be vulnerable. That's why your patients need new K-Y PLUS BRAND Spermicidal Lubricant with nonoxynol-9.

Studies show that up to 18.5% of condoms will fail¹—leaving patients vulnerable to pregnancy and STDs. Choosing petroleum- or oil-based products for lubrication is a major factor.^{2,4} And about 20% of condom users make that risky choice.³ Studies show that:

Within just 60 seconds of exposure to oil-based products, latex condoms suffer a 90% loss of strength,⁵ which may cause microscopic rips and tears. In contrast, latex condoms maintained their full integrity even after 30 minutes of exposure to new K-Y PLUS.⁶

By protecting the latex condom, new K-Y PLUS helps prevent pregnancy and STDs. Like regular K-Y[®] brand jelly—available as always—new K-Y PLUS is crystal clear and provides safe water-soluble lubrication to guard against friction and condom breakage. New K-Y PLUS also contains proven nonoxynol-9 for extra protection against unplanned pregnancy.

NEW K-Y PLUS Spermicidal Lubricant
An extra layer of protection.



References: 1. Choice of contraceptive. The Medical Letter, 1992;34(857):111-114. 2. Anderson FW. Condoms. In: The Female Patient, 1992;18:16-20. 3. Miller B, Coulter J, Berman L, et al. Condom use, 1988-1991. JAMA, 1992;267:1001-1005. 4. Morris C, Davis J, et al. Condom use, 1988-1991. JAMA, 1992;267:1001-1005. 5. Jellison B, et al. Condom use, 1988-1991. JAMA, 1992;267:1001-1005. 6. Jellison B, et al. Condom use, 1988-1991. JAMA, 1992;267:1001-1005.

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DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent and its parent corporation, Johnson & Johnson, having been furnished thereafter with a copy of a draft of complaint which the San Francisco Regional Office proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondent with violation of the Federal Trade Commission Act; and

The respondent, its parent corporation, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent and its parent corporation of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent or its parent corporation 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 respondent has 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, pursuant to Section 2.34 of its Rules, 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 Johnson & Johnson Consumer Products, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New Jersey, with its office and principal place of business located at 1999 Grandview Road, in the City of Skillman, State of New Jersey;

Johnson & Johnson is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New Jersey, with its office and principal place of business located at One Johnson & Johnson Plaza, in the City of New Brunswick, State of New Jersey.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent and the parent corporation, and the proceeding is in the public interest.

ORDER

I.

It is ordered, That respondent, Johnson & Johnson Consumer Products, Inc., a corporation, its parent corporation, Johnson & Johnson, and all the other subsidiaries of Johnson & Johnson, their successors and assigns (hereinafter collectively "the companies"), and the companies' officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale or distribution of K-Y Plus Nonoxynol-9 Spermicidal Lubricant, or any other personal lubricant and/or spermicide, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, relating to:

A. The failure rate of any method of contraception due to defects, misuse, or any other cause;

B. Any such product's ability to provide protection against the development of tiny holes in condoms during use;

C. Any such product's ability to provide protection against HIV and other viruses; or

D. The health-related benefits of any such product;

unless, at the time of making any such representation, the companies possess and rely upon competent and reliable scientific evidence that substantiates such representation. For the purposes of this order, "competent and reliable scientific evidence" shall mean those 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.

II.

It is further ordered, That the companies and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale or distribution of any "food," "drug" or "device," as those terms are defined in Section 15 of the Federal Trade Commission Act, 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, the efficacy of any over-the-counter product as a contraceptive or as a method of protection against the transmission of any sexually-transmitted disease, unless, at the time of making any such representation, the companies possess and rely upon competent and reliable scientific evidence that substantiates such representation.

III.

It is further ordered, That the companies and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale or distribution of any over-the-counter product with a use relating to human reproduction, reproductive organs or sexually-transmitted diseases, 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.

IV.

It is further ordered, That for five (5) years after the last date of dissemination of any representation covered by this order, the companies 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 such representation; and

B. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

V.

It is further ordered, That the companies notify the Commission at least thirty (30) days prior to any proposed change in the companies 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.

VI.

It is further ordered, (1) That respondent Johnson & Johnson Consumer Products, Inc., shall, within ten (10) days from the date of service of this order upon it, distribute a copy of this order to each of its operating divisions, to each of its managerial employees, and to each of its officers, agents, representatives or employees engaged in the preparation, review or placement of advertising or other materials covered by this order, and (2) that the parent corporation, Johnson & Johnson, shall, within ten (10) days from the date of service of this order upon it, distribute a copy of this order to each of its and of its subsidiaries' officers, agents, representatives or employees engaged in the preparation, review or placement of advertising of any over-the-counter product with a use relating to human reproduction, reproductive organs or sexually-transmitted diseases.

VII.

It is further ordered, That this order will terminate on January 18, 2016, 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.

VIII.

It is further ordered, That the companies shall, within sixty (60) days from the date of service of this order upon them, 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 they have complied with this order.

IX.

It is further ordered, That nothing in this order shall prohibit the companies from making any representation for any drug that is permitted in labeling for any such drug 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.

CONCURRING STATEMENT OF COMMISSIONER MARY L. AZCUENAGA

I concur in the approval and issuance of the final decision and order in this matter except to the extent that the order imposes obligations on Johnson & Johnson (the parent company of the respondent Johnson & Johnson Consumer Products, Inc.), which is not named in the accompanying complaint.

IN THE MATTER OF

BBDO WORLDWIDE, INC.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-3637. Complaint, Jan. 24, 1996--Decision, Jan. 24, 1996*

This consent order prohibits, among other things, a New York advertising firm from misrepresenting the amount of fat, calories, or cholesterol in any frozen yogurt, any frozen sorbet, and most ice cream products. This action stems from the firm's role in developing certain advertisements for Häagen-Dazs frozen yogurt products.

Appearances

For the Commission: *Anne V. Maher.*

For the respondent: *Pro se.*

COMPLAINT

The Federal Trade Commission, having reason to believe that BBDO Worldwide, 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 1. Respondent BBDO Worldwide, Inc. is a New York corporation, with its principal office or place of business at 1285 Avenue of the Americas, New York, NY.

PAR. 2. Respondent, at all times relevant to this complaint, was an advertising agency of Häagen-Dazs Company, Inc., and prepared and disseminated advertisements to promote the sale of Häagen-Dazs Frozen Yogurt, a "food" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

PAR. 3. 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.

PAR. 4. Respondent has disseminated or has caused to be disseminated advertisements for Häagen-Dazs Frozen Yogurt,