UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of

PHASEOUT OF AMERICA, INC. and PRODUCTS & PATENTS, LTD., corporations.

FILE NO. 932-3180

AGREEMENT CONTAINING CONSENT ORDER

The Federal Trade Commission has conducted an investigation of certain acts and practices of Phaseout of America, Inc. and Products & Patents, Ltd., corporations ("proposed respondents"). Proposed respondents, having been represented by counsel, are willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between Phaseout of America, Inc. and Products & Patents, Ltd., by their duly authorized officers, and their attorneys, and counsel for the Federal Trade Commission that:

- 1.a. Proposed respondent Phaseout of America, Inc. is a Delaware corporation with its principal office or place of business at 140 Broadway, Lynbrook, New York 11563.
- 1.b. Proposed respondent Products & Patents, Ltd., is a Delaware corporation with its principal office or place of business at 140 Broadway, Lynbrook, New York 11563.
- 2. Proposed respondents admit all the jurisdictional facts set forth in the draft complaint.
- 3. Proposed respondents waive:
 - 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 complaint, will be placed on the public record for a period of sixty (60)

days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondents, 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 respondents that the law has been violated as alleged in the draft complaint, 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 Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondents, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order 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 of the complaint and the decision and order to proposed respondents by any means specified in Section 4.4 of the Commission's Rules shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order. 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 respondents have read the draft complaint and consent order. They understand that they may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

- 1. "Johns Hopkins study" shall mean the study that has been reported as Stitzer, Brigham and Felch, <u>Phase-Out Filter Perforation: Effects on Human Tobacco Smoke Exposure</u>, 41 Pharmacology, Biochemistry and Behavior 748 (1992).
- 2. "Smoking-cessation product" shall mean any product or program designed to aid or assist the user to stop or reduce the cigarette urge, break the cigarette habit, or stop or reduce smoking.

- 3. "Cigarette-modification product" shall mean any product or program designed to reduce the amount of tar, nicotine, carbon monoxide or other substance that smokers get from cigarettes, or reduce their risk of smoking-related health problems.
- 4. "Substantially similar product" shall mean any smoking-cessation product or cigarette-modification product that punches one or more holes in a cigarette or pack of cigarettes.
- 5. "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 has 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. Survey evidence may be appropriate depending on the representation made.
- 6. Unless otherwise specified, "respondents" shall mean Phaseout of America, Inc. and Products & Patents, Ltd., corporations, their successors, assigns, agents, representatives and employees.
- 7. "Purchaser for resale" shall mean any purchaser or other transferee of the PhaseOut device, or of the right or license to sell the PhaseOut device, other than respondents, who sells, or who has sold, the PhaseOut device to other purchasers or to consumers.
- 8. "In or affecting commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondents, 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 the PhaseOut device or any substantially similar product in or affecting commerce, shall not represent, in any manner, expressly or by implication, that:

- A. The Johns Hopkins study proves that such product significantly reduces the amount of tar, nicotine, or carbon monoxide smokers get under normal smoking conditions;
- B. The Johns Hopkins study proves that such product is effective in enabling smokers to quit smoking; or
- C. The Johns Hopkins study proves that smokers who use such product and continue to smoke significantly reduce their risk of smoking-related health problems.

IT IS FURTHER ORDERED that respondents, 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 smoking-cessation product or cigarette-modification product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that:

- 1. The product reduces the amount of nicotine, tar, carbon monoxide, or any other component of cigarette smoke that smokers get from smoking a cigarette;
- 2. The product is effective in enabling or helping smokers to quit smoking;
- 3. The product reduces the risk of smoking-related health problems, including, but not limited to, lung cancer or heart disease, for smokers who continue to smoke;
- 4. The product reduces the amount of nicotine, tar, carbon monoxide, or any other component of cigarette smoke that smokers get without changing a cigarette's taste or draw;
- 5. Smokers using the product will not compensate for the product's effects by increasing the number of cigarettes they smoke per day;
- 6. The product is effective in enabling or helping smokers to quit smoking without withdrawal symptoms; or
- 7. The product provides immediate health benefits, including, but not limited to, reduced congestion, coughing or windedness, for smokers who continue to smoke:

unless, at the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, 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 smoking-cessation product or cigarette-modification product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the performance, benefits or efficacy of such product,

unless, at the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV.

IT IS FURTHER ORDERED that respondents, 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 smoking-cessation product or cigarette-modification product in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

V.

IT IS FURTHER ORDERED that respondents, 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 smoking-cessation product or cigarette-modification product in or affecting commerce, shall not represent, in any manner, expressly or by implication, that the experience represented by any user testimonial or endorsement of the product represents the typical or ordinary experience of members of the public who use the product, unless:

- A. At the time it is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation; or
- B. Respondents disclose, clearly and prominently, and in close proximity to the endorsement or testimonial, either:
 - 1. what the generally expected results would be for users of the product, or
 - 2. the limited applicability of the endorser's experience to what consumers may generally expect to achieve, that is, that consumers should not expect to experience similar results.

For purposes of this Part, "endorsement" shall mean as defined in 16 C.F.R. § 255.0 (b).

VI.

IT IS FURTHER ORDERED that respondents Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns shall:

- A. Within forty-five (45) days after the date of entry of this order, compile a current mailing list containing the names and last known addresses of all purchasers of the PhaseOut device since January 1, 1992. Respondents shall compile this list by:
 - 1. Searching their own files for the names and addresses of such purchasers; and
 - 2. Using their best efforts to identify any other such purchasers, including but not limited to sending by first class certified mail, return receipt requested, within five (5) days after the date of entry of this order, to all purchasers for resale with which respondents have done business since January 1, 1992, an exact copy of the notice attached hereto as Attachment A. The mailing shall not include any other documents. In the event that any such purchaser for resale fails to provide any names or addresses of purchasers in its possession, respondents shall provide the names and addresses of all such purchasers for resale to the Federal Trade Commission within forty-five (45) days after the date of entry of this order.

In addition, respondents shall retain a National Change of Address System ("NCOA") licensee to update this list by processing the list through the NCOA database.

- B. Within ninety (90) days after the date of entry of this order, send by first class postcard, postage prepaid, to the last known address of each purchaser of the PhaseOut device identified on the mailing list compiled pursuant to subparagraph A of this part, an exact copy of the notice attached hereto as Attachment B. The mailing shall not include any other documents.
- C. For one (1) year after the date of entry of this order, make the mailing described in subparagraph B of this part to any person or organization not on the mailing list prescribed in subparagraph A of this part about whom respondents later receive information indicating that the person or organization is likely to have been a purchaser of the PhaseOut device, and to any purchaser whose notification postcard is returned by the U.S. Postal Service and for whom respondents obtain a corrected address, from the U.S. Postal Service or elsewhere. The mailing required by this subparagraph shall be made within ten (10) days of respondents' receipt of a corrected address or information identifying each such purchaser.
- D. In the event that respondents receive any information that, subsequent to its receipt of Attachment A any purchaser for resale is using or disseminating any advertising or promotional material that contains any representation prohibited by

this order, immediately notify the purchaser for resale that respondents will terminate the use of said purchaser for resale if it continues to use such advertising or promotional material; and

E. Terminate the use of any purchaser for resale about whom respondents receive any information that such purchaser for resale has continued to use or disseminate advertising or promotional material that contains any representation prohibited by this order after receipt of the notice required by subparagraph D of this part.

VII.

IT IS FURTHER ORDERED that respondents Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns shall, for five (5) years after the last correspondence to which they pertain, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. Copies of all notifications sent to purchasers pursuant to subparagraphs B and C of part VI of this order;
- B. Copies of all notification letters sent to purchasers for resale pursuant to subparagraph A of part VI of this order;
- C. Copies of all communications with purchasers for resale pursuant to subparagraphs D and E of part VI of this order.

VIII.

IT IS FURTHER ORDERED that respondents Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including

complaints and other communications with consumers or with governmental or consumer protection organizations.

IX.

IT IS FURTHER ORDERED that respondents Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns shall deliver a copy of this order to all current principals, officers, directors, and managers, and to all current employees, agents, and representatives having responsibilities with respect to the subject matter of this order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order.

X.

IT IS FURTHER ORDERED that respondents Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that with respect to any proposed change in the corporation about which respondents learn less than thirty (30) days prior to the date such action is to take place, respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

XI.

IT IS FURTHER ORDERED that respondents Phaseout of America, Inc. and Products & Patents, Ltd., and their successors and assigns shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade 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.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) 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; <u>provided, however</u>, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) 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 Part.

<u>Provided, further</u>, 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 Part as though the complaint had never been 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.

Signed this	day of	, 199
		PHASEOUT OF AMERICA, INC.,
	Ву:	IRWIN PEARL President
		PRODUCTS & PATENTS, LTD.,
	Ву:	BERNARD GUTMAN President

	DAVID CLANTON Baker & McKenzie Attorney for Respondents
	DAVID LEVY Kraver & Levy Attorney for Respondents
	SHIRA D. MODELL Counsel for the Federal Trade Commission
	LESLEY ANNE FAIR Counsel for the Federal Trade Commission
APPROVED:	MICHAEL OSTHEIMER Counsel for the Federal Trade Commission
C. LEE PEELER Associate Director Division of Advertising Practices	
JOAN Z. BERNSTEIN Director Bureau of Consumer Protection	

ATTACHMENT A

BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED

[To be printed on Phaseout of America, Inc. letterhead]

[date]

Dear [purchaser for resale]:

This letter is to inform you that Phaseout of America, Inc. recently settled a lawsuit with the Federal Trade Commission ("FTC") concerning certain claims we made for our product, PhaseOut, which the FTC has challenged as deceptive. Although we do not admit the FTC's allegations, we have agreed to notify our distributors, wholesalers and others who sell PhaseOut to consumers to stop using or distributing advertisements or promotional materials containing those claims. We are also asking PhaseOut sellers to provide us with the names of their customers so that we may contact them directly.

The FTC Settlement

The FTC claimed that we made unsubstantiated claims about PhaseOut's effectiveness in reducing the adverse health effects of smoking and in helping smokers to stop smoking. The FTC also alleged that the company made misrepresentations about a study conducted at The Johns Hopkins University using PhaseOut.

• Claims that PhaseOut is effective in enabling smokers to quit smoking.

The FTC alleged that the company made unsubstantiated claims that PhaseOut is effective in enabling smokers to quit smoking. The company has agreed that it will substantiate any future claims that PhaseOut is effective in enabling smokers to quit smoking.

The FTC also alleged that the company misrepresented the Johns Hopkins test results by

The FTC alleged that the company made these claims without adequate substantiation. The company has agreed to have proper substantiation before making these claims in the future.

• Claims that testimonials and consumer endorsements used in our ads reflect the typical or ordinary experiences of PhaseOut users.

The company has agreed that it will make these claims only if they reflect the typical experience of PhaseOut users or there is a proper qualifying disclosure to the effect that the results are not typical. No issue was raised regarding the authenticity of the actual testimonials and endorsements that have been used in PhaseOut advertising.

Our Obligations to Notify Distributors and Customers

In addition to our obligations discussed above, we have also agreed to provide notification of the FTC's allegations to consumers who have purchased PhaseOut. We need your assistance in complying with certain provisions of our settlement with the FTC.

First, we request that you discontinue using, relying on or distributing any PhaseOut advertising or promotional materials currently in your possession. We also ask that you notify any of your retail or wholesale customers who may have such materials to discontinue using them. These materials may contain claims that the FTC has alleged to be false or unsubstantiated. If you continue to use those materials, we are required by the FTC settlement to stop doing business with you. You should also avoid making any of the representations challenged by the FTC, as described in this letter.

Second, please send us immediately the names and last known addresses of all persons, including other resellers and consumers, to whom you have sold the PhaseOut device since January 1, 1992. We need this list in order to provide the notification required by our settlement with the FTC. If you do not provide this information, we are required to provide your name and address to the FTC.

Phaseout of America, Inc. 140 Broadway Lynbrook, New York 11563

[Name and address of PhaseOut purchaser]

IMPORTANT HEALTH NOTICE!

Dear PhaseOut Purchaser:

Our records show that you bought the PhaseOut smoking cessation product. Phaseout of America, Inc. recently settled Federal Trade Commission charges that we made deceptive claims in our ads about the benefits of the PhaseOut product. Although we don't admit the FTC's allegations, we agreed to send this notice to people who bought the product.

According to the FTC, our ads deceptively claimed, among other things, that people who

UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

In the Matter of	
PHASEOUT OF AMERICA, INC. and PRODUCTS & PATENTS, LTD., corporations.	DOCKET NO.
	COMPLAINT

6. Respondents have disseminated or caused to be disseminated advertisements for PhaseOut, including but not necessarily limited to the attached Exhibits A through J. These advertisements contain the following statements and depictions:

INFOMERCIAL #1

- A. MASON ADAMS: You're going to see some unprecedented findings and hear some remarkable stories about a breakthrough device that can help you phase cigarettes out of your life without expensive therapies, patches or drugs. Its name is PhaseOut and its effectiveness in reducing the most harmful components of cigarette smoke has been scientifically confirmed in research conducted at such prestigious institutions as the Johns Hopkins University School of Medicine. . . . It creates an additional filter within the existing filter but it doesn't change the taste or the draw of your cigarette. (Exhibit A, p. 1).
- B. CONSUMER ENDORSER: There's no point not to use it if you're a smoker. It's not as if you can tell a difference in your cigarette. It's not as if you have to switch to a disgusting tasting cigarette with lower nicotine. It's the same thing that you've always done, only it's less harmful. (Exhibit A, pp. 2 and 18).
- C. CONSUMER ENDORSER: PhaseOut is good, it's gradual, you're not even aware that it's working. Then all of a sudden, you realize you're smoking a lot less. (Exhibit A, pp. 2 and 18).
- D. MASON ADAMS: If you're like most people, you'll start feeling better right away, while you're preparing to quit. Indeed, PhaseOut's impact is so definite, that even if you don't quit, you'll be significantly reducing the harmful effects of every cigarette. (Exhibit A, p. 2).
- E. FIRST CONSUMER ENDORSER: At least you're eliminating a lot of the irritants that are caused by the tars and nicotines. And you start feeling better, I think, almost from the beginning.
 - SECOND CONSUMER ENDORSER: I'm not as winded. I just feel, even though I'm still smoking, yes, I feel a little bit healthier. (Exhibit A, p. 2).
- F. MASON ADAMS: Now, were you a very heavy smoker?
 - DR. ARNOLD BENSON: I was a heavy smoker. I smoked for forty years exactly, and smoked not less than two packages of cigarettes a day.

ADAMS: And you attribute your quitting to PhaseOut?

BENSON: I stopped smoking because of PhaseOut. PhaseOut did it gradually for me.

ADAMS: And you're still not smoking today?

BENSON: Well, it's two-and-a-half years since I quit. Forty years of smoking and I have gone two-and-a-half-years without smoking and I don't miss it. (Exhibit A, p. 3).

- I. CONSUMER ENDORSER: I've been smoking these for about two or three years, it tastes like the same thing. (Exhibit A, p. 5).
- J. VOICE-OVER: There is medical evidence that PhaseOut lets you do something good for yourself. The April 1992 issue of *Pharmacology, Biochemistry and Behavior* published results of a research study conducted at the Johns Hopkins University School of Medicine. This prestigious journal reports that PhaseOut significantly reduced human exposure to tobacco smoke constituents. Reductions of 30% to 80% were observed for both nicotine and carbon monoxide. The report concluded that the use of the PhaseOut device could be particularly useful as a weaning method prior to smoking cessation. (Exhibit A, p. 6).
- K. MASON ADAMS: If you follow the PhaseOut plan, over a period of several weeks you will gradually reduce the levels of damaging substances in every cigarette you smoke.

Graphic: Three cigarettes, labeled 'Nicotine,' 'Tar' and 'Carbon Monoxide,' each shrinking in size

PhaseOut is a four-step program where you control your progress.

Graphic: Three cigarettes shown shrinking and labeled as follows:

Results after Phase four

Nicotine 81%
Tar 92%
Carbon Monoxide 89%

Here's how it works. Take any standard size pack of cigarettes, hard or soft, kings or 100's, put it into the PhaseOut device and press down. Microfine, almost invisible perforations now create a condensation screen that cuts nicotine levels by 26%, the levels of tar by almost 41%, and the levels of toxic gasses like carbon monoxide by 58%.

Graphic: Three cigarettes shown shrinking and labeled as follows:

Results after Phase one

Nicotine 26%
Tar 41%
Carbon Monoxide 58%

Phase two reduces nicotine nearly in half and further reduces the levels of tar and toxic gasses.

Graphic: Three cigarettes shown shrinking and labeled as follows:

Results after Phase two

Nicotine 47%
Tar 66%
Carbon Monoxide 73%

Phase three cuts levels of nicotine by nearly 64%, tar by 80%, and carbon monoxide by 83%.

Graphic: Three cigarettes shown shrinking and labeled as follows:

Results after Phase three

Nicotine 64%
Tar 80%
Carbon Monoxide 83%

By the time you reach phase four, your nicotine consumption is reduced by nearly 81%. You're also taking in 92% less tar and 89% less toxic gasses.

Graphic: Three cigarettes shown shrinking and labeled as follows:

Results after Phase four

Nicotine 81%
Tar 92%
Carbon Monoxide 89%

(Exhibit A, pp. 6-7).

- L. MASON ADAMS: You can stay on each phase as long as you like until you're ready to move on. You're in control. You know that with each phase, you're doing more good for your health. And when you get to phase four, you can quit whenever you're ready. PhaseOut has helped many smokers quit cigarettes for good and thousands of others to smoke less damaging cigarettes. (Exhibit A, pp. 7-8).
- M. CONSUMER ENDORSER: You wake up in the morning, you're not as congested, you don't have to wait for your chest to clear. I can run up and down the stairs and I can go to the park and I can play ball and I can, you know, run

- around with the kids and not be winded and not have to sit down and say "Mommy's tired. I can't do this." (Exhibit A, p. 8).
- N. BOBBY RYDELL: I've gone from over two-and-a-half packs a day to a pack a day, and I know I'm on my way to quitting because PhaseOut makes it easy. (Exhibit A, p. 8).
- O. VOICE-OVER: Nobody has to tell you the damage smoking causes. But many people still enjoy smoking. And even if you want to want to cut back or quit, most methods are annoying, painful, or expensive. But now, there's PhaseOut, a breakthrough device that drastically reduces the harmful effects of cigarette smoking without changing the taste or the pleasure. You don't have to change brands to get all the benefits of reduced nicotine, tar, and other harmful substances. PhaseOut works on any standard pack. With a simple punch, it forms a condensation filter within your cigarette, which traps more harmful substances before they ever reach your body. By the end of the program, you're smoking 81% less nicotine, 92% less tar, and 89% less toxic gasses. (Exhibit A, pp. 9, 13 and 17).
- P. VOICE-OVER: PhaseOut is a real smoker's solution. You keep smoking until you're ready to cut down or quit. And because it gradually reduces the nicotine you inhale, you don't suffer the painful withdrawal symptoms associated with going cold turkey.

Graphic:

PHASEOUT

- Smoke less harmful cigarettes
- Cut down
- Quit for good
- No withdrawal symptoms

(Exhibit A, pp. 9, 13 and 17).

Q. CONSUMER ENDORSER: We, we asked her, we ultimatumed her, everything

SECOND CONSUMER ENDORSER: With the use of PhaseOut, the system, I could only come out ahead. I would either stop, cut down, or whatever I smoked,

Yes with PhaseOut you can actually keep smoking, because smoking is less harmful until you're ready to quit. 100% guaranteed or your money back. (Exhibit C).

RADIO ADVERTISEMENT ("Advertorial")

Y. VOICE-OVER: Here's an announcement smokers everywhere have been waiting to hear: Tests at Johns Hopkins University prove a revolutionary new system called PHASEOUT eliminates up to 80% of the nicotine and carbon monoxide in any brand of cigarettes. It doesn't change the flavor or satisfaction of your favorite brand, doesn't require patches or prescriptions. . . . Smoke a pack a day? With PHASEOUT that's like cutting down to just 4 cigarettes. And as PHASEOUT gradually eliminates the nicotine it gradually eliminates your "need" for cigarettes. Now you can quit easily, without cold turkey, or continue smoking cigarettes that are far less dangerous to your health. (Exhibit D).

PRINT ADVERTISEMENT #1

Z. STOP SMOKING FOREVER -- WITH PHASE OUT® Guaranteed or your money back

NEW EASY WAY -- Clinically tested and validated by Johns Hopkins University School of Medicine to reduce up to 80% of nicotine and carbon monoxide in cigarette smoke.

- Works automatically -- no will power needed
- Virtually no change in taste or draw
- Ends nicotine craving forever
- No cravings or urges 100% safe
- No side effects or unpleasant withdrawal symptoms
- Recommended by doctors and health organizations
- Eliminates up to 80% of the tars, nicotine and poison in cigarette smoke -- so even if you decide to keep smoking, you will no longer face the same danger of cancer and heart disease (Exhibit E).

PRINT ADVERTISEMENT #2

AA. PHASE OUT

NEW Proven new device shown to reduce the dangers of cigarettes while helping even hardcore smokers quit.

Phase Out is a scientifically designed and patented mechanical device that eliminates toxins in cigarette smoke. Tests conducted at the U.S. Testing Company and confirmed in recent studies at the Johns Hopkins School of Medicine show that PhaseOut lets smokers gradually and easily withdraw form [sic] nicotine addiction without the stress and irritation of "cold turkey."

Simply place an unopened pack of cigarettes in Phase Out and press. Phase Out instantly puts tiny perforations into your filtered or unfiltered cigarette.

PRINT ADVERTISEMENT #4

CC. PRACTICE SAFE SMOKING.

* * *

Clinical research by Johns Hopkins University and tests by US Testing Company prove PHASEOUT's patented microperforation system significantly reduces all harmful substances in the cigarette brand you're lighting up right now.

It won't noticeably affect the taste or draw and you will still enjoy the pleasure and satisfaction of smoking your favorite brand. But by gently and gradually eliminating up to 80% of your nicotine intake, PHASEOUT makes it easier to quit. Without cold turkey withdrawal symptoms or side effects.

* * *

Protect yourself with PHASEOUT. Because what you don't smoke can't harm you. (Exhibit H).

PROMOTIONAL FLYER

DD. PHASEOUT

MAKES IT SAFER TO SMOKE, EASIER TO QUIT.

The amazing scientific breakthrough that makes cigarettes 80% less harmful.

* * *

PHASEOUT lets you smoke cigarettes that are over 80% less harmful. You still get the taste, pleasure and satisfaction without changing brands. You just don't get the nicotine, tars, carbon monoxide and other toxins. PHASEOUT's patented micro-perforations block them right out. So you should feel better almost immediately and you enjoy a healthier lifestyle, because what you don't smoke can't harm you!

* * *

Until today, the odds were against you: 9 out of 10 people who try to quit fail. No wonder. The withdrawal symptoms that come with the abrupt elimination of nicotine can be brutal. . . . PHASEOUT helps eliminate these withdrawal symptoms. PHASEOUT gently and gradually blocks out the nicotine, enabling your body to slowly detoxify. You're in total control. You set your own pace. For the first time, you can end your nicotine addiction completely without the symptoms of "cold turkey" withdrawal. So you will succeed . . . guaranteed!

PHASEOUT IS SCIENTIFICALLY AND CLINICALLY PROVEN

Research confirms the benefits of the PHASEOUT System. Tests conducted by Johns Hopkins University and U.S. Testing Laboratories confirm that PHASEOUT gradually eliminates over 80% of the nicotine, tars, carbon monoxide and all other tobacco toxins found in cigarette smoke. (Exhibit I).

WORLD WIDE WEB HOME PAGE

EE. PHASEOUT THE WEAN-MACHINE TO HELP YOU QUIT SMOKING

The amazing scientific breakthrough that gradually reduces NICOTINE and other unwanted substances from cigarette smoke

* * *

Depiction: Four bar graphs of shrinking cigarettes labeled "LEVELS OF

TAR," "LEVELS OF NICOTINE," "LEVELS OF CARBON MONOXIDE," and "TOTAL PARTICULATE MATTER."

Illustrated are the reductions of nicotine and other toxins during each phase. (Exhibit J).

FF. STOP SMOKING THE SAME WAY YOU STARTED...GRADUALLY

Try PHASEOUT yourself, or share it with someone you love. You may be surprised at just how easy it is to kick the habit for good.

PHASEOUT *is a treatment for your cigarettes, not you.* Its patented design allows you to punch tiny, undetectable holes in your cigarettes, causing condensation...a natural filtering process that traps **over 80%** of the toxins.

Each phase adds more perforations, further decreasing the levels of nicotine, tar and carbon monoxide. It's a safe, effective method approved by doctors and validated by Johns Hopkins University School of Medicine. (Exhibit J).

GG. PHASEOUT IS SCIENTIFICALLY PROVEN

Research confirms the effectiveness of PHASEOUT. Tests conducted by Johns Hopkins University and U.S. Testing Laboratories conclude that PHASEOUT

gradually eliminates up to 80% of the nicotine, tar, carbon monoxide and total particulate matter found in cigarette smoke. (Exhibit J).

HH. "I've been a two pack a day (and more) smoker for twenty years. I have tried almost every way to quit over the past fifteen years. None of the programs could deal with my major challenge...staying quit. I am in the third phase of the (PHASEOUT) program which means I am reducing tar by 77% and the nicotine by 66% but miraculously I am smoking less than ever. To me it is a miracle because I am trying to cut down. I want to thank everyone involved."

Donna

Akron, Ohio (Exhibit J).

- 7. The Johns Hopkins University research to which the advertisements attached as Exhibits A through J refer is a study that has been reported as Stitzer, Brigham and Felch, <u>Phase-Out Filter Perforation: Effects on Human Tobacco Smoke Exposure</u>, 41 Pharmacology, Biochemistry and Behavior 748 (1992) (hereinafter, the "Johns Hopkins study").
- 8. Through the means described in Paragraph 6, respondents have represented, expressly or by implication, that:
 - A. The Johns Hopkins study proves that PhaseOut significantly reduces the amount of tar, nicotine, and carbon monoxide smokers get under normal smoking conditions.
 - B. The Johns Hopkins study proves that PhaseOut is effective in enabling smokers to quit smoking.
 - C. The Johns Hopkins study proves that smokers who use PhaseOut and continue to smoke significantly reduce their risk of smoking-related health problems.
- 9. In truth and in fact:
 - A. The Johns Hopkins study does not prove that PhaseOut significantly reduces the amount of tar, nicotine, and carbon monoxide smokers get under normal smoking conditions. Among other reasons, that study was conducted under carefully controlled conditions that did not reflect how smokers actually smoke, in part because they did not take into account such behavior as compensatory smoking -- the tendency of some smokers who switch to lower yield cigarettes to smoke more cigarettes or smoke each one more intensively.

- B. The Johns Hopkins study does not prove that PhaseOut is effective in enabling smokers to quit smoking.
- C. The Johns Hopkins study does not prove that smokers who use PhaseOut and continue to smoke significantly reduce their risk of smoking-related health problems.

Therefore, the representations set forth in Paragraph 8 were, and are, false or misleading.

- 10. Through the means described in Paragraph 6, respondents have represented, expressly or by implication, that:
 - A. On Phase One of the PhaseOut program, smokers will reduce the amount of nicotine they get from smoking a cigarette by 26 percent, the amount of tar they get by 41 percent, and the amount of carbon monoxide they get by 58 percent.
 - B. On Phase Two of the PhaseOut program, smokers will reduce the amount of nicotine they get from smoking a cigarette by 47 percent, the amount of tar they get by 66 percent, and the amount of carbon monoxide they get by 73 percent.
 - C. On Phase Three of the PhaseOut program, smokers will reduce the amount of nicotine they get from smoking a cigarette by 64 percent, the amount of tar they get by 80 percent, and the amount of carbon monoxide they get by 83 percent.
 - D. On Phase Four of the PhaseOut program, smokers will reduce the amount of nicotine they get from smoking a cigarette by 81 percent, the amount of tar they get by 92 percent, and the amount of carbon monoxide they get by 89 percent.
 - E. PhaseOut is effective in enabling smokers to quit smoking.
 - F. PhaseOut significantly reduces the risk of smoking-related health problems, including lung cancer and heart disease, for smokers who continue to smoke.
 - G. PhaseOut significantly reduces the amount of tar, nicotine, and carbon monoxide that smokers get without changing a cigarette's taste or draw.
 - H. Smokers using PhaseOut will not compensate for the product's effects by increasing the number of cigarettes they smoke per day.
 - I. PhaseOut is effective in enabling smokers to quit smoking without withdrawal symptoms.

J. PhaseOut provides immediate health benefits, including reduced congestion, coughing, and windedness, for smokers who continue to smoke.

11. Through the means described in Paragraph 6, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the

representations set forth in Paragraph 10, at the time the representations were made.

12. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 10, at the time the representations were made. Therefore, the representation set forth in Paragraph 11 was, and is, false or misleading.

13. Through the means described in Paragraph 6, respondents have represented, expressly or by implication, that testimonials from consumers appearing in the advertisements for PhaseOut

reflect the typical or ordinary experience of members of the public who use the product.

14. Through the means described in Paragraph 6, respondents have represented, expressly or

by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 13, at the time the representation was made.

15. In truth and in fact, respondents did not possess and rely upon a reasonable basis that

substantiated the representation set forth in Paragraph 13, at the time the representation was

made. Therefore, the representation set forth in Paragraph 14 was, and is, false or misleading.

16. The acts and practices of respondents 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 , , has

issued this complaint against respondents.

By the Commission.

Donald S. Clark

Secretary

SEAL:

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

14

ANALYSIS OF PROPOSED CONSENT ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted an agreement to a proposed consent order from Phaseout of America, Inc. and Products & Patents, Ltd. This matter concerns advertising

In addition, the complaint alleges that the respondents represented without substantiation that testimonials contained in advertisements for PhaseOut reflect the typical or ordinary experience of consumers who use the product.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondents from engaging in similar acts and practices in the future.

Part I of the order prohibits the respondents from making the representations challenged as false in the proposed complaint about the Johns Hopkins study's findings concerning PhaseOut.

Part II requires respondents to possess competent and reliable scientific evidence to substantiate claims that any smoking-cessation or cigarette-modification product: A) reduces the amount of nicotine, tar, carbon monoxide, or any other component of cigarette smoke that smokers get from smoking a cigarette; B) is effective in enabling or helping smokers to quit smoking; C) reduces the risk of smoking-related health problems for smokers who continue to smoke; D) reduces the amount of nicotine, tar, carbon monoxide, or any other component of cigarette smoke that smokers get without changing a cigarette's taste or draw; E) is effective in enabling or helping smokers to quit smoking without withdrawal symptoms; or F) provides immediate health benefits, such as reduced congestion, coughing or windedness, for smokers who continue to smoke. Part II also requires respondents to possess competent and reliable scientific evidence to substantiate claims that smokers using any such product will not compensate for the product's effects by increasing the number of cigarettes they smoke per day.

Part III requires respondents to possess competent and reliable scientific evidence to substantiate any performance, benefit or efficacy claims for smoking-cessation or cigarette-modification products.

Part IV prohibits the respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or study.

Part V requires respondents either to possess competent and reliable scientific evidence to substantiate claims that any endorsement reflects the typical or ordinary experience of consumers who use the product; or to clearly and prominently disclose either: a) what the generally expected results would be, or b) that consumers should not expect to experience similar results.

Part VI requires respondents to send a postcard to identifiable past purchasers of PhaseOut notifying them of the Commission's action in this case and advising them that PhaseOut has <u>not</u> been proven to reduce the risk of smoking-related diseases or to make

respondents to maintain for five years copies of all communications with consumers and purchasers for resale pursuant to the terms of Part VI.

The proposed order also requires respondents to maintain materials relied upon to substantiate the claims covered by the order, to distribute copies of the order to certain current officers and employees, to notify the Commission of any changes in corporate structure that might affect compliance with the order, and to file one or more reports detailing compliance with the order. The order also contains a provision stating that it will terminate after twenty (20) years absent the filing in federal court, by either the United States or the FTC, of a complaint against the respondents alleging a violation of the order.

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 any of their terms.