IN THE MATTER OF

REMOVATRON INTERNATIONAL CORPORATION, ET AL.

FINAL ORDER, OPINION, ETC., IN REGARD TO ALLEGED VIOLATION OF SECS. 5 & 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket 9200. Complaint, Sept. 30, 1985—Final Order, Nov. 4, 1988

This Final Order prohibits, among other things, the Boston, Mass. sellers of an electronic device called "Removatron", from making unsubstantiated claims about the product and requires clinical testing as substantiation for future permanency claims.

Appearances

For the Commission: *David Keniry* and *David Fitzgerald.*

For the respondents: *David Lipton* and *David H. Erickson, Lipton & Pemstein,* Boston, Ma. *Judith Ashton, Davis, Malm & D'Agostine,* Boston, Ma.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Removatron International Corporation, a corporation, and Frederick E. Goodman, individually and as an officer of said corporation, hereinafter sometimes referred to as respondents, have violated the provisions of said Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint stating its charges in that respect as follows:

PARAGRAPH 1. Removatron International Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the Commonwealth of Massachusetts, with its office and principal place of business located at 215 A Street, Boston, MA.

Frederick E. Goodman is an individual and an officer of Removatron International Corporation. He formulates, directs and controls the acts and practices of said corporate respondent, including the acts and practices hereinafter set forth. His address is the same as that of said corporation.

PAR. 2. Respondents are now and have been engaged in the advertising, offering for sale, and sale of a high frequency tweezer-type epilator (hair removal device employing radio frequency energy) called Removatron to beauty salon owners and others who in turn advertise and sell Removatron treatments to consumers. The Removatron epilator is a "device" within the meaning of Section 12 of the Federal Trade Commission Act.

PAR. 3. Respondents maintain, and have maintained a substantial course of trade in or affecting commerce, including the acts and practices hereafter set forth, as "commerce" is defined in the Federal Trade Commission Act.

PAR. 4. In the course and conduct of their business, respondents disseminated and caused the dissemination of advertisements or promotional materials concerning the Removatron device through the United States mails by various means in or affecting commerce for the purpose of inducing, and which were likely to induce, directly or indirectly, the purchase of the Removatron device or Removatron treatments. The advertisements or promotional materials were and are disseminated to potential buyers of the Removatron device and through such buyers to the ultimate consumers of Removatron treatments.

PAR. 5. Through the use of the advertisements and promotional materials referred to in paragraph four, respondents have made, and in some instances are still making, the following statements concerning the Removatron device, method or treatments:

1. "Permanent hair removal."
2. "Removatron. It lets you say good-by to temporary solutions like messy creams."
3. "The method is fully ... effective ... All hairs can be treated successfully ... Removatron ... is more effective than any electrolysis machine on the market."
4. "Unwanted hair is no longer a Problem, with a series of treatments, it can be Removatroned forever!"
5. [T]he Removatron method uses modern electronic tweezers to EFFECTIVELY remove unwanted hair ... " (Emphasis in original.)
6. "alternative to electrolysis"

PAR. 6. through the use of these and other statements in the advertisements and promotional materials referred to in paragraphs four and five, and others not specifically set forth herein, respondents have represented, and in some instances are still representing, directly or by implication, that:

1. The Removatron device permanently removes hair.

2. The Removatron device is effective in removing hair on a long-term, not temporary, basis.

PAR. 7. Through the use of the representations referred to in paragraph six respondents have represented, and are still representing, directly or by implication, that, at the time of making the representations set forth in paragraph six, they possessed and relied upon a reasonable basis for those representations.

PAR. 8. In truth and in fact, at such times respondents have not possessed or relied upon a reasonable basis for those representations. Therefore the representation referred to in paragraph seven was, and is, false and misleading.

PAR. 9. Through the use of the advertisements and promotional materials referred to in paragraph four, respondents have made, and are still making, the following statement concerning the Removatron device, method or treatments: "Removatron hair removal is government F.C.C. approved."

PAR. 10. Through the use of this and other statements in the advertisements and promotional materials referred to in paragraphs four and nine, and others not specifically set forth herein, respondents have represented, and are still representing, directly or by implication, that the Federal Communication Commission has approved the Removatron hair removal method.

PAR. 11. In truth and in fact, the Federal Communications Commission has not approved Removatron hair removal. It has merely approved the operation of the Removatron device at a certain frequency to ensure noninterference with radio broadcasting.

Therefore, the representation referred to in paragraph ten was, and is, false and misleading.

PAR. 12. The aforesaid acts and practices of respondents constitute unfair and deceptive acts or practices in or affecting commerce and false advertisements in violation of Sections 5 and 12 of the Federal Trade Commission Act.

INITIAL DECISION BY

MONTGOMERY K. HYUN, ADMINISTRATIVE LAW JUDGE

JULY 15, 1987

PRELIMINARY STATEMENT

On September 30, 1985, the Federal Trade Commission ("Commission") issued an administrative complaint charging Removatron International Corporation ("Removatron International") and Frederick E. Goodman, individually and as an officer of Removatron International, with violation of Sections 5 and 12 of the Federal Trade Commission Act, as amended (15 U.S.C. 45 and 52), in connection with certain advertisements and promotional materials for Removatron, a radio frequency energy ("RFE") epilation device. On November 22, 1985, respondents filed their answer which in effect denied that they violated the Federal Trade Commission Act as charged. The answer also advanced affirmative defenses that the purchasers of Removatron are not deceived or mislead by respondents' advertising and that this proceeding was discriminatory enforcement of the Federal Trade Commission Act. By an order of February 20, 1986, the administrative law judge granted complaint counsel's motion to strike the affirmative defenses from respondents' answer to the complaint.

The parties were allowed extensive pretrial discovery and ample time to prepare for trial. Evidentiary hearings were held in November and December of 1986 and January of 1987 in Washington, D.C., and Boston, Massachusetts. Complaint counsel offered some 180 documents and 5 witnesses, including a dermatologist. Respondents offered some 80 documents and called 17 witnesses. The transcripts of hearing comprise some 2450 pages. The record was closed on March 19, 1987.[1]

Based on the complaint and answer and other pleadings of record, the following issues are the principal issues to be determined in this proceeding:

1. Whether respondents represented, directly or by implication, in certain advertisements and promotional materials, that:

[1] By order dated May 8, 1987, the time for filing this Initial Decision was extended to and including July 20, 1987.

(a) Removatron permanently removes hair or is effective in removing hair on a long-term, not temporary, basis.

(b) The Federal Communications Commission has approved the Removatron hair removal method. **[3]**

(c) Respondents had a reasonable basis for these claims.

2. Whether respondents possessed and relied on reasonable and adequate substantiation for the efficacy claims described in 1(a) when these claims were made.

3. Whether the fact that Removatron does remove hair permanently or it does not is a material fact for Removatron purchasers and their hair removal treatment customers.

4. Whether the Federal Communications Commission in fact approved the Removatron hair removal method as claimed.

5. Whether the issuance of a cease and desist order in this proceeding is in the public interest.

The proposed findings, conclusions and orders submitted by the parties and their arguments in support thereof have been given careful consideration by me and to the extent not adopted by this Initial Decision, in the form proposed or in substance, are rejected as not supported by the evidence or as immaterial. Any motion appearing on the record not heretofore or hereby specifically ruled upon either directly or by the necessary effect of the conclusions in this Initial Decision are hereby denied.

Upon consideration of the entire record in this proceeding and having considered the demeanor of the witnesses, I make the following findings of fact and conclusions of law and order based on the record considered as a whole: [2] **[4]**

I. Respondents, Their Business and Jurisdiction

1. Removatron International Corporation ("Removatron International"), the corporate respondent herein, is a corporation organized, existing and doing business under and by virtue of the laws of the

[2] For the purposes of this Initial Decision, the following abbreviations were used:

F.	-	Finding of Fact in this Decision
CPF	-	Complaint Counsel's Proposed Findings
RPF	-	Respondents' Proposed Findings
CRB	-	Complaint Counsel's Reply
RRB	-	Respondents' Reply
Tr.	-	Transcript of hearings, sometimes preceded by the name of the witness
CX	-	Complaint Counsel's exhibit
RX	-	Respondents' exhibit
Comp.	-	Complaint
Ans.	-	Answer

Commonwealth of Massachusetts, with its office and principal place of business located at 215 A Street, Boston, Massachusetts. (Ans., at 1.)

2. Removatron International was incorporated in 1978 and is the continuation of a predecessor corporation, Skin-Sation Unlimited, which did business from 1976 to 1978. (CX 721-6.) Removatron International describes itself as "[t]he leading manufacturer of facial care equipment, hair removal equipment and private label cosmetics." (CX 709.)

3. Frederick E. Goodman, the individual respondent herein, is an officer of Removatron International (Ans., at 1) and formulates, directs and controls the acts and practices of said corporate respondent, including the acts and practices hereinafter set forth. *See, e.g.*, CX 721-5 (president), 721-30 to 721-32.

4. Respondents are now and have been engaged in the advertising, offering for sale, and sale of a high frequency energy ("RFE") tweezer-type hair removal device or epilator called "Removatron" (hereafter sometimes referred to as "device" or "Removatron device") to beauty salon owners and others, who in turn advertise and sell Removatron hair removal treatments to consumer-clients. (Ans., at 1.)

II. Removatron and Marketing of Removatron

5. The Removatron device is an electric epilator which generates radio frequency energy ("RFE") at about 27.012 megahertz and transmits the RFE along a wire to a pair of tweezers attached to the end of the wire. (CX 721-44.) It is claimed that when a hair is held by the tweezers, the RFE is transmitted to the papilla and facilitates removal of the hair by heating and destroying the papilla and certain surrounding tissues, and that a series of such treatments will end the hairgrowing capability of the hair follicle containing the treated hair. (CX 712-2.)

6. Removatron is thus designed, and marketed, as a device which will destroy the tissues at the hair roots and retard and eventually stop regrowth of the treated hair, thus affecting both the structure and the function of the human body. *E.g.*, CX 712-2, 734-14, 738-2; F. 35, 86, *infra.* Respondents also expressly likened Removatron to "today's most modern medical equipment." (CX 148-4.) Therefore, Removatron is a "device" within the meaning of Section 12 of the Federal Trade Commission Act. **[5]**

7. Respondents' belated argument (RPF and RRB) that Removatron is a mere cosmetic device and as such is not a "device" within the meaning of Section 12 is contrary to the evidence and the law.

8. Respondents cause Removatron to be transported from its place of business to purchasers located in various other States of the United States and the District of Columbia, Canada, Japan and Europe. (CX 721-343, 805; Tr. 140.) Respondents maintain, and at all times relevant to this proceeding have maintained, a substantial course of trade in the Removatron device in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act. (CX 805; Tr. 140.) The volume of such business has been well over $500,000 annually. (CX 719.)

9. In the course and conduct of their business, respondents disseminated and caused the dissemination of advertisements or promotional materials concerning the Removatron device (Ans., at 2) through the United States mails by various means in or affecting commerce for the purpose of inducing, and which were likely to induce, directly or indirectly, the purchase of the Removatron device. The advertisements or promotional materials were and are disseminated to potential buyers of the Removatron device (Ans., at 2) and through such buyers to the ultimate consumers of Removatron treatments. *See, e.g.,* Removatron Sample Consultation, CX 141-62; Training Videotape, CX 251; and local advertisements, CX 177.

10. Respondents sell Removatron to owners/operators of beauty salons, skin care establishments, and hair removal businesses (CX 149-4) and to individuals for self-treatment of their unwanted hair problems. (CX 721-22.)

11. Consumers of Removatron hair removal treatments are generally women who have unwanted hair on abnormal locations or in abnormal quantities on their bodies, most often the face. Unwanted hair is regarded as a serious problem, constituting disfigurement by consumers. (Van Scott, Tr. 948.)

12. In Removatron hair removal treatment, an individual hair is grasped with the tweezer, sending RFE to the tweezer tip for a period of time, and then removing the hair with the tweezers. (CX 148-13, 148-18.) It is recommended that treatment be preceded by cleansing and moisturizing the area to be treated. *Id.* Consumers are advised to return at regular intervals in order to ensure early treatment of new or regrown hair. (CX 1-8.) It is not uncommon for some consumers to return for periodical treatments over a period of several years. *See, e.g.,* Dyal, Tr. 1280-1293; Callison, Tr. 479-480. **[6]**

13. Removatron is advertised mainly in trade magazines aimed at the owners and operators of beauty salons and epilation treatment

establishments. In *Modern Salon,* a magazine with nationwide circulation of more than 100,000 (CX 735), Removatron International advertised in March 1979 (CX 743), June 1980 (CX 815), June 1981 (CX 1-24), September 1982 (CX 1-6), July 1985 (CX 706), August 1985 (CX 139(a)), November 1985 (CX 744), December 1985 (CX 710), February 1986 (CX 709), July 1986 (CX 710) and October 1986 (CX 802, 803, and 804.) In *American Salon,* a magazine with nationwide circulation of more than 100,000 (CX 735), Removatron International advertised at least twice during 1984. (CX 1-10, 1-26.) In *Aesthetics World,* Removatron International advertised in May 1981. (CX 704, 704(a)), November 1981 (CX 39), April 1982 (CX 40, 40(b)), June 1982 (CX 52, 52(a)) and October 1982 (CX 1-9, 58.) In *National Beauty School Journal,* Removatron International advertised in October, November and December 1982, and in May and June 1983. (CX 34, 35, 36, 37, 38 and 38(a).) In *Dermascope,* Removatron International advertised four times in 1985 (CX 113, 113(a), 114, 116, and 117) and nine times in 1982-1984. (CX 121, 122, 124, 125, 127, 128, 129, 131, 132, and 132(a).) In *American Hair Dressers Salon Owners,* Removatron International advertised in January 1983. (CX 1-25.) Removatron International also advertised in the classified advertising sections in newspapers published in Chicago, Illinois, Miami, Florida, Charlotte, North Carolina, Boston, Massachusetts, Providence, Rhode Island, Hartford, Connecticut, Burlington, Vermont, Manchester, New Hampshire, and Bangor, Maine, during 1982 and 1983. (CX 727.)

14. Removatron International also regularly participated in beauty industry trade shows in various parts of the country, where it demonstrated the Removatron device and treatment. It also promoted the device with written materials handed out at the Removatron booth and with oral and video presentations. (CX 721-35 to 721-45.)

15. Removatron International distributed promotional materials to prospective device purchasers. Such materials were handed out at trade shows and were mailed to persons who read Removatron ads and contacted Removatron International offices about the device. (CX 721-35, 721-36; Tr. 1770.) Examples of such promotional materials are CX 1-11 to 1-22, 143, 149, 168, 176, 287, 290, 298, 717, 733, 737, 738 and 756.

16. Removatron International sales staff made oral representations about Removatron during telephone conversations with prospective purchasers. (Bassett, Tr. 1494-1499; Evan Goodman, Tr. 1694-1699.)

17. Removatron International continued to make representations to device purchasers after sale of the device, in written and audio materials supplied along with the product, in **[7]** an in-person training presentation, and in written and video materials and oral presentations made during the months and years following device purchase. Materials supplied along with the product include CX 141, 143, 148, 150, 284, 298, 717, 734, 737, 772 and 773. (CX 1-14.) Representations made during the training of the device purchaser are set forth in CX 170, 171, 172 and 251. Removatron International continued to make representations in newsletters sent periodically to device purchasers. (CX 179, 180, 181 and 718.)

18. During a typical telephone conversation, the individual respondent, Frederick E. Goodman, told Doris Callison, a Removatron owner, that the Removatron method did work and that it was a permanent method of hair removal. (Tr. 469.)

19. The representations made by Removatron International to device purchasers were passed on by purchasers to prospective epilation treatment consumers. Removatron International also supplied Removatron purchasers advertising "slicks" for placement in local print media. (CX 146, 147, 174(a), 169, 289 and 730; *see also* CX 732, which offers "advertising materials that will get you clients," and CX 721-230.) Respondents encouraged Removatron purchasers to advertise hair removal treatments using Removatron (CX 141-76), and Removatron purchasers did advertise Removatron services in local print media and through written promotional materials. (CX 177, 708, 740, 742, 749, 750, 752, 753, 761, 765, 766, 767 and 768.) Removatron International also prepared "Questions and Answers About Your Unwanted Hair" (CX 143, 298, 717 and 737), a promotional brochure, designed specifically for prospective consumers of Removatron services and directed device purchasers to give this brochure to each client in order to ensure that each reads it. (CX 721-160, 251-102 to 251-103.)

20. The individual respondent, Frederick Goodman, created, or reviewed and approved, all Removatron advertising and promotional materials (CX 721-83, 721-176 and 721-247) and directly supervised the Removatron International employees who made oral claims. (Evan Goodman, Tr. 1710; Patricia Collins, Tr. 278.) Therefore, he is responsible for all of the representations contained in the advertisements, promotional literature and audio or video tapes as well as oral representations made by Removatron International employees to customers regarding the device.

21. Respondents have continuously marketed hair removal devices from 1976 to the present. (CX 721-6.) Removatron International has sold some 2000 hair removal devices and also claims that Removatron is in over 3000 salons. *See e.g.*, CX 1-26. As of February 1986, Removatron International had an estimated market share of 80% in tweezer-type RFE epilators in the United States. (CX 709.) **[8]**

22. The price of each Removatron device is about $4,000. (CX 805-2; Tr. 1453, Tr. 1632.) Other pieces of equipment, such as the Misty Facial Steamer and accessory furniture, are often sold along with the Removatron device. (CX 179-2, 721-9.) Removatron International's gross sales revenue for hair removal devices and related equipment from April 1, 1980 to September 30, 1983 was $2,334,458. (CX 719.)

23. On January 19, 1982, the Food and Drug Administration (FDA) published in the Federal Register a notice of proposed rulemaking that would require pre-marketing approval of high-frequency (RFE) tweezer-type epilators. (CX 6.) The proposal was based on the recommendation of the FDA's General and Plastic Surgery Device Panel which concluded that pre-marketing approval was necessary "to assure that manufacturers demonstrate satisfactory performance of the device and, thus, assure its safety and effectiveness." (CX 6-2, 9.) The FDA agreed with the Panel's recommendation, noting "numerous discrepancies" and "inconsistencies" in the documents and arguments that had been offered as evidence of the efficacy of electronic tweezer-type epilation devices. (CX 6-9 to 9-10.)

24. On June 4, 1982, the District Director of the FDA Boston District Office issued a Notice of Adverse Findings to Frederick E. Goodman, President, Removatron International Corporation, stating that "the Food and Drug Administration objects to any labeling for your device which implies that it provides permanent hair removal." The Notice further stated: "To promote these devices as providing permanent hair removal, misbrands them under provisions of the Federal Food, Drug, and Cosmetic Act 21 USC 301 et seq." The Notice also enclosed a copy of the January 19, 1982 FDA notice of proposed rulemaking. (CX 5-3 to 5-4.)

25. Thus, the FDA has determined, and has specifically informed respondents, that representations of permanent hair removal for Removatron are objectionable and constitute illegal misbranding of the device.

III. Respondents' Advertising Claims

A. Standards for the Determination of the Meaning of Advertisements

26. The appropriate standard in determining whether an advertisement makes a particular claim is to see whether the representation or claim constitutes a reasonable interpretation of the advertisement taken as a whole. A reasonable interpretation of an ad means an interpretation to which more than an insubstantial number of readers or audiences would adhere. Since more often than not several reasonable **[9]** interpretations of a given advertisement are possible, it is not necessary that the claim found to have been made be the only or the most reasonable interpretation of the advertisement. *E.g., Thompson Medical Co., Inc., ("Thompson"),* 104 FTC 648, 789 n.7 (1984), *aff'd,* 791 F.2d 189 (D.C. Cir. 1986), *cert. denied* 107 S.Ct. 1287 (1987).

27. The primary evidence with respect to the meaning of the advertisements for Removatron is the advertisements and promotional materials in the record. This evidence is buttressed by testimony of Removatron device purchasers and Removatron treatment customers.

B. Respondents Have Made the Representation, Directly or by Implication, that Removatron Permanently Removes Unwanted Hair and that Removatron Is Effective in Removing Hair on a Long-Term, not a Temporary, Basis as Alleged in Paragraph Six of the Complaint

1. Representations Made to Prospective Purchasers of Removatron

28. Respondents expressly claimed that Removatron removes hair permanently, in many magazine advertisements from 1979 to 1986. (CX 1-6, 1-9, 1-10, 1-24, 1-25, 1-26, 38(a), 39, 40, 40(b), 52, 52(a), 58, 113, 113(a), 114, 116, 117, 121, 122, 124, 125, 127, 128, 129, 131, 132, 132(a), 139(a), 704, 704(a), 706, 743, 803 and 804.)

29. For example, CX 803 is a coupon advertisement for Removatron which was printed in the October 1986 issue of *The American Salon,* a trade magazine for beauty salon operators. A statement placed to the right of a picture of Removatron states;

> Permanent. Painless. Safe and Effective. Unwanted hair no longer a problem with a series of treatments. It can be Removatroned forever.

The coupon is worth $200 towards the purchase price of Removatron hair removal system. The meaning of this ad is simple, clear and straightforward. It expressly claims that Removatron removes hair *permanently* and that unwanted hair can be removed *forever* with a series of treatments.

30. CX 802 is a printed letter addressed to "Dear Professionals" by Karen L. Ballou, V.P., Removatron International Corporation, which was mailed about August 1983, inviting beauty salon operators and beauticians to the August 10, 1983 Skin Care Seminar given by Removatron International Corporation at its **[10]** offices in Boston, Massachusetts, in conjunction with the August 1983 AIA convention and trade show. In the first paragraph of the letter, Removatron International is identified as "manufacturers of Skin Care and Painless Permanent Hair Removal equipment." After listing the topics to be covered at the seminar, the letter states:

> We will be speaking on Painless Permanent Hair Removal which will include:
>
> * How radio frequency energy works
> * How to get results
> * The facts behind why painless permanent hair removal is BIG business

The clear meaning of this promotional piece, mailed to beauty salon professionals, is that Removatron International manufactures painless and *permanent* hair removal equipment and that seminar participants will learn about achieving painless *permanent* hair removal by using a radio frequency energy device, "the Removatron Hair Removal System."

31. CX 290 is a Removatron product brochure entitled "What you should know about Removatron, ™" disseminated by Skin-Sation Unlimited Corporation, a former name of Removatron International. In the middle of the second page (CX 290-2), it states:

> DOES REMOVATRON REMOVE HAIR PERMANENTLY?
>
> Yes, but not the first time. Permanent removal of unwanted hair is seldom accomplished in a single treatment. There are a number of reasons why permanent removal may not be achieved with a single treatment. A weak hair may break off below the skin line, or be already detached from the papilla as in the shedding process. Some hair follicles may require more R.F. intensity than can be applied in one treatment due to the variable resistance to the current or even the chemical make-up of a particular body area.

The clear and simple meaning of this brochure is: Yes, Removatron removes hair *permanently* through a small number of treatments.

32. Other Removatron advertising and promotional materials also contain implied claims that Removatron removes hair permanently. They include those which claim that Removatron is an effective alternative to electrolysis (CX 1-6, 1-26, 38(a), 139(a), 706, 709, 710, 713 and 802); or that Removatron is **[11]** "effective," "most effective," "works," or lets one "say goodby to temporary solutions like messy creams or constant shaving." (CX 1-25, 1-26, 38(a), 40(b), 52(a), 139(a), 704, 706, 727, 743 and 803.) The individual respondent also admitted that such comparisons to electrolysis were intended to convey that Removatron treatments achieve permanent hair removal (CX 721-115), and that the word "works" to mean "removes hair permanently." (CX 721-200.)

33. When a prospective purchaser responded to an ad for the Removatron device, she was shown a Removatron device and informed by Frederick E. Goodman, the individual respondent, that the Removatron method was a painless alternative to electrolysis and would give permanent results. (Tr. 528-29.)

34. Express and implied claims of permanent hair removal also appear in Removatron sales literature. (CX 168, 290, 738 and 756.) Implied claims of permanence through representations that Removatron is an "alternative to electrolysis" (CX 1-12, 149 and 186), unlike "temporary" methods (CX 1-12), and "effective" (CX 1-11, 149, 168, 176, 287, 297, 733 and 738) also frequently appear in respondents' promotional literature.

35. Respondents also implied permanent hair removal by claiming that during Removatron treatment the hair is removed "root and all" or "with its bulb" (CX 1-12, 149 and 297), and that Removatron treatment "dries up," "cooks," "coagulates" and "destroys" tissue, most notably the papilla. (CX 1-12, 149, 290, 733 and 738.)

36. The representations contained in advertisements and brochures and described hereinabove are also made orally to prospective purchasers by Removatron International sales staff by telephone and in-person at trade shows and the Removatron International offices. (Bassett, Tr. 1494-1499; Gagnon, Tr. 1627-1635.)

37. Respondents also made express and implied permanent hair removal claims to Removatron purchasers at the time of sale and on an ongoing basis thereafter. Removatron purchasers are given a book, *Theory and Practice of Pilethermology* (CX 141), which discusses

hair growth, hair removal, and operation of a hair removal business, a wall chart which pictorially and graphically compares Removatron treatment to electrolysis (CX 150), a Technician's Manual (CX 148, 772 and 773), an audio tape titled "Consultation and Approach," which contains a sample "consultation" or first presentation to a client (CX 734), a Question and Answer brochure to be given to each client at the consultation (CX 1-7, 298, 717 and 737), and an in-person training presentation by a Removatron agent, an example of which has been videotaped and is sold by respondents, (a transcription **[12]** of which is CX 251). *Also see* CX 171 and 172 (Removatron Instructor's Manual).

2. Representations Made to Removatron Hair Removal Treatment Customers

38. Some of the sales and promotional literature respondents furnish to Removatron purchasers are intended to be given to hair removal clients by Removatron operators, *e.g.*, the Question and Answer brochure; *see* CX 141-62, or are in the form of model presentations to clients to be used by Removatron purchasers, *e.g.*, CX 141-62, 251-98 and 734. In one instance the purchasers were directed that the representations be passed on, "word for word." (CX 251-39.)

39. Respondents also sell or provide at no charge to Removatron purchasers additional materials containing efficacy representations at or after consummation of the sale, including advertising slicks (CX 145, 146, 147, 147(a), 169, 289 and 730), newsletters (CX 180, 181 and 718), and the videotape discussed above (CX 251) (CX 721-35, 721-204 and 721-230). The advertising slicks and portions of the other materials, *e.g.*, CX 251-98, are directed by respondents to be passed on to clients by purchasers.

40. The materials described in the preceding Findings contain the same permanent hair removal claims as those in F. 28-35, *supra*, including express claims of permanence and the many implied claims of permanence such as "alternative to electrolysis," comparisons to temporary methods, the use of the terms "effective," "most effective," "successful," "most successful," and "works," and claims of tissue destruction.

41. These representations that respondents direct Removatron purchasers to make to their customers are in fact passed on to their prospective and actual customers by Removatron owners and operators. For example, the Question and Answer brochure (CX 1-7, 298,

717 and 737) is given to each client before treatment begins. (CX 251-102 to 251-103, 721-298.) Removatron operators give a presentation to clients based on respondents' model consultation. (CX 251, 734; Callison, Tr. 475-476.) And local advertising by Removatron purchaser-operators to local readers and customers (CX 177, 708, 740, 742, 749, 750, 752, 753, 761, 765, 766, 767 and 768) contains many express and implied permanence claims, including "permanent," *e.g.*, CX 742 and 749, "long lasting," *e.g.*, CX 177-3, "effective" and "most effective," *e.g.*, CX 740-3 and 753, and various statements distinguishing Removatron from temporary methods of hair removal, *e.g.*, CX 177-9, 708 and 761.

42. For example, Gloria Dyal, a beauty salon owner in Jessup, Georgia, offered Removatron treatments from September 1982 until she discontinued use of the device in early 1985. **[13]** During this period of time Ms. Dyal or her employee, Terry Crowe, treated approximately fifty clients with the Removatron device. (Tr. 1268-70.) During a client's initial consultation, Ms. Dyal or Ms. Crowe informed the client that it would take a series of treatments to achieve permanent hair removal and that within a period of time, from several months to one year, the customer would likely observe permanent hair removal. The basis for these representations are the representations in respondents' technician's manual and the training given by respondents' trainer, Bobbie Cavanaugh. (Tr. 1271.)

43. Gloria Dyal also regularly advertised the availability of Removatron treatments at her salon in a local newspaper, *The Wayne County Press*, and on a local radio station. (Tr. 1296 - 1297 and Tr. 1301 - 1331.) The format and content of these advertisements were derived from materials Ms. Dyal received from respondents or their trainer, Bobbie Cavanaugh. (Tr. 1297 - 1298.) Included among these advertising materials are CXs 145, 146, 147, 147(a) and 730. (Tr. 1298-1304.) In addition, Ms. Dyal composed a Removatron advertisement that aired on the local cable television channel. (Tr. 1305-07.) All information used by Ms. Dyal in composing this television advertisement was information that Ms. Dyal had received from respondents. (Tr. 1307 - 1308.) This television advertisement featured respondents' chart that compares Removatron to electrolysis. (Tr. 1309 - 1310.) The television ad contained representations that the Removatron method was a more effective method of permanent hair removal than was electrolysis. (Tr. 1305 - 1306.)

44. Gloria Dyal's radio advertisements for Removatron treatments

contained representations of permanent hair removal. Ms. Dyal believed that Removatron treatments would achieve permanent hair removal. Ms. Dyal formed this belief from her Removatron training sessions, materials she received from Removatron International and from an advertisement she saw in *Modern Salon* magazine. (Tr. 1312-1314.)

45. During the approximately four years that Doris Callison offered Removatron treatments at her salon located in Yreka, California, sixty clients received Removatron treatments. (Tr. 474-75.) Ms. Callison distributed copies of CX 298, Removatron International's Question and Answer brochure, to her clients, prospective clients, and to salons and other businesses throughout her community. CX 298 contains a representation that the Removatron method can achieve permanent hair removal, although not after the first treatment. (CX 298; Tr. 486-488.)

46. As shown in the preceding Findings, respondents placed in the hands of Removatron purchasers various advertising and promotional materials which contain many express and implied claims of permanent hair removal with the intention and express instruction that these materials be used and followed in local **[14]** advertising and hair removal client solicitations. Therefore, although the Removatron purchaser-operators are not respondents' employees or agents, respondents are, as a matter of law, responsible for the dissemination of the advertising claims which are contained in the materials and disseminated by Removatron purchasers and operators to the general public and to their customers. *E.g., National Housewares, Inc., et al.*, 90 FTC 512, 590-91 (1977).

3. Respondents' Claimed Qualifications of These Representations Were Ambiguous and Ineffectual and Amounted to Nothing More Than Mere Disavowal of an Unconditional Guarantee Made at the Point of Purchase

47. Respondents assert that, following initial contacts which may have been induced by the permanency claim contained in Removatron ads, they qualified the initial claim in subsequent contacts with presentations to Removatron purchasers, both orally and through printed literature and audio tapes, by suggesting that (1) it requires a series of treatment to achieve permanent hair removal, *e.g.*, CX 1-6, 1-7, 709, 710, 713, 734-3 and 737, (2) Removatron treatment may not work for some people, *e.g.*, CX 172, 709, 710, 713, 717, 804, and (3) there are "no guarantees," *e.g.*, CX 171-6, 251-25.

48. For example, CX 290, an early Removatron brochure entitled "What you should know about Removatron," states in part (CX 290-2):

WILL I NEED MORE THAN ONE TREATMENT?

Probably, as permanent removal is very seldom the result of only one treatment. We can only treat hairs which are above the skin surface. Hair has variable shedding cycles and some normal hair growth is below the skin line at a given point. Following initial treatment you may see hairs which are in the same area appear the next day or the next week. These are new hairs or those that were below the skin line during initial treatment. Don't forget you have approximately 1,000 hair follicles per square inch of skin. So, even if you do not have 1,000 hairs per square inch, you could have.

The net impression of this statement is clearly that one will get rid of all unwanted hair after a small number of treatments, as soon as every hair as it reaches above the skin surface, according to the growing cycle, gets treated. **[15]**

49. To cite another example, in CX 734, an audio tape "Consultation and Approach Removatron" which is furnished to Removatron purchasers, Removatron operators are instructed that, in the initial contact with a consumer, usually by a telephone call, the caller (referred to as Mrs. Johnson here) should be told: "The answer Mrs. Johnson, is yes it does [remove hair permanently], but not the first time. It does take several treatments, Mrs. Johnson." (CX 734-2.) When the caller asks how many treatments she will need, the operator is instructed to respond: "Well, as I said before Mrs. Johnson, it is very, very hard to tell, you know, over the telephone, or to diagnose, especially. It will take a few treatments." (CX 734-3.) A reasonable interpretation of these statements is that permanency is achieved after "a few treatments."

50. A caller who wants more specific or more accurate information over the phone will not get it. *See* CX 734-1 to 734-5. The salon operator is instructed not to provide any detailed information to a telephone inquiry: "the objective is to get that client into the salon but not, and I repeat not, sell the service over the telephone ... ." (CX 734-2); "the objective is strictly to get her in." (CX 734-5.)

51. Instead, the operator is instructed to say at the first visit:

As an example, Mrs. Johnson, I am going to be able to send you out today with hair-free skin. Now, it might take me two or three hours to clean that entire area. But you can rest assured, that I will decrease the time just as fast as possible. As an example, when you come back the following week, I might only have an hour's worth of

regrowth work. It might be a half-hour, it might be only fifteen minutes, I might just shake your hand and book you the following week. It all depends on what comes back. So that in two to three to four months, you'll start to see results. And you will probably be coming to me then for about once every three weeks for about an hour. And then in about say, six to eight months, you will start to see more results. And you'll probably be coming to me then about once every four weeks, for about an hour. And then in about a year's time, Mrs. Johnson, you will start to see maximum results, and you will probably be coming to me at that point, once every four weeks for only fifteen minutes

(CS 734-14 to 734-15.) **[16]**

These statements convey the suggestion that complete cure ("maximum results"), if not achieved, will be very close at hand at the end of a one year program. *See also*, CX 251-69: "in one year's time is where you'll see your maximum results, possibly all cleaned up."

52. To cite another example, prospective purchasers and treatment customers are told that 30% of treated hairs are removed permanently the first time, but the remaining 70% will grow back because the hair is in the wrong stage of growth—the papilla has detached from the root. (CX 1-8.) Respondents' sales and promotional materials state, for example: "we do destroy roughly speaking ... 30 percent the first time, and, therefore, 70 percent will come back; and that's why it takes a series of treatments to obtain permanent hair removal." (CX 251-20 to 251-21, 734-14.) The net impression of such statements is clearly that permanency will be achieved after a small number of treatments given in appropriate intervals.

53. The second claimed qualification—that Removatron treatments will not work for everyone—is also highly equivocal. Prospective purchasers and clients are told, for example, that "[T]here are no guarantees [because] [e]verybody's body chemistry is different." (CX 251-25.) "[Removatron is] an effective treatment for many" (CX 709, 710, 713, 717 and 802), "the majority of cases ... are completely normal" (CX 141-4), "everybody is different, and there are no guarantees. Most people we can clean up." (CX 251-32.) Removatron International sales employees also say, when responding to customer inquiries, that Removatron treatments are "permanent in most cases." (Evan Goodman, Tr. 1694.) When the hair keeps growing back after a course of treatments, the suggested Removatron International response is to suggest the client see an endocrinologist because she must have a hormone imbalance. (Collins, Tr. 322; Evan Goodman, Tr. 1699; Bunims, Tr. 2542.) The net impression of such statements is that Removatron will remove hair permanently after a

small number of treatments except for a small number of individuals with pathological hormone imbalance.

54. Removatron purchaser-operators made similar statements to their clients. For example, Nora Bunims does not guarantee that her clients will achieve permanent hair removal, but she does inform them that treated hairs do die off (Tr. 2520) and that the hairs do not come back. (Tr. 2521.)

55. Joyce Pipper informs all her clients that regular treatments are a necessity and that there is no way to predict how long it may take to accomplish a particular removal job. (Tr. 2124.) Some of Ms. Pipper's clients discontinued treatments after a few visits because they did not understand "at the consultation that it was a long-term thing." (Tr. 2126.) **[17]**

56. Patricia Jones tells her clients, on their initial visit, that Removatron does not work on all people and that an actual completion date cannot be given. During the same visit, Ms. Jones also tells her clients that in order to obtain permanency, more than one visit is necessary and that "it takes approximately three to six months to see a substantial amount of hair not coming back." (Tr. 2067-68.)

57. Ann Richardson tells her customers that it will take two to five years to clear them although she is living proof that it does not take two to five years. (Tr. 2036.)

58. Trenda Jean Bilbrey tells her Removatron customers "that it can become permanent, but it does take time, anywhere from 3 months to five years." (Tr. 2302.)

59. In sum, the claimed qualifications are so equivocal, vague and ambiguous that they cannot reasonably be expected to offset or undo the clear, strong, and welcome initial message that Removatron will bring about *"permanent,"* painless hair removal or that Removatron removes unwanted hair *"forever."* Respondents' claimed qualifications amount to nothing more than a disavowal of an unconditional guarantee. Furthermore, respondents' initial permanent hair removal claim is often reinforced through post-purchase contacts with purchaser/operators who in turn pass such reinforcements to their clients. *See,* F. 61, *infra.*

60. Respondents assert that Removatron is advertised and sold for the most part to beauty and skin care "professionals" who are knowledgeable and experienced in these fields and that these "professionals" are not likely to be misled or deceived by the permanent hair removal claim challenged in this proceeding. (RPF at

1-2.) Respondents also assert that, although Removatron purchasers may be initially induced to contact Removatron International by the "permanent hair removal" claim contained in the advertising material, no Removatron is in fact sold until the purchasers are made to understand the various qualifications of the permanency claim contained in sales and promotional literature and training tapes, which are provided to the purchaser at the time of the sale, and that no misrepresentation or deception could have occurred as far as the Removatron purchasers are concerned. (RPF at 1-2.)

61. However, the evidence shows that when Removatron purchasers/operators, after observing the results of serial Removatron treatments of their clients, telephoned respondents to say that they were not getting the promised results and their clients' hair kept growing back, they were told by respondents' sales employees in substance that Removatron treatments, if correctly administered, will achieve the claimed results after a **[18]** sufficient number of treatments or that the unsuccessful clients might have a pathological hormone imbalance and should be advised to consult an endocrinologist. And, these post-purchase claims are in turn passed by Removatron purchasers/operators to their clients. *E.g.*, Collins, Tr. 315-19, 322; Basset, Tr. 1501-02, 1512; Evan Goodman, Tr. 1699-1701; Bunims, Tr. 2542.

62. In any event, it is well-settled that if the initial sales contacts are induced by misleading or deceptive claims, Sections 5 and 12 of the Federal Trade Commission Act are violated even though the truth is subsequently made known to the purchaser. *E.g., Carter Products, Inc. v. FTC*, 186 F.2d 821 (7th Cir. 1951); *Thompson, supra*, 104 FTC at 708.

C. Respondents Have Represented, Directly and by Implication, that Their Advertising Claims of Permanent Hair Removal Have a Reasonable Basis

63. Respondents expressly claimed that Removatron is "clinically tested and endorsed" and "clinically tested and superior." (CX 1-26, 139(a), 706, 733 and 743.) They also claimed "Research Proves Removatron Method Destroys Hair Follicles" (CX 179-1), "Certified Medical Biopsies clinical testing on humans and animals, demonstrating papilla and follicle destruction" (CX 179-4), and "case history shows us that we do destroy, roughly, 30 percent the first time." (CX 251-41.) These express representations regarding clinical tests,

research, biopsies and case histories obviously mean that Removatron's claims regarding the device's effectiveness are based on reliable medical and scientific evidence.

64. Furthermore, respondents' product claims for their radio frequency energy epilator challenged in this proceeding are objective performance claims and, as such, they all imply that respondents possessed and relied on a reasonable scientific basis when these claims were made. This is especially true where, as here, the truth or the representation cannot be easily or reliably evaluated by the consumer and the advertiser-marketer of the product is in the better position to evaluate the truth or falsity of the claims.

D. Whether Removatron Removes Hair Permanently as Claimed by Respondents Is a Material Fact for Removatron Purchasers and Their Hair Removal Treatment Customers

65. Whether Removatron removes hair permanently as claimed by respondents is obviously a material fact for Removatron purchasers, who pay about 4,000 dollars relying on the permanency claim and offer Removatron hair removal treatment to their customers, as well as for the clients, who undergo a series of **[19]** Removatron hair removal treatments at substantial costs, relying on the permanency claim passed on to them. Frederick E. Goodman, the individual respondent, and the Removatron sales staff agree that the permanent hair removal claim is important to prospective purchasers. (CX 721; E. Goodman, Tr. 1692.) Respondents were well aware of this fact when they stated in a model consultation tape: "'Does this remove hair permanently?' The number one question." (CX 734-2.)

66. There is ample evidence that Removatron purchasers and treatment clients relied on the permanency claim contained in various ads and promotional pieces. *E.g.*, Callison, Tr. 456-457, 461; Dyal, Tr. 1242-1244, 1265-1267.

67. Furthermore, the problem of unwanted hair is often regarded by women as a serious problem, tantamount to disfigurement. (Van Scott, Tr. 948). Whether Removatron delivers permanent hair removal or whether unwanted hair can now be "Removatroned forever" (CX 803) is clearly a highly material fact to women who seek Removatron treatment. *See* CX 734-2.

E. Respondents Have Made the Representation, Directly and by Implication, that the Federal Communications Commission Has

Approved the Removatron Hair Removal Method, as Alleged in Paragraph Ten of the Complaint

68. Respondents made the representation that the Federal Communications Commission ("FCC") approved the Removatron hair removal method, as alleged in paragraph ten of the complaint. In magazine ads in 1979 to 1983, and in brochures as recently as 1984, respondents stated variously that "Removatron is safe and effective even on sensitive parts of the body—RFE is used in medical field and is government FCC approved" (CX 1-6, 1-9, 1-24, 38(a), 40(b), 52(a), and 704), "FCC approved" (CX 1-11 and 149-9), "tested and FCC approved" (CX 297), "tested and FCC approved to meet all standards" (CX 1-25), and "Removatron hair removal is government FCC approved." (CX 1-25.) One reasonable, common sense interpretation of these statements viewed in the context of the ads and brochures in which they were made is obviously that Removatron is FCC tested and approved and that Removatron hair removal is approved by an agency of the U.S. government and is safe and effective.

69. Respondents admit that the FCC has merely approved the operation of the Removatron device at a certain frequency to ensure noninterference with radio broadcasting (CX 1-5, CX 2-1, and Stipulation, approved October 23, 1986), but deny that their FCC representations are misleading. (Ans., at 3.) **[20]**

IV. Respondents Did Not Have a Reasonable Basis for Their Advertising Representations Challenged in the Complaint

A. Biology of Hair and Hair Growth — An Overview

70. As an aid to understanding the scientific issues raised by a claim of permanent hair removal in this case, a broad overview of the biology of hair and hair growth may be useful. Eugene J. Van Scott, M.D., a board-certified dermatologist and an eminent researcher in dermatopathology was called as an expert witness by complaint counsel and provided the bulk of scientific information regarding the subject matter. Dr. Van Scott currently is a dermatologist practicing at Temple University Skin and Cancer Center Hospital, Philadelphia, Pennsylvania, and is a professor of dermatology at Temple University School of Medicine. Dr. Van Scott is also a respected clinical and laboratory research investigator in the biology of hair and hair growth. Dr. Van Scott is a member of the American Society for

Experimental Pathology and one of the first members of the American Society for Dermatopathology. He was the Head of the Dermatology Service, General Medicine Branch, National Cancer Institute, NIH, from 1953 to 1961, and Chief, Dermatology Branch, National Cancer Institute, NIH, from 1961 to 1968. Dr. Van Scott has authored some 154 learned articles, treatises and chapters of textbooks, about 20 of which directly deal with hair research. Dr. Van Scott is an eminent practitioner in dermatology and dermatopathology and a respected researcher in the biology and physiology of hair and hair growth. *See* CX 720, Van Scott, Tr. 894-919.

71. Hair is a biologic fiber that originates from the hair root of the hair *follicle* and consists of fibrous proteins collectively known as *keratins.* Hair is a fiber that is continuously produced by the hair root at a continuously steady rate. Hair is not considered to be living tissue but arises from the hair root, which consists of living tissue. (Tr. 919.)

72. Hair differs from species to species, body region to body region, in color, width, degree of straightness, presence or absence of the medulla, contour, and angle of emergence. (Tr. 920.) *Terminal* hair grows long; *vellus* or lanugo hair grows short and fine from follicles substantially smaller than follicles that produce terminal hair. (Tr. 921.) The length of both terminal and vellus hair varies depending on the area of the body. Follicles producing vellus hair are interspersed with follicles producing terminal hair. (Tr. 922.)

73. A hair follicle is like a nest and is a complex cellular structure, comprised principally of *epithelial cells,* that can be analogized to a cylinder with its hollow opening **[21]** (lumen) centrally located. The upper portion of the hair follicle, at the level of the *sebaceous gland* within a layer of the skin, is the site where the follicle's epithelial cells differentiate, *i.e.,* take on a different character by changing from part of the follicle into producers of a fatty material, called *sebum,* from the sebaceous gland. Proceeding downward from the level of the sebaceous gland, the follicle contains a segment referred to as its *isthmus.* At the bottom of the cylinder-like follicle lies its hair root portion which ends in contact with the *papilla.* (Tr. 923.)

74. The *papilla* is comprised of connective tissue cells, unlike the follicle, which, as noted, is comprised of epithelial cells. (Tr. 923.) The papilla is connective tissue. It is considered part of the hair follicle but is connected to connective tissue and is thus distinct from the follicle itself. (Tr. 929.) It is not part of the nest. One might say it is structurally more in the nature of a branch on which a nest resides.

Blood vessels entering the papilla supply it with nutrients "and it is suspected that there are certain growth factors or growth hormones that are produced by the papilla and that determine how these cells divide." The area surrounding the hair root is connective tissue and the *papilla* is the derivative of the connective tissue and it is a direct extension of the connective tissue. (Tr. 930.) No other part of the follicle *per se* is made up of connective tissue. (Tr. 930.)

75. "A hair cannot grow or regrow in the absence of a papilla." (Tr. 931.) "[I]t is agreed upon by all of the people who think about this that the papilla must be destroyed in order to destroy the hair follicle's ability permanently to produce another hair." (Tr. 931.)

76. The *bulb* is an important part of the follicle. It determines the size and rate of growth of the hair. (Tr. 928.) The *bulb* includes the *matrix,* where new cells are generated at a rate of more than doubling every twenty-four hours, and which consists of "one of the most rapidly dividing tissues known in biological systems." The function of the matrix is to produce a hair fiber. The produced cells are living and, as they divide, rise in the follicle because the follicle, surrounded by connective tissue, pushes the expanding cell population toward the skin surface. (Tr. 928-932.)

77. As the cells rise through the follicle they die ("lose their capability of producing new cells") and become embedded in fibrous protein. (Tr. 932.) Keratins begin to accumulate in substantial amounts in the keratogenous zone. Cell growth and differentiation have halted by the time cells have been pushed upward to the keratogenous zone. (Tr. 935.) Above the keratogenous zone, the adult hair fiber continues to extend and "goes on extending day after day after day after year ... the **[22]** average [period of continued growth] on the human scalp being about 30 months." (Tr. 932-33.)

78. The keratins form the fibrous protein network that "accounts for the flexibility of the hair, that accounts for this hair not breaking off normally and accounts for it not shedding." (Tr. 935.) Cells generated in the skin elsewhere are shed to the outside. Hair cells are so firmly united by fibrous protein that there is no shedding. (Tr. 935.) "The hair is not shed cell by cell as it is on the skin surface. But at the end of the [growth] period, the whole hair is shed." (Tr. 936.) A terminal hair follicle on the human scalp typically descends 3.5 millimeters below the surface of the skin to its root portion, which distance may be roughly the same for terminal hair follicles on the faces of males. The depth of terminal hair follicles differs on other parts of the body. (Tr. 924.)

79. Dr. Van Scott testified that he believes that the hair's *medulla,* or "central core" (Tr. 928), lacks fibrous proteins. (Tr. 927.) Each human hair does not necessarily have a medulla. Coarser hairs are more likely to have medullas. (Tr. 927.) "[T]he medulla has no compact structure. It is made up of loose cells and air space that is presumed to exist in there." (Tr. 927.) "[I]t is fairly straight through the center of the hair but it is not so homogeneously constituted. It does contain loose cells and is not so compact." (Tr. 928.)

80. Hair has a growth pattern, known as the hair cycle. Hair grows rapidly for a period and, abruptly, cell division and production stops. (Tr. 936.) The cells then mature in the keratogenous zone. (Tr. 937.) The first phase of the hair cycle is known as *anagen* when hair grows at a vigorous rate. (Tr. 937.) The end of anagen, the involutional second phase of the hair cycle known as *catagen* begins. During *catagen,* all the hair structures, as illustrated on CX 822 and at Tr. 938 (*viz.,* the external root sheath, the internal root sheath and the working cells then existing in the matrix are converted quickly to dead cells and, except the dermal papilla, are destroyed). (Tr. 938.)

81. Examination of what occurs during the *catagen* phase is particularly instructive. The portions of the previously anagen hair, comprised of epithelium, show signs of severe destruction and damage. "There is vacuolation of cells, ... rupture of cell nuclei and the entire germinative regenerative portion of the hair is wiped out as it ascends up to the level immediately below the sebaceous gland in the area known as the isthmus. During catagen, which occurs in all follicles (Tr. 940), the papilla rises up slowly but lags behind and essentially remains unchanged. Often, the now dormant hair detaches from the papilla. (Tr. 939.) **[23]**

82. The third and final phase of the hair cycle is known as *telogen.* In *telogen,* the dead hair sits in position and is known as the club hair because when pulled out it looks like it has a club on the end of it. The *telogen* period is characterized by dormancy; the club hair merely stays where it is and does nothing. (Tr. 940.)

83. Observation of hairs extending above the skin surface does not allow one to determine whether any given hair is in the anagen, catagen or telogen phase of the hair cycle. Within a follicle may exist more than one root, perhaps as many as four on the scalp. Dr. Van Scott did not know whether this multi-root phenomenon occurs on the face. (Tr. 933.)

84. Dr. Van Scott discussed "hair problems." After puberty, men

are characterized by and pride themselves on having a beard. On the other hand, a woman is concerned about her "disfigurement" if she grows a beard. And that would be an excess hair problem to that woman. "Excess hair can occur on other parts of the body. But, it usually is women who are concerned with excess hair on their bodies, whether it is on the face or elsewhere. *Hirsutism,* a term meaning excess hair, would include unwanted hair." (Tr. 946.)

85. Excess hair is important to the individual who has it because in their eyes it represents a form of disfigurement and because "it can affect their lives, how they relate to other people, how they secure occupations and with good reason." (Tr. 948.) As a dermatologist, Dr. Van Scott considers the problem of unwanted hair as both a medical and cosmetic problem. Cosmetic substances applied to the skin do not change the form or function of the skin. Drugs change form or function. "So that a cosmetic problem [subject presumably to whether the treatment employed to address it changes form or function as the Removatron device is claimed to do], can be a medical problem as well as a cosmetic problem." (Tr. 949.) Excess hair "may represent underlying abnormalities in hormone production and, therefore, is a manifestation of a medical problem." (Tr. 949.) The disease alopecia areata, which causes loss of hair, can occur on the face and is a treatable disease. (Tr. 915-916.)

86. It is respondents' position that Removatron is a cosmetic device sold to beauty professionals and thus is distinct and separate from a medical device, which would be a "device" within the meaning of Section 12 of the Federal Trade Commission Act. However, respondents held out to the general public that Removatron is a modern radio frequency energy device which will effectively accomplish "permanent, painless hair removal" and that unwanted hair can now be "Removatroned away forever." The evidence is clear that the problem of unwanted hair is both a cosmetic and medical problem and any device which, like Removatron, is offered and sold to the public as being capable of **[24]** removing unwanted hair permanently and painlessly by destroying the underlying hair tissue structure is a device within the meaning of Section 12 of the Federal Trade Commission Act.

87. Dr. Van Scott also provided salient scientific information regarding the question of *permanent* hair removal, from the perspectives of a seasoned dermatologist and a respected research investigator in the field of dermatopathology, including hair losses associated with chemotherapy in humans.

88. In response to the question, "Is there a level of damage, an amount of damage that must be done to the hair structure to remove hair permanently?" Dr. Van Scott testified that it is generally accepted that in order to accomplish permanent hair removal, "one must destroy and must destroy absolutely and completely the hair papilla, the dermal hair papilla which is the important seed for continued hair growth" and that if damage does not destroy the papilla, "[f]rom all the data that we have and all the clinical experience that we have, the hair will regrow. As long as the dermal papilla exists down there, it serves as a magnet almost attracting, inviting the epithelium to grow down again and surround it and mate with it almost and then go down and then to participate in the growth generation of the new hair." (Tr. 951-953.)

89. Dr. Van Scott also cited examples of damage to the hair *root* that produce hair loss *temporarily* only to prove insufficient to prevent regrowth. The effect of chemotherapy on hair growth was described by Dr. Van Scott as "an example of ... insults to the growing hair where there can be severe substantial damage to the matrix. The hair falls out, it is so severe that the matrix cannot produce hair at all ... [b]ut chemotherapy has not been used in large enough doses internally to permanently affect or destroy the hair papilla so that hair characteristically regrows after the use of chemotherapeutic drugs." (Tr. 954.)

90. In the disease known as alopecia areata, an "intense inflammatory reaction" of cells "around the entire hair root portion of the follicle" occurs. This disease tends to correct itself "and despite that damage [that it inflicted] new hair emerge and the site looks entirely normal." (Van Scott, Tr. 955.)

91. Concerning the effect of manual epilation (plucking or tweezing) on regrowth of hair, Dr. Van Scott testified that, from what he and others observed in mice as well as in humans, "you can pluck out the hairs of a given region and watch the time of new hairs to emerge or take biopsies to see what has gone on. And when a hair is plucked from a mouse and presumably from man and it is an anagen [growing] hair, there is a temporary interruption of anagen but anagen resumes. When the hair is **[25]** plucked from a telogen follicle, that is, when a resting hair is plucked, it "initiates a new growth hair cycle and initiates an anagen hair which emerges thereafter." (Van Scott, Tr. 956.)

92. "Theory and Practice of Pilethermology, Removatron's School

of Pilethermology, Training and Teaching Aid No. 11" (RX 70/CX 141) also contains a discussion of the biology of hair growth (pp. 21-39) and acknowledges that complete destruction of the *papilla* is necessary in order to accomplish permanent removal of a hair. (RX 70, pp. 36-39.)

B. Respondents' Substantiation Was Inadequate When the Permanent Hair Removal Claims Were Made

1. Legal Standards Governing Adequacy of Substantiation

93. It is well established that (1) when an advertising claim of effectiveness is made with respect to the performance of a product or device the advertiser must possess and rely on competent and reliable evidence that supports the claim at the time such a claim is made, and (2) when an express advertising claim is made that a product or device is clinically tested and proven, the advertiser must possess and rely on such tests which were conducted in accordance with generally accepted scientific methodology.

94. In *Porter & Dietsch, Inc.*, 90 FTC 770, 885 (1977) *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980), the Commission ruled that "claims that any food, drug or device can help a user achieve any result ... must be substantiated by "competent scientific or medical tests or studies." A competent scientific test "is one in which persons with skill and expertise in the field conduct the test and evaluate its results in a disinterested manner using testing procedures generally accepted in the profession which best insure accurate results." *Firestone Tire and Rubber Co.*, 81 FTC 398, 463 (1972) *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973).

95. In the *Analgesics* cases and recently in *Thompson, supra*, the Commission held that when express claims of superior efficacy are made, the advertisers must possess and rely on two or more well-controlled studies which are conducted in accordance with accepted scientific methodology designed to insure objectivity and scientific validity of the tests or studies and set forth specific requirements regarding the design and execution of the test and the interpretation of the test results. *See, e.g., Thompson, supra*, 791 F.2d at 194-96.

96. The FDA regulations applicable to the marketing of medical devices are also consistent with the Commission's requirement regarding advertising claims of product efficacy. Under the provisions of the Medical Devices Amendments of 1976 to the Food, Drug and

Cosmetic Act, the FDA regulations require that medical devices intended for human use be classified as safe and effective based on "only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective" and further define "reasonable assurance" of safety and effectiveness as "when it can be determined, based on valid scientific evidence, that in a significant portion of the target population, the use of the device ... will provide clinically significant results." (21 CFR 860 (CX 816-6); §§860.7(c)(1), 7(c)(2), 7(e)(1).) "Valid scientific evidence" is further defined by FDA and must "have been developed over a period of years and are recognized by the scientific community as the essentials of a well-controlled clinical investigation." (21 CFR 860.7(f)).

2. Consumer Testimony and Other Anecdotal Evidence and the Need for Well-Controlled Studies

97. As substantiation for the permanent hair removal claim, respondents presented, among others, testimony of a number of Removatron purchaser-operators and their hair removal treatment clients. (RPF 31-36.) Respondents also rely on letters received from purchaser-operators who indicated that they were happy with Removatron and that Removatron worked on their clients or so called user-customer surveys. *E.g.*, RX 70, 73, 76. However, it is well established that subjective assessments, such as consumer testimonials and consumer surveys, are anecdotal evidence at best and are not adequate substantiation for claims of product performance or the device's scientific or biomedical efficacy.

98. It is well settled that testimony of satisfied users of a product is of little evidentiary value in determining the adequacy of substantiation for an advertising claim of effectiveness of a product or device, especially in cases where, as here, faced with contrary testimony of the only dermatological expert who testified in this case. *See Stauffer Laboratories Inc. v. FTC,* 343 F.2d 75 (9th Cir. 1965). In *Simeon Management v. FTC,* 579 F.2d 1137, 1143 (9th Cir. 1978), the court, citing *Weinberger v. Hynson, Westcott and Dunning,* 412 U.S. 609, 618-19, 629-30 (1973), stated that "[a]nedcotal evidence, such as testimonials by satisfied patients or statements by doctors that, based on their experience, they believe a drug is effective do not constitute adequate and well-controlled investigations and cannot, therefore, provide substantial evidence of effectiveness." **[27]**

99. Dr. Van Scott, the only practicing dermatologist and researcher

in dermatopathology who testified as an expert witness in this case, testified in essence that, while lay opinion or user testimony regarding effect of treatments will be noted as a piece of information, such lay or user testimony does not constitute scientifically acceptable evidence. (Van Scott, Tr. 958.) Dr. Van Scott further testified that the problem is further compounded in this case by the fact that the user testimony favorable to Removatron dealt with or came almost entirely from women who were still undergoing a series of Removatron treatments. When such a woman observes no hair growing back after following a hair removal treatment, it can be a temporary stoppage and the time must be long enough to determine whether the hairless condition is merely a temporary condition or a permanent one. (Tr. 960, 965, 967.)

100. Dr. Van Scott stated in effect that the same problems or subjectivity and bias exist with such observations made by a single subject or a group of subjects, including Removatron operators, or observations made by physicians essentially because of the lack of necessary controls. (Tr. 965-967, 973-974.)

101. Dr. Van Scott testified that "scientifically acceptable evidence" is based usually on a *prospectively* designed experiment or study in which "the conditions were such that there were groups of controls and ... few variables" and from which one is able to conclude from the evidence that a certain event or result happened or did not happen. (Tr. 958-959.)

102. Dr. Van Scott's description of such a study includes the basic elements of a "competent and reliable scientific study" that the Commission requires with respect to claims of product or device efficacy. These requirements are well known and accepted by scientific research investigators and generally conform to the FDA requirements described in F. 96, *supra*. Such a study in this case should include (Van Scott, Tr. 1064-1067):

(i) comparison of the results of Removatron treatments, manual epilation (a control) and in the same or a different study, electrolysis treatments (as another type of control);

(ii) the different types of treatments should be administered to symmetrical (comparable) sites on the human body;

(iii) the treatment sites must be identifiable, *e.g.*, by small tattoos, to be absolutely sure that one is dealing with the same site all the time; **[28]**

(iv) the Removatron treatment "should be carried out as recommended by either the manufacturer or the reliable operators for a time considered to be sufficient to demonstrate these changes one is looking for" "by expert operators" selected by the company;

(v) the length of the series of treatments would be in the order of nine months before cessation;

(vi) observations of treated sites could then be made over the next six-month interval, "either once, twice, three times" or more:

(vii) hairs within the treatment sites should be clipped after each observation and their length and caliber determined;

(viii) the study population should include at least ten paid preferably healthy volunteers with "sufficient growth of excess hair that would lend itself to the end point of the study";

(ix) the investigator must be reliable; and

(x) finally, the investigator should be "blinded." There should be an observer to ascertain that the treatment has been carried out and a judge later to examine the treated areas without knowledge of what has been done. Also, determination of the data on the dimensions of hairs should be made by a disinterested observer.

Dr. Van Scott estimated, based on calculations of the cost of each component he outlined, that the cost of a clinical study like that he described would not exceed $40,000 today. (Van Scott, Tr. 1069.)

103. Dr. Van Scott also testified that one controlled study, which is flawless in every respect "would hopefully establish what one was looking for," but two controlled studies would be "more convincing" and "preferable." (Van Scott, Tr. 1068.) **[29]**

3. Scientific Materials Offered As Substantiation by Respondents

104. The bulk of scientific material proffered as substantiation was evidently obtained by respondents *after* the challenged permanency claims were made, except for such claims contained in the 1986 ads (CXs 802-804), and cannot be relied on as substantiation for the pre-1986 claims. *See* Order Reopening Record to Dispose of Certain Evidentiary Matters and Revising Briefing Schedule, dated March 19, 1987, at 2.

105. In any event, the scientific material referred to in the preceding Finding includes: (1) one animal study conducted with Removatron (the so-called Foster Study, RX 71); (2) a number of reports of, or references to, biopsies conducted with Depilatron and other RFE epilation devices; (3) a number of affidavits or testimonials authored by scientists and clinicians about various RFE-type epilation devices; and (4) parts of or excerpts from various scientific literature discussing theories or hypotheses regarding hair removal, which have some scientific support but the validity of which remains to be established by controlled tests or studies.

106. It is concluded that none of the above scientific material,

considered singly or as a whole, constitutes "competent and reliable scientific or medical evidence" required by the Federal Trade Commission or "valid scientific evidence" required by the FDA. (CX 816.)

a. *Removatron Studies*

(1) The Foster Study (CX 157/RX 71)

107. The Foster Study is a report of the only scientific test conducted with Removatron in the record. The study was not designed to demonstrate the ability of Removatron to remove hair permanently in humans. Dr. Foster, an ophthalmologist, told Frederick Goodman that he could conclude nothing about permanence from this study. (Foster, Tr. 1559.) He also testified that, contrary to what a Removatron newsletter of Summer 1984 headlined as "Research Proves Removatron Method Destroys Hair Follicle" referring to his study, his research did not prove that Removatron destroys 30% of treated hair the first time. Nor did it prove permanent destruction of hair follicles at any time; what it showed was "damage." (Foster, Tr. 1558-1559.) And Dr. Foster presently has no opinion about the ability of Removatron to remove hair permanently. (Foster, Tr. 1960.) In these circumstances, it would be somewhat farfetched to conclude that the Foster Study is adequate scientific substantiation for respondents' permanent hair removal claims. However, in the **[30]** interest of completeness, a review and evaluation of the Foster Study and Dr. Foster's testimony follows.

108. Charles Stephen Foster, M.D., is an ophthalmologist and has been associated with the Massachusetts Eye and Ear Infirmary in Boston, Massachusetts for some eleven years. His curriculum vitae is included in the record as RX 305. (Foster, Tr. 1521-1522.) In addition, for the past ten years, Dr. Foster has engaged in research in animal models of eye inflammation which has revolved exclusively around histopathologic and immunopathologic analysis of experimental inflammatory diseases of the eye. (Tr. 1529.)

109. Dr. Foster has treated a rare disorder called pemphigoid, one by-product of which is scarring of the conjunctiva resulting in an inturning of the lids and the rubbing of eyelashes onto the surface of the cornea. In addition to controlling the underlying inflammation process, Dr. Foster felt obligated to prevent corneal damage through destruction of the eyelashes. And, plucking the eyelashes is not acceptable because they grow back. (Foster, Tr. 1523.)

110. Dr. Foster and others had employed electrolysis but had largely abandoned it, because of the very high rate of regrowth of lashes, and had turned almost exclusively to cryotherapy, a procedure producing temperatures of between minus 40 and minus 60 degrees centigrade at the level of the eyelash, which kills the hair roots and thus stops the growth of lashes. Although it is effective, it is a relatively brutal procedure in that injection of a local anesthetic into the lid is required and the patients have significant sense of discomfort during the procedure. And lid swelling and inflammation afterwards is substantial. (Tr. 1524.) At some point Dr. Foster obtained a Removatron epilator and used it for one to two years on the lashes of patients with pemphigoid. (Foster, Tr. 1526, 1527.)

111. Frederick Goodman, the individual respondent, approached Dr. Foster at some point to ask if he would perform a study "which could look at the question from a scientific, objective standpoint of whether or not the energy delivered by the device did, in fact, reach the hair root and produce damage to it." (Tr. 1527.) Subsequent discussions also included, as a "corollary goal" so to speak, the question of whether or not the device would produce clear-cut, measurable permanent removal of hair. Dr. Foster also testified that Mr. Goodman "was clearly aware" of the fact that measurement to determine whether the hair shaft is capable of conducting radio frequency energy was not his area of expertise. (Foster, Tr. 1527-1530.)

112. Dr. Foster chose an animal model, using black mice because Mr. Goodman had an impression that darker individuals seemed to get better results from Removatron treatments. In the **[31]** study, the specific hairs on the snouts of mice were treated with Removatron for a total of 69 seconds and the control group mice were given a sham treatment. After the mice were killed, the tissue around the treated hair was sectioned, stained and microscopically analyzed. The slides were prepared by technicians and analyzed by Dr. Foster. (Tr. 1530-1532.)

113. For this litigation, respondents and Dr. Foster produced CX 157(a) (RX 71), Dr. Foster's December 12, 1983 letter to Mr. Goodman, CX 728, Dr. Foster's October 18, 1983 letter to Mr. Goodman, and CX 736, five slides of specimens referred to in Dr. Foster's report. All other records of the Foster Study were unavailable and apparently lost during a move of Dr. Foster's laboratory. (Foster, Tr. 1555.) Dr. Van Scott, complaint counsel's expert witness, reviewed CX 157(a) (RX 71), CX 728, and CX 736 (RX 80) and

testified unequivocally that Dr. Foster's work does not establish the efficacy of the Removatron device in bringing about permanent hair removal. (Van Scott, Tr. 1033.)

114. In the December 1983 letter to Mr. Goodman (CX 157(a)/RX 71), Dr. Foster wrote that he observed "33% of treated hairs harvested one day or more after treatment showed histopathologic evidence of damage of the hair follicle." After reviewing the Foster letters and photographs of tissue specimens, Dr. Van Scott concluded that they "describe changes that I do not consider to be very good evidence of very substantial damage." In Dr. Van Scott's view, the changes are "on the minimal side rather than on the major side." (Van Scott, Tr. 1034.)

115. Referring to a slide (CX 736-1), Dr. Van Scott observed that it showed the keratogenous zone of a normal hair because one can still see remnants of the cells and the nuclei of the cells and had the process of maturation been completed and the shaft been all finished in its formation, this cellular detail would not be discernible. (Van Scott, Tr. 1036.)

116. Turning to another slide, CX 736-2, Dr. Van Scott testified that it shows a section taken "at quite a bit higher level up the follicle" than was represented on CX 736-1 and that it is "certainly far above the hair bulb and it is above the keratogenous zone." (Van Scott, Tr. 1037, 1039.) Dr. Van Scott disagreed with Dr. Foster's description of the changes reflected on CX 736-2. Dr. Van Scott further observed that what is shown on CX 736-2 "might simply be an emerging new hair or ... a smaller hair in another part of the skin in which one can see the external root sheath, the internal root sheath and the hair and the medulla is smaller," (Van Scott, Tr. 1037) and that even if the vesicles shown were changes due to radio frequency energy, they were "minimal." (Tr. 1037.) Alternatively, what appear to be changes may simply be artifacts created by either untimely fixation of the specimen or its overdehydration if the specimen passed through alcohol during the preparation for the review **[32]** process. (Van Scott, Tr. 1037, 1038.) In any event, Dr. Van Scott would wish to view and compare a larger number of histologic specimens of hair follicles in order to determine whether the changes observed in CX 736-2 reflected any degenerative change. (Van Scott, Tr. 1039-41.)

117. Finally, Dr. Van Scott observed that whatever these changes represent, it is in an area of the hair root that is inconsequential to the area where the damage is important, namely down at the hair bulb

and in the *papilla* (Tr. 1046, 1047) and that the hair will regrow unless *papilla* has been destroyed. (Van Scott, Tr. 1049.)

118. In contrast, in a slide showing a complete destruction of the *papilla*, as occurs with electrolysis, and stained in the same manner as was CX 736-4, one would observe homogeneous and diffuse blue color and there would be no recognition of form and no trace of former cells. (Van Scott, Tr. 1055.)

119. CX 736-3 shows untreated specimens. Turning to CX 736-4, Dr. Foster's slide 4 showing a Removatron treated mouse hair, Dr. Van Scott agreed with Dr. Foster that the section appeared to have been cut through the hair root showing a dermal hair papilla and in direct continuity with the connective tissue below, which is surrounded by a hair bulb consisting of the matrix. (Van Scott, Tr. 1053.)

120. Although Dr. Van Scott agreed with Dr. Foster that CX 736-4 slide showed distinct changes in the matrix that indicate loss of nuclear detail in the columnar cells next to the dermal papilla as well as balloon degeneration, Dr. Van Scott insisted that the papilla was not obliterated. He stressed that damages short of complete obliteration of the papilla could be transient and that, although it may change the hair that emerges later from the damaged root, the hair will grow back. (Van Scott, Tr. 1054.) Dr. Van Scott pointed out that one sees similar changes occurring in other hair roots from damage caused by drugs and radiation but hair regrowing from the damaged hair roots.

121. An examination of CX 157(a) (RX 71) itself demonstrates that the December 12, 1983 letter to Mr. Goodman is not adequate substantiation for Removatron's permanency claims. First, the evidence of damage to the hair follicle referred to in the second paragraph is not evidence of obliteration of the papilla or substantial damage to the papilla, or any other damage approaching the location and extent needed to prevent regrowth of hair. The only conclusion to be fairly drawn from this paragraph is that 67% of the Removatron-treated mouse hairs showed no damage and no pathological changes. If we add in the four specimens discussed in the preceding Findings, this study shows that in 70% of the cases, 69 seconds of Removatron treatments had no effect on the treated mouse hair. **[33]**

122. Dr. Foster's interval harvesting procedure indicates that at 24 hours 2 of 8, or 25%, of the harvested specimens "exhibit[ed]" pathologic changes, while 5 of 12, or 42%, did so in the specimens harvested 48 hours after treatment, 2 of 8 or 25% did so in those specimens harvested 72 hours after treatment and 3 of 8 or 37.5% did

so in those specimens harvested 96 hours after treatment. Recognizing that the numbers are, as a whole and as subsets, statistically insignificant, the time line of 25%, 42%, 25% and 37.5% does not indicate a clear trend in support of the proposition that the effects of Removatron treatment takes some time to become evident as suggested by respondents.

123. Furthermore, the Foster Study is an animal study. The use of mice, as subjects, whose papillae were significantly closer to the Removatron tweezer tip during the study than are human papillae during treatments, given the different depths of papillae in mice and men, was clearly inappropriate where human subjects were readily available. Moreover, Dr. Van Scott testified that the medulla running through rodent hair is more common and more pronounced than that in human hair.

124. Equally important, Dr. Foster did not employ a positive treatment control, *e.g.*, electrolysis, which would have allowed him and others to compare whatever damage caused by the Removatron device with permanent damage which prevents regrowth of hair.

125. Prior to submitting his December 12, 1983 letter to Mr. Frederick Goodman, Dr. Foster had submitted an October 18, 1983 letter to Mr. Goodman. (CX 728.) The October 18 letter, according to its first sentence, was Dr. Foster's "final report" to Mr. Goodman "on the results of our research ... ." The December 12 letter contained a number of changes requested by respondents or their counsel. Dr. Foster insisted that these changes were mere clarifications made to render technical language more understandable to laymen. (Foster, Tr. 1553-1554.)

126. One important change Dr. Foster made involved the second sentence on page 2 of the October 18 letter which read: *"The papilla itself never appeared damaged,* though the cells within the papilla region appeared more 'lacey' in the normal specimens and more condensed in the treated specimens, with less distinct nucleoli." (Emphasis added.) That sentence became two sentences in the December 12 letter. They read, beginning six lines from the bottom of page 1: "Some changes in the cells within the papilla region were observed. Some of the cells appeared more condensed than in normal specimens with less distinct nucleoli." **[34]**

127. Another important change related to Dr. Foster's October 18 conclusion which says: "Removatron therapy produced histopathologic evidence of hair follicle epithelial damage in 33% of treated

specimens." His December 12 corresponding conclusion became: "Removatron therapy produced changes in 33% of the treated specimens." Thus in both cases, the language indicating that the study did not uncover any damage to the papilla was deleted and more generalized and diffuse language substituted, which had the effect of masking the original meaning of the October 18 report.

128. Dr. Foster testified to his "clinical impression" that "a significant number of treated hairs did not regrow" (Tr. 1542) and that some of the treated lashes were "permanently destroyed." (Tr. 1544.) But, he also said that he would retreat the ones that regrew "again and again and again, but there was always a certain regrowth rate, and that plus the time required to treat was what made me give it up" (Tr. 1544), that, although he could not give a proportion of those that grew back and those that did not, he could comfortably say that more came back than did not (Tr. 1544-1545), and further that "many," perhaps all but 15 to 20 of upward to 60 patients who received Removatron treatments ultimately received cryotherapy in order to cure their lash problem. (Tr. 1548.)

129. Dr. Foster suggested to Mr. Goodman a "randomized controlled clinical trial [involving humans]" (Tr. 1552) with sequence photography but not involving biopsy, including placebo controls and "analysis of the photographs by masked observer." (Tr. 1551.) The photos "were to be the tool for analysis" of efficacy. (Tr. 1552.) However, Mr. Goodman chose not to do such a clinical study, according to Dr. Foster, but rather to do the more limited mouse study. (Tr. 1552.) After his mouse study, Dr. Foster offered to design a protocol for a clinical study on humans, but such a study was not done. (Tr. 1552, 1553.)

130. After submitting his report to Removatron International, Dr. Foster recommended to Frederick Goodman that Mr. Goodman consult with a pathologist to obtain a qualified opinion concerning what the Foster slides showed. (Tr. 1556.) Mr. Goodman never obtained such an opinion. (CX 721-314 to 721-317.)

(2) The Egg White Experiment and Other Tests

131. RX 81, the so-called Removatron Egg White Experiment, contains electromicrographs of an experiment conducted with Removatron in order to demonstrate that sufficient radio frequency energy is transmitted over a hair shaft held by Removatron tweezers to coagulate egg white. Respondents rely on RX 81 as a visual

demonstration of Removatron's ability to **[35]** transmit radio frequency energy to the hair root. However, RX 81 does not constitute a competent and scientific evidence to show that Removatron removes hair permanently.

132. Gale Watriss, who obtained these electromicrographs for respondents, is a technical writer who was requested sometime around 1979 or 1980 to find some technical information which Removatron International could use to show that "something was happening" when the Removatron tweezers were being used that heat was actually traveling down the shaft of the hair and had the "potential for doing something." (Watriss, Tr. 1790-1795, 1801-1805.) Ms. Watriss testified that she made necessary arrangements for the egg white experiment, but could not recall where she obtained the idea about the egg white experiment or where the experiments were conducted. No record of the experiments were maintained, except a few slides of electromicrographs. (Watriss, Tr. 1805.)

133. CX 180 is an undated Removatron International "Newsletter" and shows prints of the photographs contained in RX 81. CX 180 describes three experiments. According to CX 180, in the first experiment, egg white was "cooked" by radio frequency energy traveling down a hair, which is attached to a Removatron device, dipped into egg white and energized by Removatron for 22 seconds. In the second, a hair was plucked, photographed with a high power microscope, then held with the Removatron tweezers, energized for 22 seconds and photographed again. The experiment is said to illustrate "that radio frequency energy is transmitted by the tweezer and travels through and around the hair, right down to the papilla. When the [RFE] comes into contact with the moisture of the papilla it is converted to heat energy .... Heat cooks. That is why we hold the hair for 22 to 25 seconds. You don't take a 3-minute egg out of the pot in 2 [and one-half] minutes, and expect the same results." In the third experiment, Removatron International "hoped to demonstrate one other suspected result: that the distribution of important substances inside the hair shaft would be different after that hair had been treated with [RFE]." The results, according to CX 180-2,3, of an examination of one plucked eyebrow and one eyebrow Removatroned for 22 seconds, were that "the distribution of potassium in the untreated hair is very distinct," in "peaks" on the graph whereas, "in the treated hair, the potassium is evenly distributed, so the graph shows no unusually high points. The [RFE] clearly scrambled the interior of the hair shaft. Further indication of tissue destruction."

134. Dr. Van Scott, complaint counsel's expert witness, however, testified that none of these experiments show that Removatron treatment will remove hair permanently or will destroy papilla completely or do any material damage to the hair or hair root. **[36]**

135. As to the first study, it tells nothing about the ability of Removatron to remove hair permanently. For one thing, egg white is different from both a hair root and a papilla. For another, coagulation of egg white can be detected at a relatively low temperature, *e.g.*, around 108 to 110 degrees Fahrenheit, a temperature to which the skin is frequently exposed and at which the skin begins to feel uncomfortable. "So it depends on the resistance of the protoplasm that one is dealing with. An egg white may coagulate and be denatured by that but other proteins will not be." (Van Scott, Tr. 1031-1032.) As to the second and third experiments, they have nothing to do with removal of hair, either temporarily or permanently. It is to be expected that when one applies electric current to hair or any structure containing chemical elements, those elements in the structure will line up on the line of current. However, such a change in the distribution of potassium or sulfur in the energized hair does not mean that any damage was inflicted on the *papilla.* (Van Scott, Tr. 1030-1031.)

136. CX 158(a) is a safety test of Removatron in which Dr. Appleton measured the amount of radiation present at various places on or near the device and is not a study of Removatron's efficacy in removing hair.

137. Finally, Robert Bielawa, an engineer of the firm which manufactures Removatron for Removatron International, testified for respondents. Mr. Bielawa generally explained medical and other applications of microwave energy. He also testified as to the power output of Removatron. (Bielawa, Tr. 1916-18.)

138. William Huggins, who designed Depilatron, another RFE type epilator, testified for respondents that Removatron and Depilatron were both RFE type epilators and that his inspection of a Removatron device showed both to be essentially the same, except that Removatron appeared capable of delivering somewhat higher power output than Depilatron. (Huggins, Tr. 1959.)

139. However, the evidence shows that there are a number of differences between Depilatron and Removatron both in design, operation and treatment. The record does not establish that Depilatron and Removatron are essentially the same devices in all material respects. *See* Tr. 1914, 1927, 1941, 1966-1968, 1973; CX 179.

b. *Depilatron Studies*

140. The general rule regarding the use, for substantiation purposes, of scientific tests conducted with other products was set forth in *Pfizer*, 81 FTC at 68, as follows:

> The fact that apparently there did exist a valid efficacy test for a competing product **[37]** of similar composition which was known to and verified by respondents, however, might have provided a reasonable basis for similar efficacy claims.

Thus, respondents must demonstrate that (1) the two products are sufficiently similar, and (2) they verified a valid efficacy test for the other product. In this proceeding, the evidence shows that both Removatron and Depilatron are RFE tweezer-type epilation devices. Beyond that the evidence of similarity is inconclusive at best. And there is nothing in this record to indicate that respondents *verified* any of the Depilatron tests. On the contrary, the evidence supports the conclusion that respondents came into possession of the bulk of the Depilatron documents they proffered as substantiation after the challenged permanent hair removal claims were made and, for that reason as well, cannot be used by respondents to substantiate their claim.

141. More importantly, however, none of the Depilatron documents respondents proffered as substantiation constitutes a well-controlled test which establishes that Depilatron achieves permanent hair removal. Therefore the Depilatron documents reviewed hereinbelow do not constitute adequate substantiation for respondents' permanent hair removal claims. However, for the sake of completeness, the Depilatron-related documents are reviewed hereinbelow.

142. Some ten years ago, Dr. Van Scott, complaint counsel's expert witness, conducted two hair removal tests with Depilatron at the request of Dr. Harvey Glass of Depilatron Co. (RX 10.) The first, conducted in 1975, consisted of the administration of the Depilatron treatment and a form of traditional electrolysis treatment to symmetrical portions of the scalps of one male and female volunteer produced for Dr. Van Scott by Depilatron Company. (RX 10.) Dr. Van Scott provided Dr. Glass with a basic study protocol that outlined not only what procedures he proposed to employ in his study but also the study's two goals: "determine (a) the permanency of hair removal expected from the Depilatron procedure and (b) whether the procedure causes coarse hair to be restored to finer calibre." (RX 10-2.) The

second study, (RX 10-4 through 7), transmitted to Depilatron on July 8, 1976, compared the effects on regrowth of manually plucked hairs with regrowth of Depilatron-epilated hairs. In this study, performed according to specifications arrived at by discussion with Dr. Harvey Glass (RX 10-5), five females with moderate degrees of hirsutism (excessive hair growth) were tested. Three had symmetrical areas on their upper lips selected as test sites; one had symmetrical areas on her chin selected; and one had symmetrical areas on her chest selected. All manually plucked hairs were extracted on each of three occasions at two-week intervals. All Depilatron-epilated hairs were treated and removed during each of the same occasions. Regrowth was then **[38]** assessed at 3 weeks, 7 weeks and 11 weeks after the final epilations. Dr. Van Scott recorded at each examination the number of hairs and their morphologic characteristics. Close-up photographs were made at the beginning of the study and at each assessment examination. Examination of hairs occurred at each assessment after carefully clipping the largest of the hairs from each site and measuring microscopically their lengths and diameters.

143. After comparison of results at the 3 weeks after last treatment assessment with those at the 10-11 weeks after last treatment assessment, Dr. Van Scott summarized the results (RX 10-7):

(a) the total number of plucked hairs examined at the 3 week assessment was 28; they averaged roughly 5.24 millimeters in length and 95 microns in diameter;

(b) the total number of Depilatron-epilated hairs examined at the 3 week assessment was 26; they averaged roughly 3.9 millimeters in length and 80.6 microns in diameter;

(c) the total number of plucked hairs examined at the 11 week (10 in one case) assessment was 68; they averaged roughly 6.24 millimeters in length and 79.6 microns in diameter; and

(d) the total number of Depilatron-epilated hairs examined at the 11 week (10 in one case) assessment was 72; they averaged roughly 6.72 millimeters in length and 75.2 microns in diameter.

Dr. Van Scott transmitted his study and results to Dr. Glass on July 8, 1976. (RX 10-4.) By way of a summary comment, Dr. Van Scott stated: "In some ways the data suggest Depilatron epilation is effective but analyzed in other ways the argument can be made that no difference exists between the results of manual epilation and Depilatron epilation."

144. According to Dr. Van Scott's August 9, 1976 letter to Dr. Glass, RX 10-8, Dr. Glass requested a summary of the conclusions Dr.

Van Scott drew from his studies. Dr. Van Scott responded that clinical inspection as well as test areas failed to show any major difference in pattern of regrowth or in numbers of hair regrowing. He also explained that the data seemed to suggest that both the length of the hairs and the diameter were **[39]** less on the Depilatron side. However, at seven and at ten and eleven weeks after treatment their difference did not prevail and evaluation of the data reveals no statistical difference between the treatment sites both in regard to the length of hairs and diameter. Dr. Van Scott therefore concluded that Depilatron removal of hairs as performed in this study does not cause permanent removal of hair any better than does simple manual epilation.

145. It is noted that respondents rely "first and foremost" on certain "studies" performed by Drs. Harvey Glass, Melvin Shiffman and Walter Lever with Depilatron. Respondents assert that "each of those studies concluded, based upon histopathological examination of treated hair follicles," that Depilatron "was capable of permanently removing hair." (RPF 14 and 15.) However, for the same reasons set forth in F. 140, 141, *supra,* none of these "studies" constitute competent and reliable scientific evidence to establish that Removatron removes hair permanently in humans as claimed by respondents. A brief review of these Depilatron "studies" follows.

The Glass Documents

146. Dr. Harvey Glass was a Medical Director of Depilatron, Inc. RX 31 is an undated and unsigned "To Whom It May Concern" letter, typed on the letterhead of Harvey Glass, M.D. Addressing the question of the scientific validity of conduction in a swine hair epilation study conducted with a Depilatron device to show its "efficacy" and "permanency," the writer in effect states that a swine hair study is inappropriate because human and swine hair have "a marked anatomical difference" and therefore there is "little validity in correlation of data from one to the other."

147. RX 32 is a one-page letter by Dr. Glass to Depilatron, Inc., dated December 29, 1975, in which Dr. Glass expressed his opinion "as a practicing Board Certified dermatologist that the DEPILATRON technique is a permanent, safe and painless method of removing unwanted hair." Dr. Glass states that his conclusion is based on his study of the Depilatron epilation method "from both a theoretical and practical point of view" and that his research studies comprised review of tissue biopsies of Depilatron treated areas done

by other pathologists showing "definite proof" of thermal damage to the "growing portion of the follicle." However, the evidence is clear that "the growing portion of the follicle" does not include the papilla. In any event, RX 32 does not refer to any specific studies or investigations which another investigator can evaluate independently. Thus, RX 32 is a mere opinion letter of a dermatologist and does not rise to the level of competent and reliable scientific evidence.

148. RX 64 is a signed but unsworn affidavit of Dr. Glass prepared on or before December 17, 1975. RX 8 is duplicate of RX **[40]** 64 and was reviewed by Dr. Van Scott. In RX 64, Dr. Glass states his opinion, based on (1) a personal examination of a single slide, out of several slides, of biopsy of the scalp performed two hours after Depilatron treatment of unspecified duration, and (2) a review of four biopsy reports of Dr. Kurt Stenn of forearm and calf performed at different times following Depilatron treatments, that the particular Depilatron machines used in these biopsy studies permanently removed hair from human body. Dr. Glass states that he observed hair bulb necrosis and degenerative changes of follicular sheath cells in the slide he examined and noted reports of various degrees of cellular damage of the hair follicle, basophilic alternations of the dermal papilla, acute cytolytic and coagulative necrotic changes in the deep portions of the hair follicle bulb, and in one case acute degenerative changes of the epidermis with acute inflammatory perifollicular cellular reaction as well as intact hair follicles.

149. However, Dr. Kurt Stenn, the author of the four biopsy reports reviewed by Dr. Glass in RX 64, told the FDA General and Plastic Surgery Device Classification Panel that histological analysis was not an appropriate method to determine the permanency of hair removal and also that the question of permanency could be determined only through clinical trials. (RX 4(a)-41.) Furthermore, Dr. Glass's observations from the Stenn biopsy reports cast some doubt about his view regarding what is required to effect permanent hair removal. While Dr. Van Scott insisted on a showing of complete obliteration of papilla to show permanent hair removal, Dr. Glass appears to infer permanent hair removal from such things as cellular and other damages of hair follicle and from what he calls "basophilic alterations of dermal papilla," all falling short of a complete obliteration of the papilla.

150. RX 13 is a sworn affidavit of Dr. Glass, executed on November 26, 1976, wherein he concludes that the Depilation DP 206 machine

will permanently remove hair from the human body if properly applied by a competent operator. His opinion was based on the four biopsies discussed in RX 64 above, plus three biopsies of Depilatron-treated hair follicles. It suffices to say that the damage observed in the biopsies discussed in RX 13 fell far short of what is required for a permanent hair removal, namely, a complete obliteration of the papilla.

151. Dr. Van Scott, complaint counsel's expert witness, identified Dr. Glass as a practicing dermatologist and medical director of Depilatron, Inc., who came to him in 1975 and asked to become "involved in studies with the Depilatron instrument compared to electrolysis for the removal of hair." (Tr. 987.) Dr. Van Scott, commenting on RXs 8, 9, 13, 31, 32, and 64, testified in effect that these biopsy reports describe various degrees of change or damage to the hair root portions of the hair **[41]** follicle and some to the papilla area but that, in his judgement, these damages or changes "are not absolute and complete eradication of those structures" and that in fact they do not indicate anything approaching complete destruction, as does occur with electrolysis. (Van Scott, Tr. 989-992.)

152. Dr. Van Scott also recalled that Dr. Kurt Stenn, one of the pathologists relied on by Dr. Glass, expressed "grave misgivings" about assuming that damage observed histologically represents complete destruction, in a hearing before FDA's General and Plastic Device Classification Panel. Citing RX 4, a transcript of that Panel's March 24, 1978 meeting, Dr. Stenn, Dr. Van Scott recollected, "repeatedly states that the morphologic damage do not necessarily predict what happens to the follicle." (Van Scott, Tr. 993.) *Also see* RX 4(a)-41, 50, 51.

153. Dr. Van Scott explained that the changes described in the Glass documents are the same changes that can be observed during catagen state when hair root destroys itself in the normal course of the hair cycle, and that they can be completely discounted because hair can still regenerate after such changes. In sum "the most important morphologic change is the eradication, complete destruction of the dermal hair papilla" and there is "no evidence that that has occurred" here. (Van Scott, Tr. 994-995.)

The Lever Documents

154. RXs 7, 11, 23, 52, 53 and 54 are Dr. Lever's reports of his observations of certain slides received from Dr. Glass, Medical

Director of Depilatron. Dr. Lever is known to Dr. Van Scott as an astute pathologist and retired chairman of the Department of Dermatology at Tufts University. (Van Scott, Tr. 999.)

155. In RX 7, an affidavit executed November 22, 1976, Dr. Lever states, based on his December 15, 1975 examination of seven slides of biopsies and May 6, 1976 examination of three scalp biopsy specimens, all received from Dr. Glass, that he observed various degrees of damage to the hair papilla and hair matrix cells and the damage seemed either so severe that "it can be assumed" that the damage was permanent or, though less severe but nevertheless severe enough "to be most likely permanent."

156. RX 11 appears to be another slightly longer version of RX 7, both executed on the same day. Suffice it to say that none of the damage referred to by Dr. Lever in RX 11 shows an absolute, complete eradication or destruction of the papilla and that partial damage of papilla or any damage observed in hair follicles does not show that the hair will not grow back. **[42]**

157. RX 23 is a one-page affidavit of Dr. Lever wherein he states that his examination of the seven slides (evidently the same S-1038-75 A to F and 19529-75 discussed in RX 11) showed damage to the hair papilla and the hair matrix cells in four slides, and that this damage is "similar to" the damage reported by a Dr. Kigman as the result of electrolysis. Dr. Lever also states in RX 23 that "in order to establish permanency of the damage, clinical observation is necessary," meaning that the hairs may grow back. This is consistent with Dr. Van Scott's testimony that he observed hair growing back after damage to the papilla unless the papilla has been completely obliterated.

158. RX 52 is a one-page letter of Dr. Lever to an attorney dated June 22, 1976, discussing the same biopsy slides he discussed in RXs 7 and 11 and generally restating his opinions regarding likelihood of permanent damage to the treated hairs. RX 52 does not add anything to RXs 7 or 11.

159. Dr. Van Scott agreed that other physicians could express views different from his regarding any histopathological specimens, but he insisted that nothing less than "total wipe-out" of the papilla constitutes evidence of the inability of the damaged follicles to produce hair and that anything less was insufficient evidence of permanent hair removal (Van Scott, Tr. 1167), and finally that to predict from sub-threshold degree of damage short of destruction that

the hair will not grow back, as Dr. Lever did, would take divinely-endowed clairvoyance. (Tr. 1169-70.)

The Shiffman Documents

160. RXs 21, 40 and 62 are a series of documents prepared by Dr. Melvin Shiffman, or documents appended thereto, and contain reports of biopsies of Depilatron-treated hair prepared by Dr. Shiffman and examined by a laboratory pathologist, who is not known to Dr. Van Scott to be a dermatologist. Dr. Van Scott reviewed RXs 21, 40 and 62 and testified that none of them shows evidence of a complete destruction of the papilla of the treated hair.

161. RX 40 comprises three separate documents which were received as RX 6, RX 62 and RX 63 and are discussed individually hereinbelow. RX 6 is a two-paragraph letter from Dr. Shiffman to D. Deichmiller, President of Depilatron, dated December 4, 1975, in which he states that he studied the Depilatron method both clinically and with biopsies and that biopsy specimens he studied show "incontrovertible proof of thermal damage to the hair follicle" contrary to previous claims that Depilatron is no more than simple plucking of hair. Obviously this testimonial attesting to proof of some thermal damage to the hair follicle is not competent and reliable scientific evidence. **[43]**

162. CX 62 is a two-page affidavit of Dr. Shiffman executed December 11, 1975, in which he states that reports of a qualified pathologist, Eugene S. Strout, M.D., established incontrovertible proof of thermal damage to the hair follicle, including the papillary elements, internal and external root sheath. Dr. Shiffman further states that the damage was "similar to that caused by electrolysis" and opines that these studies conclusively show permanent hair loss in the follicles treated by Depilatron. Thus, CX 62 is similar to RX 6 and failed to answer the key question of whether the damage was sufficient enough to prevent regrowth of hair. (Van Scott, Tr. 1005.)

163. RX 63 is a short Shiffman letter to D. Deichmiller of Depilatron forwarding certain slides and pathology reports on biopsies of Depilatron treated hair in which Dr. Shiffman states his opinion that the enclosed material showed "permanent loss of hair in the follicles so treated." The attachments to the letter, however, raises several serious questions regarding Dr. Shiffman's stated opinion. *See* F. 166, *infra.*

164. RX 21 is an undated two-page report entitled "Depilatron

Epilation: Preliminary Report" listing "Melvin A. Shiffman, M.D." as the author, and reports the preliminary results of a comparative study of simple tweezer plucking and Depilatron epilation on human subjects using both "clinical observation" and selective biopsies. The preliminary report concludes that Depilatron is a "safe and effective method for permanent hair removal" based on observations of regrowth after four months and of thermal damage to the hair follicle and papilla. Thus, RX 21 adds nothing of significance to the material reviewed hereinabove, which purported to show varying degrees of tissue damage to hair follicle. The key question which remains unanswered in all of these materials is the depth and the adequacy of that damage to prevent regrowth of hair. (Van Scott, Tr. 1004-1005.)

165. All through the Shiffman documents reviewed hereinabove, Dr. Shiffman repeats the statement that the slides show "thermal damage to the hair follicle and papilla *consistent with* permanent hair loss (emphasis added)." However, nowhere does Dr. Shiffman describe the extent of the damage he observed in detail. Nor does he discuss the extent of damage that is *necessary to cause* permanent hair loss. In this context, it is difficult, if not impossible, to determine whether Dr. Shiffman's "damage consistent with" permanent hair loss necessarily means the same thing as "damage sufficient, or necessary, to achieve permanent hair loss."

166. Similar difficulty also permeates RX 63, which is accompanied by reports and comments of Dr. E. Strout, the pathologist, who prepared the slides and examined them. A careful reading of RX 63-1 through 3 shows, for example, that **[44]** Dr. Strout's "IMPRESSION" of slides A, B and D that "HAIR SHAFTS SHOWING HISTOPATHOLOGIC CHANGES CONSISTENT WITH ELECTROLYSIS" (RX 63-3) is not based on any observations or comments appearing on RX 63-1 and 2. Clearly his description of specimens 1, 2, and 4 does not approach the "wipe-out" of cells that Dr. Van Scott testified occurs with electolysis. The only mention of the *papilla* of the eleven specimens Dr. Strout examined states "there is early cytolysis and nuclear degeneration of ... papillary elements." (RX 63-3, #1.) This observation does not indicate that the papilla or any of its elements has been obliterated or destroyed.

167. From the foregoing, it is found that none of the Glass, Lever or Shiffman documents reviewed hereinabove, either singly or collectively, measure up to competent and reliable scientific evidence which will substantiate respondents' permanency claim and that respondents'

168. Respondents did not refer to, cite or specifically rely on a number of other Depilatron-related scientific documents in the record. For the purposes of this case, it sufficies to say that none of them shows an absolute, complete destruction of the papilla as the result of Depilatron treatment. And, in any event, the evidence does not establish that Depilatron is the same or essentially the same as Removatron, except that both are RFE tweezer-type epilators. However, for the sake of completeness, a brief discussion of these Depilatron materials follows.

169. Dr. Van Scott reviewed RXs 25 and 28. They are reports by Dr. Ken Hashimoto on Depilatron. Neither of these reports constitutes adequate substantiation of respondents' permanency claims. RX 25, titled, "Depilatron Study," and dated February 2, 1976, is a comparative study of Depilatron epilation and electrolysis. (RX 25-2.) In the study, vellus, not terminal, leg hairs of a male were removed by various means (Depilatron, electrolysis, and plucking) and examined under a microscope. Dr. Hashimoto observed that one Depilatron-treated hair bulb showed vacuolization, particularly in the nucleus, and commented in substance that vacuolization of a large number of cortical cells indicates that the matrix cells of the cortex are severly damaged and that the vacuolization of matrix cells of the cortex seems to be severe enough that there is a reasonable probability that a regrowth of the damaged hair will be prevented. However, he also observed that recovery of the damaged matrix cells may occur in spite of the severe vacuolization, or damaged cells may be replaced by healthy cells and regrowth of the hair may be retarded but not totally interrupted.

170. Regarding RX 25, Dr. Van Scott testified that Dr. Hashimoto has a good reputation as a dermatologist and that **[45]** RX 25 is a piece of evidence in support of the proposition that radio frequency energy epilators effect permanent hair removal, but that it is insufficient to conclude that the damage results in permanent loss of the ability of the follicle to produce a new hair. Dr. Van Scott concluded that RX 25 would not allow him to accept the effectiveness proposition as scientifically established. (Tr. 1014, 1015.)

171. RX 28 is a February 2, 1976 "To Whom It May Concern" letter of Dr. Ken Hashimoto. In this one-paragraph statement, Dr. Hashimoto states, on the basis of an examination of thirteen unidentified affidavits and one statement by a Dr. Wohl (possibly RX 18 or RX 26) that, although these observations were not made by

specialists, in view of his own studies attached it is his opinion that the length of time wherein no regrowth of hairs was observed seems to be long enough (six months to one year) to believe that those hairs, removed by a Depilatron device, were permanently removed. However, no studies are attached to RX 28. If he were referring to RX 25 discussed in the preceding Findings, that study contains no information regarding the length of time during which no regrowth of the hairs was observed. Neither does the December 15, 1975, statement by Dr. Richard H. Wohl (RX 18 and RX 26) contain any information concerning length of treatments or length of time since last treatment. Since Dr. Wohl's statement is dated December 15, 1975, the thirteen affidavits referred to by Dr. Hashimoto in RX 28 could be the thirteen affidavits dated between December 12, 1975 and December 16, 1975 found in RXs 38, 65 and 68. These affidavits referred to by Dr. Hashimoto and the information contained in each relating to "length of time wherein no regrowth was observed" and summarized in CPF 208. Judging from the evidence regarding hair growth cycles and the need to observe the patient for a significant length of time after treatment has ceased, RX 28's conclusion about permanence is not justified. Without the affidavits, RX 28 does not contain sufficient information to judge its adequacy or credibility. With them it is clearly inconsistent and confusing. In any event, RX 28, together with the thirteen affidavits (summarized in CPF 208) and the Wohl statements or separately, does not constitute competent and reliable scientific evidence to substantiate respondents' permanency claim.

172. RX 37 is a letter of Dr. K. Stenn to Francis X. McDonough of the Federal Trade Commission staff, dated January 11, 1977, in which Dr. Stenn summarizes his review of slides of tissue specimens, which is set forth in RX 12. In RX 37, Dr. Stenn states: "I concluded that slides 8 and 11 [discussed in RX 12], contained follicles which showed sufficient damage to consider regrowth unlikely." RX 12 is a "To Whom It May Concern" letter by Dr. Kurt Stenn, dated December 14, 1975, in which he refers to his examination of twelve histological slides by light microscopy. The first six listed slides appear **[46]** to be the same as those which were presented by Dr. Strout to Dr. Shiffman and were the subject of Dr. Lever's comments. None of the first six slides examined by Dr. Stenn is found among the group of two which in RX 37 he said he thought indicated sufficient damage "to consider regrowth unlikely." Yet Dr. Stenn's descriptions of his observations of the specimen on slides one through six inexplicably contain medical

language similar to those contained in others' descriptions of biopsy specimens. RX 37 is generally in accord with what Dr. Stenn stated to the FDA General and Plastic Surgery Device Classification Panel on March 24, 1978. Dr. Stenn stated then: "there really isn't that good correlation between [a] given amount of damage and the recurrence of hair growing. We just don't know that ..." (RX 4(a)-50.)

173. RXs 17, 20 and 39 comprise three documents authored by Dr. Harold Pierce and related to Depilatron. They were reviewed by Dr. Van Scott. (Van Scott, Tr. 1017-1019.) RX 17 is an affidavit with attached "Depilatron Study" dated January 28, 1976. RX 17 reports the results of a series of experiments to simulate the magnitude of temperature rise caused by Depilatron treatments. Three of the experiments involved measuring temperature changes in a solution into which a Depilatron-treated boar bristle was placed. The conclusion in all three wâs "NO definitive findings." The fourth part measured temperature changes under the skin surface near a Depilatron-treated hair. Temperature rises were recorded. Whether the effect has any consequence for hair growth is not stated. There is no evidence to suggest that this thermal effect would completely destroy, or even damage, the papilla.

174. RX 39, titled "Depilatron Study," and dated December 1975 through April 1976, is a report by Dr. Pierce on his observations of regrowth after Depilatron treatments of varying durations and at varying intervals over a five month period. RX 39 concludes, "it would seem that Depilatron ... is an effective way to remove hair. However, a study over a longer period would seem to be indicated in order to ascertain permanence."

175. RX 20 is a March 29, 1978 letter to the Federal Trade Commission from Dr. Harold Pierce. The letter is captioned, "re: Depilatron Study - January 28, 1976." After acknowledging that he was not a dermatopathologist, Dr. Pierce wrote that he reviewed "a number of slides that had previously been examined by Doctors Stenn, Shiffman, Snyder, Ackerman and Lever." After characterizing the findings of these physicans as varying "from acute cellular damage of superficial portions of the external hair follicle, to all levels of the hair follicle with basophilic alterations of the dermal papilla, and acute degenerative changes of the epithelial portions of the hair follicles at all levels, perifollicular cellular reaction, necrotic changes of the cells in the inner root sheath, and coagulative necrotic and **[47]** hemorrhagic changes of the follicular dermal papilla," Dr. Pierce concludes that

"these changes would be incompatible with continued viability of individual depilatron treated hairs, and could in fact render that papilla incapable of further hair development."

176. Dr. Van Scott, complaint counsel's expert witness, identified Dr. Pierce as "a dermatologist in Philadelphia" and "not known as a researcher or a clinical investigator." (Van Scott, Tr. 1018.) Summarizing his view regarding all studies and reports he reviewed, that were authored by Drs. Glass, Lever, Shiffman, Pierce and Hashimoto, Dr. Van Scott testified that none of them reported complete obliteration of the dermal papilla (Tr. 1027) and further that none of them demonstrates the efficacy of radio frequency energy epilators in effecting permanent hair removal. (Tr. 1028.) Also, Dr. Harold Morowitz, one of Depilatron's presenters to the FDA Panel, repudiated Dr. Pierce's temperature measurement report. (*See* RX 39.) Thus, based on the opinion of Dr. Van Scott and, with respect to RX 17, the opinion of Dr. Morowitz, the Pierce documents do not constitute adequate substantiation for respondents' permanency claim for Removatron.

177. Respondents also offered eight documents (RXs 1, 15, 16, 19, 30, 41, 42 and 66) written by Dr. Harold Morowitz, a professor of molecular biophysics and biochemistry at Yale University, whose curriculum vitae is appended to RX 15. According to his curriculum vitae, Dr. Morowitz has published some 103 articles, chapters or books. None of them contains the words "hair," "follicles" or "papilla" in its title and none appears to be directly related to the biology of hair growth or prevention of regrowth. Dr. Morowitz appeared on behalf of Depilatron before the FDA Device Classification Panel considering the effectiveness of Depilatron. (RX 3 and 4.) Dr. Morowitz' work includes theoretical discussions and some experiments designed to show that energy flows from the Depilatron device to the papilla of the treated hair. However, none of them is an actual test on human or animal subjects. Dr. Morowitz also reviewed reports of others relating to the Depilatron device and examined treatment cards of Depilatron operators. The Morowitz documents submitted to the FDA Panel were rejected as substantiation for Depilatron's efficacy. (CX 6-9 to 6-10, CX 3-5.) None of them demonstrates that Depilatron removes human hair permanently. A brief review of the Morowitz documents follows.

178. RX 1 is an undated two-page letter of Dr. Morowitz to the FDA and appears to be a covering letter forwarding RX 42. RX 42 is

Dr. Morowitz' undated report titled "Analysis of Field Data on Use of the Depilatron DP-206," and it represents an effort "to evaluate the efficacy of the DP-206 in actual field use" (RX 42-2) using the information contained in thirty client treatment cards. Following a review and analysis of the treatment **[48]** information and Depilatron operator comments contained in these cards, which he treats as a kind of sample survey (RX 42, "Introduction"), Dr. Morowitz concludes that "[i]f the total treatment asymptotically approaches a limit where the treated area is recognized as satisfactory by patron and operator, we may define the effect as permanent" and that "[t]his study then establishes that in ordinary field use the Depilatron DP-206 is an effective device for the permanent removal of hair." (RX 42-6, 7.)

179. However, RX 42 is not a controlled experiment. (RX 42-6.) At best, it is a selective review of assessments of the effects of Depilatron treatment of a small number (30) of patrons by Depilatron user-operators. Moreover, these thirty patrons were still undergoing treatment. (RX 1, RX 41.) RX 42 was summarily rejected by the FDA as not a "double-blind study conducted by competent, independent investigators." (RX 3-5.)

180. RX 15 is a three-page "report" discussing "the problem of the mechanism of thermal inactivation of cells" and "the ability to detect heat damaged hair follicle cells by cytological techniques." RX 15 does not purport to establish permanent hair removal and was considered and rejected by the FDA Panel. (CX 6-9, 6-11, Ref. 160.)

181. RX 16 is a five-page "report" in which Dr. Morowitz purports to analyze the energy from the electrode of Depilatron to the "hair forming tissue in the follicle" and calculates the expected temperature increase at the follicle through the use of a mathematical formula, which is based on a variety of assumptions. Thus, RX 16 does not purport to establish permanent hair removal effectiveness. It was also considered and rejected by the FDA Panel.

182. RX 19 is a three-page report of an experiment Dr. Morowitz conducted to show that a Depilatron-treated hair could heat a saline solution. From the results he hypothesizes on the thermal energy that may reach the papilla of a treated hair and the cell damage that may be caused by that energy. RX 19 does not purport to establish permanent hair removal and it was considered and rejected by the FDA Panel. (CX 6-9, 6-11, Ref. 164.) One of Dr. Morowitz' assumptions in RX 19 that the vitreous membrane is a direct channel to the papilla (RX 19-3) was challenged by Dr. Van Scott. (Van Scott, Tr. 1202.)

183. RX 30 is a December 11, 1975 affidavit of Dr. Morowitz filed in opposition to motion for preliminary injunction by Depilatron, Inc., in a proceeding before U.S. District Court for the Southern District of New York. Based on his review of the material submitted by the petitioners in the case, some "user reaction" documents, histological studies of Depilatron treated hair follicles and "physical theory and measurements on the **[49]** delivery of power to the bulb region of the follicle," Dr. Morowitz concludes that "the evidence used to indicate its [Depilatron] DP-206 is ineffective is without standing and is not based upon recognized or scientific theory." (RX 30-3.) Obviously, RX 30 is not a "substantiation" document for the permanent hair removal claim by anyone. RX 66 is another affidavit of Dr. Morowitz in the same litigation and contains similar information discussed in RX 30.

184. RX 41 is a June 9, 1978 letter of Dr. Morowitz to the Federal Trade Commission, responding to an inquiry from a Federal Trade Commission staff member. it does not purport to substantiate anything.

185. RX 67 is a two-page affidavit of Dr. Ivan S. Cohen, a dermatologist, which was filed on behalf of Depilatron, Inc., in the New York injunction proceeding along with RXs 30 and 66 discussed hereinabove. In RX 67, Dr. Cohen states that the two pathology reports prepared by others he reviewed indicated "permanent loss of the subject hair" and that, if the report that the treated hairs did not grow back "for a period in excess of four to five months" is to be believed, he would conclude that the unwanted hair "has been permanently removed and will not regrow." (RX 67-2.) However, RX 67, like RXs 42 and 66 discussed hereinabove, does not substantiate permanent hair removal claim of respondents.

186. RX 24 is a two-page deposition of Dr. Stuart H. Bender, a dermatologist, dated December 14, 1975. Based on a review of biopsy reports of Dr. Strout, Dr. Stenn and Dr. Ackerman, an affidavit of Dr. Morowitz "which indicate permanent damage to the hair follicles," and affidavits of "numerous" Depilatron operators and their patrons, Dr. Bender stated an opinion "with reasonable medical probability that the Depilatron DP-206 machine permanently removed hair from the human body." RX 24 is not adequate substantiation for respondents' permanent hair removal claim.

187. RX 14 is a "Declaration" of one W. Delmar Hershberger, dated December 6, 1976, apparently prepared for use in a California advertising litigation involving Depilatron. The Hershberger "declara-

tion" has two attachments. The second attachment (Exhibit B) is said to be the declarant's "report." The purpose of the report was "to examine critically the physical basis underlying the Depilatron Model DP 206 Epilator" and is to have been based on a series of experiments he conducted with a Depilatron DP-206 and "written communications" of ten scientists including Drs. Morowitz, Glass, Lever, Hashimoto, Stenn, Cohen and Bender, whose documents relating to Depilatron have been discussed hereinabove. RX 14 is not adequate substantiation for respondents' permanent hair removal claim. **[50]**

188. RX 89 (CX 152(a)) is a "Memorandum of Intended Decision," by Judge Claude Owens, dated September 20, 1978, in the matter of *People of the State of California v. Depilatron, Inc., et al.*, the first page of which is a "Minute" reflecting Judge Owens' order to file his decision. (RX 89-1.) The California enforcement action, instituted on November 5, 1976, charged among other things that defendants violated California law by disseminating misleading advertising for the Depilatron device. (RX 89-2.) In his decision, the judge found that the defendants had violated the law and ordered prospective relief as well as the payment of civil penalties. (RX 89-8.) In essence, the judge ordered that defendants could not represent that Depilatron is "permanent" or "effective" or that it "destroys the papilla" or "gets results," unless such language is accompanied by clear qualifying language stating that these things *may* occur depending on a number of factors. (RX 89-8.) Respondents' suggestion that this opinion substantiates their permanent hair removal claim (RPF 18) is rejected. With all due respect to the California state court, its decision has no precedential value in this Section 5 proceeding where the issue is whether respondents' permanent hair removal claim for Removatron was based on competent and reliable scientific evidence when the claim was made. Furthermore, the FDA Device Classification Panel, after a careful and thorough review of scientific evidence, rejected permanency claims of RFE tweezer-type epilators, including Removatron. Also, the California court appears to have accorded substantial weight to the testimony of consumers and device operators. (RX 89-3 through 89-6.) This is contrary to the well established rule in Section 5 cases of according little weight to users' subjective assessments of efficacy claims for devices.

189. RX 47, a two-page document, purports to be a translation of a passage attributed to the May 1975 issue of a Japanese *Journal of Plastic and Reconstructive Surgery.* Under a numbered subheading

"Depilation Experience by Use of DEPILATRON," one Yasuo Muto of the "Central Plastic and Reconstructive Surgery Department, Sapporo" wrote that his department acquired a Depilatron apparatus in August of 1973 and obtained "excellent clinical results." The writer further states that the "effective rate of removal of hair by one operation reaches 50 to 80%." When asked about the long term results, the writer stated that his department did not have enough experience "after the improvements of the technique" to be able to evaluate the long term results and that he may "assume" that the rate of remaining hair after three treatments "might be about 10%." Given the somewhat confusing translation of a short excerpt and given the lack of any information from which the scientific merit could be evaluated, it is not possible to give RX 47 any weight in this proceeding.

190. RX 48, a three-page document, appears to be a translation of a question and answer exchange involving Yasuo **[51]** Muto, which appears under a heading which reads "Effects of an Electric Depilator by Use of High Frequency Wave" and attributed to a *Japan Medical Journal* of June 5, 1975. Here, Mr. Muto briefly compares the operating procedures for electrolysis and RFE epilator called Depilatron, and states in effect that Depilatron is not superior to other epilation methods but is "clinically convenient." RX 48 contains no information regarding permanent hair removal and is not relevant to any issue in this proceeding.

191. RX 69 (CX 151(a)) is a copy of a four-page article entitled "Study of a New Depilatory Method" by Dr. Ursula Hill, Schwalmstadt, which appeared in *Aesthetics World* (undated), a trade magazine. The article is the report of a questionnaire survey of about forty women with unwanted hair on their upper lips who underwent depilatron treatments for varying periods. Thus, RX 69 is a compilation of subjective assessments of the treatments by participants to the survey. The survey subjects were limited to those with "no further sign of virilization" or "a rapid release in beard growth." (RX 69-1, col. 2.) Dr. Hill states in conclusion that "considered in light of the patients' subjective evaluation the depilatron method provides a good possibility of therapy for the hirsute woman." In any event, this survey report does not measure up to competent and reliable scientific evidence which substantiates respondents' permanent hair removal claim for Removatron.

192. RX 68 is an affidavit by then President of Depilatron, Inc.,

Arthur C. Deichmiller, dated December 16, 1975, and was in opposition to motion for preliminary injunction in the matter of *Depilatron, Inc. v. Kree Institute of Electrolysis, et al.*, 75 Civ 5617 (S.D.N.Y.). Mr. Deichmiller states his belief, based on his own observations, reports of Depilatron operators in this country and abroad and numerous customers, that, when properly used, Depilatron is effective in the "permanent removal of hair from human body." (RX 68-2 and 3.) He further stated that he had been advised by medical experts that biopsies show "thermal damage to the hair follicle, papilla and germinative cells" after Depilatron treatment and that such damage results "in the permanent removal of hair." (RX 68-3.) RX 68 is accompanied by affidavits by Drs. Morowitz, Shiffman and Cohen and Depilatron operators and their patrons. (RX 68-5.) RX 68 does not constitute adequate substantiation for respondents' permanent hair removal claim.

c. *Scientific Literature and Writing Which Discuss Theories or Hypotheses*

193. The law is well settled that in a Section 5 proceeding an advertising claim regarding product performance or efficacy must be substantiated by competent and reliable scientific evidence and that mere theories or hypotheses that remain to be **[52]** tested and verified do not constitute such evidence. During trial Dr. Van Scott, complaint counsel's expert witness, explained the scientific rationale for the rule that the scientific community does not accept as valid a theory or hypothesis, however plausible it may be, until its validity is established by controlled tests or experiments designed and executed by qualified investigators in such a way as to minimize chance and insure objectivity.

194. Regarding scientific writings or reports which espoused physical or medical principles that might make it possible to achieve permanent hair removal by the use of a RFE tweezer-type epilator, such as Removatron, Dr. Van Scott stated that the development of a device usually begins with a hypothesis. Hypotheses have varying degrees of believability or probability, but all have merit in that each sets "the stage to determine whether the end result as proposed in the hypothesis does in fact occur." (Van Scott, Tr. 975.)

195. Dr. Van Scott stressed that the hypothesis "does not establish proof" and that the "proof is the event itself." He stated in effect that while there is a lot of "suggestive" material in this case, there is a

noticeable lack of the required experiment to determine whether the hypothesis is in fact true. (Van Scott, Tr. 975.) The problem in relying on writings which show "how a device could work in theory based on principles" is that one does not know if he will get there "until one really gets there." Dr. Van Scott referred to many of his own "wonderful hypotheses of great cures or great answers to perplexing problems" which often "have not turned out to be valid in truth." (Tr. 976.)

196. Dr. Van Scott explained that a "theory" is generally farther removed from "probability" than a "hypothesis." (Tr. 977.) A hypothesis has "more merit," "some basis in fact, some basis in the minds of the informed examiner" and has a "greater possibility of being the truth." But *all* hypotheses must be tested to determine whether a particular hypothesis is in fact valid or invalid. (Tr. 977-8.)

197. Thus, the documents that discuss theories or hypotheses and do not test the actual effects of Removatron treatment on human tissue or hair growth, do not constitute adequate substantiation for respondents' permanent hair removal claim. Such scientific documents include RXs 15, 16 and 19 written by Dr. Morowitz and RX 70.

198. As discussed hereinabove in F. 180-182, *supra*, the Morowitz documents are primarily theoretical discussions and experiments designed to show energy flow from Depilatron to the papilla. None of them, however, contains any test data on human or animal subjects. RX 15 is a discussion, citing two other **[53]** pieces of literature, of (1) "the problem of the mechanism of thermal inactivation of cells," and (2) "the ability to detect heat damage hair follicle cells by cytological techniques." (RX 15-2.) RX 15 is a discussion of scientific phenomena that are related to possible hair loss but it does not purport to show that permanent hair loss in fact does occur. It was considered and rejected by the FDA. (CX 6-9, 6-11, RE. 160.) RX 16 is also a general scientific discussion, citing other literature (including a report by Dr. Harold Pierce, RX 17, discussed earlier). It calculates the expected temperature increase at the follicle through the use of a mathematical formula which is based on a variety of assumptions. RX 16 is not a test to show that Depilatron removes hair permanently. It was also considered and rejected by the FDA.

199. RX 70 (CX 141) is a 56-page booklet titled "Theory and Practice of Pilethermology" and is published by Removatron International as Removatron School of Pilethermology Training and Teaching Aid # 11. Most of RX 70 is a reproduction of a book titled

"Electrolysis, Thermolysis and Blend," by Arthur Hinkle. (CX 721-128.) RX 70 contains five chapter headings: Causes and Hair Problems; Structure and Dynamics of Hair and Skin; Treatment of Specific Areas; Sample Removatron Consultation; and Developing A Practice. It contains many statements claiming that the piletherm-ological method, such as Removatron, is capable of permanent hair removal, but it does not contain any test data purporting to show that this result in fact does occur. It also acknowledges the proposition that a hair will grow back unless the papilla is completely destroyed. (RX 70, pp. 36-39.)

d. *Other Miscellaneous Documents*

200. In addition, respondents offered a number of other miscellaneous documents as substantiation of their permanent hair removal claim. They comprise excerpts from various beauty aids and skin care books, consumer guides and articles and letters which appeared in trade and popular magazines. These documents, however, do not rise to the level of competent and reliable scientific evidence by any stretch of the imagination and are not accorded any weight as substantiation for respondents' permanent hair removal claim. For the sake of completeness, a brief review of these documents follows.

201. RX 82 (CX 178) is an excerpt from *Dr. Zizmor's Skin Care Book,* by Jonathon Zizmor, M.D., a practicing dermatologist. Styled by its authors as a "do-it-yourself guide" it tells readers that Depilatron is better than conventional electrolysis because it is "safe" and "somewhat more effective." (RX 82, p. 67.) This undated document contains no information from which to assess its adequacy or credibility or Dr. Zizmor's experience with any device. **[54]**

202. RX 86 is a 32-page booklet titled "All About Permanent Hair Removal," by Sophie K. Horchem, published in 1976. Ms. Horchem is an electrologist and purports to present in this booklet "the essential facts about electrolysis - the safe, permanent method of hair removal." (RX 86-1.) In the final chapter, Ms. Horchem discusses Depilatron and states that "it takes multiple treatments to remove all hair permanently." (RX 86-18.) RX 68 contains no information about the author's scientific qualifications or the basis of her opinion regarding Depilatron.

203. CX 291 is an excerpt of a book titled "Adrien Arpel's 3-Week Crash Makeover/Shapeover Beauty Program" (1977) and was written by Adrien Arpel with Ronnie Sue Ebenstein. Ms. Arpel described

herself as the "owner of a multi-million dollar cosmetics company [who] has spent years supervising and doing makeover/shapeover on thousands of women." (CX 291-3.) In Chapter 9, Ms. Arpel discusses the problem of unwanted hair and states that there are "two hair removal techniques considered permanent ... electrolysis and Depilatron." (CX 291-19-20.) However, CX 291 does not disclose the basis for the conclusions.

204. RX 84 (CX 174) is an article titled "Permanent Hair Removal—salon service on the rise" which appeared in *Modern Salon*, a trade magazine, in June 1980. The article is essentially an interview with the owner of an unidentified electronic hair removal device, which appears to be Removatron, who had owned it for a year.

205. RX 85 (CX 167) is an article by Patti Pietschmann titled "The Bare Facts About Hair Removal" which appeared in Playgirl's *Slimmer* magazine in January 1981. Giving an overview of different methods of hair removal, Ms. Pietschmann states that electrolysis and Removatron are considered "permanent procedures." The article also reports that specialists opposed to the process contend that "it isn't permanent."

206. RX 92 (CX 178) is an excerpt from a 1980 book titled "a doctor discusses Skin Care," by Richard G. Mills "in consultation with" John W. Weiss, M.D. Page 59 of this excerpt discusses "Ultrasonic Waves" and states that this process "kills" the hair root with ultrasonic waves and "is claimed to be very safe and even more effective than electrolysis in preventing hair return."

207. RX 93 (CX 173) is an article titled "Mechanical Hair Removal" that appeared in the November 1983 issue of *Modern Salon*, a trade magazine for beauty salon operators. Written jointly by an owner and technician at a salon in Oak Park, Illinois, and appearing under page headlines "NEW PROFIT CENTERS: SKINCARE ... COSMETICS - A PROFITABLE SALON SERVICE," RX 93 is essentially a promotional piece. **[55]**

208. RX 96 is a letter to a syndicated beauty columnist from "F.G., a trained technician, Framingham." The column in which the letter appears, memorialized on Removatron International stationery, apparently appeared in the "Boston Herald American" on October 26, 1981. Taking exception to some statements regarding "electronic tweezers" in an earlier column, "F.G." wrote to "set the record straight." Citing a California court proceeding, "F.G." wrote that, "After a lengthy testing period, the system was found to be effective

under the right conditions. However, the manufacturer was found guilty of misrepresenting the word permanent."

209. RX 98 (CX 175) is an excerpt from "Chapter 11 - Depilatories," of a book titled "Consumer's Guide to Cosmetics" and, following a review of available epilation methods including RFE tweezer-type devices, states that "the FDA has taken manufacturers of the [electrified] tweezer process to court claiming that the tweezer technique is not as effective as the [electrolysis] needle."

e. *User-Consumer Testimony, Testimonial Letters, Hair Removal Surveys and Federal Trade Commission Interview Reports*

210. The parties were allowed to call a limited number of Removatron user-operators and their hair removal patrons. The testimony of those user-patrons is divided and inconclusive. In any event, their testimony related to the subjective observations of individuals regarding Removatron's ability to achieve "permanent" hair removal and does not rise to the level of competent and reliable scientific evidence. Therefore, the user-patron testimony in the record is accorded little weight in evaluating the scientific validity of respondents' permanent hair removal claim.

211. Respondents rely on the trial testimony of a small number of user-consumers they were permitted to call in their defense, all of whom testified generally in support of respondents' claim that Removatron removes hair permanently. Respondents' seven user-operator witnesses upon whose testimony respondents rely include (RPF 31-33): Trenda Bilbrey (Tr. 2296-2332), Patricia Jones (Tr. 2063-91), Kathleen Thomas (Tr. 1979-2015, 2141-67), Karen Newcombe (RX 500), Nora Bunims (Tr. 2515-61), Joyce Pipper (Tr. 2119-40), and Ann Richardson (Tr. 2023-59). They testified in substance that they achieved permanent hair removal in 70 to 100 percentage of their clients who regularly received Removatron hair removal treatments.

212. Three of the user witnesses, namely Kathleen Thomas, Karen Newcombe and Ann Richardson, also testified that they had been treated with the Removatron method and each had achieved the **[56]** permanent removal of unwanted facial hair which each described as extensive.

213. Respondents' Removatron treatment customer witness was Stacy Baughman (Tr. 2093-2115), who testified that as a result of

Removatron treatments she achieved permanent hair removal from her face.

214. Some of respondents' employees also received reports from Removatron operators concerning the results of Removatron treatments on their clients. (Tr. 1638, Tr. 1700.) Respondents' employees testified that most of these reports from Removatron operators were favorable (Tr. 1638), and that many operators reported that they were observing permanent hair removal. (Tr. 1501, Tr. 1626-1627, 1701.) *Also see* F. 61, *supra.*

215. Complaint counsel's user-patron witnesses generally testified that Removatron did not accomplish permanent hair removal based on their personal observations and experiences with Removatron. These witnesses include: Doris Callison (Tr. 452-524); Florence Fuchs (self-treatment only) (Tr. 527-75); Gloria Dyal (Tr. 1239-95).

216. Respondents also rely on a Removatron hair removal survey (RX 73) and a collection of testimonials solicited and/or received from Removatron operators. RX 73 is an October 16, 1985 cover letter to Mr. Fred Goodman from Shari Straatmeyer of Stewart Beauty Schools, Sioux Falls, South Dakota, and thirteen attached anonymous responses to a "Hair Removal Survey." Ms. Straatmeyer wrote that she did a client survey to see how her clients felt about the service they had received, and that she had each hair removal technician in her salons send out approximately twenty survey letters to clients who were either finished or nearly finished with their hair removal treatments. About 200 were sent out and she received "40 plus" responses. (RX 73-1.) After reading these responses, Ms. Straatmeyer concluded that both Removatron and electrolysis are equally effective, but those who received Removatron treatment were "more positive about their experience because it involved no pain." (RX 73-1.) Attached to Ms. Straatmeyer's October 16, 1985 letter is a copy of an envelope and thirteen wholly or partially completed "Hair Removal Survey" questionnaires. None of the responses are signed. In any event, a review of these responses shows that none of the thirteen responses had achieved permanent hair removal.

217. RX 76 is purported to be a collection of eighty-three letters from Removatron operators or patrons stating that Removatron is effective in removing unwanted hair permanently. Several letters appear to have been solicited. *See e.g.,* RX 79-7, 29, 30, 31. Several others were simply interested in locating Removatron salons or getting into the hair removal business. *See* **[57]** *e.g.,* RX 76-109-111,

114, 118. Most of the letters indicated that Removatron treatments were painless but none claimed that treated hairs were removed permanently or did not grow back.

218. RX 88 is a letter, apparently dated June 24, 1982, to Fred Goodman from Judith G. Stephens, MS, RD, Certified Electrologist. Ms. Stephens no longer uses Removatron but wrote she had been using it for more than two years and "feel[s] the Removatron method has proven to be superior and faster method of hair removal."

219. RX 38 appears to be a collection of some twenty-odd Depilatron testimonials from operators and is not adequate substantiation for respondents' permanent hair removal claim.

220. Other Removatron testimonials include CX 288, CX 296 and RX 181. None of the three is adequate substantiation for respondents' permanent hair removal claim.

221. CX 723 comprises a series of letters, Depilatron testimonials and copies of advertisements. It appears to include many letters found in RX 73 and RX 76 referred to hereinabove. In any event, none of the documents in CX 723 is adequate substantiation for respondents' permanent hair removal claim.

222. RX 49 is a Federal Trade Commission Interview Report with James O. Perkins, dated June 16, 1978. It contains an account of the operating experiences of Mr. Perkins and his wife in using two types of "electronic tweezers." Both of them believed the electronic tweezers they have used were effective based on their observations of results on their patrons. Their subjective observations of course do not support the conclusion that permanent hair removal is achieved. A friend of Ms. Perkins reported to her that she had successfully treated more than 300 people with Depilatron and about 60 with Depillex, both electronic tweezers. RX 49 is accorded no weight as substantiation for respondents' permanent hair removal claim.

223. Finally, RX 50 is a Memorandum to the File, dated February 10, 1978 by Francis X. McDonough of the Federal Trade Commission staff. This memorandum memorializes the substance of a meeting between representatives of the Commission and counsel for Depilatron, Dr. Harold J. Morowitz, Dr. Preston Cosgrove, who said he was a physician in Massachusetts, Ms. Sandy Tandy, a Depilatron device owner and operator, and Trudy Cummings, one of Dr. Cosgrove's patrons. The observations contained in RX 50 do not support the conclusion that Depilatron achieves permanent hair removal. On the contrary, some of the observations contained in RX 50 tend to support

the proposition that Depilatron does not achieve permanent hair removal. In any event, RX 50 is accorded no weight as substantiation of respondents' permanent hair removal claim. **[58]**

f. *The FDA Device Classification Panel Has Also Determined that Reasonable Assurance of Efficacy of RFE Tweezer-Type Epilation Devices Has Not Been Demonstrated by Requisite Scientific Evidence*

224. On January 19, 1982, the Food and Drug Administration published in the Federal Register a notice of proposed rulemaking that would require pre-market approval of high-frequency (RFE) tweezer-type epilators. (CX 6-7.) The FDA proposal was based on a recommendation of FDA's General and Plastic Surgery Device Classification Panel, which had determined, after a review of available scientific evidence regarding the safety and efficacy of such epilation devices, that pre-market approval was necessary "to assure that manufacturers demonstrate satisfactory performance of the device and, thus, assure its safety and effectiveness." (RX 6-2, 9.) The FDA Panel concluded:

> No substantial data now exist to provide this assurance.... The Panel based its recommendation on the Panel members' personal knowledge of the device, and on the absence of convincing clinical and scientific data demonstrating a specific action of the device on the process of hair removal.... In the Panel's judgment, the information presented in support of the device has not provided reasonable assurance of its safety and effectiveness.

225. The standard used by the FDA—"reasonable assurance of effectiveness"—requires the same kind of analysis as the Commission's reasonable basis test. FDA regulations require the manufacturer to "substantiate" the product's effectiveness. (21 CFR 860.7(c)(1), CX 816-8.) Also similar to the Federal Trade Commission in cases involving health or safety issues, the FDA relies upon "valid scientific evidence to determine if effectiveness is substantiated." *Id.* Section 860.7 of the FDA's regulations defines "valid scientific evidence" as:

> evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can be fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and **[59]** effectiveness of a device under its conditions of use.

(CX 816-8.)

226. In concluding that the effectiveness of the device was not substantiated, the expert Panel and the FDA considered and rejected as inadequate, documents authored by several of the authors of documents in this proceeding. The FDA record refers to documents by, among others, Drs. Van Scott, Morowitz, and Pierce. (CX 6-11.) In finding that these documents, and all of the other information presented, did not provide reasonable assurance of safety and effectiveness, the FDA stated:

> In reviewing the reports listed in the reference section, the agency notes numerous discrepancies among Dr. Morowitz's arguments [Refs. 159 and 160], Dr. Pierce's findings in support of the instrument [Ref. 161], and the work of Dr. Sternberg and Dr. Klein [Refs. 162 and 163]. Dr. Sternberg's and Dr. Klein's histological analyses do not support Dr. Morowitz's prediction of "excessive cell damage" upon application of the device [Ref. 164]. No experimental evidence has been presented to support Dr. Pierce's statement [Ref. 161] that "numerous pathologists" and "eminent dermatologists" have obtained research data showing "destructive changes in dermal papilla" caused by high-frequency tweezer-type epilators.

(CX 6-9 to 10.)

227. Another indication of the FDA Panel's reasoning appears at RX 3-5, a transcript of a Panel meeting at which Dr. Morowitz discussed his theoretical work. The Panel's acting chair observed that Depilatron had made at least three presentations to the Panel, had been told to produce a "double-blind study conducted by competent, independent investigators" and had returned with "these logarithm graphs." (RX 3-5.) Dr. Morowitz told the Panel that studies were in progress. (RX 3-6.) Respondents did not offer such studies in this case. The absence of later Depilatron or Removatron studies from our record and the FDA record warrants the inference that none was ever done or that the results did not establish permanent hair removal by RFE tweezer-type epilators.

228. Frederick Goodman, the individual respondent in this case, was aware of the FDA's January 19, 1982 notice when it was published (CX 721-371) and obtained and read RX 3 (the transcript **[60]** of the January 12, 1979 meeting of the FDA Panel) and RX 4 (the FDA Panel transcript of the March 24, 1978 meeting). In these meetings, Dr. Morowitz made presentations and his papers were discussed by the Panel members. Respondents' reliance on RXs 3 and 4 is inexplicable.

229. About six months after the FDA notice was published, the

FDA's Boston District Director, on June 4, 1982, issued a Notice of Adverse Findings to Frederick E. Goodman, President, Removatron International Corporation, stating that "the Food and Drug Administration objects to any labeling for your device which implies that it provides permanent hair removal." The Notice further states: "To promote these devices as providing permanent hair removal, misbrands them under provisions of the Federal Food, Drug, and Cosmetic Act 21 USC 301 et seq." The Notice also enclosed a copy of the January 19, 1982 FDA notice discussed in the preceding Findings. (CX 5-3 to 5-4.)

230. Respondents, in an apparent attempt to cast doubt on the expertise of the FDA Panel, called as a witness Dr. Budd Appleton to testify about his studies which tested whether exposure to microwave can induce cataracts in humans. However, Dr. Appleton's studies deal solely with the issue of device safety and did not purport to show permanent hair removal. Thus, the Appleton studies add nothing to respondents' claimed substantiation for their permanency claim.

231. Dr. Appleton testified that in his view the FDA Panel's potential safety concerns were not justified. He further stated that two of his studies, published in 1975 and 1977 respectively, "pretty much laid the question [whether exposure to microwave will cause cataracts in humans] to rest." (Tr. 2225.) Dr. Appleton also agreed with respondents' counsel that, if the FDA Panel was concerned with cataracts in 1982, it was "somewhere between five and seven years out of sync ... with the published data on the question." (Tr. 2235.) However, Dr. Appleton admitted that the cataractogenic properties of microwave irradiations are "controversial" (Appleton, Tr. 2266) and that many experts, long after 1977, in published books and articles, expressed concern about microwave cataract formation or disappointment at the inadequate state of knowledge on the subject. *E.g.* Appleton, Tr. 2239, 2240-41 and 2250. In addition, an American National Standards Institute committee, of which Dr. Appleton is a member, is currently "agonizing" over the standard for microwave exposure; some members want to lower the level, others want to raise it. (Appleton, Tr. 2262.)

232. The FDA Panel's findings and determinations discussed hereinabove reflect the reasoned judgement of an expert body regarding the question whether there is reliable scientific evidence to assure the safety and effectiveness of RFE tweezer-type epilators

weight in a Section 5 proceeding. They also demonstrate that respondents' claimed reliance on the scientific material they proffered as substantiation for their permanent hair removal claim was not, and is not, reasonable by any standard. The fact that the proposed FDA rule requiring premarketing approval of high frequency epilation devices has not been adopted and made effective by the Department of Health and Human Services does not affect the scientific findings and conclusions of the FDA Panel.

C. Respondents' Failure To Possess and Rely on a Reasonable Basis for Their Permanent Hair Removal Claim Is a Violation of Section 5 of the Federal Trade Commission Act

233. The preceding Findings in IV demonstrate that respondents did not have, and do not now have, a reasonable basis for the permanent hair removal claims. Their claims implied that those claims were supported by a reasonable basis. And, in the context of this case, the reasonable basis is nothing less than competent and reliable scientific tests. Failure to have a reasonable basis in these circumstances is a deceptive practice in violation of Section 5 of the Federal Trade Commission Act.

234. Respondents also expressly claimed that clinical tests proved that Removatron was superior. As demonstrated hereinabove, these specific and express claims are not supported by adequate substantiation. Several of the representations claimed that Removatron was "clinically tested." When asked about the basis for one of them, "clinically tested and shown superior," Mr. Goodman stated that this referred to Dr. Foster's study. (CX 721-340.) However, Dr. Foster's Removatron study was an animal study. And, in Dr. Foster's own opinion, it merely showed that Removatron-treated mice hair showed some effect on tissue. And, there is no "clinical test" of Removatron in the record. Also referring to Dr. Foster's study, respondents claimed "Research Proves Removatron Method Destroys Hair Follicle." (CX 179-1.) However, Dr. Foster testified that his study did not prove destruction of hair follicles or permanent hair removal. (Foster, Tr. 1559-60.)

235. During the trial, respondents appeared to espouse the theory that each Removatron treatment results in pathologically recognizable tissue and cell damage in the treated hair follicle and the papilla itself and that a series of Removatron treatments has the *possibility* of a serial destruction of the papilla, ultimately resulting in permanent hair

removal. In fact, all of respondents' operator witnesses testified that they observed that the hair which grew back in Removatron treated areas of their clients were either "finer," "lighter," "softer" or some combination of these three. (Bunims, Tr. 2520, 26; Pipper, Tr. 2129; Jones, Tr. 2070; Richardson, Tr. 2040-41; Bilbrey, Tr. **[62]** 2304-05; Thomas, Tr. 2004-05; Newcombe, Dep. (RX 500) Tr. 28, 46.) In their Proposed Findings of Fact and Brief, respondents did not discuss or rely on this theory. However, in their Response To Complaint Counsel's Proposed Findings of Fact, respondents referred to "the possibility" of a serial destruction of the papilla. Respondents argue that Dr. Van Scott, complaint counsel's expert witness, "was uncertain if this was a possibility" and that he admitted that the "observations of treated hair regrowing with a finer texture was consistent with the theory of serial destruction of the papilla." (RRB at 2-3.)

236. This argument, however, is not persuasive. Respondents' own publication, "The Theory and Practice Of Pilethermology" notes that treated hair "usually returns in the form of fine hairs which require many weeks to darken and deepen into the original type of hair" (CX 141-40/RX 70, p. 37), and also acknowledges that a complete destruction of the papilla and connective tissues is necessary in order to prevent the treated hair from growing back (CX 141-39-42/RX 70, pp. 36-39). Thus, the regrowth of Remoatron-treated hair in finer form suggests, if anything, that it is merely a temporary condition and that respondents' serial destruction theory remains a mere "possibility" and, at best, a hypothesis whose validity must be established by competent and reliable clinical tests. And, respondents have not produced a single clinical test to establish that a series of Removatron treatments results in permanent hair removal in humans. Furthermore, none of the biopsy reports of Depilatron-treated specimens showed a complete destruction of the papilla.

V. Respondents Representations That the Federal Communications Commission has Approved the Removatron Hair Removal Method is False and is a Violation of Section 5 of the Federal Trade Commission Act

237. Respondents claimed by implication that the Removatron hair removal method and its efficacy are approved by the FCC. Respondents admit that (1) the FCC has not approved the Removatron hair removal method (CX 1-5 and 2-1), and (2) the FCC has merely

approved the operation of the Removatron device at a certain frequency to ensure noninterference with radio broadcasting. (CX 1-5, CX 2-1, and Stipulation, approved October 23, 1986.) Thus, by respondents' own admission the representation that the FCC approved the Removatron hair removal method is false. **[63]**

VI. Respondents' Practices Have Caused Substantial Consumer Injury

A. Financial Injury

238. Respondents sell Removatron to beauty salons, skin care establishments, and free standing hair removal businesses. Respondents also sell the device to individuals for self-treatment of their own unwanted hair problems. *See* F. 4, *supra.*

239. The price of each Removatron device is approximately $4,000. (Tr. 1453, Tr. 1632, CX 805-2.) Other equipment, such as the Misty Facial Steamer, is often sold as part of the Removatron package. (CX 721-9, 179-2.) Respondents' gross sales revenue for hair removal devices and related equipment from April 1, 1980 to September 30, 1983 was in excess of $2.3 million. (CX 719.) Respondents have sold about 3000 such devices. (CX 1-26.)

240. Removatron owner-operators expend substantial sums of money to purchase Removatron devices and their patrons expend substantial amounts of money for Removatron treatments. The failure of Removatron treatments to permanently remove hair causes substantial economic injury to owner-operators and their patrons alike. The scope of respondents' business operations makes the economic injury to consumers substantial and widespread.

241. For example, Doris Callison, a Removatron owner-operator, purchased a Removatron in 1980 and paid approximately $3500 for it. (Tr. 454.) About sixty customers received Removatron treatments at Ms. Callison's salon according to Ms. Callison. (Tr. 470.) Ms. Callison discontinued use of Removatron in 1984. Ms. Callison's Removatron treatment customers paid approximately $35 per hour for treatment. (Tr. 472.)

242. Arlene Cioppa, a patron, received Removatron treatments every two weeks at Ms. Callison's shop for approximately three and one-half to four years. Ms. Cioppa received treatments lasting at least one hour. Ms. Callison later increased the length of these treatment sessions to one and one-half or two hours. (Tr. 479, 480.) Ms. Callison's hourly rate for Removatron treatments is $35. (Callison, Tr.

472). Thus, Ms. Cioppa's bi-weekly treatment sessions over a three and one-half to four year period would have cost her about $3,000.

243. Shelia Meamber, another patron, received weekly Removatron treatments at Ms. Callison's shop for a period of three to three and one-half years. Each treatment session on Ms. Meamber lasted an hour or longer. At Ms. Callison's hour rate of $35, Ms. Meamber's weekly treatments over a period of **[64]** three to three and one-half years would have cost her in the range of $5,400 - $6,300.

244. In 1982, Gloria Dyal purchased a Removatron device for approximately $4,000, in order to offer hair removal services at her salon. (Dyal, Tr. 1241.) Ms. Dyal understood that these hair removal services would entail permanent hair removal, as did her clients. (Tr. 1313.) According to Ms. Dyal, some fifty patrons received Removatron treatments until she discontinued the use of Removatron in 1985. (Dyal, Tr. 1323.) Ms. Dyal's Removatron customers paid approximately $30 per hour for treatment. (Tr. 1271.)

245. Sherry Griffis received weekly Removatron treatments at Ms. Dyal's salon for about two years. Each treatment session lasted about thirty minutes. (Tr. 1290, 1291.) Ms. Dyal charged clients $20 for a thirty minute treatment session. (Tr. 1326, 1327.) Thus, Ms. Griffis' weekly treatment sessions over about a two year period would have cost her about $2,000.

246. Florence Fuchs purchased a Removatron device in 1982 in order to treat her own hair problem and to treat a few customers on a part-time basis. (Fuchs, Tr. 528.) Ms. Fuchs paid approximately $5,000 for the device and accessory furniture. (Fuchs, Tr. 530.) Ms. Fuchs stopped using Removatron after approximately eighteen months of self-treatment. (Fuchs, Tr. 537-539.) The Removatron device and accessory furniture are now stored in her cellar. (Tr. 532.)

B. Non-Financial Injury

247. The evidence clearly shows that the problem of unwanted hair is a serious emotional, social and economic problem for those who suffer from it. It affects their emotional well-being, social activities and often affects their ability to secure certain types of employment. Testimony to this effect is legion, from both complaint counsel's and respondents' witnesses. *See e.g.*, Callison, Tr. 481-483; Dyal, Tr. 1293-1296; Thomas, Tr. 1990, 2158-2159; Bilbrey, TR. 2309, 2311; Richardson, Tr. 2030, 2059; Bunims, Tr. 2535-2536. Respondents' operator-witness Ms. Richardson testified that one of her female

patrons with an unwanted hair problem had attempted suicide. (Richardson, Tr. 2059.)

248. Complaint counsel's expert witness, Dr. Eugene Van Scott, a respected practicing and research dermatologist, testified that a woman with a full beard may consider suicide. (Van Scott, Tr. 1082.) Dr. Van Scott also testified that excess hair, to the individual who has it, represents a form of disfigurement. That disfigurement is a very important and serious condition to people who have the problem "because it can **[65]** affect their lives, how they relate to other people, how they secure occupations and with good reason." (Van Scott, Tr. 948.)

249. The record is clear that unwanted hair, particularly unwanted facial hair, is a serious and sensitive personal problem, often accompanied by emotional distress, for many females who seek Removatron treatments. The failure of Removatron to remove unwanted hair permanently as respondents claimed it will, not only causes significant financial injury to those who purchase Removatron or seek Removatron treatments, but also exacerbates the serious emotional distress that accompanies their unwanted hair.

VII. Relief

A. The Nature and Scope of Relief

250. With respect to respondents' advertising claims which were false or for which respondents did not have a reasonable basis, the customary remedy in Section 5 cases is an order to cease and desist. Also, the power of the Commission to issue orders containing fencing-in provisions is well-established. *See, e.g., FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952); *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 394-95 (1945). The Commission has wide discretion in fashioning orders to prevent resourceful respondents from a course of conduct similar to those found to have been unfair or deceptive in the past. However, the Commission's discretion is subject to two constraints: (1) the order must be clear and precise to be understood by the violator; and (2) the order must bear a reasonable relationship to the unlawful practice found to exist, citing *Colgate-Palmolive*, 380 at 392; *Jacob Siegel Co. v. United States*, 327 U.S. 608, 612-13 (1946). *Thompson Medical Co.*, 104 FTC at 832-33. In *Thompson*, to ensure that a multiproduct fencing-in order bears a reasonable relationship to the unlaw practice found to exist, the Commission considered three factors. They were: (1) the seriousness and deliberateness of the

present violation; (2) respondent's past history of violations; and (3) the transferability of the unlawful practices to other products. *Thompson,* 104 FTC at 833; *American Home Products v. FTC,* 695 F.2d 681, 706 (3rd Cir. 1982); *Sears, Roebuck and Co.,* 676 F.2d 385, 392 (9th Cir. 1982). All three factors need not be present, and as the egregiousness of a particular element increases, it becomes less important that another element be also present. *Thompson,* 104 FTC at 833.

251. In this proceeding, respondents' violations have been serious and deliberate and their unlawful practices are readily transferable to hair removal products or devices of respondents other than Removatron. Therefore, the provision of the cease and desist order must be broad enough to preclude respondents from **[66]** false or unsubstantiated advertising claims in the future. Such false or unsubstantiated claims include:

(a) False claim:

(1) Removatron hair removal method is approved by the FCC. (Comp. ¶9.)

(2) Removatron International possessed and relied upon a reasonable basis for representations of permanent or long-term hair removal claim. (Comp. ¶¶7 and 8.)

(b) Unsubstantiated claims:

(1) Removatron permanently removes hair, or it is effective in removing hair on a long-term, not temporary, basis. (Comp. ¶6.)

252. Respondents' violations are serious because they not only caused substantial financial injury to Removatron purchaser-operators and Removatron treatment customers but also caused profound emotional injury to Removatron patrons by causing severe emotional distress and exacerbating their unwanted hair problems through false and unsubstantiated advertising claims. The record as a whole clearly shows that Removatron purchasers are led by respondents' false and unsubstantiated claims to purchase Removatron devices and often accessories at substantial costs in the belief that by offering painless, permanent hair removal by an advanced RFE device, to their salon customers, they could enter a new, highly profitable venture. As for treatment customers, the record as a whole also shows that they are attracted to Removatron by respondents' false and unsubstantiated claim of permanent hair removal which are passed on by the operators to customers, and are induced to undertake long series of treatments

in the belief that the next treatment might bring the promised permanent hair removal. The claimed qualifications of permanency claim were ambiguous and ineffectual. The record on this point is consistent with the conclusion that the so-called qualifications were a mere artifice, which had the effect of luring the unsuspecting with irresistible permanent hair removal claims and leading the doubters and the discouraged on with tantalizing suggestions that the promised result might be just around the corner.

253. Respondents' violations are also serious because of their wide scope and long duration. Respondents have been making **[67]** the unsubstantiated efficacy claims since they began advertising the Removatron device in 1976. These claims have appeared on numerous occasions in nationally circulated trade publications and in many other print media, both local and national.

254. Respondents' violations also have been deliberate. The wide scope and long duration of respondents' dissemination of unsubstantiated claim supports a conclusion that the challenged ad claims were not accidental or isolated instances. *Thompson Medical Co., supra,* 104 FTC at 834. Indeed, the record as a whole supports a conclusion that respondents knew or should have known that the efficacy of RFE tweezer-type epilators had not been proven by any clinical test, and yet they chose to ignore Dr. Foster's proposal for a controlled clinical trial. The record shows that an acceptable clinical test would cost about $40,000 today, a small portion of respondents' gross revenue. Instead, respondents asserted during trial that they had relied on numerous documents which had been turned over to them by complaint counsel during post complaint discovery. It is clear, however, that they never possessed nor saw many of these documents until they received those documents from Commission staff. (Tr. 1570, 1573, 1580.)

B. Respondents' Argument That This Proceeding and Order Lack Public Interest Is Without Merit

255. Respondents contend that this proceeding and any cease and desist order are not in the public interest because the complaint proceeding as well as the Federal Trade Commission investigation which preceded it are largely the result of numerous complaints generated by electrologists and in particular by Mr. Fino Gior, the founder and past-president of the International Guild of Electrologists (IGE). Respondents further contend that these complaints are rooted

in the economic interest of electrologists in destroying the competitive position of marketers of RFE epilation devices. (Tr. 107-108.) In order to support their argument, respondents introduced three documents (RXs 75, 77 and 87) and called Mr. Gior (also known as Gionardo) as a witness. Respondents' requests to depose and to call as their witness Francis X. McDonough, a Commission consumer protection specialist, who participated in the Commission investigation of this case and assisted complaint counsel during trial, were denied pursuant to Section 3.36 of the Commission's Rules of Practice in Adjudicative Proceedings. The administrative law judge also rejected a written offer of proof by respondents' counsel describing at length what respondents hoped to prove through Mr. McDonough's testimony if allowed to call him.

256. Respondents elicited extensive testimony from Mr. Gior regarding the role of the International Guild of Electrologists **[68]** (IGE) in the Federal Trade Commission investigation. (Gior, Tr. 2339-2485.) The record demonstrates that respondents were allowed extraordinary leeway and ample opportunity to show that the institution of this proceeding or the issuance of a cease and desist order in this matter is not in the public interest for the reasons they advanced. Mr. Gior's testimony disclosed no basis for respondents' lack of public interest allegations. Nor did Mr. Gior's testimony suggest any impropriety on the part of Mr. Gior, the IGE, or Commission staff during this proceeding or the investigation that preceded it. There is no basis in Mr. Gior's testimony from which to conclude that the investigation that resulted in this proceeding was anything other than thorough and impartial. (Gior, Tr. 2339-2485.)

257. None of the three documents introduced by respondents supports respondents' contention of impropriety. RXs 75 and 77 are IGE newsletters, which were fully discussed during Mr. Gior's testimony. RX 87 is a list of complaints against Removatron from Federal Trade Commission files. This list simply shows that the Federal Trade Commission had received at least 112 complaints against Removatron and that most of them had been forwarded to the Federal Trade Commission by electrologists. Although the record shows that some of respondents' advertising was evidently targeted to potential customers of electrologists and that the Commission received and considered the letter complaints from numerous electrologists, these facts do not affect the conclusion that this proceeding is in the public interest and that there has been no showing of impropriety by

258. Contrary to respondents' arguments, the record evidence is compelling that respondents should be ordered to cease and desist from deliberately disseminating false and unsubstantiated permanent or long-term hair removal claims, which have caused substantial financial injury to Removatron purchasers and substantial financial and non-financial injury to Removatron treatment patrons. It is high time that the Commission put a stop to respondents' unlawful practices found to exist in this proceeding.

C. The Specific Provisions of the Order

259. The provisions of the order are appropriate, necessary, and fully warranted by respondents' longstanding and deliberate dissemination of false and unsubstantiated claims in connection with the promotion and sale of Removatron

260. Paragraph I.A. of the order prohibits respondents from making efficacy representations, specifically including representations concerning permanent or long-term hair removal, unless respondents, at the time they make such representations, possess and rely upon at least two well-controlled clinical **[69]** studies that substantiate the representations. The prohibition of unsubstantiated permanence claims is the core of any effective remedy in this case. "Where a fair assessment of an advertiser's conduct shows a ready willingness to flout the law, sufficient cause for concern regarding further, additional violations exists." *Sears, Roebuck and Co. v. FTC,* 676 F.2d 385, 392 (9th Cir. 1982). The record amply demonstrates that this is such a case.

261. Removatron is a "device" under Section 12 of the Federal Trade Commission Act. The level of substantiation required for respondents' efficacy claims for Removatron or any hair removal device herein is consistent with recent Commission orders involving unsubstantiated efficacy claims for products within the purview of Section 12. *See, e.g., Thompson Medical Co., Inc. v. FTC, supra.* The requirement for two clinical studies as a reasonable basis is further warranted by expert testimony in this case and by the substantial financial and serious emotional injury that has occurred, and could recur, should respondents resume making efficacy claims without adequate scientific substantiation.

262. Paragraph I.B. of the order prohibits respondents, for a period of five years, from claiming that Removatron or any other high frequency (RFE) tweezer-type epilation device is able to remove hair

unless respondents make a clear and conspicuous disclosure that adequately qualifies the claim in order effectively to disabuse the readers and viewers of such ads of the impression that the device removes hair permanently or on a long-term basis. This affirmative disclosure provision is necessary because of respondents' longstanding and frequent use of unqualified and unsubstantiated permanent hair removal claims and is designed to prevent any reader or viewer of respondents' hair removal claim in the future from perceiving such a claim to mean that Removatron or any RFE tweezer-type epilator being advertised removes hair permanently as has long been claimed by respondents with respect to Removatron. The Commission's authority to issue remedial order requiring affirmative disclosures, including corrective advertising, is well-established. *See, e.g., Southwest Sunsites, Inc. v. FTC,* 785 F.2d 1431, 1439 (9th Cir. 1986); *Amrep Corp. v. FTC,* 768 F.2d 1171, 1180 (10th Cir. 1985), *cert. denied,* 106 S.Ct. 1167 (1986); *Warner-Lambert Co. v. FTC,* 562 F.2d 749, 756-762 (D.C. Cir. 1977), *cert. denied,* 435 U.S. 950 (1978). The need for such affirmative disclosure with respect to Removatron or other similar RFE tweezer-type epilator advertised by respondents is well-established in the record. The five-year requirement is eminently reasonable in the circumstances of this case. This affirmative disclosure requirement is limited to the Removatron epilator and other similar RFE tweezer-type epilation devices, **[70]**

263. Paragraph I.C. of the order prohibits the respondents from representing that the Removatron device, or any treatment employing such device, is approved by the FCC unless it is conspicuously disclosed that the FCC approval relates only to the use of a particular radio frequency, and not to the safety or efficacy of any device or treatment. This provision prohibits a representation made by respondents that was alleged to be false and which the record demonstrates is false and is intended to prohibit the recurrence of the representation found to be unlawful and is reasonably necessary to prevent such abuse in the future.

264. Part II of the order prohibits respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or study. This provision is predicated upon respondents' past misrepresentations and misuse of test results and similar reports and is necessary to ensure that respondents do not continue to disseminate such misrepresentation of test results or similar materials in the future.

265. Paragraph III.A. of the order requires respondents to provide past purchasers of Removatron with a copy of this order and a notice that such purchasers must discontinue use of any of respondents' advertising and promotional materials that contain the representations prohibited by parts I and II of this order. This provision is necessary to ensure that Removatron operators do not continue respondents' misrepresentations and consumer injury, by continuing to rely upon and to disseminate materials and representations which were previously put into the stream of commerce by respondents. Such material would include any offending advertising slicks, brochures, leaflets and other material furnished by respondents containing, for example, any language comparing Removatron with electrolysis, or distinguishing Removatron from other temporary hair removal products or devices, or claiming that the device is "effective," "works," or employing such words as "permanent" "forever" or any other words or phrases which suggest anything other than a temporary result in connection with hair removal. Without such a provision, the intended remedy will be ineffective and will, as a practical matter, sanction continued dissemination of false and unsubstantiated claims contained in Removatron advertising and promotional material by purchasers and operators of Removatron who acquired the device and the offending material prior to the effective date of this order.

266. Paragraph III.B. of the order requires respondents to provide future purchasers of hair removal devices with a copy of this order and to obtain from each purchaser a signed form acknowledging the receipt of a copy of this order prior to the sale. This provision is ancillary to paragraph III.A. of the order and is reasonably necessary to ensure that future device **[71]** purchasers and operators do not engage in the representations proscribed in parts I and II of this order.

267. Paragraphs IV through VIII of the order contain a number of provisions that impose upon respondents several recordkeeping, reporting, and notification requirements designed to ensure that the order provisions are being complied with by respondents.

VIII. Conclusions of Law

1. The Federal Trade Commission has jurisdiction over respondents and over their acts and practices that are the subject of this proceeding.

2. Removatron is a "device" within the meaning of Section 12 of the Federal Trade Commission Act.

3. Respondents have made representations about the efficacy of their device that are likely to mislead reasonable Removatron purchaser/operators and their patrons acting reasonably, and these representations are material.

a. Respondents have made advertising representations about the efficacy of their device without possessing and relying on a reasonable basis when such representations were made.

b. Respondents have made express advertising representations about the level of substantiation, *e.g.*, clinical tests, supporting their efficacy claims without having such level of substantiation.

c. Respondents have falsely represented that the Federal Communications Commission has approved their hair removal method and its efficacy.

4. Respondents' representations have been relied on by purchasers of the device and consumers of Removatron hair removal treatments to their substantial financial detriment and severe emotional injury.

5. Respondents' advertising representations described herein above are false, misleading and deceptive and in violation of Sections 5 and 12 of the Federal Trade Commission Act.

6. The order entered in this proceeding is necessary to remedy the violations of law committed by respondents and to protect the public now and in the future and is in the public interest. **[72]**

DISCUSSION

1. Removatron.

The principal issue in this case is whether respondents' ad claim that Removatron, a radio frequency energy (RFE) tweezer-type epilation device, removes unwanted hair permanently is based on competent and reliable scientific evidence. This initial decision has determined that it was not so based when made and that it is not so based now.

2. The Challenged Permanent Hair Removal Claim.

Since about 1976, respondents have advertised Removatron mainly in various trade magazines intended for the beauty salon and skin care trades and also regularly promoted the device at annual conventions and trade shows of beauty salon trade groups. Removatron is generally sold to beauty salon operators (at about $3,500 to $4,000), who administer hair removal treatments to their clients. The

fee for Removatron treatments varies anywhere from about $10 for a 15 minute session to about $35 for a 60 minute session. Respondents have sold some 3,000 Removatrons in this country and abroad, and the dollar volume of such sales has been well over $500,000 annually. Respondents' gross sales revenue for Removatron and related accessories from April 1, 1980 to September 30, 1983 was over $2.3 million.

With respect to the permanent hair removal claim challenged in this case, respondents do not dispute that certain of their ads and promotional materials contain such a claim, either expressly or impliedly, but assert that these claims are not supposed to be made, and were not made, without appropriate qualifications and that, as a result, no purchaser of Removatron or her patron has been misled or deceived by respondents' permanency claim. However, the evidence is overwhelming that both salon operators and their patrons are initially attracted by the "painless, permanent hair removal" claim they read; in trade journals and trade shows in the case of salon operators, and in local ads, classified directories and from salon operators in the case of patrons. The law is clear that if the initial sales contacts are obtained through misleading ad claims, Section 5 is violated even if the truth is made known to the purchaser before the sale is consummated. *See* F. 62, *supra.*

As to the "appropriate qualifications" respondents point to, they boil down to three: (1) the treatment must be applied correctly; (2) it requires a series of treatments, a sufficient number, so as to treat each hair as it grows above the skin line according to hair growth cycle; and (3) although it works (achieves permanent hair removal) for most people, there are no guarantees because some people may have hormonal imbalance and need medical treatment. However, these "qualifications" are so **[73]** ambiguous and confusing that they may fairly be said to be nothing more than hedges obliquely placed after the initial sales contacts and designed to avoid an unconditional guarantee. Indeed, the record is consistent with the conclusion that the effect of respondents' advertising and promotional practices is to lure the salon operator with the prospect of a new, high profit business and the hirsute woman with a promise of painless, permanent hair removal, and that the doubters and the discouraged are led on by respondents' tantalizing suggestion that the promised permanent freedom from unwanted hair might be just a few more treatments away.

3. Respondents' Claimed Substantiation

Respondents in their Proposed Findings of Fact and Brief rely "first and foremost" on a number of affidavits and testimonial letters by dermatologists and pathologists, which were filed in a California state court action charging certain distributors of Depilatron, another RFE tweezer-type epilation device, with misleading and deceptive advertising. These documents, discussed in the Findings as Glass, Shiffman and Lever documents, are conclusionary statements of opinions citing or referring mostly to others' reports of Depilatron-treated skin biopsies, and none of them is a controlled clinical test. Also, the evidence is inconclusive on whether Depilatron and Removatron are substantially similar except that both appear to be RFE tweezer-type epilation devices. In any event, the bulk of those Depilatron-related documents appears to have come into respondents' possession after the commencement of this case. And these same observations apply equally to other testimonials and opinion letters filed in a federal district court injunction action involving Depilatron. *See* F. 104, 140-192, 254, *supra.*

The Foster Study, also discussed in the Findings, is the only experiment conducted with Removatron. But, none of the Foster studies or his opinion testimony purports to establish clinically that Removatron treatments achieve permanent hair removal in humans. *See* F. 107-130, *supra.* In fact, Dr. Foster's 1983 recommendation that respondents conduct a controlled human clinical test with Removatron appears to have been ignored.

The testimony of Removatron users and patrons, as well as user testimonials and user surveys, were considered but given little weight as substantiation for respondents' permanent hair removal claim.

Finally, the FDA Device Classification Panel's 1982 findings and determination that no substantial scientific data exists to provide reasonable assurance of the safety and effectiveness of high frequency tweezer-type epilation devices, such as Removatron, under the regulations promulgated pursuant to the Devices Amendment to the Food, Drug and Cosmetic Act, and the **[74]** Secretary's institution of a rulemaking proceeding which would require FDA pre-marketing approval for such devices, highlights the lack of adequate scientific substantiation for the permanent hair removal claim challenged in this proceeding. In fact, the FDA Panel considered and rejected much of the documents and material respondents rely on in this proceeding. In the same year, FDA's Boston District Office issued a Notice of

Adverse Findings to Frederick E. Goodman, President, Removatron International Corporation, stating that "the Food and Drug Administration objects to any labeling for your device which implies that it provides permanent hair removal." The FDA notice further states that "To promote these devices as providing permanent hair removal, misbrands them under the provisions of the Federal Food, Drug, and Cosmetic Act 21 USC 301 et. seq." and enclosed a copy of the January 1982 notice of proposed rulemaking referred to hereinabove.

The accompanying order will, among other things, place a similar proscription against respondents' advertising claim that Removatron provides permanent hair removal.

ORDER

I.

It is ordered, That respondent Removatron International Corporation, a corporation, its successors and assigns, and its officers, and respondent Frederick E. Goodman, individually and as an officer of Removatron International Corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacture, labeling, advertising, offering for sale, sale or distribution of the Removatron epilator or any other hair removal device, as "device" is defined in the Federal Trade Commission Act, or other hair removal product in or affecting commerce, as "commerce" is defined in the Federal Trade **[75]** Commission Act, do forthwith cease and desist from representing in any manner, directly or by implication, that:

A. Any such hair removal device or other hair removal product, or any treatment employing any such device, will or may achieve permanent hair removal or hair removal on a long-term and not temporary basis, or is otherwise effective, using those words or words of similar import or meaning, unless, at the time of the making of such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates such representation; provided, however, that, for purposes of this order, for any evidence to be competent and reliable it must include at least two adequate and well-controlled, double-blind clinical studies conforming to acceptable designs and protocols and conducted by different persons, indepen-

dently of each other, who are qualified by training and experience to conduct such studies.

B. The Removatron device or any other RFE tweezer-type epilation device or any treatment employing any such device is intended to or is able to **[76]** remove hair, using those words or words of similar import or meaning, unless the representations clearly and conspicuously discloses the following statement: "IMPORTANT: There is no reliable evidence that [name of device treatments] provide anything more than *temporary* hair removal"; *provided, however,* that in any written materials this disclosure shall be in typeface at least as large as the largest typeface in the label, advertising, or any document, and in any multipage documents the disclosure shall appear on the cover or first page, and provided further that this provision shall terminate after five (5) years from the date on which this order becomes effective.

C. The Removatron device or any other RFE tweezer-type epilation device, or any treatment employing such device, is FCC approved, using those words or words of similar import or meaning, unless the representations clearly and conspicuously disclose that the FCC has only approved the use of a certain radio frequency by such device and has not approved the safety or effectiveness of such device or the safety or **[77]** effectiveness of any treatment employing such device.

II.

It is further ordered, That respondent Removatron International Corporation, a corporation, its successors and assigns, and its officers, and respondent Frederick E. Goodman, individually and as an officer of Removatron International Corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacture, labeling, advertising, offering for sale, sale or distribution of the Removatron epilator or any other hair removal device, as "device" is defined in the Federal Trade Commission Act, or other hair removal product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or study. **[78]**

III.

It is further ordered, That respondents shall:

A. Within ninety (90) days after the date of service of this order, send by first-class mail, a copy of this order and a notice that the purchaser shall immediately cease using any Removatron advertising or promotional materials containing representations prohibited by parts I and II of this order, to each purchaser of any of respondents' hair removal devices since January 1, 1976, who is identifiable from respondents' sales records, testimonial letters, mailing lists or other documents containing an address or telephone number for that purchaser. Such advertising and promotional materials include, but are not limited to, any writing, audio tape or other material which employ such words as "permanent," "effective," "forever," "long-term," or "works," or which compares the device to electrolysis or distinguishes it from temporary hair removal devices or products. **[79]**

B. Provide a copy of this order to each purchaser of any of respondents' hair removal devices prior to the consummation of the sale, and obtain from each purchaser a signed form acknowledging the receipt by the purchaser of a copy of this order prior to the sale.

IV.

It is further ordered, That respondents, their successors and assigns, shall maintain for at least three (3) years from the date of the last dissemination of each representation which is subject to this order, and make available to the Federal Trade Commission upon request, complete and accurate records demonstrating compliance with this order, including but not limited to the following:

A. Advertisements and labeling and promotional materials for any hair removal device or other hair removal product, and such records as will show when and where each advertisement was published;

B. Tests, studies, surveys, affidavits, letters, complaints, articles or other materials substantiating, contradicting, or otherwise **[80]** relevant to the validity of any such representation;

C. The signed forms received from purchasers pursuant to paragraph III.B. of this order;

D. Such business records as will demonstrate notification to purchasers pursuant to paragraph III.A. of this order; and

E. Sales invoices or such other business records as will disclose the name, address, and date of purchase for each purchaser of a hair removal device from respondents.

V.

It is further ordered, That respondents shall distribute a copy of this order to all present and future personnel, agents and representatives having sales, advertising, or policy responsibilities with respect to the subject matter of this order and that respondents shall secure from each such person a signed and dated statement acknowledging receipt of said order. **[81]**

VI.

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

VII.

It is further ordered, That, for a period of ten (10) years from the date of service of this order, the individual respondent shall promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment involving the advertising, offering for sale or sale of any hair removal device or other hair removal product, or any treatment employing such device or other product, and with each such notice include his new business address and a statement of the nature of the business or employment in which he is newly engaged as well as a description of his duties and responsibilities in connection with such business or employment. **[82]**

VIII.

It is further ordered, That the respondents herein shall, within ninety (90) days from the date of service of this order, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

OPINION OF THE COMMISSION

BY CALVANI, *Commissioner:*

I. INTRODUCTION

Respondents and Their Business

Respondents Removatron International Corporation and Frederick E. Goodman, its president, sell a hair removal device called "Removatron." The Removatron device is an electric epilator that generates radio frequency energy ("RFE") along a wire to a pair of tweezers. In the Removatron treatment, individual hairs are grasped by the tweezers sending RFE to the tweezer tip. After a period of time the hair is then removed. IDF 12.[1] Respondents claim that this procedure transmits RFE to the hair root and surrounding tissue of a treated hair, which eventually destroys the tissue and prevents regrowth of the hair. IDF 5, 6. A series of such treatments supposedly destroys the hair growing capability of the follicle containing the treated hair. IDF 5.[2] **[2]**

Respondents sell the Removatron device primarily to owners and operators of beauty salons, skin care establishments, and epilation businesses (IDF 10, 13) who in turn market Removatron treatments to consumers. IDF 19. The machine costs about $4,000 (IDF 22); individual treatments are in the range of $30-35 per hour. IDF 241, 242. Consumers of Removatron treatments generally are women who have unwanted hair on their bodies, most often on the face. IDF 11. Consumers receiving treatments are advised to return at regular intervals. IDF 12.

The respondents advertise mainly in trade magazines aimed at beauticians, cosmetologists, and operators of epilation businesses. IDF 13. Respondents also participate in beauty industry trade shows and advertise in the classified sections of newspapers. IDF 13-14. They

[1] The following abbreviations are used in this opinion:

IDF	-	initial decision finding number
T.	-	transcript of testimony page number
CX	-	complaint counsel's exhibit number
RB	-	respondents' brief

[2] A few definitions are helpful for understanding the issues in this case. "Hair" is a biologic fiber that originates from the hair root of the hair follicle. It is continuously produced at a steady rate. IDF 71. The "hair follicle" is a cylinder-like cellular structure comprised principally of epithelial cells. Its lowest portion contains the hair root which ends in contact with the papilla. IDF 73. The "papilla" is a group of connective tissue cells that surrounds and comes in contact with the follicle. *See* T. 930. It is suspected that the papilla produces growth factors or hormones necessary for hair growth. IDF 74.

maintain a sales staff and distribute promotional materials to prospective purchasers. IDF 15, 16. After the sale, respondents provide purchasers of the device with written and video training materials, in-person training, newsletters, advertising "slicks" for placement in local print media, and a question-and-answer brochure for consumers. IDF 17, 19.

The individual respondent, Frederick E. Goodman, is the president of Removatron International Corporation. He created or approved all of the company's advertising and promotional materials and directly supervised the sales staff. IDF 20.

Respondents have an estimated 80 percent share of the market for tweezer-type RFE epilators. They have been selling such devices since 1976. IDF 21.

Procedural History

On September 30, 1985, the Commission issued a complaint charging respondents with false and unsubstantiated advertising in connection with certain claims made for the Removatron device. In particular, the complaint charged that respondents claimed, without a reasonable basis, that the Removatron device permanently removes hair and is effective on a long-term, not temporary basis. Complaint ¶¶6-7. Respondents were also charged with falsely claiming that they possessed a reasonable basis for their permanency claims. Complaint ¶8. The complaint further alleged that respondents falsely claimed that the Federal Communications Commission ("FCC") had approved the Removatron hair removal method when in fact the FCC had only approved operation of the device at a particular radio frequency. Complaint ¶¶9-11.

Administrative Law Judge Montgomery K. Hyun entered an initial decision on July 15, 1987, finding against respondents on all charges. His order prohibits respondents from representing that any hair removal product, device or treatment **[3]** will achieve permanent hair removal unless respondents rely on competent and reliable scientific evidence consisting of at least two well-controlled, double-blind clinical studies. The order further prohibits representations that any RFE device will remove hair unless respondents disclose that there is no reliable evidence that the device provides anything more than temporary hair removal.[3] In addition, respondents are precluded from: (1) representing that Removatron is FCC-approved absent a clear and

[3] The respondents are required to make the affirmative disclosure for a period of five years.

conspicuous statement that the FCC has only approved its use at a certain radio frequency; and (2) misrepresenting the results of any test or study. The order also contains two notification requirements. Respondents must send past purchasers of the device a copy of the order and a notice not to rely on any Removatron advertising or promotional materials containing the prohibited representations. They must also provide a copy of the order to future purchasers and obtain a signed form acknowledging its receipt.

Respondents appeal from Judge Hyun's decision and order. Their principal contentions are that: (1) the judge erred in finding that they made unsubstantiated representations that Removatron achieves permanent hair removal and false representations that they had a reasonable basis for such claims; (2) the judge erred in holding that a reasonable basis for respondent's permanency claims requires competent and reliable scientific evidence consisting of two clinical studies; (3) the judge erroneously concluded that respondents lacked reliable and credible evidence that would constitute a reasonable basis for their claims; and (4) the order is overbroad and bears no reasonable relationship to the alleged violations.[4]

We generally agree with Judge Hyun's findings and conclusions and adopt them as our own, except where they are inconsistent with this opinion. In sum, we find that respondents represented both that the Removatron device achieves permanent hair removal, and that such representation is supported by a reasonable basis. We also find that respondents lacked a reasonable basis for the permanency claims. Accordingly, respondents' failure to possess a reasonable basis for its claims renders them false and deceptive. We affirm the order in all respects, except that we modify the two-clinical substantiation **[4]** requirement and delete the provision requiring notification of future purchasers.

II. Did Respondents Make the Representations Alleged in the Complaint?

Legal Framework

In determining whether advertising makes a particular representation, the Commission applies the standard enunciated in *Thompson Medical Co.*, 104 FTC 648, 788 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir.

[4] Respondents do not appeal Judge Hyun's finding that they falsely represented that the Removatron method is FCC-approved. Accordingly, the Commission adopts the Judge's findings and conclusions on this issue. IDF 68-69, 237.

1986), *cert. denied,* 107 S. Ct. 1289 (1987) [hereinafter "*Thompson*"] and *Cliffdale Associates, Inc.,* 103 FTC 110, 164-66 (1984) [hereinafter "*Cliffdale* "]. The Commission deems an advertisement to convey a claim if consumers acting reasonably under the circumstances would interpret the advertisement to contain that message. *Thompson,* 104 FTC at 788; *Cliffdale,* 103 FTC at 165. In evaluating what message the ad may reasonably be interpreted as containing, we distinguish between express and implied claims. Express claims directly state the representation. *Thompson,* 104 FTC at 788.[5] When a claim is implied,[6] the Commission determines its meaning by examining a number of factors, including the contents of the advertisement, the juxtaposition of various phrases therein, the nature of the claim and surrounding circumstances. *Thompson,* 104 FTC at 789; *Cliffdale,* 103 FTC at 166. Extrinsic evidence may be necessary where the implied meaning can not be determined from a facial examination of the advertisement. *Thompson,* 104 FTC at 789; *Bristol-Meyers Co.,* 102 FTC 21, 319 (1983), *aff'd,* 738 F.2d 554 (2d Cir. 1984), *cert. denied,* 469 U.S. 1189 (1985) [hereinafter "*Bristol-Meyers* "]. In short, the Commission considers the net impression that the ad makes on reasonable members of the public. *Bristol-Meyers,* 102 FTC at 320. We avoid interpretations that would render an ad deceptive merely because it could be unreasonably misunderstood by a very small and unrepresentative segment of the audience to whom it was directed. *Cliffdale,* 103 FTC at 165. **[5]**

Claims that Removatron Removes Hair Permanently

Judge Hyun found that respondents' advertising and promotional materials made express and implied claims that Removatron permanently removes hair. IDF 28-38. We agree. The express claims were contained in materials stating that hair removal would be "permanent," that unwanted hair is "no longer a problem" and can be "removed" or "Removatroned forever." IDF 28, 29; *see, e.g.,* CX 1-6, 1-9, 1-10, 1-24, 1-25, 1-26, 38(a), 40(b), 52(a), 113(a), 132(a), 139(a), 704, 706, 743, 804. As the administrative court concluded, these are express claims and, therefore, their meaning is clear from

[5] Thus, for example, an ad expressly stating that a shampoo will cure baldness contains that express claim. *See Thompson,* 104 FTC at 788-89 n.6.

[6] An implied claim is any claim that is not express. For example, in *Thompson,* the Commission found that the following ad for "Aspercreme," an arthrities pain remedy product, contained an implied representation that Aspercreme is a new product. "At last! A remarkable breakthrough for arthritis pain: Aspercreme." *Thompson,* 104 FTC at 811.

the ads themselves. *Thompson,* 104 FTC at 788; *Cliffdale,* 103 FTC at 166-67.

We also uphold Judge Hyun's finding that respondents made implied claims of permanency with statements that Removatron is "effective," is an "alternative to electrolysis," or "works." IDF 32, 34; *See, e.g.,* CX 1-6, 1-12, 139(a), 149-2, 297, 706, 709, 710, 713. Many of these implied claims are bolstered by express statements of permanency. *See, e.g.,* CX 1-6, 1-26, 139(a). Other implied claims include additional representations about the damage Removatron inflicts on the hair follicle, surrounding tissue and papilla.[7] *See, e.g.,* CX 1-20, 149-12, 290-2, 297, 298-2. For example, one promotional piece containing the heading "SAFE, PAINLESS, EFFECTIVE" explains that transmission of RFE into the follicle "works towards dehydrating and destroying the papilla, which is the source of nourishment for the hair. Once the papilla is destroyed, further hair growth is prevented." CX 149-12. Similarly, statements that the device causes the "coagulation" of the papilla thus "preventing or retarding regrowth" convey a permanency message. CX 290-2. In short, viewed as a whole, these materials convey an overall impression that Removatron will permanently remove hair.

Respondents make several arguments in order to challenge Judge Hyun's finding of both express and implied representations. First, they assert that the Administrative Law Judge ignored that the selling of Removatron was a process, and that no one bought the device on the basis of one advertisement. RB at 23-35. Thus, it is argued that he failed to consider the net impression of the representations by refusing to look at the sales process as a whole. Second, they argue that he erred in finding that the permanency claims were unqualified. RB at 29-35. Respondents assert that they qualified the permanency message with statements that the treatment is not 100 percent effective, that hair removal requires a series of treatments and there are no guarantees. RB at 30-32. They contend further that **[6]** the nature of the sales process was such that it dispelled any notions of permanency. RB at 32-33.

We affirm the finding that respondents made unqualified permanency claims. Judge Hyun correctly considered the net impression of individual advertisements and was not required to consider the meaning of the claims in the context of the total sales process. *See*

[7] It is generally accepted that a hair cannot grow or regrow in the absence of the papilla, which is the lowest portion of the hair root. IDF 73, 75.

Chrysler Corp., 87 FTC 719, 751-52 (1976) (Commission evaluates each advertisement on its own merits without regard to whether it was published once or in conjunction with an extended advertising campaign. The fact that nondeceptive ads may be part of an ad campaign is no basis for ignoring those that are deceptive.). Thus, as Judge Hyun correctly found, an initial ad may be deceptive even though the truth is subsequently made known to the purchaser. IDF 62 *citing Carter Products, Inc. v. FTC*, 186 F.2d 821 (7th Cir. 1951); *Thompson*, 104 FTC at 708. In any event, as we discuss below, respondents fail to show that they made the truth known to their customers.[8]

The Judge properly concluded that the purported qualifications failed to dispel the permanency message. IDF 47-59. In particular, he found that the claimed qualifications were "equivocal, vague and ambiguous" and could not reasonably be expected to offset or undo the clear and strong initial message that Removatron achieves permanent hair removal. IDF 59. In our view, most of the ads that respondents cite as containing a qualified message expressly or impliedly promise permanent and effective hair removal. For example, CX 1-8, which respondents cite as containing a qualified permanency message (RB at 31), explains the necessity of a "series of treatments" and further cautions that "there is no way of knowing the exact length of time your treatment will take." These statements are but a few phrases in a promotional piece that otherwise promises a "more effective painless solution to your cosmetic problem;" "a **[7]** totally safe, effective, painless hair removal treatment" that "lets you say goodbye to temporary solutions...." We hold that the net impression of these claims is that permanency will be achieved after a series of treatments.

Similarly, we reject respondents' argument that CX 298-2, a question and answer brochure, contains qualified claims simply because it states that Removatron will not work the first time. RB at 31. Rather, in our view, the claimed qualification conveys the meaning that permanency will be achieved at some later date. The statement

[8] Respondents cite *Mahler's Inc.*, 52 FTC 1217 (1956), to support the argument that Judge Hyun erred in refusing to consider the sales process as a whole. There, an advertisement soliciting inquiries for a product omitted certain safety information but the initial mailing, which all consumers received upon making their inquiry, contained the necessary disclosures. The Commission decided that the public interest did not support issuance of an order where the record suggested that all purchasers received nondeceptive information about the product before the purchase. 52 FTC at 1238. Thus, contrary to respondents' contention, the Commission did not interpret the advertisement in light of the sales process as a whole, but rather determined that the public interest did not warrant an order where consumers could not have been deceived.

appears in response to the question "DOES REMOVATRON REMOVE HAIR PERMANENTLY?," responding "YES. But not the first time." The brochure further asserts that Removatron "works," is "effective," "dries and destroys the papilla (root bulb) which is the source of nourishment for the hair," provides a *skin free of hair for the rest of your life.*" (emphasis in original) CX 298-2. Clearly, the net impression of these statements, and others containing similar purported qualifications, is that Removatron will eventually remove hair permanently. *See* IDF 48-49, 51-52.

Respondents also seek solace in statements made in a training session that purchasers attend before the sale is finalized. RB at 31-32. In particular, prospective purchasers are warned that "there are no guarantees," that "body chemistry is different," and that certain individuals should be referred to an endocrinologist. *See, e.g.,* CX 251-25, 251-138. However, as with the other materials containing so-called qualifications, the training session taken as a whole conveys the net impression that permanency will be achieved after a series of treatments, except for a few individuals with hormonal problems. *See* CX 251-23 ("yes, we do obtain permanent hair removal, painlessly, but it is not...an overnight procedure."); CX 251-29 (if progress is not significant after six to seven months, "it's quite possible that you would have a glandular problem..."); CX 251-32 (most people we can "clean up" in about a year to a year and a half); CX 251-40 ("Does this remove my hair permanently?...Yes it does; but not the first time."); CX 251-68 (case history shows 30 percent destruction the first time, which is "why it takes a series of treatments to obtain permanent hair removal.").

Accordingly, neither argument permits respondents to avoid their representations. In so concluding we uphold Judge Hyun's finding that the ads conveyed an unqualified permanency message both to purchaser/operators and to their clients. IDF 60-61.[9] **[8]**

[9] Citing *Waltham Precision Instrument Co. v. FTC,* 61 FTC 1027 (1962), *aff'd,* 327 F.2d 427 (7th Cir.), *cert. denied,* 377 U.S. 992 (1964), respondents argue that the ads were directed to a beauty professional audience who would not reasonably have interpreted them as containing a permanency message. RB at 26-28. In *Waltham,* however, the hearing examiner observed that the term "ruby" jewel, apparently a reference to color as opposed to ruby content, had a particular meaning in the industry and would not likely confuse the technical experts to whom the claims were directed. *Id.* at 1041. Here, by contrast, we find no reason for concluding that beauty professionals would interpret respondents' claims any differently than ordinary consumers—that use of the device prevents regrowth of hair. In any event, the record is clear that the permanency claims were passed on to ordinary consumers. IDF 38-44.

Representation That Respondents Had a Reasonable Basis For The Claim That Removatron Removes Hair Permanently

The complaint alleges that respondents represented directly or by implication that they possessed and relied upon a reasonable basis for their permanency and effectiveness claims. Complaint ¶¶ 6-7. Judge Hyun found that respondents made this reasonable basis representation. More specifically, he found that they expressly and impliedly claimed to have scientific evidence supporting their claims. IDF 63-64.

We adopt the finding that respondents represented directly and by implication that their advertising claims are supported by a reasonable basis. Moreover, we conclude, as did Judge Hyun, that respondents expressly represented that Removatron's effectiveness is supported by scientific evidence. IDF 63. We also find that respondents' ads and promotional materials contain implied representations of a scientific level of support, an issue the administrative court did not specifically address.[10]

To understand these conclusions, it is useful to keep in mind the different types of claims and the amount of substantiation they require. The first consists of "puffing" **[9]** claims for which neither the Commission nor the consumer would expect substantiation. *Thompson,* 104 FTC at 815 n.42 *citing Pfizer, Inc.,* 81 FTC 23, 64 (1972). Puffing claims are highly subjective, not capable of measurement and are not taken seriously. *Bristol-Meyers,* 102 FTC at 321; *Sterling Drug, Inc.,* 102 FTC 395, 749 (1983), *aff'd,* 741 F.2d 1146 (9th Cir. 1984), *cert. denied,* 470 U.S. 1084 (1985). An advertisement touting a foreign sports car as "the sexiest European," for example, fits into this category. *Bristol-Meyers,* 102 FTC at 321.

Puffing claims are distinguished from objective product claims. The latter contain affirmative information about a product's attributes, performance or efficacy and require some level of substantiation in support. *See Bristol-Meyers,* 102 FTC at 321; *Pfizer, Inc.,* 81 FTC 23, 64 (1972). In particular, as we stated in *Thompson,* objective product claims imply support by a reasonable basis. 104 FTC at 813. The Commission determines what level of substantiation constitutes a

[10] Judge Hyun concluded that the permanency representations are objective performance claims and as such imply that respondents possessed and relied on a reasonable *scientific* basis for support. IDF 64. We decline to adopt this finding. As discussed *infra,* simple objective performance claims, *e.g.,* "Removatron treatment is permanent," imply support by an *unspecified* (not necessarily scientific) reasonable basis. The precise amount and type of substantiation is determined by weighing several factors. By contrast, the claims at issue here contain express and implied representations that they are supported by scientific substantiation. The precise amount depends on the view of the relevant scientific community.

reasonable basis by weighing several factors set forth in *Pfizer* and subsequent cases. *Thompson,* 104 FTC at 813; *Bristol-Meyers,* 102 FTC at 321. However, if the ad contains express representations regarding the particular level of support that the advertiser has for the claim (*e.g.* "tests prove") or implies a particular level of substantiation to reasonable consumers application of the *Pfizer* factors is not required. The reasonable basis consists of the amount and type of substantiation the advertiser claimed to have. *Thompson,* 104 FTC at 813.

Applying these standards to the ads and promotional materials at issue, we find that the permanency representations are objective product claims representing expressly and by implication that they are supported by a reasonable basis. The key issue then is whether the claims contain express or implied representations of a scientific level of support requiring substantiation of that type and amount, *or* are simple efficacy claims for which the reasonable basis is determined by applying the *Pfizer* factors. Advertising that expressly or impliedly represents support by a scientific level of substantiation contains such words as "tested," "established," "here's proof" or "medically proven." *See Thompson,* 104 FTC at 814; *Bristol-Meyers,* 102 FTC at 321. It may also use visual aids that clearly suggest a scientific foundation. *Bristol-Meyers,* 102 FTC at 321 (citations omitted). *See also Porter & Dietsch, Inc.,* 90 FTC 770, 865 (1977), *aff'd,* 605 F.2d 294 (7th Cir. 1979), *cert. denied,* 445 U.S. 950 (1980), [hereinafter *"Porter & Dietsch"]* (statements such as "Laboratory Science has perfected a tiny pre-meal tablet..." "clinic tested ingredients" "medically recognized" implied both the existence of substantiation, and that it consisted of competent scientific proof). **[10]**

If an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth. *Thompson,* 104 FTC at 821-22 n.59; *Bristol-Meyers,* 102 FTC at 321, 331. In *Thompson,* for example, we found that three of the ads at issue expressly represented that efficacy claims had been scientifically proven. Two stated that the product was "tested," with one referring to "clinical tests," and the third claimed that Aspercreme's active pain reliever "is clinically proven." Because the representations referred to a scientific level of substantiation, we did not weigh the *Pfizer* factors. *Thompson,* 104 FTC at 814-15.

We find that most, if not all, of respondents' ads and promotional

materials expressly and impliedly promised a scientific level of substantiation. Respondents have expressly claimed that their device is "[C]linically tested and endorsed" (CX 1-26, 139(a), 706, 746); "clinically tested and shown superior" (CX 733(a)); and "MEDICALLY ENDORSED...GOVERNMENT APPROVED-TESTED" (CX 743). *See also* CX 179-1 (Removatron owners can receive "documented clinical testing" for $12.95). They have also proclaimed that "RESEARCH PROVES REMOVATRON METHOD DESTROYS HAIR FOLLICLE," (CX 179-1); that their training video demonstrates "Certified Medical Biopsies clinical testing on humans and animals..." (CX 179-4); that "case history" shows 30 percent destruction after the first treatment (CX 251-41, 68); and that "recent scientific technology" has produced the Removatron method. CX 149-2. Moreover, these and other ads and promotional materials provide specific information about papilla dehydration and coagulation, tissue destruction and follicle damage. *See, e.g.*, CX 1-6, 1-9, 1-20, 1-24, 1-25, 141-63-64, 52(a), 113(a), 132(a), 143-1-2, 704, 706, 746. Some ads also contain diagrams depicting the papilla, follicle and other important elements of the human hair. *See, e.g.*, CX 1-20, 141-25-26, 141-28-30, 141-33, 141-35-36, 148-16, 297.

We hold that references to clinical testing, research and case studies are express claims that the respondents' representations are supported by scientific evidence. *See Thompson*, 104 FTC at 814. In addition, the claims of tissue destruction, papilla dehydration and coagulation, together with the visual depiction of the hair's elements, provide a scientific aura and can reasonably be interpreted as implying a scientific level of support. *See Bristol-Meyers*, 102 FTC at 329. Accordingly, we find that the net impression of these advertisements and promotional materials is that respondents' claims were based on competent scientific proof. *See Bristol-Meyers*, 102 FTC at 321; *Porter & Dietsch*, 90 FTC at 865. Given this finding, we need not apply the *Pfizer* analysis in **[11]** determining the reasonable basis for respondents' claims. *See Thompson*, 104 FTC at 815 and 821-22 n.59.[11]

In summary, we find that respondents expressly and impliedly represented that their permanency claims were supported by compe-

[11] In *Thompson*, we did not undertake the *Pfizer* analysis in determining the appropriate level of substantiation for the three advertisements which expressly represented a scientific level of support. 104 FTC at 815. The remaining ads, however, were simple objective product claims that implied an *unspecified* reasonable basis as support. For these ads, we were required to conduct the *Pfizer* analysis to determine the appropriate level of substantiation. 104 FTC at 821 n.59.

tent scientific proof. Accordingly, in considering whether these claims are deceptive, we first determine the specific level of scientific proof required to substantiate the claims and then decide whether the respondents' substantiation meets this standard.

III. Did Respondents Possess Adequate Scientific Substantiation For Their Permanency Claims

Legal Standards

The ALJ determined that in the context of this case, the reasonable basis is nothing less than competent and reliable scientific tests. IDF 233. We agree but impose a higher standard, finding that the reasonable basis consists of adequate and well-controlled double-blind clinical testing. Our conclusion is based on the notion that where advertising expressly or impliedly represents that it is based on scientific evidence, the advertiser must have that level of substantiation, and, in particular, must satisfy the relevant scientific community that the claim is true. *Thompson,* 104 FTC at 813; *Bristol-Meyers,* 102 FTC at 321. Here, where respondents have represented that the claims are based on scientific evidence, we must determine whether the evidence they possessed meets the relevant scientific standards. In particular, as we stated in *Thompson,* complaint counsel was required: (1) to establish the particular evidence that would pass muster in the medical (or scientific) community for the types of claims made; and (2) demonstrate that the proffered substantiation failed to meet these standards. 104 FTC at 820. As we discuss below, complaint counsel satisfied this burden.

Requisite Scientific Proof

The record reflects no dispute as to the particular evidence required to show permanent hair removal. Dr. Eugene Van Scott, a **[12]** practicing dermatologist and researcher in dermatology, provided the only expert opinion on this issue.[12] His testimony was that the scientific community generally accepts the notion that preventing regrowth of hair requires complete and total destruction of the hair papilla. T. 931, 952. He testified that if the papilla is damaged and not completely destroyed, "from all the data that we have and all the clinical experience that we have, the hair will regrow." T. 953.

[12] Respondents find no fault whatsoever with Dr. Van Scott's qualifications as an expert on these issues. During oral agrument respondents' counsel acknowledged that Dr. Van Scott is a "well known, well qualified dermatologist" and an "eminent medical scientist." Argument on Appeal From Initial Decision at 12, *Removatron International Corporation,* D. 9200.

Respondents presented no evidence to contradict this conclusion. Indeed, its instructional handbook for device operators confirms that the papilla must be destroyed and even suggests that some additional damage to the surrounding tissue may also be required. CX 141-37-9.

Dr. Van Scott testified that only a "prospectively designed experiment," or other acceptable experiment with controls and few variables would, in his opinion, be "scientifically acceptable" to establish respondents' permanency claim. T. 958-59. In particular, his undisputed testimony suggests that only a controlled, blinded clinical study using human subjects would establish the efficacy of the Removatron device. T. 1064-68. Such a study would: (1) compare the results of Removatron treatment with a control treatment such as electrolysis or manual epilation (tweezing) on comparable sites on the human body (T. 1064-65); (2) take place over a nine-month period, with observation of the treated sites several times during the six-month period following treatment (T. 1065); (3) be undertaken by a "blinded" investigator who would either examine the treated areas without knowledge of the treatment employed or evaluate the results from close-up photographs with no association to the patient at all (T. 1067-68); and (4) include approximately ten human subjects with sufficient excess hair in the study population (T. 1066-67). *See also* ID 102. In Dr. Van Scott's view, one controlled study "would hopefully establish what one was looking for. Two would be more convincing...[and] preferable, and of course, three studies would be superb." T. 1068. He estimated the cost of an appropriate test using ten subjects over a nine-month interval at $40,000. T. 1069.

Dr. Van Scott's testimony that Removatron's effectiveness must be demonstrated with controlled clinical evidence is consistent with the Food and Drug Administration's ("FDA") treatment of RFE hair removal devices. Under the Medical Device **[13]** Amendments of 1976, Pub. L. 94-295, 90 Stat. 540 (1976), which established a medical device approval process, the FDA created multiple panels of experts to recommend proposed rules classifying such devices into various categories. Responsibility for RFE epilators[13] fell to the General and Plastic Surgery Device Classification Panel. The Panel recommended that these devices be classified in "Class III," requiring manufacturers to obtain pre-market approval to assure that they could demonstrate satisfactory performance, safety and efficacy. CX 6-9 (47 FR 2810,

[13] RFE epilators are considered medical devices under 21 U.S.C. 321(h) (West Supp. 1987) (definition of "medical device" includes products that affect the structure or function of the human body).

2844 (1982)). In determining that no substantial data existed to provide such assurance for RFE epilators, the Panel rejected materials submitted as substantiation for Depilatron, another RFE hair removal device. The rejected materials consisted of some of the same data submitted in this proceeding—articles, clinical evaluations, affidavits—which the Panel found did not amount to "convincing *clinical* and scientific evidence" demonstrating the efficacy of that device. CX 6-9 (47 FR 2844 (emphasis added)).

The FDA issued a proposed rule in accordance with the Panel's recommendations stating that the evidence did not support predictions of extensive cell damage upon application of an RFE device. CX 6-10 (47 FR 2845). The FDA further noted the absence of experimental evidence that would show destructive changes in the papilla or justify the inference that the papilla is permanently destroyed following tweezer contact. CX 6-10 (47 FR 2845). Although the FDA has not as yet promulgated a final rule requiring pre-market approval for RFE devices, its current medical device regulations require "valid scientific evidence" to substantiate their safety and efficacy. CX 816-8 (21 CFR 860.7(c)(1)). Valid scientific evidence consists of, among other things, data from well-controlled investigations or other studies from which qualified experts would conclude a device is effective and safe. CX 816-8 (21 CFR 860.7(c)(2)).[14] **[14]**

In sum, undisputed expert testimony, FDA's proposed rules for classifying RFE devices and its current regulations for substantiating the safety and efficacy of medical devices all support the finding that respondents were required to substantiate their claims with competent and reliable scientific tests showing total destruction of the papilla. IDF 106, 233. Both Dr. Van Scott's testimony and FDA regulations make clear that papilla destruction must be demonstrated by controlled clinical evidence. Accordingly, inasmuch as the appropriate reasonable basis for respondents' claims consists of the level of evidence that would pass muster in the scientific community, we find that respondents were required to possess evidence from controlled clinical testing showing complete obliteration of the papilla. We therefore examine the record to determine if respondents' substantiation constitutes the requisite scientific proof of papilla destruction.

[14] 21 CFR 860.7(c) defines "valid scientific evidence" as:

> evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls...reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of the device....

Existence of Scientific Proof

We note at the outset that respondents possess no clinical tests whatsoever that would substantiate their claims. Indeed, the Judge found, and we affirm, that respondents' substantiation did not rise to the level of competent and reliable scientific tests that would substantiate their claims. IDF 106, 233. In support of their claims, respondents offered testimony from satisfied Removatron users and scientific materials as substantiation. Judge Hyun found that the consumer testimony was entitled to little weight in evaluating the scientific validity of respondents' claims. IDF 210. *See also* IDF 97-98. We agree. These testimonials do not amount to valid scientific tests establishing Removatron's ability to destroy the papilla and permanently remove hair. *Firestone Tire & Rubber Co.*, 81 FTC 398, 463 (1972), *aff'd*, 481 F.2d 246 (6th Cir.), *cert. denied*, 414 U.S. 1112 (1973).[15] Moreover, anecdotal evidence, such as testimonials by satisfied patients or statements by doctors, does not constitute well-controlled clinical investigations. *Simeon Management Corp. v. FTC*, 579 F.2d 1137, 1143 (9th Cir. 1978) (citations omitted). *Cf. Thompson*, 104 FTC at 828 (individual testimony on behalf of product no substitute for factual evidence as a basis for objective product claims). **[15]**

Judge Hyun also found that respondents' "scientific" materials failed to substantiate their claims. IDF 106, 233. This evidence consists of: (1) one scientific study ("Foster Study"); (2) two experiments conducted by a non-expert ("Watriss tests"); (3) documentary material concerning Depilatron, another RFE-type hair removal device ("Depilatron" materials); and (4) scientific literature, testimonials from scientists and clinicians, and other miscellaneous documents. Judge Hyun dismissed this evidence as inadequate for various reasons (IDF 104-209), but most importantly because it did not constitute the requisite scientific proof that Removatron or any other RFE hair removal device caused complete destruction of the papilla. *See, e.g.*, IDF 107, 135, 141, 145, 159, 160, 167-68.

In addition, Judge Hyun accorded substantial weight to the FDA findings in its proposed rulemaking that the efficacy of RFE hair

[15] In *Firestone*, we defined a valid scientific test as:

> one in which persons with skill and expertise in the field conduct the test and evaluate its results in a disinterested manner using testing procedures generally accepted in the profession which best insure accurate results.

removal devices has not been substantiated with valid scientific evidence (IDF 224, 232) and to the fact that the FDA rejected some of the Depilatron documents respondents submitted as substantiation in this proceeding. IDF 177, 182, 226-27. He further found that even if the Depilatron materials could be considered reliable scientific evidence of Depilatron's effectiveness, they would not constitute substantiation here inasmuch as the evidence of similarity between the two devices was inconclusive. IDF 139, 141. Finally, insofar as respondents obtained most of the Depilatron materials after making the challenged claims, Judge Hyun concluded that such material did not constitute adequate substantiation because it was not possessed and relied upon prior to dissemination of the challenged advertising. IDF 104, 141.

Based on our review of the record, we agree that none of these materials separately or in combination constitutes the requisite scientific proof in support of respondents' claims. The Foster study, which is the only scientific test conducted on Removatron (IDF 107), was conducted by Charles Foster, M.D., an ophthalmologist, to determine whether the energy delivered by the device did in fact reach the hair root and damage it. T. 1527. *See also* IDF 111. In that experiment, the snout hairs of one group of mice were treated with Removatron for 69 seconds. A control group was given a sham treatment in which the hair was grasped by the tweezers without the current turned on. T. 1531. After treatment, Dr. Foster microscopically analyzed the treated hairs "blindly" without knowing which treatment had been employed. T. 1531. Dr. Foster concluded that one third of the specimens treated with Removatron exhibited some tissue damage to matrix cells adjacent to the papilla. T. 1541, 1545-46.

This study did not show complete obliteration of the papilla (T. 1054 (Van Scott); T. 1559 (Foster)) and is unreliable in other important respects. In particular, Dr. Foster himself testified that his experiment did not demonstrate permanent hair **[16]** removal. T. 1560. He also confirmed that his research failed to substantiate respondents' claims that Removatron destroys 30 percent of treated hair the first time or that it destroys the hair follicle. T. 1558-59. Indeed, he stated that his study did not show destruction at all—all it showed was "damage." T. 1559. Moreover, Dr. Van Scott, complaint counsel's expert, after reviewing the slides, concluded that the test did not establish

permanent hair removal. T. 1033[16] Finally, because the test was conducted on animals, not humans (IDF 123), and failed to employ a positive treatment control (IDF 124), its conclusions are inherently limited.

The Watriss tests are similarly deficient. In the first test, Ms. Watriss observed changes in photographs of treated human hairs, testifying that the distribution of sulfur and potassium within the hair shaft changed after treatment. T. 1810. In the second, radio frequency energy travelled down a hair shaft that was dipped into egg white and "cooked" the egg. CX 180-1. *See also* RB at 49. These tests are not controlled, blinded scientific studies. Moreover, they fail to support the efficacy of radio frequency in permanent hair removal, are not evidence of papilla damage and show nothing about Removatron's ability to remove hair permanently. T. 1030-32 (Van Scott).

We also affirm Judge Hyun's findings that the studies on the effectiveness of the Depilatron device failed to substantiate respondents' claims. IDF 140-87.[17] We find these materials **[17]** inadequate for several reasons. First, the record does not show that Depilatron and Removatron are sufficiently similar that Depilatron materials can be used to substantiate effectiveness claims for Removatron. Although the two machines operate at the same radio frequency and

[16] Dr. Van Scott testified that one slide made by Dr. Foster demonstrated destruction of a portion of the papilla, which respondents portray as confirming their reliance on the Foster Study. RB at 46. However, Dr. Van Scott also stressed that damage short of complete obliteration could be transient. T. 1054.

[17] The Depilatron material consists of the following documents: (1) Two tests conducted in 1975-76 by Dr. Van Scott (the FTC's expert) who at the time was a consultant to the company. After performing the tests, Dr. Van Scott concluded that Depilatron removal of hairs "as performed in this study does not cause permanent removal of hair any better than does simple manual epilation (tweezing)." IDF 144.

(2) The "Glass" documents include several letters and affidavits in which the author, who was a Medical Director of Depilatron, opines that Depilatron is a permanent method of hair removal. Dr. Glass based his opinion, among other things, on "research studies" and a review of tissue biopsies performed by a Dr. Kurt Stenn. Judge Hyun found these materials unreliable because: (a) they are mere opinion letters (IDF 147); (b) Dr. Stenn, author of the biopsies, believed that his analysis was an inappropriate scientific method and that clinical trials were required (IDF 149); (c) Dr. Glass inferred permanent hair removal from cellular and other damage to the hair follicle rather than from observing complete destruction of the papilla (IDF 149); and (d) Dr. Van Scott, after reviewing the biopsies, concluded that the damage or changes to cells did not indicate anything approaching complete destruction. IDF 151.

(3) The "Lever" documents are reports of Dr. Lever's observations of certain slides he received from Dr. Glass, some of which showed damage to the papilla. Judge Hyun found, relying on Dr. Van Scott's testimony, that none of the damage showed an absolute, complete eradication of the papilla. IDF 156, 159. Moreover, in one document, Dr. Lever confirms that "in order to establish permanency of the damage, clinical observation is necessary." IDF 157.

(4) The "Shiffman" documents are similar biopsy reports in which the author, Dr. Melvin Shiffman, stated that Depilatron causes thermal damage to the hair, including the papillary elements, internal and external root sheath. IDF 161-62. Dr. Shiffman opined that the damage is sufficient to prevent regrowth of hair. IDF 162. However, Dr. Shiffman failed to describe the extent of the damage he observed or whether that amount is enough to cause permanent hair loss, and his observations do not indicate that the papilla or any of its

have similar power outputs (RB at 44), there are also notable differences in design and operation. For example, unlike Depilatron, Removatron has an automatic power adjustment and coated tweezers. T. 1927, 1966.[18] Second, an FDA **[18]** panel reviewed much of the Depilatron materials and found that they did not substantiate the effectiveness of the device. IDF 226-27. Third, Dr. Van Scott's undisputed testimony establishes that none of the Depilatron materials shows complete obliteration of the papilla or establishes the efficacy of RFE epilators in general. T. 1027-28. Fourth, respondents obtained most of these materials after making the challenged claims (IDF 104), and they cannot therefore be considered pre-claim substantiation. *Pfizer*, 81 FTC at 64.[19]

Finally, the miscellaneous documents (scientific literature, testimonials from scientists) clearly do not even amount to scientific tests. IDF 193-209. These materials address such issues as energy flow to the papilla and thermal inactivation of cells but do not test the actual effects of Removatron treatment.

In summary, our review of the record confirms the findings that respondents produced no clinical tests to support their permanency claims. Accordingly, we find that none of respondents' substantiation materials constitutes the requisite scientific proof. The initial decision discusses all the evidence in painstaking detail, and we affirm Judge Hyun's numerous findings on these matters and his reliance on the **[19]** undisputed testimony of Dr. Van Scott. We also uphold his conclusion that the FDA's determination that RFE devices have not been proven effective is entitled to substantial weight. It is well settled that in establishing substantiation requirements, the Commission accords substantial weight to FDA regulations and proposed rules. *See*

[18] In *Pfizer*, the Commission suggested the conditions in which a respondent might be permitted to use a competitor's substantiation materials:

> The fact that apparently there did exist a valid efficacy test for a competing product of similar composition which was known to and verified by respondent, however, might have provided a reasonable basis for similar efficacy claims ....

81 FTC at 68. We adopt Judge Hyun's findings that the Depilatron materials would be rejected under this standard inasmuch as the evidence of similarity is inconclusive, and respondents failed to verify the Depilatron materials before making the challenged claims. IDF 140.

We also adopt the decision to exclude the so-called "Mehl" documents. Order dated February 13, 1987. Contrary to respondents' argument (RB at 40), the record lacks any evidence whatsoever that the Mehl device is similar to Removatron or that respondents verified these materials. Indeed, respondents' counsel conceded that respondents did not know of the Mehl documents until receiving them during this litigation. T. 2578.

[19] Respondents argue that Judge Hyun erroneously admitted certain Depilation materials on a limited basis as post-claim substantiation. RB at 36-39. We note, however, that the ALJ carefully considered all Depilation materials, concluding that none constituted valid substantiation for the permanency claims. IDF 141.

Thompson, 104 FTC at 828-29, *aff'd*, 791 F.2d 189, 193 (D.C. Cir. 1986).

In concluding that respondents lacked the requisite scientific basis for their claims, we reject the arguments to the contrary. First, respondents contend that the Commission must weigh the *Pfizer* factors in determining the appropriate level of substantiation. They argue that in failing to weigh these factors, Judge Hyun erroneously adopted a new, stringent substantiation standard requiring two clinical tests for any claim that a device can achieve a particular result. RB at 8. At the outset, we disagree that Judge Hyun adopted a new, stringent substantiation standard. Indeed, he expressly found that in the context of this case, a reasonable basis "is nothing less than competent and reliable scientific tests." IDF 233. Although the Judge made this finding without applying the *Pfizer* factors, this analysis is not required here where respondents' advertising expressly and impliedly represented that scientific proof existed. Respondents were required to possess the evidence they claimed to have in their ads, *i.e.*, scientific proof. In other words, respondents' substantiation had to consist of the precise type and amount of proof that would satisfy the relevant scientific community—in this case, clinical testing. *Thompson*, 104 FTC at 820; *Bristol-Meyers*, 102 FTC at 321.[20] **[20]** Our conclusion, that the reasonable basis for respondents'

[20] We note that application of the *Pfizer* factors, although not required in cases such as this where a specific type of substantiation is claimed, would result in a finding that respondents were required to possess one controlled double-blind clinical test to substantiate their claims. The *Pfizer* factors include (1) the product involved; (2) type of claim; (3) benefits of a truthful claim; (4) ease of developing substantiation; (5) consequences of a false claim; and (6) amount of substantiation experts in the field would agree is reasonable. *Thompson*, 104 FTC at 839-40. Our application of these factors, based on evidence in the record, leads to the following conclusions.

(1) *Type of product.* While not a drug or product that directly affects human safety where more substantiation may be properly required (where two tests *might* be required), the device certainly involves more than a purely cosmetic treatment (for which no clinical test might be required). This suggests that one clinical may be appropriate.

(2) *Type of claim.* Our prior cases have identified two types of claims requiring a high level of substantiation: (1) claims referring to specific facts and figures of a product's capabilities; and (2) claims whose truth or falsity would be difficult or impossible for consumers to evaluate by themselves. *Thompson*, 104 FTC at 822 (citations omitted). The record contains substantial evidence that the claims of permanent hair removal are difficult for consumers to evaluate themselves during the early course of treatments. *See, e.g.*, T. 960, 964-65, 967 (Van Scott). On the other hand, at some point consumers do realize the device is ineffective because the hair grows back. With analgesics, by contrast, the ability to evaluate a claim is often impossible because headaches may disappear on their own or the products, themselves, may have a placebo effect. On balance, consumers' limited ability to evaluate the permanency claims militates in favor of a one-clinical requirement.

(3)&(4) *Benefits of a truthful claim and ease of developing substantiation.* These two factors together seek to ensure that the level of substantiation we require is not likely to deter product development or prevent consumers from being told potentially valuable information about product characteristics. *See Thompson*, 104 FTC at 823. Here, the benefits of an RFE hair removal device that achieves permanent hair removal would be significant. The record certainly suggests that a market exists for an effective alternative to electrolysis which,

ads is determined by the express and implied representations in the ads themselves, renders many of respondents' additional contentions without merit. For example, respondents quote language from *Pfizer* that a reasonable basis consists of "such information as would satisfy a reasonable and prudent businessman, acting in good faith, that such representation was true." RB at 22 *citing* 81 FTC at 64. They argue that regardless of whether the proffered substantiation demonstrates permanent hair removal, in relying on it, the individual respondent acted reasonably and in good faith and thereby satisfied the reasonable basis requirement. RB at 22, 49, 57. The quoted language, however, has been taken out of context. The quote itself comes from *H.W. Kirchner*, 63 FTC 1282, 1294 (1963), *aff'd*, 337 F.2d 751, (9th Cir. 1964), and was repeated only to differentiate the reasonable basis standard being set forth in *Pfizer* from prior Commission law. Indeed,

for certain individuals, is painful and causes scarring. *See, e.g.*, T. 1991. *See also* IDF 216. However, the record is less clear as to whether the cost of requiring one or two well-controlled clinicals will deter development of alternative hair removal products. The ALJ found that the cost of one clinical test, $40,000, would be but a small portion of respondents' gross revenue, which he estimated at over $500,000 annually. IDF 8, 254. Compared to *Thompson*, where the company's annual sales were $6 million and the cost of conducting a clinical test was between $10,000 and $15,000, the cost here seems more substantial. Accordingly, this analysis suggests that requiring two clinicals could possibly deter product development, and that only one clinical should be required.

(5) *Consequences of a false claim.* This factor also supports a one-clinical requirement. Unlike the consequences of the claims in cases involving certain analgesics for which two clinicals were required ["*Analgesics* cases"], the record reflects no apparent side effects from using the Removatron device. Nor does the evidence show that consumers have foregone medical consultations or were in any manner harmed physically by using the product. Further, while the record clearly demonstrates that the problem of unwanted hair itself creates severe emotional and psychological distress, we find little support for the finding that use of the product has caused substantial emotional injury. IDF 249. Accordingly, the primary injury is financial. *See, e.g.*, IDF 238-246. This injury is substantial, however, inasmuch as purchasers paid on average $4000 for the Removatron machine, and consumers received weekly treatments at approximately $35 per hour over a period of years. In addition, consumers who may otherwise have used the electrolysis method are left with unwanted hair. Although we have required two clinicals where the consequences from false claims were purely economic (*Thompson*, 104 FTC at 824 (the Commission imposed a two-clinical requirement even though it found no health consequences from the false claim), in this instance, the economic consequences combined with other factors weigh against a two-clinical requirement.

(6) *Expert Opinion.* The final factor is the amount of substantiation experts agree is reasonable. Judge Hyun relied in part on the expert testimony and FDA regulations in imposing the two-clinical requirement. IDF 96, 103, 261. Both support a finding that the claims should be substantiated with well-controlled clinical evidence. Similarly, while not an expert on these issues, Dr. Foster's testimony supports a clinical testing requirement. T. 1551-52. None of this evidence, however, mandates a two-clinical standard. To our knowledge, the FDA has taken no position on the number of clinicals needed to substantiate claims for RFE devices. Nor does Dr. Van Scott's testimony suggest that the scientific community would necessarily require two clinicals to substantiate these claims. Indeed, we read his testimony as suggesting that only one clinical ought to be required. Thus, the record is insufficient to establish the number of clinicals that the scientific community agrees is reasonable. In *Thompson* and in the *Analgesics* cases, for example, both the FDA standards and the testimony of several experts established that a two-clinical requirement was the generally-accepted substantiation standard.

Therefore, our review of the *Pfizer* factors confirms the conclusion that respondents were required to possess one well-controlled blinded clinical study to substantiate claims that Removatron achieves permanent hair removal.

in *Pfizer*, the Commission made clear that the reasonable basis standard focuses in large part on the adequacy of the underlying evidence and is not solely a "reasonable man" test. Thus, the standard

> rounds out the *Kirchner* case [and] evaluates *both* the reasonableness of an advertiser's actions and the adequacy of the evidence upon which actions were based.

Pfizer, 81 FTC at 64. Thus, whether respondents acted resonably is not controlling. Instead, we consider whether the substantiation they possessed amounted to controlled clinical testing to support their claims. Since respondents possessed no clinical evidence demonstrating complete destruction of a papilla, their good faith in relying on the proffered substantiation is irrelevant.[21] **[23]**

In any event, the record disputes the notion that respondents acted reasonably or in good faith. The individual respondent Frederick E. Goodman failed to follow Dr. Foster's recommendation that a clinical study be conducted to test Removatron's effectiveness. T. 1552-53. The record suggests that Mr. Goodman also ignored the suggestion that he consult a pathologist to verify Dr. Foster's results. T. 1556. Moreover, respondents were on notice that the FDA objected to their permanency claims and had rejected the Depilatron materials as insufficient substantiation for the effectiveness of the device. IDF 229, 232. Thus, respondents' reliance on their substantiation cannot be considered reasonable or in good faith given what they learned from the FDA.[22] Finally, the finding that respondents' actions were deliberate (IDF 254), which we adopt, disputes their assertions of good faith.[23]

IV. Respondents' Advertising Violates the FTC Act

The Commission will find an act or practice deceptive if, first, there

[21] Cf. *National Dynamics Corp.*, 82 FTC 488, 553 (1973), *aff'd and remanded on other grounds*, 492 F.2d 1333 (2d Cir.), *cert. denied*, 419 U.S. 993 (1974) (certain claims were adequately substantiated where respondents relied in good faith on independent experts it had hired to evaluate the validity of the claims). Unlike the respondents in *National Dynamics*, respondents here did not seek the advice of any independent experts before making the challenged claims.

[22] Respondents object to the administrative court's reliance on an FDA Notice of Adverse Findings issued to them stating the FDA's objection to any claims that Removatron provides permanent hair removal. RB 41. We affirm the finding that the notice demonstrates that respondents knew or should have known that the permanency claims were suspect. IDF 229.

[23] Respondents present other arguments that are similarly unpersuasive. They dispute the finding that the Removatron and Depilatron devices are dissimilar, arguing that the Depilatron materials would alone constitute a reasonable basis for the claims (RB at 43-5); they contend that the Foster study is scientifically valid, and that Dr. Van Scott's testimony confirms its results (RB at 46); and they claim that Judge Hyun erroneously concluded that consumer testimony was inconclusive and accorded it insufficient weight. RB at 49-53. However, as we have already discussed, in the absence of any scientific basis whatsoever for their claims, these contentions are unconvincing.

is a representation, omission, or practice that, second, is likely to mislead consumers acting reasonably under the circumstances, and third, the representation, omission, or practice is material. *Southwest Sunsites, Inc. v. FTC,* 785 F.2d 1431, 1436 (9th Cir.), *cert. denied,* 107 S. Ct. 109 (1986); **[24]** *Cliffdale,* 103 FTC at 165. A claim is material if it involves information that is important to consumers and, hence, likely to affect their choice of or conduct regarding the product. *Cliffdale,* 103 FTC at 165. The Commission presumes as material express claims and implied claims pertaining to a product's purpose, safety, efficacy or cost. *Thompson,* 104 FTC at 817.

We have found that respondents' advertising and promotional materials represented first, that the Removatron device is effective in permanently removing hair, and second, that its permanency representations were supported by scientific proof—in this case clinical testing. We also find that these claims are material inasmuch as they pertain to the very purpose and efficacy of the product (IDF 65-67), and that respondents' proffered substantiation does not support its permanency claims. Accordingly, we uphold Judge Hyun's finding that respondents' failure to possess adequate substantiation renders their advertising false and deceptive in violation of Sections 5 and 12[24] of the FTC Act. IDF 233-34.[25]

V. Scope of Relief

The Commission has wide latitude in fashioning appropriate orders subject to two constraints. First, the remedy must bear a **[25]** reasonable relation to the unlawful practices found to exist. *FTC v. Colgate-Palmolive Co.,* 380 U.S. 374, 394-95 (1965); *FTC v. Ruberoid Co.,* 343 U.S. 470, 473 (1952); *Jacob Siegel Co. v. FTC,* 327 U.S. 608, 613 (1946). In ensuring that this relationship is reasonable, the Commission considers the deliberateness and seriousness of the violations, the respondent's history of violations, and the transferability of the unlawful practices to other products. *Thompson,* 104 FTC at

[24] Section 12 of the FTC Act prohibits "false advertising" of any food, drug or device, which is defined as advertising that is misleading in a material respect. 15 U.S.C. 55(a)(1). The definition of a Section 12 "device" includes any instrument, apparatus, or contrivance intended to affect the structure or function of the body. 15 U.S.C. 55(d). Inasmuch as Removatron transmits radio frequency energy to the human body in order to affect the tissue structure of human hair, we adopt the finding that it is a Section 12 device. IDF 6, 88. Accordingly, respondents' advertising, which we find to be misleading in a material respect, violates Section 12.

[25] Respondents also argue that this proceeding is not in the public interest but is a private dispute based on the complaint of a biased competitor. Further, they contend that Judge Hyun erred in excluding the testimony of a Commission employee on this issue. RB at 64, 66-67. However, Judge Hyun permitted respondents to introduce three documents and to call as a witness the competitor whose complaints allegedly instigated the case. IDF 255-58. Accordingly, we adopt the finding that the record discloses no basis for this allegation.

833 (citations omitted). Second, the order's provisions must be sufficiently clear and as precise as circumstances permit. *FTC v. Colgate Palmolive,* 380 U.S. at 393; *American Home Products Corp. v. FTC,* 695 F.2d 681, 705 (3d Cir. 1982).

The Administrative Law Judge's order contains several key provisions designed to prevent respondents from making false and deceptive hair removal claims without a reasonable basis. In particular, paragraph I.A. prohibits representations that any hair removal device, product or treatment will achieve permanent, long-term or effective hair removal unless respondents possess reliable scientific evidence consisting of at least two well-controlled, double-blind clinical studies. Paragraph I.B. prohibits representations that Removatron or any RFE device or treatment will remove hair unless respondents also affirmatively disclose that "[t]here is no reliable evidence that [the device or treatment] provides anything more than temporary hair removal."[26] Paragraph II prohibits respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or study. The order also requires respondents to send past purchasers a copy of the order and a notice not to rely on the prohibited advertising and promotional claims. They must also provide the order to future purchasers and obtain a signed form acknowledging receipt. Judge Hyun concluded that a broad order was appropriate, finding that respondents' violations were serious and deliberate, and that their unlawful practices are readily transferable to other hair removal products and devices. IDF 251-54.

Respondents appeal the imposition of a two-clinical substantiation standard and the decision to require an affirmative disclosure and notification provision. RB at 68-71. The clinical requirement, they argue, is inappropriate inasmuch as Removatron is a cosmetic product that does not affect health or safety. Moreover, they urge that Judge Hyun erred in not applying the *Pfizer* factors. Respondents also contend that the Judge failed to consider the legal requirements for corrective advertising in requiring the affirmative disclosure and notification provisions. Complaint counsel, on the other hand, urge the Commission to uphold the order in full. They argue that **[26]** respondents' violations were both deliberate and serious, and that the remedy fashioned by the administrative court is reasonably related to preventing similar unlawful conduct in the future.

We generally affirm the findings and conclusions concerning the

appropriate relief. The order we issue is identical to the order below in all respects except that we have changed paragraph I.A., the substantiation provision, and deleted paragraph III.B., requiring notification of future purchasers. The record evidence on the level of substantiation sufficient to satisfy the relevant scientific community consists of Dr. Van Scott's undisputed testimony that only a controlled, blinded clinical study using human subjects would establish the efficacy of the Removatron device. T. 1064-68. He testified that one such study "would hopefully establish what one was looking for. Two would be more convincing ... [and] preferable and, of course, three studies would be superb." T. 1068. Thus, at least one blinded clinical test is required.

Chairman Oliver and I would require respondents to possess only one clinical test. Commissioners Azcuenaga and Strenio would require that respondents possess two clinical tests. Inasmuch as two Commissioners would require one clinical test and two would require two clinical tests, this case does not resolve the issue of whether similarly-situated respondents should undertake one or two in like circumstances. Rather, the Commission reserves this question for future decision. Given an evenly-divided Commission on this issue, we order respondents to possess clinical testing as substantiation since the Commission is unanimous that at least one test is required under the circumstances of the instant case. We also affirm Judge Hyun's findings concerning the seriousness and deliberateness of respondents' violations. IDF 251-54. Accordingly, we modify paragraph I.A. of the order to require adequate and well-controlled double-blind clinical testing.[27] This substantiation requirement is the law of the case with reference only to respondents Removatron International Corporation and Frederick E. Goodman, with resolution of the ultimate decision for a future case.

In upholding the remaining provisions of the order, we also affirm the conclusion that the need for the affirmative disclosure and notification of past purchasers is "well-established in the record." IDF 262. These provisions are **[27]** designed to prevent future deceptive permanency claims, and, given the deliberateness and seriousness of the violations, are reasonably related to respondents' unlawful actions.[28] However, in view of these provisions, we have decided that

[27] Although we reject the contention that the administrative court erred by failing to apply the *Pfizer* analysis, we nevertheless have concluded that application of those factors produces this same result. *See* note 20, *supra.*

[28] We note that the order's affirmative disclosure requirement is triggered by claims that Removatron is able

(footnote continued)

notification of future purchasers is not necessary. Accordingly, although Judge Hyun included this requirement to prevent future purchasers from making the prohibited representations (IDF 266), we believe the order is sufficiently broad that it will produce this same result. Therefore, we have deleted paragraph III.B. of the order.

VI. Conclusion

For the reasons set forth above, we affirm the Administrative Law Judge's finding of liability and modify his initial decision and order as described.

Statement of Commissioner Mary L. Azcuenaga, Concurring in Part and Dissenting in Part

I concur in the finding of the majority that the respondents represented that the Removatron epilator removed hair permanently, and that those representations were unsubstantiated. I also agree that the respondents claimed to have evidence in the form of clinical testing to substantiate those permanency claims. But I do not agree that one controlled clinical test would provide sufficient substatiation for Removatron's permanency representations. I also dissent from the Commission's failure to require respondents to provide a copy of the order to future purchasers of the Removatron device. Finally, unlike the majority, I would not order respondents to continue to disclose that there is no reliable evidence that their device removes hair permanently even if they are able to produce such evidence at some future time.

Paragraph I.A. of the Administrative Law Judge's order would require respondents to have "at least two adequate and well-controlled, double-blind clinical studies" to substantiate claims that the Removatron epilator removes hair permanently. I agree that the final order in this case should require Removatron to have two clinical studies to substantiate permanency claims. That conclusion is based on my analysis of the six factors identified in *Pfizer, Inc.*, 81 FTC 23 (1972), and subsequent cases. Those six factors are: (1) the type of product advertised, (2) the type of claim, (3) the benefits of a truthful claim, (4) the cost of developing substantiation for the claim, (5) the

to remove hair, and therefore, it does not constitute corrective advertising. The latter requires disclosures in future advertisements regardless of the contents of those advertisements. *See American Home Products Corp. v. FTC*, 695 F.2d at 700 (3rd Cir. 1982). Accordingly, we are not bound by the more rigorous test for corrective advertising.

consequences of a false claim, and (6) the amount of substantiation that experts in the field would require. *Thompson Medical Co.*, 104 FTC 648, 821 (1984).

1. Type of Product

Because the primary purpose of the Removatron epilator is to alter and improve physical appearance, it is appropriate to describe it as a cosmetic device. But since that description apparently encompasses both mascara (to which respondents compare the Removatron device) and plastic surgery (to which complaint counsel compare it), it is too broad to be of much use in determining how much substantiation is required for claims for a particular product. A certain level of substantiation may be appropriate for one cosmetic product, while a different level may be appropriate for a different product.

The Commission's substantiation cases have involved a wide variety of products. Of all those products, the electric razors that were the subject of *Sperry Corp.*, 98 FTC 4 (1981), and **[2]** *North American Philips Corp.*, 101 FTC 359 (1983), seem most analogous to the Removatron product. In those cases, the Commission issued orders requiring substantiation in the form of two well-controlled clinical studies for claims that certain electric razors alleviated a skin condition known as "razor bumps."

2. Type of Claim

Our cases have identified two types of claims that require a high level of substantiation: those that refer to specific facts or figures, and those whose truth or falsity is difficult or even impossible for consumers to evaluate by themselves. *Thompson Medical*, 104 FTC at 822. This case clearly involves the latter type of claim.

Dr. Van Scott testified that he would be "very, very skeptical" of subjective assessments of the Removatron epilator's effectiveness by consumers. Temporary interruptions of the hair growth cycle may appear to be permanent, particularly if treatment continues at regular intervals. Many factors unrelated to removal treatment (including certain medications and hormonal changes related to aging or pregnancy) may affect the hair growth cycle. As in *Thompson Medical*, where the Commission required two tests, "it [is] hard for individual consumers to assess for themselves" whether changes in the number, color, or texture of hair in a treated area "is due to a particular treatment . . . or is a natural phenomenon." *Id.* at 823.

3. Benefits of a Truthful Claim

4. Costs of Developing Substantiation

These two factors, which are usually considered together, do not strongly indicate that either a one-test or two-test requirement is appropriate. An effective alternative to electrolysis would certainly provide consumers with benefits, but the relative significance of those benefits is difficult to quantify on this record. The cost of performing an additional test here has been estimated at $40,000. IDF 102. That amount is comparable to the costs in other cases where two tests have been required, although the cost of the second test here is relatively greater when compared to the respondent's actual revenues. Of course, the cost of a second test here is small in comparison to the potential revenues that Removatron might realize if the effectiveness of its device were clearly substantiated.

5. Consequences of a False Claim

If Removatron's claims prove to be false, the resulting harm is both emotional and financial. On this record, it is difficult **[3]** to quantify the emotional injury, but the financial injury is clear. Removatron treatments typically cost $30-40 per hour; some consumers have spent hundreds or even thousands of dollars on a series of treatments. IDF 241-245. The financial consequences of a false claim, therefore, are substantial.

6. The Opinion of Experts

Although the Food and Drug Administration has not yet issued a final regulation that states how many studies are necessary to demonstrate the safety and efficacy of hair-removal devices, the FDA does have a two-test standard for over-the-counter drugs. 21 CFR 314.111(a), 330.10(a)(4)(ii) (1988).

The only expert who testified on this issue, Dr. Van Scott, said that one test "would hopefully establish what one was looking for. Two would be more convincing . . . [and] preferable and, of course, three studies would be superb." Tr. 1068. While Dr. Van Scott did not completely reject the possibility that one test would be sufficient to substantiate Removatron's claims, his clear preference was for at least two tests.

Because several of the factors discussed above weight heavily in favor of a two-test order provision while none of them strongly

supports a one-test requirement, I would affirm the ALJ's decision to require two controlled clinical studies to substantiate any claims that the Removatron epilator removes hair permanently. I believe that paragraph I of the Commission's order, which requires "clinical testing" to substantiate claims that the Removatron epilator removes hair permanently, should be read as requiring respondent to possess and rely on at least two clinical tests before making such a claim.

The Commission's opinion states that the *Pfizer* analysis is "not required in cases such as this where a specific type of substantiation is claimed." Op. at 31 n.20. The Commission need not undertake the *Pfizer* analysis to decide whether Removatron's express and implied substantiation claims were true or false, but it is not clear that all of Removatron's advertisements and promotional materials included such claims.[1] It is appropriate, therefore, for the Commission to weight the factors identified in *Pfizer* and subsequent cases to determine "the appropriate level of substantiation for ads that do not expressly or impliedly claim a particular level of substantiation." *Thompson Medical,* 104 FTC at 822 n.59. Those factors are also relevant to the **[4]** Commission's determination of what level of substantiation Removatron should be required to possess before making permanency claims in the future. Although Dr. Van Scott's expert testimony is certainly something the Commission should consider before determining the appropriate scope of relief, I would not base that determination solely on Dr. Van Scott's opinion.[2]

Paragraph III.B. of the ALJ's order would have required Removatron to provide a copy of the Commission order in this case to each person who purchased one of its devices in the future. The Commission has decided to delete that requirement from its order because "notification of future purchasers is not necessary." The Commission has affirmed paragraph III.A. of the ALJ's order, which required respondents to provide to each past purchaser of the Removatron device a copy of the order and a notice directing him or her to stop distributing any promotional materials containing prohibited representations in order to prevent future misrepresentations by salon operators to their customers. Unless respondents are ordered to provide a copy of the order to salon operators who purchase the Removatron device in the future, those operators may unknowingly

[1] The Commission's opinion finds that "most, if not all" of those advertisements contained express and implied substantiation claims. Op. at 16.

[2] I agree with Commissioner Strenio that Dr. Van Scott's testimony indicates that two clinical tests would be the appropriate level of substantiation for Removatron's "establishment" claims.

make such misrepresentations. The cost of providing a copy of the Commission's brief order to each future purchaser is negligible, particularly in relation to the cost of the device, which is approximately $4000. IDF 22. I would not, therefore, delete paragraph III.B. from the order, although I would limit its duration to five years to make it consistent with paragraph I.B. of the order.

Finally, I would modify paragraph I.B., which requires Removatron to disclose in conjunction with any hair-removal claims it makes in the next five years that "[t]here is no reliable evidence" that the Removatron device "provide[s] anything more than temporary hair removal." What if Removatron produces two well-controlled clinical studies substantiating its permanent hair-removal claims next year, or the year after that? The Commission order would require Removatron to make the paragraph I.B. disclosure, even though that disclosure would no longer be true, until the five-year "sunset" period had run. And what if the FDA establishes standards for radio-frequency epilators before five years have passed, and Removatron's device passes FDA muster? The Commission order would still require Removatron's ads to state that "[t]here is no reliable evidence" for its claims even though the FDA had concluded that Removatron's device was effective. **[5]**

While Removatron could petition for a reopening and modification of the order if either of those events occurred, I believe the order itself should provide for such contingencies. I would amend paragraph I.B., therefore, to require the affirmative disclosure to be made for five years, until Removatron produced substantiation that satisfied the requirements of paragraph I.A., or until the FDA promulgates a standard (or an FDA advisory review panel issues a monograph) substantiating Removatron's claims,[3] whichever comes first.

[3] Paragraph I of the Commission's order in *Jerome Milton, Inc.*, D. 9187 (Oct. 27, 1987), contains such a provision.

STATEMENT OF COMMISSIONER ANDREW J. STRENIO, JR.
CONCURRING IN PART AND DISSENTING IN PART

With the exceptions noted below, I concur in the majority opinion and order. In particular, I agree respondents made unsubstantiated representations that the Removatron epilator removes hair permanently.

I also agree that even if within five years respondents should produce well-controlled clinical studies allegedly substantiating the permanent hair-removal claims, or if the Food and Drug Administration establishes standards which the Removatron device allegedly meets, respondents still should be required to state in advertisements that "[t]here is no reliable evidence" for the claims. In such circumstances, respondents may petition for a reopening of the proceeding to consider whether the order should be modified (as provided by Section 2.51 of the Commission's Rules of Practice). Adherence to this procedure will protect the public from additional unsubstantiated advertising while permitting respondents to secure such relief as is justified.

In addition, I agree with the majority that where advertising is of the "establishment" variety,[1] respondents are required to possess proof that would satisfy the scientific community. Application of the *Pfizer* factors is not required with respect to establishment claims.[2]

However, I dissent in two regards from Commissioner Calvani's opinion in which Chairman Oliver concurs. First, I read Dr. Van Scott's testimony as indicating that two—not one—clinical tests would be the preferable level of proof for the scientific community. Second, I agree with Commissioner Azcuenaga, for the reasons expressed in her separate statement, that respondents should be required to rely upon at least two well-controlled clinical tests for any "non-establishment" claims that the Removatron epilator removes hair permanently.

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[1] Establishment claims are those for which advertisers assert they have scientific proof. Non-establishment claims are those for which advertisers do not make such an assertion. *See Bristol-Myers Co.*, 102 FTC 21, 321 (1983).

[2] *See Thompson Medical Co.*, 104 FTC 648, 813 (1984) ("If the advertisements contain express representations regarding a particular level of support that the advertiser has for the product claim (*e.g.*, 'tests prove') or when the ad implies to reasonable consumers that the firm has a certain level of support, the Commission expects the firm to have that level of substantiation. If the ad does not expressly or impliedly refer to a particular level of substantiation, the Commission determines the adequacy of the advertiser's existing substantiation using a number of factors—such as the ease of obtaining substantiation or the cost of a false claim—identified in *Pfizer, Inc.*, 81 FTC 23 (1972) and subsequent cases.").

FINAL ORDER

I.

It is ordered, That respondents Removatron International Corporation, a corporation, its successors and assigns, and its officers, and respondent Frederick E. Goodman, individually and as an officer of Removatron International Corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacture, labeling, advertising, offering for sale, sale or distribution of the Removatron epilator or any other hair removal device, as "device" is defined in the Federal Trade Commission Act, or other hair removal 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, that:

A. Any such hair removal device or other hair removal product, or any treatment employing any such device, will or may achieve permanent hair removal or hair removal on a long-term and not temporary basis, or is otherwise effective, using those words or words of similar import or meaning, unless, at the time of the making of such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates such representation; provided, however, that for purposes of this order, "competent and reliable scientific evidence" is defined as adequate and well-controlled, double-blind clinical testing conforming to acceptable designs and protocols and conducted by a person or persons qualified by training and experience to conduct such testing.

B. The Removatron device or any other RFE tweezer-type epilation device or any treatment employing any such device is intended to or is able to remove hair, using those words or words of similar import or meaning, unless the representations clearly and conspicuously disclose the following statement:

"IMPORTANT: There is no reliable evidence that [name of device treatments] provides anything more than *temporary* hair removal"; provided, however, that in any written materials this disclosure shall be in typeface at least as large as the largest typeface in the label, advertising, or any document, and in any multipage documents the disclosure shall appear on the cover or first page, and provided further that this provision shall terminate after five (5) years from the date on which this order

C. The Removatron device or any other RFE tweezer-type epilation device, or any treatment employing such device, is FCC-approved, using those words or words of similar import or meaning, unless the representations clearly and conspicuously disclose that the FCC has only approved the use of a certain radio frequency by such device and has not approved the safety or effectiveness of such device or the safety or effectiveness of any treatment employing such device.

II.

It is further ordered, That respondent Removatron International Corporation, a corporation, its successors and assigns, and its officers, and respondent Frederick E. Goodman, individually and as an officer of Removatron International Corporation, and respondents' agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacture, labeling, advertising, offering for sale, sale or distribution of the Removatron epilator or any other hair removal device, as "device" is defined in the Federal Trade Commission Act, or other hair removal product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or study.

III.

It is further ordered, That respondents shall, within ninety (90) days after the date of service of this order, send by first-class mail, a copy of this order and a notice that the purchaser shall immediately cease using any Removatron advertising or promotional materials containing representations prohibited by parts I and II of this order, to each purchaser of any of respondents' hair removal devices since January 1, 1976, who is identifiable from respondents' sales records, testimonial letters, mailing lists or other documents containing an address or telephone number for that purchaser. Such advertising and promotional materials include, but are not limited to, any writing, audio tape or other material which employs such words as "permanent," "effective," "forever," "long-term," or "works," or which compares the device to electrolysis or distinguishes it from temporary hair removal devices or products.

IV.

It is further ordered, That respondents, their successors and assigns, shall maintain for at least three (3) years from the date of the last dissemination of each representation which is subject to this order, and make available to the Federal Trade Commission upon request, complete and accurate records demonstrating compliance with this order, including but not limited to the following:

A. Advertisements and labeling and promotional materials for any hair removal device or other hair removal product, and such records as will show when and where each advertisement was published;

B. Tests, studies, surveys, affidavits, letters, complaints, articles or other materials substantiating, contradicting, or otherwise relevant to the validity of any such representation;

C. Such business records as will demonstrate notification to purchasers pursuant to paragraph III of this order; and

D. Sales invoices or such other business records as will disclose the name, address, and date of purchase for each purchaser of a hair removal device from respondents.

V.

It is further ordered, That respondents shall distribute a copy of this order to all present and future personnel, agents and representatives having sales, advertising, or policy responsibilities with respect to the subject matter of this order and that respondents shall secure from each person a signed and dated statement acknowledging receipt of said order.

VI.

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

VII.

It is further ordered, That, for a period of ten (10) years from the

date of service of this order, the individual respondent shall promptly notify the Commission of the discontinuance of his present business or employment and of his affiliation with a new business or employment involving the advertising, offering for sale or sale of any hair removal device or other hair removal product, or any treatment employing such device or other product, and with each such notice include his new business address and a statement of the nature of the business or employment in which he is newly engaged as well as a description of his duties and responsibilities in connection with such business or employment.

Commissioners Azcuenaga and Strenio concurring in part and dissenting in part.