

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of)	
)	
MID-SOUTH PCM GROUP, P.C.,)	FILE NO. 962 3279
EYE AND VISION CLINIC, P.C., and)	
INTERNATIONAL COMPUTERIZED)	
ORTHOKERATOLOGY SOCIETY, INC.,)	AGREEMENT CONTAINING
corporations, and)	CONSENT ORDER
)	
J. MASON HURT, O.D.,)	
individually and as an officer)	
of the corporations.)	

The Federal Trade Commission has conducted an investigation of certain acts and practices of Mid-South PCM Group, P.C. (“Mid-South”), Eye and Vision Clinic, P.C. (“Vision Clinic”), and International Computerized Orthokeratology Society, Inc. (“ICOKS”), corporations, and J. Mason Hurt, O.D., individually and as an officer of the corporations (“proposed respondents”). Proposed respondents, having been represented by counsel, are willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

1.d. Proposed respondent J. Mason Hurt, O.D., is the sole owner and President of the corporate respondents. He formulates, directs, and controls the policies, acts or practices of the corporate respondents. His principal office or place of business is the same as that of the corporate respondents.

2. Proposed respondents admit all the jurisdictional facts set forth in the attached draft complaint.

3. Proposed respondents waive:

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

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of sixty (60) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondents, in which event it will

7. Proposed respondents have read the attached draft complaint and consent order. They understand that they may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

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

1. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
2. "Clearly and prominently" shall mean:
 - A. In a television or video advertisement, the disclosure shall be presented simultaneously in both the audio and video portions of the advertisement. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The video disclosure shall be of a size and shade, and shall appear on the screen for a duration, sufficient for an ordinary consumer to read and comprehend it.
 - B. In a radio advertisement, the disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it.
 - C. In a print advertisement, the disclosure shall be in a type size, and in a location, that are sufficiently noticeable so that an ordinary consumer will see and read it, in print that contrasts with the background against which it appears. In multipage documents, the disclosure shall appear on the cover or first page.
 - D. In an advertisement on any electronic media received by consumers via computer, such as the Internet's World Wide Web or commercial on-line computer services, the disclosure shall be in a type size, and in a location, that are sufficiently noticeable so that an ordinary consumer will see and read it, in print that contrasts with the background against which it appears. In multi-screen documents, the disclosure shall appear on the first screen and on any screen containing ordering information.

Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement.

3. “Refractive vision deficiency” shall mean any vision deficiency treatable by corrective lenses, including but not limited to nearsightedness (myopia), farsightedness (hyperopia), astigmatism (distorted vision), and presbyopia (aging eyes).
4. “Substantially similar service” shall mean any ophthalmic service or procedure using contact lenses or similar devices to modify the shape of the cornea and reduce or eliminate refractive vision deficiencies.
5. Unless otherwise specified, “respondents” shall mean Mid-South PCM Group, P.C., Eye and Vision Clinic, P.C., and International Computerized Orthokeratology Society, corporations, their successors and assigns and their officers; J. Mason Hurt, O.D., individually and as an officer of the corporations; and each of the above’s agents, representatives and employees.
6. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

I.

IT IS ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division, or other device, including franchisees or licensees, in connection with the advertising, promotion, offering for sale, sale, or distribution of Precise Corneal Molding (“PCM”) services or any substantially similar service, in or affecting commerce, shall not represent, in any manner, expressly or by implication, that:

- A. Such service provides a cure for any refractive vision deficiency thereby permanently eliminating the need for all corrective eyewear, including eyeglasses and contact lenses;
- B. All people can achieve normal vision without eyeglasses or contact lenses on a permanent basis if they wear devices used with such service occasionally or at night;
- C. Such service has been approved by the Federal Aviation Administration and all branches of the United States military for use in correcting refractive vision deficiencies; or
- D. Studies at the University of Houston College of Optometry (1976-77), University of California at San Diego Medical School (1980), University of California at Berkeley College of Optometry (1982-83), and Pacific University College of Optometry (1984), prove that such service is safe and effective in correcting nearsightedness, farsightedness, and astigmatism.

II.

IT IS FURTHER ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division, or other device, including franchisees or licensees, in connection with the advertising, promotion, offering for sale, sale, or distribution of PCM ortho-k services or any substantially similar service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about:

- A. The number of people who can achieve normal vision without eyeglasses or contact lenses on a permanent basis if they wear devices used with such service occasionally or at night;
- B. The number of people who will experience stabilized vision after only a few weeks or months of treatments under such service;
- C. The ability of such service to prevent or reverse deteriorating nearsightedness in children;
- D. The comparative safety of such service and contact lenswear;
- E. The comparative effectiveness of such service and refractive surgical methods in eliminating nearsightedness, farsightedness, or any form of astigmatism; or
- F. The number of people whom such service has helped achieve normal vision;

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

III.

IT IS FURTHER ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division, or other device, including franchisees or licensees, in connection with the advertising, promotion, offering for sale, sale, or distribution of any service, procedure, or product in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions or interpretations of any test, study, or research.

IV.

IT IS FURTHER ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division, or other device, including franchisees or licensees, in connection

with the advertising, promotion, offering for sale, sale, or distribution of any service, procedure, or product in or affecting commerce, shall not represent, in any manner, expressly or by implication, that such service, procedure, or product is endorsed or approved by any governmental or professional organization or association, or complies with or meets standards or guidelines for such services, procedures, or products established by any such organization or association, unless such is the case.

V.

IT IS FURTHER ORDERED that respondents, directly or through any partnership, corporation, subsidiary, division, or other device, including franchisees or licensees, in connection with the advertising, promotion, offering for sale, sale, or distribution of any service, procedure,

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

VII.

IT IS FURTHER ORDERED that respondents shall:

- A. Not disseminate to any optometrist or eye care provider any material containing any representations prohibited by this order;
- B. Send by certified mail, return receipt requested, an exact copy of the notice attached hereto as Attachment A to each optometrist or eye care provider with whom respondents have done business since January 1, 1994, within thirty (30)

VIII.

IT IS FURTHER ORDERED that respondents Mid-South, Vision Clinic, and ICOKS, and their successors and assigns, and respondent J. Mason Hurt, O.D., shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation;

B.

IT IS FURTHER ORDERED that respondent J. Mason Hurt, O.D., for a period of five (5) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current businesses or employment, or of his affiliation with Mid-South, Vision Clinic, or ICOKS, or of his affiliation with any new business or employment. The notice shall include the respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580.

XII.

IT IS FURTHER ORDERED that respondents Mid-South, Vision Clinic, and ICOKS, and their successors and assigns, and respondent J. Mason Hurt, O.D., shall, within sixty (60) days after the date of service of this order, and one year thereafter, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XIII.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

Signed this _____ day of _____, 1997.

MID-SOUTH PCM GROUP, P.C.,

By: _____
J. MASON HURT, O.D.
President

EYE AND VISION CLINIC, P.C.,

By: _____
J. MASON HURT, O.D.
President

INTERNATIONAL COMPUTERIZED
ORTHOKERATOLOGY SOCIETY, INC.,

By: _____
J. MASON HURT, O.D.
President

J. MASON HURT, O.D., individually
and as an officer of the corporations

JOHN L. RYDER
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Attorney for respondents
Attorney for respondents

Christa Van Anh Vecchi
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APPROVED:

Dean C. Graybill
Associate Director for
Service Industry Practices
Bureau of Consumer Protection

CONCUR:

Joan Z. Bernstein, Director
Bureau of Consumer Protection

Attachment A

BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED

[To Be Printed on International Computerized Orthokeratology Society, Inc. letterhead]

[date]

Dear [optometrist or eye care provider]:

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of)	
)	
MID-SOUTH PCM GROUP, P.C.,)	DOCKET NO.
EYE AND VISION CLINIC, P.C., and)	
INTERNATIONAL COMPUTERIZED)	
ORTHOKERATOLOGY SOCIETY, INC.,)	
corporations, and)	
)	
J. MASON HURT, O.D.,)	
individually and as an officer)	
of the corporations.)	

COMPLAINT

The Federal Trade Commission, having reason to believe that Mid-South PCM Group, P.C., Eye and Vision Clinic, P.C., and International Computerized Orthokeratology Society, Inc., corporations, and J. Mason Hurt, O.D., individually and as an officer of the corporations ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

1. Respondent Mid-South PCM Group, P.C. ("Mid-South") is a corporation formed under the laws of the state of Tennessee, with its principal office or place of business located at 2865 Summer Oaks Drive, Bartlett, TN 38134.
2. Respondent Eye and Vision Clinic, P.C. ("Vision Clinic") is a corporation formed under the laws of the state of Tennessee, with its principal office or place of business located at 2865 Summer Oaks Drive, Bartlett, TN 38134.
3. Respondent International Computerized Orthokeratology Society, Inc. ("ICOKS") is a corporation formed under the laws of the state of Tennessee, with its principal office or place of business located at 2865 Summer Oaks Drive, Bartlett, TN 38134.
4. Respondent J. Mason Hurt, O.D., is the sole owner and President of the corporate respondents. He formulates, directs, and controls the acts and practices of the corporate respondents, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of the corporate respondents.

5. Respondents are engaged, and have been engaged, in the promotion, offering for sale, sale, and distribution to the public of ophthalmic services, including orthokeratology (“ortho-k”) or “Precise Corneal Molding” (“PCM”) services, which involve the use of a series of contact lenses purportedly to reshape the cornea gradually for the treatment of myopia (or "nearsightedness"), hyperopia (or "farsightedness"), and astigmatism. The contact lenses used in these PCM ortho-k services are “devices,” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

6. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

7. In the course and conduct of their business, respondents have disseminated or have caused to be disseminated advertisements or promotional materials for the purpose of promoting the sale of PCM ortho-k services. Respondents advertise and promote their services through the use of print advertisements, radio and television advertisements, internet advertisements, free consultations, videos, brochures, and pamphlets, which are provided to patients and prospective patients, and some of which are provided to other optometrists for distribution under their own name to patients and prospective patients. Respondents' advertisements and promotional materials include, but are not necessarily limited to, attached Exhibits A through H.

8. The advertisements and promotional materials referred to above, including but not necessarily limited to attached Exhibits A-H, contain the following statements:

A. **"21st Century Eyecare"**

“Saturday 10 a.m. - 12 p.m. ET

It sounds too good to be true -- a safe, non-surgical alternative to restore clear vision safely, gently, and permanently.

In a modest departure from ordinary talk radio, Talk America will air a new program featuring an emerging national network of eye doctors who are performing a new, non-evasive (sic), non-surgical corrective vision procedure that reshapes the cornea, much like (sic) braces straighten teeth. It’s called 21st Century Eyecare....

thirty years. Orthokeratology involves reshaping the cornea by fitting patients with a series of special hard contact lenses, each having a slightly different curve. Orthokeratology was limited by the older technology of the lenses and the difficulty in precisely monitoring and controlling the reshaping process.

Send Email Directly to Dr. Hurt and Sam Cooper.”

(Exhibit A) (Internet Ad)

B. "Precise Corneal Molding (PCM): Your Clearest Choice, Your Greatest Freedom"

“...In many cases, just a matter of days to weeks frees the majority of the patients from their dependence upon eyeglasses or contacts during daytime hours.

...By slight modification in the shape of the cornea, clear functional vision may be restored to the individual.

Recently several surgical procedures have been developed to attempt to accomplish the same purpose. However, their limited success has been due to the effects off (sic) scarring, irregular healing and most importantly, its temporary effect....In addition, the surgical scars cause surface irregularities on the cornea, resulting in permanent blurring that even glasses or contacts cannot eliminate. Molding avoids those complications since there is not injury to any eye tissue. The soft cornea simply reshapes itself to fill the mold. The mold is similar to a contact lens in its appearance and sensations upon wearing. The mold is worn while sleeping and/or while awake. The procedure takes just hours in mild cases to a few months in very difficult cases to reach good functional vision. The mold is worn regularly until the best vision is achieved and the cornea is allowed to stiffen in its new shape. At that point the mold wearing is gradually reduced until a minimal wear time is established that maintains that shape and good functional vision. This guarantees continued clarity without the gradual blurring that usually accompanies the surgery. Therefore, the cornea can easily be fine tuned the rest of ones (sic) life by minor modification in the retainer mold.

...PCM opens new horizons to everyone regardless of age, occupation, or ability to wear contact lenses in the past.

PCM is safe, reliable and inexpensive. PCM gives you a cure, not a maintenance of your visual handicap....”

(Exhibit B) (Patient Handout)

C. **"Precise Corneal Molding"**

“....‘I shifted from soft contact lenses to PCM and I can see 20/20 when I take them off!’ -- T.K

‘I have been through the program and I am very happy with the results. I’m taking my daughter in for Precise Corneal Molding, too!’ -- A.S.

....

COMPARE

PCM is a safe, gentle, affordable, non-surgical alternative for wearers of glasses.

	Surgery	PCM
Age as a limiting factor	Yes	No
Reversibility	No	Yes
Loss of work time	Yes	No
Worsening of night vision	Yes	No
FAA and military approval	No	Yes

What is PCM?

Imagine being able to easily read an alarm clock without your glasses, see street signs clearly, or participate in sports without lenses of any kind....

....Because the procedure is non-invasive, PCM has provided thousands of patients with better vision without the risks or complications of surgery.

....PCM utilizes a series of prescription eye molds to reshape the cornea much like orthodontists use braces to straighten teeth....

....The benefits are realized in weeks or months, depending on the severity of vision problems. Retainer molds will be used on a limited basis to maintain the new shape of the cornea.

Since 1962, PCM and its predecessor, Orthokeratology, have been used to help pilots, athletes and others requiring unaided vision. Now, new research developments such as computerized corneal topography and new mold designs and materials have established PCM as the eye care trend of the future.

The Safest Option

In contrast to Radial Keratotomy and laser surgery, PCM does not require injury to the eye, resulting in glare-inducing scars. There is also no disruption of vision as eyesight improves.

PCM for Children

One of the most exciting uses for PCM is controlling nearsightedness in children....PCM prevents deteriorating vision and even reverses it.

Proven Safe Results

PCM is highly effective in correcting nearsightedness, farsightedness and astigmatism....University research studies have shown corneal molding to be safe and effective. These studies include The University of Houston College of Optometry (5 years), University of California at San Diego Medical School (7 years), University of California at Berkeley College of Optometry (3 years), and Pacific University College of Optometry (5 years).”

(Exhibit C) (Patient Handout)

D. “

To eliminate vision disorders, surgical procedures have been developed and introduced but with limited results. In the 1960's, before the popularity of soft contact lenses, an ortho-keratology procedure was developed that could actually reshape the cornea of the eye and caused improved vision for a limited time.

The procedure was accepted by the FAA, a department of the Federal Government that regulates the airline industry....

In 1992, Dr. J. Mason Hurt, an optometrist, perfected a process called Precise Corneal Molding or PCM. With PCM, patients who had previously worn glasses or contact lenses were able to see without the use of either and without surgery. Here is why.”

DR. J. MASON HURT, O.D. (*perfected P.C.M. process*): “Corneal molding is very safe and effective, and I would like to show you why (*standing in front of diagram of the eye*). The cornea or the clear window that we see through is very soft and is subject to change. It changes its shape on a very regular basis....

The cornea wants to change shape. Now we just guide it to the shape we would like for it to have, and we do that by building a mold which will rest (*draws on diagram*) in the zone where we are having our shape problems, and we can reshape this cornea in a fashion very similar to wearing of contact lenses in a safe, nonsurgical, noninvasive technique that we call Precise Corneal Molding.”

STEVEN FENSLER, *Computer Programmer*: “....And for the past two years, I had been wearing reading glasses along with my contacts so that I could read pages, and then I was getting very tired. Been on molds for seven months, and I don't use my reading glasses anymore at all, either with my contacts or without them. I can see everything at work I want to see....”

PEGGY COLLINS, *College Coordinator*: “You can see. It does correct your vision....There is no surgery, there is no blood....Just little contacts in your eyes, you sleep with them at night....I recommend it.”

....

CONNIE BRADEN, *Homemaker*: “Scott [her son] had broken his glasses at school, and we came to get his eyes checked, and his eyes had gotten so bad in just a few months that I was told that he would have to have glasses changed every six months. So we started with the contacts, and within one week, he could see 20/20.”

CRAIG JARRELL, *Oriental Rug Sales*: “For anyone that has problems seeing, I would recommend it to all my friends that wear glasses; they need to come up here and get this done. It’s just great to be able to take contacts out and still be able to see.”

....

ANN POSEY, *School Teacher*: “...my vision had just gotten so bad, and I couldn’t wear contacts any more, didn’t like wearing glasses, wasn’t wanting to have any type of surgery....Knowing that my vision is going to be 20/20 all the time is just really exciting....”

....

JACKIE GREENE, *Sales Manager*: “I heard about this procedure and it really sounded too good to be true. But I am so excited about it now because I’ve probably had the procedure maybe six weeks, and already, within six weeks, I can drive my van without any corrective lenses whatsoever....”

....

DR. HURT: [*explains the PCM procedure to a patient by using the map of her cornea*] “...As we keep it centered, all of these [*pointing to various parts of the cornea*] will mold away. So we are going to be able to mold away your astigmatism as well as your nearsightedness. And as we end up with this pink, what I call smiley face down here, then you will have your bifocal as well....”

....

ANN POSEY, *School Teacher*: “Number one, it is wonderful to be able to wake up in the morning and to open my eyes and to see everything around me with no contacts in, nothing in, just to be able to open them up and to see....Number two, there is such security knowing financially that later in life I am not going to have to buy more glasses, change my prescriptions, get more prescription sun glasses. I am not going to have to lose a contact and find it or anything like that. I know that my vision, I am going to be able to see. And that is just wonderful.”

....

NARRATOR: “...Now, through Precise Corneal Molding you can see clearly day or night and continue to see clearly for the rest of your life without depending on glasses or contact lenses....”

....

JACKIE GREENE, *Sales Manager*: “I am very excited about this procedure, because it will work for children and I have four kids of my own. And for them not to have to go through what I went through in the third grade, if any of them for any reason has a vision problem and needs corrective lenses, they will definitely get this procedure.”

....

ELLYN BENGAL, *bookkeeper*: “I have been doing this about a year now....If for some reason I need my glasses, I have to hunt for them up now....But mostly, I don't wear, you know, hat

- F. NARRATOR: “Thousands of men, women and children all over the country are experiencing the gift of improved vision without glasses or contact lenses. Precise Corneal Molding, three words that will change the way you see the world. Precise Corneal Molding is a safe, gentle, nonsurgical, affordable procedure that corrects nearsightedness and farsightedness.

PCM eliminates the need for glasses and contact lenses forever. The PCM practitioner in your area is offering you a free Precise Corneal Molding consultation. All you have to do is call 1-800-305-5030. The call is free, and the improved vision without glasses or contact lenses is well, priceless....”

(Exhibit F) (Short Video Promotion)

- G. **"Precise Corneal Molding Success Stories: From the offices of J. Mason Hurt, O.D."**

“PCM is wonderful! I can see clearly now, even when Scuba Diving. Before PCM, I had Poor Vision. Yet with PCM, I went back to 20-20, without surgery. I am so excited that I tell everyone about the benefits of PCM.’

Peggy Collins, College Co-Ordinator.

‘PCM is like a Miracle. It’s hard to believe I can see so well without glasses and without Surgery. I would recommend PCM to anyone who is Near-Sighted, Far-Sighted or has Astigmatism.’

Sara Ann Nichols, Systems Analyst

‘Before PCM, my son Scott had to change glasses every six months. Yet after PCM, he could see 20-20 within one month.’

Connie Braden, Housewife.

‘Before PCM, I could hardly see my computer monitor, and for the last two years, I wore both contacts and glasses. After PCM, I can see clearly and I am very happy.’

Steven Fensler, Computer Programmer.”

(Exhibit G)

- H. **“WELCOME TO THE PCM TEAM”**

“....

PCM is virtually problem free, and there is no risk. It is safer than contact lens wear. Unlike surgery, there is no such thing as mistakes. Nothing that may be

induced by molding cannot be undone and fixed. If illness or extenuating circumstances occur, this only delays for a short time the final success of PCM....

A SAFE ALTERNATIVE TO RK SURGERY

In contrast to radial keratotomy surgery, which involves making incisions on the eye, PCM does not leave scar tissue which may cause vision glare at night or other side effects. PCM is also free of surgical complications or pain, and there is no disruption of vision as eyesight improves.

SAVING CHILDREN'S VISION

One of the most exciting uses for PCM is controlling myopia (nearsightedness) in children.

....PCM prevents this deteriorating vision in children by actually halting myopia in its tracks and even reversing it.

RESULTS

Myopia (nearsightedness): PCM is highly effective in improving myopia. Mild to moderate degrees of myopia are corrected and higher degrees of myopia can be controlled to allow functional vision without lenses as well.

Astigmatism: PCM usually either eliminates or greatly reduces astigmatism to great functional clarity.

Hyperopia (farsightedness): Mild to moderate cases may be improved as well.

NATURAL VISION IMPROVEMENT

....

....The procedure, which is also known as PCM, has provided corrective eye care to thousands of patients without the risks or complications associated with surgery.

....PCM utilizes a series of molds prescribed in progressive stages to gently reshape the cornea, similar to the way braces are used to straighten teeth.

The PCM procedure involves thorough examinations, lens changes and/or lens modifications as needed until desired results are achieved. The process can take from a few weeks to a few months or longer to complete, depending on the

severity of the problem. The result is dramatically improved vision with retainer molds being worn on a limited basis, sometimes only a few nights a week while you are sleeping, to maintain the new shape of the cornea.

SAFETY

10. In truth and in fact,
- A. PCM ortho-k does not provide a cure for any refractive vision deficiency thereby permanently eliminating the need for all corrective eyewear, including eyeglasses and contact lenses.
 - B. All people cannot achieve normal vision without eyeglasses or contact lenses on a permanent basis if they wear PCM ortho-k devices occasionally or at night.
 - C. PCM ortho-k has not been approved by the Federal Aviation Administration and all branches of the United States military for use in correcting refractive vision deficiencies.
 - D. Studies at the University of Houston College of Optometry (1976-77), University of California at San Diego Medical School (1980), University of California at Berkeley College of Optometry (1982-83), and Pacific University College of Optometry (1984), do not prove that PCM ortho-k is safe and effective in correcting nearsightedness, farsightedness, and astigmatism.
 - E. Testimonials from consumers appearing in the advertisements for respondents' PCM ortho-k services do not reflect the typical or ordinary experience of members of the public who receive those services, which experience is that respondents' PCM patients typically achieve 20/20 vision and no longer need corrective eyewear.

Therefore, the representations set forth in Paragraph 9 were, and are, false or misleading.

11. Through the means described in Paragraph 8, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9 A - B, at the time the representations were made.

12. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9 A - B, at the time the representations were made. Therefore, the representation set forth in Paragraph 11 was, and is, false or misleading.

13. Through the means described in Paragraph 8, respondents have represented, expressly or by implication, that:

- A. A significant number of people can achieve normal vision without eyeglasses or contact lenses on a permanent basis if they wear PCM ortho-k devices occasionally or at night.
- B. All or most people will experience stabilized vision after only a few weeks or months of PCM ortho-k treatments.
- C. PCM ortho-k prevents and reverses deteriorating nearsightedness in children.
- D. PCM ortho-k is safer than contact lenswear.
- E. PCM ortho-k is more effective than refractive surgical methods in eliminating nearsightedness, farsightedness, and all forms of astigmatism.
- F. PCM ortho-k has helped thousands of people achieve normal vision.

14.

ANALYSIS OF PROPOSED CONSENT
ORDER TO AID PUBLIC COMMENT

The Federal Trade Commission has accepted, subject to final approval, an agreement to a proposed Consent Order ("proposed order") from Mid-South PCM Group, P.C., Eye and Vision Clinic, P.C., the International Computerized Orthokeratology Society, Inc., and J. Mason Hurt, O.D., the sole owner and President of the corporations.

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

Paragraph I of the proposed order prohibits proposed respondents from claiming that PCM ortho-k, or any substantially similar service (defined as any ophthalmic service or procedure using contact lenses or similar devices to modify the shape of the cornea and reduce or eliminate refractive vision deficiencies): (1) provides a cure for any refractive vision deficiency thereby permanently eliminating the need for all corrective eyewear, including eyeglasses and contact lenses; and (2) has been approved by the Federal Aviation Administration and all branches of the United States military for use in correcting refractive vision deficiencies. Paragraph I further prohibits proposed respondents from representing that: (1) all people can achieve normal vision without eyeglasses or contact lenses on a permanent basis if they wear devices used with PCM ortho-k or any substantially similar service occasionally or at night; and (2) four named University studies prove that PCM ortho-k or any substantially similar service is safe and effective in correcting nearsightedness, farsightedness, and astigmatism.

Paragraph II of the proposed order prohibits proposed respondents from making any representation for PCM ortho-k, or any substantially similar service, about: (1) the number of people who can achieve normal vision without eyeglasses or contact lenses on a permanent basis if they wear devices used with such service occasionally or at night; (2) the number of people who will experience stabilized vision after only a few weeks or months of treatments under such service; (3) the ability of such service to prevent or reverse deteriorating nearsightedness in children; (4) the comparative safety of such service and contact lenswear; (5) the comparative effectiveness of such service and refractive surgical methods in eliminating nearsightedness, farsightedness, or any form of astigmatism; and (6) the number of people whom such service has helped achieve normal vision, unless, at the time the representation is made, proposed respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Paragraph III of the proposed order prohibits proposed respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Paragraph IV of the proposed order prohibits proposed respondents from representing that any service, procedure, or product is endorsed or approved by any governmental or professional organization or association, or complies with or meets standards or guidelines for such services, procedures, or products established by any such organization or association, unless such is the case.

Paragraph V of the proposed order prohibits proposed respondents from representing that the experience represented by any user testimonial or endorsement of any service, procedure, or product represents the typical or ordinary experience of members of the public who use the

service, procedure, or product, unless the representation is true, and competent and reliable scientific evidence substantiates that claim, or respondents clearly and prominently disclose either: (1) what the generally expected results would be for program participants; or (2) the limited applicability of the endorser's experience to what consumers may generally expect to achieve, that is, that consumers should not expect to achieve similar results.

Paragraph VI of the proposed order prohibits proposed respondents from making any representation about the relative or absolute efficacy, performance, benefits, safety, or success of any ophthalmic service, procedure, or product purporting to treat, mitigate, or cure any refractive vision deficiency, unless the representation is true and, at the time the representation is made, proposed respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Paragraph VII of the proposed order requires that proposed respondents: (1) not disseminate to any optometrist or eye care provider any material containing any representations prohibited by the order; (2) send a required notice to each optometrist or eye care provider with whom proposed respondents have done business since January 1, 1994 requesting that the optometrist cease using any materials previously received from proposed respondents that contain any claims violative of the order, informing the optometrist of this settlement, and attaching a copy of this proposed complaint and order; (3) in the event that proposed respondents receive any information that subsequent to receipt of the required notice any optometrist or eye care provider is using or disseminating any advertisement or promotional material that contains any representation prohibited by the order, immediately notify the optometrist or eye care provider that proposed respondents will terminate the optometrist or eye care provider's right to market and/or perform PCM ortho-k if he or she continues to use such advertisements or promotional materials; (4) terminate any optometrist or eye care provider about whom proposed respondents receive any information that such person has continued to use advertisements or promotional materials that contain any representation prohibited by the order after receipt of the required notice; and (5) for a period of three (3) years following service of the order, send the required notice to each optometrist or eye care provider with whom proposed respondents do business after the date of service of the order who has not previously received the notice; the notices shall be sent no later than the earliest of: (1) the execution of a sales or training agreement or contract between proposed respondents and the prospective optometrist or eye care provider; or (2) the receipt and deposit of payment from a prospective optometrist or eye care provider of any consideration in connection with the sale of any service or rights associated with PCM ortho-k. The mailing shall not include any other documents.

Paragraph VIII of the proposed order contains record keeping requirements for materials that substantiate, qualify, or contradict covered claims and requires the proposed respondents to keep and maintain all advertisements and promotional materials containing any representation covered by the proposed order. In addition, Paragraph IX requires distribution of a copy of the consent decree to current and future officers and agents. Further, Paragraph X provides for Commission notification upon a change in the corporate respondents. Paragraph XI requires

proposed respondent J. Mason Hurt, O.D. to notify the Commission when he discontinues his current business or employment and of his affiliation with any new business or employment. The proposed order, in paragraph XII, also requires the filing of a compliance report.

Finally, Paragraph XIII of the proposed order provides for the termination of the order after twenty years under certain circumstances.

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