IN THE IOWA DISTRICT COURT FOR POLK COUNTY

STATE OF IOWA ex rel. THOMAS J. MILLER, ATTORNEY GENERAL OF IOWA, 99AG25112 Plaintiff , vs. NEW WOMYN, INC. and DAN KAISER, Defendants.	)	EQUITY NO. CE-39318 AFFIDAVIT OF DR. STEPHEN BARRETT

1. I, Dr. Stephen Barrett of Allentown, Pennsylvania, being first duly sworn on oath, depose and state as follows:

2. I submit this declaration as an expert in the fields of quackery, “alternative medicine,” health fraud, peer review, and the analysis of unusual health claims. I intend this declaration to serve as expert testimony on the matters set forth herein. All opinions rendered herein are my professional and expert opinion, as consistent with my special knowledge, skill, training, education, and experience.

3. I have been asked by Investigator Barbara Blake of the Consumer Protection Division of the Iowa Department of Justice to review Paragraph 9 (a)-(d) of the Petition and Application to Enforce Civil Investigative Demand filed in the above-captioned matter. I have been asked to assume that the alleged representations as set forth below were made for a device called

"Stimulations VII" that was to be used by persons to enhance breast size. I have been further asked to express an opinion regarding the amount of substantiation experts in the field would agree is reasonable for the types of claims set forth below.

4. The claims set forth in the Petition are:

(a). That Stimulations VII will permanently grow breast tissue;

(b.) That Stimulations VII will cause breast enlargement of 2, 3 or even 4 cup sizes;

(c.) That Stimulations VII has been scientifically proven safe and effective for breast enlargement;

(d.) That Stimulations VII will regrow breasts that have been removed via mastectomy.

BACKGROUND AND EXPERIENCE

5. I have thorough grounding in the nature of science, the scientific method, and the evaluation of scientific data. I graduated from the Bronx High School of Science in New York City and completed my premedical and medical education at Columbia University. During this time, I received extensive training in scientific subjects, including medical statistics. This, plus 35 years of experience in professional practice and more than 25 years of experience in investigative journalism, editing, and consulting with experts, enables me to evaluate scientific studies and to form reliable opinions of claims made in the

health marketplace. A true and correct copy of my curriculum vitae is attached hereto as Exhibit A.

6. My basic training and extensive practical experience in evaluating medical literature enable me to judge whether most studies I review are soundly designed and properly reasoned.

7. Since the early 1970s, I have spent considerable amounts of time gathering and evaluating information about nonstandard health-care approaches. (Today these methods are commonly referred to as "alternative" methods.). My efforts have culminated in editing or co-authoring 47 books, 10 textbook chapters, and hundreds of articles in lay and scientific publications. I also maintain five Web sites containing more than 500 articles related to making intelligent decisions about health matters.

8. My expertise in judging the quality of health information, particularly with respect to nonstandard methods, has been recognized in many ways:

(a) I am a member of the peer-review panels of three of the word's most prestigious medical journals: the Journal of the American Medical Association (JAMA), the New England Journal of Medicine, and the Annals of Internal Medicine. 1998, I reviewed more JAMA submissions related to "alternative" topics than any other external reviewer. In 1999, the Annals of Internal Medicine gave me a letter of commendation stating: "The quality and timeliness of your reviewing ... placed the work you did for us in the top 10% of

all reviews in 1999." A copy of that letter is attached as Exhibit B.

(b) I am an editorial board member of the Internet's most prestigious medical Web site (Medscape) and its peer-reviewed scientific journal (MedGenMed).

(c) I am an editorial board member of the Scientific Review of Alternative Medicine, (a peer-reviewed journal) and serve a scientific and/or editorial advisor to many other health-related organizations and publications.

(d) My Quackwatch Web site has won more than 50 honors and awards. U.S. News & World Reports has rated it one of the top three medical sites. The Journal of the American Medical Association has listed it as one of nine "select sites that provide reliable health information and resources."

(e) I was the principal author of the American Medical Association's 1993 book "Alternative Health Methods," which is an annotated bibliography of more than 1000 published studies.

(f) I prepared several of the American Cancer Society's position papers on questionable methods of cancer management and co-edited a book on this subject published by the Society's Florida division.

(g) Consumers Union, publisher of Consumer Reports, used me as a consultant on quackery for 25 years. I was the

primary author of its book on quackery published in 1990, entitled “Health Schemes, Scams and Frauds.”

(h) In 1998, I served on a National Institutes of Health Special Emphasis Panel that evaluated proposals for research grants related to “alternative medicine.” This involved judging the experimental design of about 50 proposed studies as part of a team of about 30 experts.

(i) I receive frequent invitations and have delivered more than 100 lectures at colleges, universities, medical schools, hospitals, and professional meetings.

(j) I have participated as a consultant during regulatory actions by the U.S. Food and Drug Administration, the Federal Trade Commission, the U.S. Postal Service, and the attorneys general of several states.

(k) My college textbook “Consumer Health: A Guide to Intelligent Decisions,” is widely respected as the best book of its type for college and postgraduate health education. The sixth edition was published in December 1996 and the seventh is being prepared.

(l) I am included in Marquis “Who’s Who in America” and will receive the Distinguished Service to Health Education Award from the American Association for Health Education in 2001.

THE SCIENTIFIC METHOD: HOW FACTS ARE ESTABLISHED

9. Reliable health information comes primarily through using the scientific method, a procedure for exposing hypotheses (assumptions) to critical examination and testing. It provides an objective way to collect and evaluate data. Findings must not be contaminated by the personal beliefs, perceptions, biases, values, wishful thinking, or fraudulent conduct of the researcher. Scientific research requires proper sampling techniques, the highest possible accuracy of measurement or observation, and appropriate statistical analysis of the findings.

10. Personal experiences and testimonials should be given very little credibility in judging the value of a health-related method. Well-documented observations may provide impetus for scientific study. However, they should not be regarded as definitive evidence of value.

11. Controlled clinical trials offer the most credible evidence. These compare an experimental group of people who receive the treatment being tested and a control group of people who receive a different treatment or no treatment. For example, members of the experimental group may be exposed to a device, while those in control group are not. Studies may be conducted "blind" or "double-blind" to minimize or eliminate the effect of bias on data collection and interpretation. In blind studies, the participants do not know which treatment they receive. In double-blind studies, neither the people administering the treatment nor the experimental subjects know who gets what. If

separate treatment and control groups are used, care must be taken to ensure that they are comparable to begin with.

12. Reputable scientists strive to publish their findings in peer-reviewed journals so that scientific knowledge can advance. Properly written reports include enough detail to enable them to be judged and be reproducible by others.

SPECIAL CONSIDERATIONS FOR BREAST-ENLARGEMENT STUDIES

13. Many pills, potions, creams, and devices have been claimed to enlarge the breast. To date, no product marketed for this purpose has been demonstrated to work as advertised. If a device could actually regrow a removed organ or section of the body, the inventor would make headlines everywhere, win the Nobel Prize in Medicine, and become a billionaire.

14. It is a basic principle of science that extraordinary claims require extraordinary evidence. For this reason, testing of an alleged breast-enlargement product should include many safeguards to ensure that any “before and after” differences are due neither to chance nor to other factors such as observer bias, variability of body weight, measurement variations, postural variations, and variability or shifting of body fluid content. The design features that should be considered include:

(a) The measurement process should be properly standardized, recorded, and judged. Standardization would involve determining how breast size can be reliably measured. The measurements must be made in

the same way each person each time. All measurements should be made at the same time of day. The measuring tape or other instrument must be applied with the same tension each time. The individual's posture and position should not vary. Since chest circumference changes when people breathe in and out, the measurement should take place at the same phase of the respiratory cycle. The measurements should be recorded, and the process should be documented with videotapes and/or photographs.

(b) Water retention and excretion can cause weight to fluctuate throughout each day and also in connection with the menstrual cycle. Measurements should be made often enough to detect and compensate for any such variation. Frequent measurements would be desirable for this purpose—daily at first and later biweekly.

(c) Lifestyle changes should be recorded. Since overall fat-reduction through dieting and exercise can influence breast size, weight should be monitored and the extent of diet and exercise should be recorded.

(d) The experiment should be long enough to be meaningful. To document a claim that breast enlargement is likely to be permanent, several years of follow-up study would be needed.

(e) Observer bias could result in deliberate or unknowing measurement variations. For this reason, the observers should not know whether or not the people they measure

are using the product. Further blinding can take place by preventing the observer from seeing the identity of the subjects they measure.

15. The claim of regrowth of a removed breast is so extraordinary that it would not be credible unless witnessed and photographed by several independent observers, with safeguards against fraud.

16. I have reviewed Patent #6,042,537 issued on March 28, 2000, to Daniel Kaiser and do not find it persuasive. The concepts it discusses are largely based on other tissues and don't apply to the breast. The document does not describe any experiments in which Mr. Kaiser's apparatus or a similar device was found to influence breast size. It merely claims that when human cells are sufficiently stressed, they will increase in size and their external structure will also deviate to accommodate any vacuum or negative force applied to the cell. Even assuming that this is true of cells, it would be irrelevant to use of Mr. Kaiser's Simulations VII. .

17. Applying a vacuum to the outside of the breast might slightly stretch tissue on the surface, but it will not change the shape of cells below the skin. Stretching tissue can cause fluid build-up, similar to what happens with hormonal change during the menstrual cycle. A device might temporarily stretch the skin of the breast, but in order to achieve true enlargement, the glandular and fatty tissue inside must increase. This can only occur with cell growth in either number or size. Glands grow in response to hormones. There is no

preferential way to grow fatty tissue in this location. Growth of fibrous tissue does not enlarge the breasts. I don't see how the a vacuum device would result in long-term changes to the breast that will increase its size. There may be some short-term changes in the skin, but they are unlikely to be permanent.

Stephen Barrett, M.D.

Subscribed and sworn to before the undersigned this 18th day of December, 2000.

Notary Public

NOTARIAL SEAL
JASON M. FRETTI, NOTARY PUBLIC
ALLENTOWN, LEHIGH COUNTY
MY COMMISSION EXPIRES JUNE 28, 2004