DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

IN THE MATTER OF

A RULEMAKING PROCEEDING

CONCERNING LAETRILE

) ) Docket No.

AFFIDAVIT OF STEPHEN BARRETT, M.D.

County of Lehigh ) ss
Commonwealth of Pennsylvania ) ss

Before me personally appeared Stephen Barrett, M.D., who being first duly sworn, deposes and says:

1. I am a physician, licensed to practice in the Commonwealth of Pennsylvania.

2. I received a Bachelor of Arts Degree from Columbia University in 1954 and a Doctor of Medicine Degree from Columbia College of Physicians and Surgeons in 1957.

3. I completed a three year psychiatric residency at Temple University Hospital in 1961 and have been in the private practice of psychiatry (psychotherapy of adults and children) since 1963.

4. I have been a Staff Psychiatrist at Allentown State Hospital since 1967, Psychiatrist at Allentown Hospital Psychiatric Clinic since 1968, and a Psychiatrist at Muhlenburg Medical Center since 1971, on a part-time basis.

5. My Curriculum Vitae and Bibliography is attached hereto as Exhibit 1. It provides a summary of my education, training, and experience, a list of my publications, and a list of my memberships on committees concerned with the subjects of quackery and health fraud, including the
Pennsylvania Medical Society's Committee on Quackery and the Committee on Health Fraud of the Pennsylvania Health Council.

6. Since 1970 I have been Chairman of the Board of Directors of the Lehigh Valley Committee Against Health Fraud, Inc., an independent, non-profit Pennsylvania corporation formed to combat deception in the field of health. The purposes of this Committee are:

   a. To investigate false, deceptive or exaggerated health claims;
   b. To conduct a vigorous campaign of public education;
   c. To assist appropriate government and consumer-oriented agencies;
   d. To bring problems to the attention of lawmakers.

7. The Lehigh Valley Committee Against Health Fraud, Inc., opposes "legalization" of Laetrile (also known as amygdalin or "Vitamin B-17") whether by court order or by legislation. Proponents of Laetrile (and other such unproven remedies) have failed to convince scientific evaluators that their products work. Having failed to do so, they are trying to gain respectability by political means — by turning to courts and legislative bodies. Labeling their products "harmless nutrients" or "vitamins", they suggest that people should be free to get them if they so desire. However, Laetrile is not a vitamin — and it appears that by "harmless", its promoters mean it won't kill you on-the-spot. Laetrile is harmful because many cancer patients use it instead of effective treatment.

8. I am co-editor of a book entitled "The Health Robbers — How To Protect Your Money and Your Life", (The George F. Stickley Co., Philadelphia, Pennsylvania 1976). This book is a comprehensive expose of health quackery with each of the 24 chapters written by an acknowledged expert on his or her specialty. Two chapters from "The Health Robbers" which discuss cancer quackery in general and Laetrile in particular are attached hereto as Exhibit 2.
9. In my capacity as co-editor of "The Health Robbers" and as a member of the committees on quackery and health fraud on which I serve, I have spent a great deal of time studying the promotional politics of many types of questionable and unproven "health" matters. One subject of particular interest has been phony cancer "cures". From the viewpoint of a psychiatrist, I can state that cancer patients often become desperate and are easily misled. Laetrile (or amygdalin or "Vitamin B-17" as it is also called) leads today's list of all forms of cancer quackery. There is no scientific evidence that Laetrile is safe and effective as a primary or adjunctive treatment for cancer, and Laetrile's backers have not even been able to prove that it can control cancer in animals.

The "evidence" supporting Laetrile is based merely upon stories of people supposedly cured by it. However, such evidence is not reliable. Many cancer patients have given testimonials, believing themselves cured, only to discover later that they still have the disease. Some people who believe that Laetrile cured them never had cancer to begin with. Other reports originate from patients who used ineffective methods together with good medical care but are misled into thinking that the ineffective method is what helped them. These cancer "cures" often receive promotion and support through the media via mass circulation newspapers and magazines and from radio and television talk shows. Thus, unable to prove its scientific merit, proponents of Laetrile are attempting to gain respectability through the media and by political means -- by turning to courts and legislative bodies. In the case of desperate cancer patients, any form of legalization of Laetrile or amygdalin will make it still easier to mislead them as such patients will use Laetrile instead of known, effective treatment. Any psychological "benefits" in these "apparently hopeless" cases are far outweighed by the disastrous results of using Laetrile instead of effective treatment.
10. Laetrile (amygdalin) is now banned in the United States by laws which require that no substance be marketed until proven safe and effective. These laws are designed to protect all of us. "Popularity" or "public demand" should not be allowed to replace scientific experimental evidence as the standard of proof for "alleged" cancer remedies. Nor should our society allow the pockets of those who make false claims to be lined by the money and lives of the unfortunates who fall for such claims. Incurable cancer patients who waste their life's savings on false hopes such as Laetrile, and potentially curable patients who die from delay of proper treatment by electing instead to use Laetrile, are victims of quackery at its cruellest. In conclusion, there is a mandatory need for regulatory action, both on the Federal and State levels, to protect persons afflicted with cancer.

Stephen Barrett, M.D.

Subscribed and sworn to by the said Stephen Barrett, M.D., before me this 14th day of March, 1977.

Cynthia J. Bishop, Notary Public

Cynthia J. Bishop, Notary Public
Lehigh County, PA.
My Commission Expires March 14, 1978