

CONSUMERS UNION / A NONPROFIT ORGANIZATION / PUBLISHER OF CONSUMER REPORTS  
Washington Office: 1714 MASSACHUSETTS AVE., N.W. WASHINGTON, D.C. 20036/202-785-1906

March 25, 1977

Hearing Clark  
Food and Drug Administration  
Room 4-65  
5600 Fishers Lane  
Rockville, Maryland 20857

VERIFIED COMMENTS  
LAETRILE

Dear Sir or Madam:

These are the comments of Consumers Union of United States, Inc. on the laetrile issue in response to the call for these comments by HEW as published in the Federal Register of February 13, 1977.

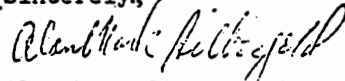
1. Safety and efficacy: Consumers Union knows of no scientifically controlled data published in a reputable medical literature attesting to the efficacy of laetrile. In addition, the question of safety has never been satisfactorily resolved by adequate testing in animals or humans.

2. Probability of class inclusion under "grandfather" clause because of use prior to Kefauver Amendment of 1962: Laetrile has never been officially sanctioned by the Food and Drug Administration on the basis of safety data. Proponents marketing it for use by cancer patients have claimed it is, variously, an anti-cancer drug, a vitamin and an analgesic. Yet, the purported mechanism of action of laetrile is entirely theoretical and is senseless to scientific scrutiny. Allegations that it is a vitamin are false and misleading. The "active ingredient"--amygdalin--has no known function in human physiology or biochemistry. Its action as an analgesic has never been validated.

Consumers Union contends that approval of laetrile for use as an anti-cancer drug would devastate the carefully structured consumer protection drug laws enacted in modern times. Moreover, such approval would undermine consumer confidence in federally monitored health programs and, in effect,

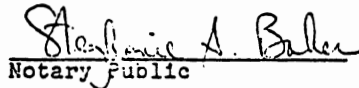
open the door to the legitimization of quackery. The rationale for the use of laetrile as a placebo for the terminally ill cancer patient is faulty and stands in violation of basic patient rights against being duped and offers a false sense of hope.

Sincerely,



Alan Mark Silbergeld  
Acting Director, Washington Office

Subscribed and sworn to before  
me this 25th day of March, 1977.



Notary Public

My Commission Expires March 31, 1979