IN THE UNITED STATES DIS..ICT COURT

WESTERN DISTRICT OF OKLAHOMA

GLEN L. RUTHERFORD, individually and on behalf of a class composed of terminally ill cancer patients	)	
Plaintiffs,	)	VERIFIED STATEMENT OF T. E. BYERS
vs.	)	
UNITED STATES OF AMERICA, JOSEPH A. CALIFANO, JR. Secretary of Health, Education, and Welfare, and DONALD KENNEDY, Commissioner of the Food and Drug Administration	)	
Defendants.	)	

1. I am the Associate Director for Compliance of the Bureau of Drugs of the United States Food and Drug Administration. As such I am the senior official in the bureau responsible for regulation and enforcement actions relating to drugs. I have read the Opinion and Order of December 5, 1977, in this proceeding and have been asked for my opinion concerning its regulatory and public health significance.

2. In my opinion the District Court's findings are disasterous. Unless stayed they will unleash a torrent which threatens to inundate cancer victims, their loved ones, and all Americans who are frightened by and concerned about cancer in a torrent of Laetrile. The penchant of Laetrile advocates to promote the drug by whatever means are effective to persuade the desperate, frightened, and gullible can be expected to result in wholesale representation that the federal judiciary approves Laetrile and has declared it safe for use. Desperate people who have or think they have cancer will be induced to use the drug. In all probability many will rely on Laetrile and delay or avoid swift treatment with effective modalities. Some will die from their avoidance or proper treatment. Others may be poisoned by cyanide.

3. The inability of federal health authority to stop international and interstate traffic in Laetrile by employing the premarketing approval mechanism of the new drug provisions of the law will result in general availability of the drug to anyone who has been persuaded or frightened into trying it. This would appear to be the result of the Court's order which prevents FDA from interferring with "any per " who traffics in the drug on the ground that it is not the subject of an approved new drug application.

4. While it is true that FDA still has the misbranding provisions of the law, whether we may rely on those to regulate Laetrile effectively is conjectural. The District Court found that anyone who wants to use Laetrile has a constitutional right to import or cause it to be imported and then shipped in interstate commerce. If we were to attempt to cleanse the market of Laetrile by charging, for instance, that its labeling is misleading, or that it fails to bear adequate directions for use, it would appear that FDA might be in contempt of the District Court's order.

5. Even assuming we were able to rely upon the misbranding provisions, most of those provisions merely purport to require that certain information such as the name of the manufacturer and a description of ingredients appear on the label. Most important, however, is that the burden of protecting patients is turned upside down. Under the new drug provisions manufacturers and sellers have the burden of proving their products are safe and effective or showing that they are generally so recognized. In a misbranding case FDA has the heavy burden of proving the articles are misbranded. It is beyond our resources to try more than a handful of such cases at a time. Since the Court's order lifts the floodgates for Laetrile, FDA will be hard pressed to offer the public a modicum of protection against this unworthy and dangerous drug.

6. I hereby verify under penalty of perjury that the foregoing statement is, to the best of my knowledge and belief, true and correct.

T. E. BYERS

Date