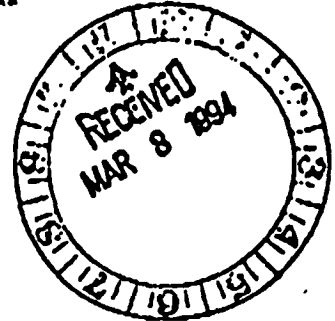


# Coalition on Smoking OR Health

March 7, 1994



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American Cancer Society

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American Lung Association

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- Society of Cardiovascular & Interventional Radiology

David Kessler, M.D.  
Commissioner  
Food and Drug Administration  
14-71 Parklawn Building  
5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner Kessler:

The Coalition on Smoking Or Health was pleased to receive your letter of February 25, 1994 responding to the various petitions that we have filed with the Food and Drug Administration since 1988.

We, like you, regard the issue of tobacco and cigarette regulation as a major public health issue deserving of careful attention by both the FDA and Congress. It has been thirty years since Dr. Luther Terry issued the first Surgeon General's Report on smoking and recommended that FDA be given regulatory jurisdiction over tobacco products. Until your letter, little leadership has been provided by the federal government to ensure proper regulation of tobacco, this nation's single most preventable cause of death.

Since filing our first petition with the FDA in 1988, we have, as you know, made supplemental filings with the agency as new information has come to our attention indicating that cigarettes should fall within the FDA's jurisdiction. As that information continued to accumulate, the Coalition reached the same conclusions that you outlined in your recent letter. We also believe that there is growing evidence to indicate that today's cigarette products are highly technological products designed by tobacco manufactures to both affect function and structure of the body as well as to mitigate and prevent disease.

The Coalition was in the process of preparing a petition to the FDA based upon our own review of the accumulating evidence that we believe warrants your agency to consider classifying all cigarette products as "drugs" under the Food, Drug and Cosmetic Act. The Coalition has decided to proceed with the filing of that petition to complement the conclusions and directions contained in your letter. It is clear in our view that the tobacco industry crossed over the statutory line years ago and that it has been in the business of selling "drugs" as defined by the Food, Drug and Cosmetic Act.

Be assured that as additional information comes to our attention regarding the intent of tobacco manufactures to sell their products as "drugs," we will file that information with the agency for review and consideration.

Sincerely,  


Scott D. Baffin  
Chairman  
Coalition on Smoking OR Health  
Vice President for Public Affairs  
American Heart Association



Fran Du Melle  
Deputy Managing Director  
American Lung Association



Michael F. Heron  
National Vice President  
Advocacy and Relationship Management  
American Cancer Society