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Joan Claybrook, President

October 24, 2005

Andrew Von Eschenbach, M.D., Acting Commissioner  
U.S. Food and Drug Administration  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Von Eschenbach,

On March 28<sup>th</sup> of this year, we petitioned the FDA to immediately ban the attention deficit drug Cylert (pemoline--Abbott) and all generic versions of pemoline because of clear evidence that the drug causes liver failure and that it has no unique advantage over other drugs used to treat this condition. For the past year, we have warned people on our Web site [worstpills.org](http://worstpills.org) not to use the drug. At the time of our petition, the FDA was aware of 13 cases of drug-induced liver failure that had resulted in either death or the need for liver transplants in addition to eight other cases of liver failure. Many of these cases were in children. Shortly after our petition was filed, Abbott announced that it would discontinue marketing and sales of the drug, citing economic reasons--a loss of market share to generic companies--rather than admitting how dangerous the drug is. There was no response from the six companies selling generic versions of the drug.

The FDA announced today that generic companies would no longer sell or market pemoline because "the overall risk of liver toxicity from Cylert and generic pemoline products outweighs the benefits of this drug" and because the "reporting rate for liver failure with pemoline is 10 to 25 times greater than the background rate of liver failure in the general population."<sup>1</sup>

Despite this serious risk of liver damage, the FDA has stated that "Cylert [and its generic versions] will remain available through pharmacies and wholesalers until supplies are exhausted; no additional product will be available." Between the time our petition was filed and the end of September, more than 60,000 prescriptions for these drugs have been filled in U.S. pharmacies. Even though Abbott announced in the spring that it would no longer market or sell

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<sup>1</sup> <http://www.fda.gov/cder/drug/InfoSheets/HCP/pemolineHCP.htm>

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Cylert, almost 10,000 prescriptions since April 2005 were for its version of the drug.

It is reckless and insensitive to the health and lives of children and adults using this drug for the FDA and the involved drug companies to fail to institute an immediate recall of these dangerous products. Otherwise, when the next case of liver damage, fatal or otherwise, occurs, the parents and other relatives of the drug's victim will ask the government and the companies, "Why did you allow this to happen?" There is a lack of any sense of urgency in today's FDA announcement, which is inconsistent with the agency's repeated claims that it is doing an adequate job in communicating information about serious risks of drugs. We urge you to immediately tell these companies to recall all outstanding supplies of pemoline and to urge patients and parents of patients to immediately see their physicians about alternative treatments. We look forward to a prompt response to this request.



Sidney Wolfe MD  
Director



Peter Lurie, MD, MPH  
Deputy Director  
Public Citizen's Health Research Group