



Office of The Attorney General
State of Connecticut

*TESTIMONY OF
ATTORNEY GENERAL RICHARD BLUMENTHAL
BEFORE THE SENATE COMMITTEE ON THE JUDICIARY
JULY 31, 2007*

I appreciate the opportunity to submit testimony on OxyContin and other defective products that cause death or serious injury. I commend the committee for holding a hearing on this important issue and Senator Specter for his continuing concern about the need for greater criminal penalties to deter knowing distribution of dangerously defective products.

OxyContin is the latest grim example of corporate greed and arrogance causing death and serious injury. More than one hundred years ago, a similar corporate mindset led to many federal and state consumer protection and employee rights laws. The question we must ask is whether these laws offer sufficient deterrence -- and the answer clearly is no.

Purdue Pharma conducted focus groups and determined that physicians would be reluctant to prescribe OxyContin because its main ingredient, oxycodone, is so addictive. Purdue Pharma also determined that physicians were looking for effective pain medication with low risk of addiction. Although Purdue Pharma knew that OxyContin was highly addictive, it instituted a comprehensive marketing campaign that continuously marketed OxyContin to health care providers as a pain management drug with low risk for addiction.

While Purdue Pharma made hundreds of millions of dollars in profits, more than 300 people died as a result of overdoses of OxyContin.

I urge Congress to consider several initiatives to toughen our criminal sanctions and strengthen our oversight agencies to prevent a recurrence of the tragedy of OxyContin:

- Classify as a federal felony any knowing distribution of a product that is defective and causes serious injury or death
- Require mandatory prison terms for any individual convicted of such felony.
- Require the Food and Drug Administration to make a final ruling on Citizen's Petitions within six months of submission unless extended through agreement with the petitioner.

Corporate officials who knowingly and willfully distribute a defective product where the defect directly causes death or serious injury should be held to the same standard as an individual who kills or injures another person.

Many victim families are understandably disappointed in the plea agreement between Purdue Pharma executives and the United States Attorneys office because it failed to require any prison terms for the individuals who knowingly allowed a false marketing campaign. Payment of hundreds of millions of dollars in fines and forfeitures may be appropriate and commendable, but significant deterrence usually depends on prison terms.

Individuals who engage in illegal actions that cause significant financial harm are imprisoned. Why not corporate officials who engage in illegal actions causing death and serious injury?

Federal law must mandate minimum prison terms for individuals whose illegal corporate activities cause death or serious injury.

While strengthening federal deterrence is important, Congress should also consider making federal oversight agencies more effective in preventing such tragedies.

The Food and Drug Administration (FDA) is charged with ensuring that prescription drugs are safe and effective, and properly marketed. Yet, the FDA turned its back on its serious responsibility with regard to OxyContin. Despite all the evidence available to the FDA -- through public media reports and private government channels -- the FDA never even required Purdue Pharma to add a black box warning or implement a Risk Management Plan until 2001, five years after the drug was launched.

On January 23, 2004, after a year-long investigation of Purdue Pharma and after uncovering alarming evidence that the company knew the drug was being mis-prescribed by physicians but not taking appropriate action to warn them, I filed a detailed Citizen's Petition with the FDA. The petition requested the FDA require Purdue Pharma to expressly warn prescribers of the increased occurrence of side effects or potentially serious adverse reactions resulting from prescribing OxyContin at dosing intervals less than the manufacturer's recommended 12 hours. The petition suggested strengthening the drug's black box warning statement, supplementing the labeling with additional bolder warnings and initiating a "Dear Healthcare Professional" letter.

More than 3 years have passed and the FDA has yet to rule on -- or even substantively answer -- the petition. While federal law establishes a Citizen's Petition process, there is no deadline within which the agency is required to make a final ruling. I have enclosed my recent letter to the FDA expressing my concern and frustration with the lack of response.

Early and aggressive FDA action on this petition may have saved lives. The FDA's glaring and galling failure to act demonstrates the need for wide-ranging reform of the agency.

I urge Congress to consider legislation to require the FDA to rule on citizen's petitions within 6 months of the filing of such petition unless the petitioner agrees to extend such period. Congress should also initiate oversight hearings into the FDA's role in the OxyContin issue. These proceedings will hold the FDA accountable and responsible.