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Good Afternoon, Ladies and Gentlemen. I am glad not to have to have worried over having a chance to speak today. No lottery possibility as in December's SSRI Hearing.

I am a member of the Alliance for Human Research Protection. I am also the mother of a beautiful son, Rob, who died on October 5, 2002 after taking Zyprexa at the suggestion of Maryland Medicaid, gaining 100 pounds, falling into a coma, and dying of profound hyperglycemia. I also represent many friends who have lost their children to psychotropic drugs but are unable to be here today.

In behalf of my grieving friends and myself, I would like to come right to the point: We do not approve of the FDA taking a dime of Pharma money to do any drug safety activities. We see this possibility as that of letting the fox into the henhouse. There are always strings attached to money and there are already too many strings attached to the money Pharma currently gives the FDA for drug approval activities.

The money, and the regulatory power that goes with it, for improvement of FDA's practically defunct drug safety activities, must come from Congress. Since the Democrats took over, there are already two bills in the works for this; the Grassley, Dodd, Mikulski, Bingaman bill and the Kennedy Enzi bill. In addition. Various Congressional committees are examining the activities of the FDA and its relationship to Big Pharma. Representative Dingell's Committee on Energy and Commerce met just the other day.

I see the scheme of taking Pharma money to help with Drug Safety as a smokescreen; a way to say to Congress, "See, we are already busy working on this". And I do not think it will fly. The material handed out by the FDA about this possibility stated that various consumer groups thought it was a good idea. I would be interested to know what consumer groups these were. No one asked me: No one asked your harshest constituency, the families of the dead.

There is no question that the Institute of Medicine Report was correct: Drug Safety at the FDA has nowhere to go but up. I know this firsthand. I learned why my son died from Public Citizen, just as I learned that in 2001, one of your colleagues and Dr. Doriswaimey from Duke studied your very own Medwatch for Zyprexa and found 23 deaths. I found that Japan and the UK required warning labels on Zyprexa in the Spring of 2002. You did nothing. In the Spring of 2003, I got a front page story in the Baltimore Sun about the dangers of Zyprexa. It was followed by front page stories in the Wall St Journal and New York Times. Your response was nothing.. However, I did hear you were embarrassed, and Lilly was worried. Finally, instead of immediately acting on Zyprexa, at the end of 2003, you told all the atypicals to place a warning. Two of them had hardly been out on the market. In taking this terribly belated action, the CATIE --proven lethal nature of Zyprexa was hidden in amongst the rest. To finish the Zyprexa lact of action, other than a black box for dementia for all atypicals, you have done nothing. 26,000 people have settled with Lilly, with more to come. Nothing. Two million children on atypicalsl off-

label. Nothing. Revealing stories in the New York Times showing that Lilly knew of the Zyprexa dangers before it even went on the market. Nothing.

I would say that drug safety at the FDA is currently a dead letter.

It is not a letter that should be read by Pharma. FDA must remember that it is the regulator, not the friend , of Pharma. It must remember that people like my friends and myself are still waiting for justice. So far there is no justice. There is supposed to be justice in America.

I urge you to drop this idea and wait for Congress to take its rightful actions, actions that were not taken during the Republican-led Congress.