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A Representative of Families Hurt by Unsafe Drugs

before the
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives
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Assessing the Safety of our Nation's Drug Supply

Mr. Chairman, Members of the Committee:

Thank you very much for inviting me to testify at today's important hearing.

I would like you to hear how corporate greed, our woefully inadequate mental health system and over-reliance on pharma-psychiatry, and the little pink pill, Paxil, have forever altered the life of my most precious gift from God, my daughter Michelle.

Michelle was raised in a loving, stable home in the small town of Dunellen where she participated in many community events and was proud to be a girl scout.

In 1995 American Standard transferred my husband to their European Division in Brussels, Belgium.

Michelle, who had always been an honor roll student, attended St. John's International School in Waterloo. Michelle traveled and explored many European countries. She became fluent in the French language.

Our family returned to the United States in the summer of 1999. Our life, as we once knew it, would change dramatically. Michelle began complaining of ill health and missed her friends in Belgium. She was also upset over the declining health of her grandmother.

In April of 2000 Michelle continued to complain of ill health, she was losing weight and had stopped eating. She was admitted to Somerset (New Jersey) Medical Center's eating disorder unit, where she was diagnosed with depression and anorexia nervosa and was prescribed the antidepressant Zoloft. Within hours of digesting Zoloft, she reported to hospital staff that she had the urge to hurt and cut herself and two days later, again reported she was uncomfortable taking the medication. Her complaints were dismissed. Several weeks later, Zoloft was discontinued due to dramatic orthostatic changes and bradycardia. (very slow heart beat). Michelle became very hyperactive and was diagnosed with a personality disorder. No one apprised me of what was happening to her. She was fourteen; I should have been informed.

In June 2000 Michelle was placed on Paxil. Within a few weeks she began to self-mutilate with knives, razors and broken plastic CD cases. She became verbally abusive and was displaying extreme oppositional behavior, along with severe insomnia, diarrhea, chest pain, weak muscles, and on a few occasions vomited blood and had rectal bleeding.

In August 2000 the Paxil was increased to 40 mg along with a diagnosis of major depressive disorder with psychotic features.

In September Michelle's self mutilating behavior was increasing. During one episode, she had inflicted over twenty-three wounds and cut the word "die" onto her abdomen.

She became violent and suicidal and was hospitalized because she was deemed to be a danger to herself and others. Her Paxil was reduced from 40 to 20 mg and Depakote was prescribed.

On October 6, 2000 my daughter Michelle attempted suicide and became extremely violent. She assaulted her brother as he was desperately trying to keep her from killing herself. He was just four days shy of his twelfth birthday. She then viciously attacked three police officers and managed to escape from her handcuffs twice. She was kicking, spitting and screaming obscenities. She even attempted to kick out the rear window of the patrol car. When they arrived at the hospital, it took five men to place her in leather humane restraints. The next day Michelle awoke dystonic and unaware of her surroundings. Again, she became violent and had to be restrained.

Michelle was transferred to UMDNJ Behavioral Health. Paxil was discontinued, but she was then prescribed Celexa and Risperdal (what I didn't know then, but have since learned, was that Michelle was placed in a clinical trial of these drugs without my knowledge or consent). Within 36 hours, Michelle again became violent and self mutilated. She was injected with Thorazine for her out-of-control behavior.

Approximately two weeks later, she was released from UMDNJ with a three day supply of medication (what I know now and didn't know then, was that this was a very dangerous thing to do). In an abrupt withdrawal, Michelle again became violent and threatened to kill me. She thought I was the devil and told me I was evil.

In April of 2001 Michelle was removed from all psychotropic medication. Recovery was a long, tedious process. Everything Michelle endured while on the drugs was suffered through the withdrawal process.

Michelle's Paxil-induced psychosis, self-mutilation, violent, and suicidal behavior are gone now. What remains upsetting is that the physical scars of her self mutilation will be with her forever.

Michelle's beautiful smile and sweet disposition were returned. Michelle never had violent and suicidal behavior prior to taking antidepressants, nor displayed this behavior after recovering from withdrawal.

I believe, without question, drug companies and their apologists are putting a great deal of pressure on the FDA. Despite all of the controversy and exposed failures surrounding the FDA in the last few years, it appears that the FDA simply cannot muster the guts to act without industry influence. Absent this influence, there would be no reason why the FDA wouldn't insist on label warnings for all ages on anti-depressants. No doubt drug companies are a formidable force, but the FDA must remember whose interests it is supposed to protect. If it does not, the representatives of the people, Congress, will have to step in and do it for them.

I would like to show you about a minute and half of a video of Michelle and other families' children who have suffered because the FDA failed to better warn the public about dangerous side effects.

Legislative Suggestions

So that other families are saved from the tragedy and heartbreak that my family and other families in this hearing room have endured, I urge you to approve—as part of the must-pass user fee legislation—the strongest possible FDA drug safety reform legislation.

PDUFA: Break the ties that are distorting the FDA's mission. First, on the extension of the Prescription Drug User Fee Act (PDUFA IV), I know that the FDA needs the resources, and more, that the user fees bring. The user fees need to be continued, and expanded to provide more resources for safety.

But under the current law, the industry's user fee money comes with a huge cost. It comes with detailed requirements to serve the drug industry—and that is a cancer that is eating at the culture and integrity, both real and perceived, of the FDA. If anyone doubts that the user fees are having a corrupting influence on the culture of the FDA, I urge them to read last summer's poll by the Union of Concerned Scientists, to which about 1000 of the FDA's medical scientists responded. Many poured out their frustration at being pressured to approve drugs on which they had serious safety concerns, and a number cited PDUFA as an inherent conflict of interest. A recent study by a group of Harvard researchers has found that drugs approved just in time to meet the PDUFA time goals have many more post-market safety problems than drugs which receive more review time. An earlier study by Harvard Professor Daniel Carpenter pointed out that the FDA's time-to-approve drugs was declining in the years before PDUFA's first passage in 1992; the study found that the FDA staff was being increased through regular appropriations, and that every 100 person increase in staff was resulting in a 3.3 month decline in approval times. I think this study shows that while the FDA does need more resources, it does not need the rigid framework of PDUFA.

This Committee is famous for its tough oversight. I am sure that you can make sure that the user fee money is well spent and that the FDA continues to give priority, timely attention to truly life-saving drugs. Therefore, I urge you to break the entangling webs of obligations that come with the user fees and just let the FDA use the fee money to do its job. Congressman Hinchey has previously introduced legislation that would achieve this reform.

Kennedy-Enzi (S. 1082), and Waxman-Markey (HR 1561)

The bill the Senate is passing makes important improvements for safety. And in many ways, the bill by Representatives Waxman and Markey is even better, because it

> --requires a warning signal for the first two years a drug is on the market (an important fact for consumers, since the real test of a drug's safety comes once

it is mass marketed and used by the general population);

--requires a review of a drug's safety history after 7 years (important because only about half of a drug's side effects and labeling changes are detected in the first 7 years it is on the market);

--provides much more meaningful civil monetary penalties than the Senate bill;

--protects the public from overuse of particularly dangerous drugs by limiting direct-to-consumer ads for up to three years; the First Amendment does not give the drug companies the right to kill Americans, and moderation of ads on a new drug with serious warning signs of danger should be one of the FDA's tools;

--ensures that the results of all clinical trials (other than Phase 1 trials) will be made publicly available in a timely manner.

To save other families from future drug safety disasters, I urge you to take this best opportunity in the next five years to pass this kind of legislation, and I urge that it be made even stronger.

We need a better Adverse Event/MedWatch Reporting system. The Senate bill includes a major new monitoring of huge medical databases to detect quickly problems with drugs. It is said that the problems with Vioxx might have been detected in about three months under such a system.

But I believe we also need to educate and involve the American consumer more in reporting adverse events. Today, the average citizen has no idea how or where to report a problem with a drug. I urge you to require all drug ads to prominently display a 1-800 number where problems can be reported. The FDA should also start using the tools of the

Internet and e-mail to, with patients' permission, periodically query people who are taking a new drug whether they notice any adverse reactions. Instead of passively waiting for reports of trouble, a modern FDA should be seeking out the areas of danger.

We need someone responsible and accountable for safety at the FDA. I support a separate Office of Drug Safety in the FDA, one that will be free of the control and overwhelming presence of the Office of New Drugs.

The FDA Commissioner and many others have said that a separate office would be duplicative, expensive, and hold up approvals. If that is a problem, the same goal of accountability for safety could be achieved by giving the head of the Office of Drug Safety the power to call for a safety action (a REMS adjustment in HR 1561). If the head of the Office of New Drugs disagreed, the Commissioner would decide between them, all within a week or so (so that there can be no charge that we are delaying the approval of vital new drugs). There needs to be a locus of safety accountability in the FDA. This proposal, or a wholly separate office, would achieve that goal.

No Conflicts of Interest (COI) in FDA Advisory Committees. The FDA recently announced guidance that makes major improvements in the Advisory Committee (AC) process: no participation in an AC if one has over $50,000 in conflicts, and participation in the AC, but no vote if one has *any* conflict. I hope you will codify the FDA's action, but go beyond it by requiring the active recruitment of COI-free experts, and prohibiting those with conflicts from sitting with the AC (they can testify, but they should not be part of the camaraderie-building AC process where they can influence outcomes even though they can not vote).

Thank you for your consideration of these legislative ideas. If enacted, you could give the American people the FDA they need and deserve.