

1 thank the committee for the opportunity to address
2 you on this issue. My name is Bob Cloud, and I
3 would like to briefly talk to you, first about my
4 own long, personal use of Xyrem, and I will call it
5 Xyrem not GHB or sodium oxybate and, secondly, my
6 very serious concerns as director of Narcolepsy
7 Network, which is a national non-profit, primarily
8 patient organization. In that capacity we have
9 received funds, a minor amount of funds, perhaps
10 ten percent of our revenues, from Orphan Medical
11 over the last several years.

12 First, my personal experience with Xyrem
13 as a narcolepsy patient with cataplexy. I am 57
14 years old, married, have two adult children, and I
15 am an attorney in private practice, primarily
16 family, probate and criminal law which sometimes
17 can be intense and have a few emotions attached to
18 it.

19 I believe I am the first American to have
20 used Xyrem for narcolepsy, and I am probably the
21 longest continuing user of Xyrem which now
22 approaches 19 years every night without fail. My
23 narcolepsy/cataplexy symptoms began in the mid-30's
24 and by age 39 included severe and recurring
25 cataplexy together with excessive daytime

1 sleepiness and sudden sleep attacks. My cataplexy
2 caused numerous daily episodes of complete body
3 collapse, such that I couldn't leave my office or
4 home without risk of harm to myself or others.
5 Feeling any emotion, humor, anger or mere
6 enthusiasm, would result in sudden immediate
7 collapse. I guess we are all ignorant of what
8 diseases feel like that we don't have them, but my
9 best description of the sudden collapse of
10 cataplexy would be to imagine a puppet on strings
11 and suddenly the strings, which are your muscle
12 tone, are immediately let go and so you fall to the
13 ground immediately, and your head comes down last
14 and whips against whatever -- sidewalk or table
15 corner or escalator or whatever might be there. I
16 have been rescued by police and emergency squads
17 and life guards and well-meaning strangers and
18 friends.

19 Obviously no injury for me has been fatal
20 because I am here, but unfortunately I do know
21 others whose fall has occurred at the top of the
22 stairs and they fell down backwards and killed
23 themselves, and there are others that I don't know
24 about.

25 In 1982 my treating physician sent me to

1 Sunnybrook Medical Center in Toronto, Canada to
2 begin prescriptive use of Xyrem under the research
3 being conducted by Dr. Mortimer Mamelak. After
4 three weeks I returned home and continued using
5 Xyrem, always prescribed by my local physician
6 under his own individual investigational new drug
7 application. My severe cataplexy symptoms
8 disappeared almost overnight. I was immediately
9 able to return to my full-time law practice and I
10 have continued to this day to use Xyrem under that
11 individual application and subsequently in the
12 clinical trials under the Orphan Medical
13 application. During these 19 years, I have never
14 changed the dose. I have never experienced
15 tolerance. I have never noted side effects.
16 Simply stated, the drug is as safe and effective as
17 it was on day one. It is hard to imagine a
18 pharmaceutical product having such a quick,
19 complete, safe and enduring benefit.

20 As director of Narcolepsy Network, I have
21 said on a number of occasions that I think the
22 greatest tragedy in the treatment of people with
23 narcolepsy is that Xyrem or GHB has not been
24 available so that other patients could benefit from
25 it as I have. Hopefully, this committee will

1 remedy that.

2 We are sensitive to the reports of
3 injuries and deaths and other victimizations from
4 the abuse of GHB and, as an organization, we work
5 with law enforcement and community drug agencies to
6 partake in their activities to limit that and
7 correct that. I think it is obvious that Orphan
8 Medical is going above and beyond the call of duty
9 to also contribute to restricting the unlawful use
10 of GHB.

11 In closing, I submit that our concern for
12 patients with narcolepsy should receive your
13 highest considerations so that people can
14 rediscover their economic and particularly their
15 family lives and avoid disability. Thank you.

16 DR. KAWAS: Thank you, Mr. Cloud. The
17 next speaker is Cindy Pekarick from Pennsylvania.

18 MS. PEKARICK: Hi. My name is Cindy
19 Pekarick, and I am here today to tell you how GHB
20 killed my daughter. In October of 1998, my
21 daughter Nicole, a college student and gym
22 enthusiast met a new boyfriend who introduced her
23 to a product called Renewtrient. In November she
24 researched the product over the Internet and
25 received only positive information. She could take

1 it before bedtime and wake up in only four hours
2 feeling refreshed, well-rested, and all her muscles
3 would be completely recovered and ready for another
4 workout.

5 In December I found out she was taking
6 this supplement. I didn't believe the promises
7 made by the advertisers. Arguments ensued and she
8 promised she wouldn't drink it anymore. She was
9 away at school from mid-January until April.

10 In April she returned home. She was
11 behind in all her bills. She was black and blue on
12 her arms and legs. She stopped attending classes,
13 and she kept losing things. In May I discovered
14 she had essentially dropped out of school.

15 In June I could see mild changes in her
16 behavior. She began taking power naps, as she
17 called them. She would sleep three hours in the
18 middle of the day and get up at four o'clock and go
19 to work. She continued losing things and having
20 difficulty paying her bills. I searched her room
21 and car but found no evidence of substance abuse.

22 By July, my younger daughter, Noelle,
23 informed me that Nicole was having problems. She
24 said, "mom, she isn't taking anything bad or
25 illegal. She takes a muscle supplement that

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