

FDA PCNS Committee Meeting (June 6, 2001)
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There is no way to crush five years of intensity into five minutes. I have lived and breathed GHB issues since June 1996 when I was first assigned to handle it for LAPD. Four young men collapsed; two literally died and were brought back by paramedics. I was stunned that hardly anyone knew anything about this drug, but one thing was clear-----people were dying from GHB and it was being missed due to lack of ability to test for it and lack of knowledge that it even exists.

I'm not a doctor or a chemist. I realize research is important, but I'm sickened when reality is brushed off with "Oh well, that wasn't a clinical study" or "You can't PROVE it was GHB versus an analog." In some cases we can prove it; meanwhile, no federal agency has made any systematic effort to make such identification possible. I live in a real world of suffering people that can't be captured by clinical studies. I see both immediate disasters and long-term aftermath of GHB. I'll try to cover as much as I can because I feel an obligation to victims of GHB worldwide.

I have read the research. I've talked to hundreds of GHB users/dealers plus patients/doctors in the narcolepsy/cataplexy research. I've reviewed or consulted on hundreds of sexual assault cases where GHB has been identified as the weapon or where symptoms point to GHB. I've helped more than 300 GHB addicts, each of whom can name dozens more just like them and many with 3-5 impaired driving incidents in just a few months. They are in virtually every state of this country and several foreign countries. They aren't whom you would expect; they are businessmen, bodybuilders, airline employees, athletes, exotic dancers, bodybuilders, computer wizards and more bodybuilders. Most of them believed they were taking a safe workout or sleep aid, but then it took over their bodies and souls. I have worked closely with several dedicated doctors during the 17 months we have operated the GHB addiction helpline via www.projectghb.org (aka www.ashesonthesea.com/ghb). We have learned so much about GHB from these previously unrecognized and still typically undertreated addiction cases. I have seen the pain of the families/friends of GHB death victims, the horror of overdoses. My addicts have lost relationships, jobs, fortunes, suffered ongoing disabling injuries. Some lost their lives to GHB, whether by overdose, traffic accident or suicide. The suicidal depression associated with GHB withdrawal is stunning. I have GHB addiction/withdrawal related suicides and/or currently suicidal people from New Zealand to Sweden. I have some "MIAs" who probably did end their lives. Grieving parents have told me their stories; my office wall bears the pictures they have sent me. It has been a heartbreaking five years, mixed with the privilege of learning more and teaching others to recognize the rape, OD and death cases or getting rape victims into treatment or convincing youngsters not to try GHB. It has also been very lonely at times when agencies who should care don't.

DEA has reviewed and documented 71 deaths related to GHB, but stopped counting once the drug was controlled. No one at FDA has ever expressed interest in actively identifying these cases. My database includes about 200 GHB-related deaths now. Robert McCormick of the FDA's orphan drug unit told me emphatically that he did not care how many people had died or were addicted to GHB, as he intended to approve it anyway. Something is wrong with this picture. This is truly the most horrid drug I have encountered in 25 years as a police officer. Much new info has come to light during the past two years, none of it good. Around the world, countries are now just awakening to their problems with GHB, and restrictions on it are tightening. New Zealand tried it as a prescription drug and now realize it was wrong. France is backing away. NIDA is releasing \$2 million in research about this drug. This is clearly NOT a time to be pushing it forward on unsuspecting American citizens.

You are here today to approve GHB (disguised as sodium oxybate) for use with narcolepsy/cataplexy. Orphan's investors have been assured (according to their message board posts) that you will approve it (FYI--news reports said that Orphan stock dropped 30 percent when you canceled the previous meeting). But doing so would contribute to the internet-generated belief that real GHB is safe and would simply lead to a rush for the "good stuff." You have not seen my video tapes of the day-to-day struggle of GHB addicts, clearly showing that GHB gives previously healthy people symptoms that can only be described as

narcolepsy/cataplexy. They are destroying themselves with it; wives are terrified of their husbands and often have no idea what is happening to them; many are being locked into psych wards instead of being treated because ERs and doctors don't recognize GHB psychotic episodes and withdrawal syndrome; and they are killing themselves/others behind the wheel. I often hear, "GHB (withdrawal) leaves a hole in your soul." Many are suffering long-term anxiety and depression, Parkinson-like shakes, etc. even 18 months after detoxing. There are no answers for them yet, so how can it be approved, letting it cause similar damage to others?

I am deeply concerned about the "off label use" policy that would enable any doctor to prescribe this drug for any condition as I have no faith that its use will be limited to narcolepsy/cataplexy. Look at the chatter around Orphan about fibromyalgia, for example, a condition with vague symptoms for which a drug seeker could easily get a prescription. And, I know that doctors won't realize that Xyrem (sodium oxybate) is GHB. I called an FDA doctor who had written about the dangers of GHB, but another person had taken over GHB issues. The assistant passed the info I gave her to this person, who then called and said that I must be nuts. She had looked on FDA's orphan drug list and didn't find GHB. And, she checked the Orphan website and found that they weren't researching GHB either. She clearly proved my point-----If an FDA employee assigned to know all about GHB can't figure it what sodium oxybate is, the vast majority of doctors around the country would not realize it was GHB! I see no significant talk on the legitimate narcolepsy websites about this impending new drug, but message boards where GHB addicts hang out are buzzing about it. In fact, one of the key figures in illegal GHB internet sales is behind the original posted website www.xyrem.com!

There is very little drug diversion enforcement in the US. Only a handful of agencies devote one iota of time to the diversion of prescription medications to abuse. It is a very small portion of DEA effort. Most state narcotics agencies are too busy with meth, cocaine, heroin, etc., to have anyone assigned to diversion. State pharmacy and medical boards aren't staffed adequately. A doctor, for example, testified before the California Legislature that he was illegally prescribing GHB to his narcolepsy patients (being illegally imported from Europe by a compounding pharmacy) and was untouched because no one had time to follow up. He has a narcolepsy practice and puts out a radical narcolepsy newsletter (which openly attacks the FDA and doesn't identify a publisher), and will undoubtedly be included on Orphan's list of approved doctors. Therefore, Orphan's proposed voluntary (keyword: voluntary) promises of careful controls are frightening. They are designed to put at ease those precious limited resources devoted to drug diversion so that no one will worry about taking time to look at them. And, there are no real penalties associated with failure to abide by their voluntary conditions! The drug can be taken off the market, but how long would that take? The FDA is a huge, cumbersome bureaucracy that has been incredibly slow in dealing with this drug. It took a legislative subcommittee on oversight to demand a scheduling report from FDA in response to DEA's proposal!

Orphan representatives and others have claimed that Xyrem will be too expensive for addicts. But that contradicts the facts. GHB addicts pay up to \$100 per day or more for a 2 oz bottle that may be near 100 percent or a 32 oz bottle that may be watered down to even as little as 5 percent. GHB addicts often find themselves with all their credit cards maxed out by their GHB purchases (up to \$30,000 in a year). GHB addicts will be diagnosed as narcoleptic/cataplectic because they essentially become that! A number reportedly have done so. I was once personally misdiagnosed as having narcolepsy once when in fact I merely had Epstein Barre virus.

More importantly, once in possession of that prescription and a bottle of Xyrem, the addict will be "home free." There is no "field test kit" for GHB at this time. Thus ALL investigations of GHB cases are difficult. Encountering a prescription (real or counterfeit) and Xyrem bottle, the officer would have absolutely no ability to determine if it contained the prescription product or had been refilled with street GHB or its analogs. NO POSSIBILITY at the street level. It would require elaborate circumstances (establishing a high level of "probable cause" to believe that the bottle contained something other than the legitimate product) to even think of justifying further lab testing. In an impaired driving case, it doesn't matter (in states with thorough DUI laws) since impairment is the issue, not illicit versus licit drugs. In terms of possession cases, few if any agencies will have or be willing to expend the resources to do a detailed analysis (assuming it's even possible to tell the difference). At this moment GHB rape cases go

undetected and/or unprosecuted due to lack of training and testing capabilities. Agencies dread investigating possession cases because of the lack of a test kit. They dread sales cases because of the complexity of analog issues and deceptive practices being used (hiding it as weight belt cleaner, plant food, ink jet cartridge cleaner, etc.). Few agencies are equipped to handle internet sales cases because of the deceptive practices and the difficulty in physically “finding” the internet companies.

To those who claim that “real” GHB is safe and that only the street stuff is dangerous, I say “poppycock.” Addicts have used everything from European pharmaceutical grade GHB, carefully manufactured GHB to horribly tainted products, plus varying quality GBL, BD and a third analog. For every one of them who swears that he was “OK” when taking GHB but got in trouble when he took GBL (or BD), there is one who says the opposite. Besides, no matter which one you take, you urinate out GHB. Yes, there have been cases where the medical problems involved high pH (drain cleaner) product or contamination by other toxic solvents; these are rather obvious. The vast majority of incidents are clearly consistent with GHB-related problems. Let’s stop ignoring reality.

The unprecedented split scheduling of GHB was an unwise decision, clearly impossible to enforce. Those of us involved in the federal legislation were forced to accept what we knew was an insane compromise or face no scheduling of the drug at all. I know because I flew to Washington, D.C., at my own expense for the privilege of attending a small, by-invitation-only meeting. There were no doctors or scientists, just two Legislators with differing legislation on the issue, a few of their staffers, and a PR representative from Orphan Medical, a representative from the Rare Disease Foundation and me. The agenda was clear. GHB would be Schedule III (second legislation introduced), with Orphan Medical offering their first draft of “voluntary controls,” and the previously submitted Schedule I legislation would be killed. Undaunted by what I felt was an intimidation effort, I—and others-- fought like hell for Schedule I behind the scenes anyway and ended up with the split compromise. It was no small political victory just to bring it up to that.

It has been frustrating to watch a drug company dictating to various states how to word their legislation on GHB to meet the drug company’s demands and in general calling all the shots. This hasn’t been about science or medicine, but about politics. It has indeed been a slick PR operation by a company that clearly has inappropriate political clout (as even commented on by their own investors on their finance message board!) and that has played on the hopes of those with narcolepsy/cataplexy in their drive to make big bucks from a drug of devastation. I have never before seen drug companies openly paying people at forensic conferences to attend their presentations (\$175 per person). Inexplicable amounts of money have been spent to “PR” this drug.

Meanwhile, I have lost all respect for one of the current narcolepsy trials doctors, who volunteered his concerns about this drug to me and then, two years later, recanted all of his statements suddenly, after I brought that info into the open. I must assume that his reversal was at the company’s request. I have my doubts that narcolepsy/cataplexy trials are as successful and promising as we have been lead to believe. I do feel that those with narcolepsy/cataplexy need a longer-acting, safer “cousin,” not GHB; an opinion also expressed by Dr. Mortimer Mamelak on prior occasions.

I can’t stand by quietly and let this travesty occur. In my opinion, this would be the biggest mistake ever made by the FDA and the drug would have to be taken off the market in the near future but it won’t be soon enough. The now known tragedies and the massive “unknowns” about GHB truly outweigh potential benefits. Please read the “viewers comments” section at www.projectghb.org and vote against approval of this drug at this time.