HOUSE OF REPRESENTATIVES
COMMONWEALTH OF PENNSYLVANIA

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House Bills 111 & 183

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House Judiciary Committee

Room 205, Capitol Annex
Harrisburg, Pennsylvania

Monday, March 8, 1999 - 9:40 a.m.

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BEFORE:

Honorable Thomas Gannon, Majority Chairperson
Honorable Patrick Browne
Honorable Daniel Clark
Honorable Brett Feese
Honorable Stephen Maitland
Honorable Kevin Blaum, Minority Chairperson
Honorable Frank Dermody

IN ATTENDANCE:

Honorable Kerry Benninghoff
Honorable Sara Steelman

KEY REPORTERS
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ALSO PRESENT:

Brian Preski, Esquire
Majority Chief Counsel

Judy Sedesse
Majority Administrative Assistant

Michael Rish
Minority Executive Director

Beryl Kuhr, Esquire
Minority Chief Counsel

Richard Scott, Esquire
Counsel, Democratic Caucus

Cathy Hudson
Minority Committee Secretary

LeAnne Bronstein
Minority Research Analyst

Dave Callen
Research Analyst II to Representative Peter Daley

C O N T E N T S

ACTING CHAIRPERSON MAITLAND: Good morning, ladies and gentlemen. I'd like to call this public hearing of the House Judiciary Committee to order. I'm State Representative Steve Maitland of the 91st Legislative District in Adams County.

Our hearing today is on House Bills 111 and 183 that have to do with the appropriate scheduling of the date rape drug, gamma-hydroxybutyrate. We have three prime sponsors of the legislation with us this morning. I'd like to introduce them and ask them for their testimony and the reasoning behind their introductions of this legislation.

Up first is the Honorable Kerry Benninghoff of the 171st Legislative District. Good morning, Kerry.

REPRESENTATIVE BENNINGHOFF: Thank you very much, Representative Maitland. As I was saying to some of the other people here today, I think one of the important things about having a public hearing is to get all the different interests, comments and feelings regarding any type of public policy that has to be stated. That's my whole emphasis for

introducing this legislation along with some specified concerns which I'll share. If you let me begin, I'll share a few comments with you and then take some questions later.

First of all, I'd like to say thank you to Chairman Gannon who allowed me to do this, the Minority Chairman and the rest of the members of the Judiciary Committee for affording me this time to introduce my legislation known as House Bill 183. I'd also like to say thank you for placing this important bill so early on the legislative calendar of your committee.

My legislation is to place GHB, gamma-hydroxybutyrate, and possibly its precursor chemical GBL, and gamma-hydroxybutyric acid sodium salt under the Controlled Substance Act.

I have introduced this legislation for several reasons. First by suggestion of my wife, which I have to give credit to this for; she had brought this to my attention after seeing its devastating effects on two young college students who had overdosed and were patients in the Critical Care Unit in a hospital within my legislative district in which she is

employed.

Some of you are aware that my district represents parts of Penn State University. I must say that this incident truly hit home and showed how easily an overdose like this can affect people, more specifically, the young people right in our own neighborhoods.

A second reason is a result of my past work as Centre County coroner and my nearly nine years service as an autopsy assistant. During those years, I saw too many lives claimed by the ever-increasing abuse of so-called recreational or party drugs, most specifically, when mixed with alcohol.

As coroner, I was always frustrated that by the time I received a patient it was after the fact; after the time that I could do anything to prevent that death, especially to those that were due to foolish, accidental or vicious acts of another. It was always very tough to knock on a parent's door to notify them of their loss, but more frustrating when it was due to something that was preventable.

Today, you and I have the opportunity to make a difference before another

accident or deliberate poisoning occurs. For the purpose of the remainder of my comments, I will refer to this drug as GHB and its major compound as GBL.

I have three major areas of concern with this drug. The first is the ever-increasing recreational abuse by party-goers for its euphoric and aphrodisiac effects, or in layman's terms, another drug to get high on. The second concern is how easily and readily accessible it is; i.e., ordering it over the Internet without a prescription, warnings or monitored dosages.

In the July 1998 publication of GHB Briefing Book by the United States Department of Justice, Drug Enforcement Administration, it was documented that there were 3,500 incidents of GHB abuse, a number which dramatically increased from 16 cases in 1992. Since 1992, the DEA reports a total number of reported deaths caused by GHB has risen to 32. I highlighted the word reported because sometimes I think the things are not always diagnosed adequately or often reported. So these numbers could be lower than what we think; they could be for real.

This article went on to say that in Pennsylvania at least six individuals have experienced life-threatening comas following ingestion of GHB in 1998. Known abuse of GHB has occurred so far in three counties of Pennsylvania, Bucks, Indiana and Centre. And again, I highlighted the word known because I'm sure there are probably cases we're not aware of or have been misunderstood.

The Bucks County case was that of three young boys found unconscious by their parents after the boys used GHB purchased in a kit over the Internet.

My third concern and probably the most frightening is the fact that GHB has become the new date rape drug of choice. Why, might you ask? Well, it's readily available; it is clear, nearly tasteless and odorless. Most of the cases I've read about, the victims had no idea that they had taken a drug at all.

Because of its transparent appearance, the predator simply slips it into a victim's drink, which quickly makes the victim suffer severe nausea, vomiting, and even hallucinations. Most victims slip into an

unconscious or coma state leaving them helpless, unaware, and unable to protect themselves from a sexual assault. The period of unconsciousness can last four to eight hours dose dependent with the victims suffering amnesia.

In some instances and again dose dependent, a victim can suffer respiratory and cardiac arrests. Think about it. We have non-medically trained, unlicensed individuals giving unknown and unmeasured amounts of a life-threatening drug to innocent victims. This is plain, outright wrong. We would never allow licensed physicians to dispense medication in this irresponsible manner. No one else should be able to do it either.

Last fall, I read an article about a case in Indiana County where prosecutors were unable to pursue charges in a case in which GHB was to be used without the victim's knowledge. This was because the drug is not illegal in the State of Pennsylvania.

In the past six months, I have done a lot of reading as well as interviews with physicians, nurses, and law enforcement officials in my area, as well as others that I

know from across the state.

Even though I am continuing my research on this issue, I have learned all I need to confirm my earlier intentions. Today, I am formally announcing to you and your committee that my intention is to amend this bill to list GHB as Schedule I Controlled Substance.

This drug is not approved by the Food and Drug Administration. Even more significantly, the article stated that the FDA has sent a warning out to consumers alerting them not to purchase or consume this product.

These compounds are found in products that claim to build muscle, improve physical performance, enhance sex, reduce stress and induce sleep. These enhancements are far too often marketed to our young, immature, less knowledgeable and highly impressionable sector of our population. As policymakers, I think we have the responsibility to protect these young people.

This drug does not have any proven medical necessity, even it were approved by the FDA. While some may claim the need for this drug to treat narcolepsy and cataplexy, I'll

argue that there are already at least five FDA and clinically-proven prescription medications available to these patients. These drugs are currently in use and do not possess the life-threatening side effects that we have seen with GHB.

Below I have listed an excerpt from page 1449 in my Merck Manual, 16th Edition. This is a manual of diagnosis and therapy. It should be noted that just last month, January 1999, the FDA approved Provigil as a new, effective drug to treat narcolepsy.

Approved treatments for narcolepsy and cataplexy, a symptom of narcolepsy can be treated with one of various FDA approved drugs. The Merck Manual stated: Stimulant drugs may help; the dosage is regulated according to individual need. Ephedrine 25 mg, Amphetamine 10-20 mg or Dextroamphetamine 5-10 mg orally every three to four hours during daylight. The recommend doses are tolerated without serious untoward effects. Imipramine 10-75 mg a day is the drug of choice to treat cataplexy.

It is important to note that I could find no knowledge of an antidote for GHB as

well, a scary thought for those in the EMS field and Emergency Room personnel who often receive these patients in respiratory or full cardiac arrest.

In conclusion, I think it is important to note that while we know GHB is not approved by the FDA, that there is no known antidote and that there is no clinically proven or accepted medical use for this compound, we do know the following:

GHB has a high potential for abuse primarily in teens and young adults. GHB is addictive, creates substantial levels of dependency. GHB is the fourth most popular date rape drug of choice. Four, GHB's effects are significantly enhanced when combined with alcohol. GHB when abused can be life-threatening; and finally, GHB does not meet the criteria, in my opinion, of Schedule IV.

I have been given the expressed support of scheduling GHB as a Schedule I drug by my District Attorney, Ray Gricar; by Centre County coroner, Scott A. Sayers; State College Police Chief, Thomas King; and Doctor Margaret Spears, Director of University Health Services

at Penn State and Chair of the Penn State Sexual Assault Committee.

As a father of four, I do all I can to protect them. As a legislator, we have the opportunity to try to protect all of our young people, yours, mine and many that we don't even know.

As a fellow legislator, I ask that after you listen to today's testimony and you ask questions and you draw conclusions; that you join me and our steadfast Attorney General as we move to make GHB a Schedule I drug, and make Pennsylvania a safer place for our young people.

Let's send a clear message to those who would choose to victimize someone unknowingly that we won't tolerate this in Pennsylvania. Date rape is wrong. I have a couple references on the back for any of you that might have questions. I thank you.

ACTING CHAIRPERSON MAITLAND: Thank you, Representative Benninghoff. Before I continue, I'd like to note the presence of Representative Kevin Blaum, the Democratic Chairman of the committee on my right, and to my left Brian Preski, the Majority Chief Counsel.

Now I'd like to ask the Honorable Sara Steelman, of the 62nd Legislative District, for her remarks this morning.

REPRESENTATIVE STEELMAN: Thank you Representative Maitland. I appreciate the opportunity to offer testimony on the issue of controlling the manufacture and sale of date rape drugs in Pennsylvania and commend the Judiciary Committee for holding today's hearing.

About a year ago, I became interested in the problem of reducing the availability of drugs such as Rohypnol and gamma-hydroxybutyric acid because of an incident in the Borough of Indiana, which I represent. The police raided a house where there was reason to believe that drug synthesis was taking place.

In the event, however, the district attorney discovered that he could not prosecute the lab operators from making gamma-hydroxybutyric acid because, although it is a felony in Pennsylvania to use these drugs to commit sexual assault, it is not illegal to make or possess them.

This event happened a short time after we had passed Representative Ellen Bard's

legislation criminalizing the use of these drugs, and at about the same time I read a report on the efforts of other states to ban their manufacture, possession, use or delivery. It seemed clear to me that we needed legislation to do the same thing in Pennsylvania, and I had a bill drafted that added Flunitrazepam, a name for Rohypnol, and gamma-hydroxybutyric acid to Schedule IV of the Controlled Substance, Drug, Device and Cosmetic Act.

This bill was introduced in June of last year, but like most bills introduced in the last quarter of the legislative session, it did not come before the House.

In the flurry of co-sponsorship memos that marks the beginning of every new session, I received two memos proposing legislation similar in intent to House Bill 2680. In looking at House Bill 183, Representative Benninghoff's bill; House Bill 111, Representative Dermody's bill; and H.B. 2680, it's clear that all three have the same intent but slightly different language.

The two major differences seem to be in the way the drugs are added to the schedule

and the specific drugs that are proposed to be scheduled. We've just heard from Representative Benninghoff that he also plans to make major amendments to his bill and move this schedule from Schedule IV to Schedule I. My inclination, obviously, in thinking about this was to consider these as Schedule IV drugs, and I look forward to hearing today's discussion.

I added both gamma-hydroxybutyric acid and Flunitazepam which is similar but not the same. It has somewhat different effects and it's different chemicals, but I think it should also be added to the Controlled Substance List because Rohypnol has been implicated in several cases in sexual assault. However, as Representative Benninghoff pointed out, GHB may actually represent more of a threat because it's easier for an amateur chemist to synthesize.

In any case, I think we should move promptly to refine the language of the final bill, bring it out of the House and encourage the Senate to move on it with equal dispatch.

In the months since I first became interested in this issue because of the problems I was seeing in my own district, things have

gotten worse, not better. In addition to being used as an adjunct to sexual assault, these substances are apparently more commonly becoming drugs of abuse. We need to pass this legislation to give local law enforcement officials the tools they need to do their job and protect the citizens of Pennsylvania from an increasing threat to their safety.

ACTING CHAIRPERSON MAITLAND: Thank you very much, Representative Steelman. I have been joined on my left by the Chairman of the Committee, Representative Tom Gannon.

Now we'd like to hear the testimony from Representative Frank Dermody, of the 33rd Legislative District, who is also a member of this committee. Representative Dermody.

REPRESENTATIVE DERMODY: Thank you, Mr. Chairman, and I thank the committee for the opportunity to testify here today. Liquid E, Liquid X, Gamma-OH, these are some of the names given to gamma-hydroxybutyric acid, or GHB. The drug is also known as the date rape drug because it is well known for the role it plays in violent crimes against women. Dispensed in small liquid doses, GHB is difficult to detect

with the senses and can easily render users unconscious.

It has been marketed as a steroid alternative for body building, and it has gained favor as a recreational drug because of its intoxicating effects.

It is important to note that the United States Food and Drug Administration has not regulated GHB. In lieu of federal regulation, many states have begun to regulate it. According to the Drug Enforcement Administration, 18 states have listed GHB as a controlled substance and three have criminalized it.

Most of the states who have regulated GHB have done so through statutes; only two have done so through regulations. We have distributed maps to all the members here today in attendance to indicate which states have regulated GHB. And you will note it's Texas, I think New Jersey and Massachusetts that have even criminalized it.

Regulating the drug is important. It will determine how enforcement agencies and prosecutors should respond to the possession,

use and selling of the drug.

It is vital that Pennsylvania regulate this drug so that we can protect our children. In Michigan, a 15-year old girl died after drinking alcohol that was laced with a date rape drug. We can't let that happen here.

GHB doesn't just render people unconscious. In higher doses the drug can cause breathing problems, seizures, coma and death. In 1997, the FDA blamed GHB for at least three deaths.

Just the other day I was surfing the Internet and put G-H-B into a search engine. What I found shocked me. I came across a message board on the drug. Let me read to you a little of what I found.

This was written by anonymous and posted on the site just a month ago: I can tell you that GHB kicks women out within 20 minutes. Once asleep you can do what you want for four hours, and generally have a great time. Even if they wake up, which does happen, they will fall back to sleep within a few seconds, and you can continue whatever you feel like doing. They will never remember anything. As long as they

do not wake up in a strange place or in strange circumstances, they will not suspect anything.

From here, the message becomes extremely graphic and describes things one can do to a person under the influence of GHB.

I found other web sites that told people where to buy the drug, how to use it and how it can affect you. I have even found several companies who sell the drug over the Internet. Now, those companies did say they couldn't ship to states that have restricted the drug, but they also said that their mailing lists were confidential and their orders were shipped in a plain, sealed carton.

It's time to put a stop to the abuse of this deadly drug, but first we must regulate it. Thank you. Thank you, Mr. Chairman.

CHAIRPERSON GANNON: Thank you, Representative Dermody. Any questions? Representative Maitland.

REPRESENTATIVE MAITLAND: Representative Dermody, could you give a brief description of what the different schedules mean? What's the difference between I, II and IV?

REPRESENTATIVE DERMODY: The different schedules indicate, for the most part, its usefulness and whether or not there's any medical purposes or medical use to the drug at all. The Schedule II, for instance, has a high potential for abuse, currently accepted medical use in the United States but with severe restrictions.

A Schedule IV, for instance, that there's a low potential for abuse and it has some higher medicinal purposes. Therefore, the Schedule IV substance would be able to obtain with a prescription. Schedule I, obviously, is outlawed and virtually that the manufacture of the drug would be prohibited.

REPRESENTATIVE MAITLAND: Thank you. Representative Steelman, you discussed also adding Flunitazepam. Could you describe that a little bit again? I didn't quite catch why you wanted to include that as a controlled substance.

REPRESENTATIVE STEELMAN: Well, Flunitazepam is a chemical name for the drug Rohypnol. Rohypnol, although, apparently, it's not directly related, it's not a synthetic

product of GHB, but nevertheless, has many of the same hypnologic anesthetic properties. It has been implicated in similar types of sexual assault to that which is noncharacteristic with GHB. It seems to me that whatever we are doing about GHB we may also want to do to control the availability of Flunitazepam.

REPRESENTATIVE MAITLAND: Representative Benninghoff, you testified that kits are available over the Internet. Does that mean that you can make this stuff at home?

REPRESENTATIVE BENNINGHOFF: As Representative Dermody said, yes, it can be prefabricated at home. That's a concern. Obviously, when someone else is mixing it, you don't know what they may or may not be including in it; whether they are mixing the compound according to any type of instructions that may be included.

As I said, I worked in an E.R. for many years, and one of the biggest concerns we had with drug abuse was how it was cut and what it was cut with. That sometimes the pure form of different drugs or the pharmaceutically distributed drugs sometimes were not as

dangerous as the cut drugs. I think that really leaves a large door open to all types of problems with subsequent chemical compounds that may be mixed up.

REPRESENTATIVE MAITLAND: One last question for any of you that wish to answer. Representative Benninghoff stated that there's no proven medical necessity for this particular drug, GHB, and that there are alternative medicines available. Do you all agree with that?

REPRESENTATIVE DERMODY: Well, I don't know that we're sure. We understand that there's some treatment for narcolepsy, I believe; is that right?

REPRESENTATIVE BENNINGHOFF: Yes.

REPRESENTATIVE DERMODY: I think we'll hear some evidence and testimony on that subject today. So that may well clear that up.

REPRESENTATIVE STEELMAN: I'm looking forward to hearing from the pharmacologists and clinicians about the drugs.

REPRESENTATIVE BENNINGHOFF: Since I made the comment, I'd just like to say I think it's important that the FDA, one of our

governing bodies who has given approval for these drugs, does not approve it. I think that's a pretty loud statement. In addition to that, as I said, according to my Merck Manual, there are at least five other FDA prescribeable drugs to treat narcolepsy as far as cataplexy as well. As I said, I'm willing to listen to testimony, but I think there are other alternatives out there.

REPRESENTATIVE MAITLAND: Thank you. No more questions, Mr. Chairman.

CHAIRPERSON GANNON: Thank you very much, Representative Benninghoff, Representative Steelman and Representative Dermody for appearing before the committee and sharing your thoughts on this important legislation. If you would wish to join the committee, you are welcome to do so.

Our next witness is the Honorable Michael Fisher, Attorney General for the Commonwealth of Pennsylvania. Welcome, General Fisher, and you may begin when you are ready.

ATTORNEY GENERAL FISHER: Mr. Chairman, members of the committee, I'm very pleased to be here today. I'm joined by Andy

Dermarest, Senior Deputy Attorney General from our office who has worked with me on this issue involving GHB.

First of all, I'd like to commend Representative Benninghoff, Representative Dermody, and Representative Steelman for their legislative efforts in introducing the legislation that they previously appeared before this committee on.

As you know, at the present time GHB is not illegal under Pennsylvania law. Therefore, narcotics agents across the state are unable to stop this drug from getting into the hands of the wrong people. Although GHB has been criminalized now in 22 states, the people of Pennsylvania are still unprotected. That's why I strongly recommend to this committee that it pass legislation to place GHB under the Controlled Substances Act and to list it as a Schedule I drug.

GHB users by the thousands have suffered life-threatening medical emergencies, dozens have died, and many women have been victims of GHB-induced rape.

Here's just one story: A little

over two years ago, Andrea Jeffries, then a 23-year old college student living in Southern California, learned all about GHB. Andrea reported how a man pressured her to drink an alcoholic beverage he bought for her at a bar. Immediately I felt buzzed said Andrea. I couldn't see clearly. I started to fall out of my chair. It was like I was very drunk, but it didn't make any sense because I had only had one drink. Within the next few minutes Andrea blacked out.

She recalls slipping in and out of consciousness throughout the night until she awoke on the floor of the shower in the man's apartment. She was naked, lying in a fetal position. I remember him coming into the bathroom, says Andrea. At that point, he raped her. It was like everything was in slow motion, she recalls.

She blacked out again, and when she came to she was still being raped. This time he was holding me down by my neck and I was screaming, says Andrea. After the attack, she balled up on the bed and cried.

As the effects of GHB began to wear

off, Andrea grabbed a cordless phone, locked herself in the bathroom and called the police. Meanwhile, the man ripped the phone unit out of the wall and began ramming the door. Moments after he burst in, the police arrived and ushered her to safety.

The man was convicted and sentenced to jail, but Andrea is still living with the terror of that night. I'm not the same person I was before, she said. All I took was one drink, and my life has been changed forever.

GHB is hardly the only date rape drug to make the headlines. Until recently, Rohypnol, which is a Schedule I controlled substance, was the most affective date rape drug.

But, one twist makes GHB much scarier than Rohypnol. Unlike Rohypnol, which can only be manufactured commercially, GHB is easily produced at home. Anyone with Internet access can find a way to buy the recipe and the kit and cook up a batch. I heard Representative Dermody referring to the ease with which GHB can be concocted.

It also has dual action on the

brain. Like cocaine, it stimulates nerve cells that respond to the chemical messenger dopamine, producing an excitatory effect. Like heroin, it activates natural opium-like substances within the brain, causing sedation. Taking GHB is sort of like taking heroin and cocaine at the same time. Because it's home-brewed, its potency can vary widely from batch to batch. This means even a single dose could prove deadly.

Those who make GHB at home don't realize that the formulas aren't exact, and the amount that simply intoxicated someone the first time can just as easily kill them the next.

Let's take a look at the results of GHB use in the past two months. On January 16th, 1999, two 15-year old girls from Michigan drank a GHB-laced beer at the apartment of an older boy they had just met. Both girls went into comas. One girl awoke from that coma 15 hours later. The other girl did not. She was later pronounced dead.

On January 24th, at 5:30 a.m. an 18-year old boy from New York was found collapsed, convulsing and foaming at the mouth on a loading dock next to a nightclub. When the

ambulance arrived, young Jimmy Lyons was pronounced dead at the scene. The cause of death was an overdose of GHB. Just a week before this tragedy, a dozen young patrons of another New York nightclub overdosed on GHB.

On February 17, two brothers were found guilty of raping a Georgia college student. The brothers bought some GHB near the school and offered it to two female students. One of the women passed out in the bathroom, near death, and the brothers brutally assaulted the other while she was unconscious in her dorm room. A male friend of one of the girls who stopped by noticed the girls seemed disoriented and called 911. Paramedics arrived while the dazed woman was still being raped.

On February 20th, three Florida teenagers were rushed to the Emergency Room after drinking GHB they concocted from a recipe they found on the Internet. The father of two of the boys found his sons vomiting violently and called rescue crews. Their friend was found an hour later lying unconscious in a bush near the family's driveway. The night before the boys' mother found a recipe for GHB lying on the

older son's desk.

These are just some of the tragedies. Most incidents go unreported.

In September of 1998, I petitioned the Pennsylvania Department of Health's Drug, Device and Cosmetic Board and asked the agency to use its authority to classify GHB as a Schedule I controlled substance. The Drug, Device and Cosmetic Board heard testimony this January of my petition. The board recommended that the Secretary classify GHB as a controlled substance, but it recommended that it be placed in Schedule IV.

Although we are pleased that the board wanted to criminalize this dangerous drug, I reiterated my position that the correct classification for GHB is Schedule I and not Schedule IV. We are still awaiting the Secretary of Health's decision on this.

Schedule IV, in my opinion, is clearly the wrong schedule for GHB. Schedule IV is for drugs that can be prescribed for medical use. It is illegal to prescribe GHB for medical or other use. GHB has been banned for medical use by the Federal Food and Drug Administration.

The FDA has conducted over 45 criminal investigations of those who sell GHB.

So, considering GHB as a Schedule IV at this point is really moot. Even if Pennsylvania were to schedule the drug as a IV, it would still be illegal to prescribe it under federal law. Even if it were approved by the FDA, and this is pure speculation--There's no indication at this time that the FDA has this under any serious consideration--it should not be placed on Schedule IV.

In order to meet the criteria for IV--I think you heard some of that, but let me repeat--the drug must have a low potential for abuse. Second, it must have a currently, and I emphasize currently accepted medical use relative to substances in Schedule III, and have limited physical or psychological dependence liability relative to substances in Schedule III. GHB does not meet any of these criteria.

First, there is a high potential for abuse. According to the Drug Enforcement Administration, GHB is used to get high in 80 percent of the cases and is mixed with alcohol or other drugs in a hundred percent of those

cases. It's abused by party-goers for its euphoric and aphrodisiac effects. It also is used as an alternative to Ecstasy and amphetamine sulfate.

In 1990, the FDA banned CHB stating: It had caused more than 30 people to become ill with symptoms ranging from nausea and vomiting to severe respiratory problems, seizures and comas. Because of its continued abuse, the FDA had to repeatedly issue warnings that GHB is illegal and widely abused.

The DEA has documented over 3,500 incidents of GHB abuse, a number which has increased dramatically from 16 cases in 1992. The total number of deaths caused by GHB has risen to 32. In Pennsylvania, at least eight individuals have experienced life-threatening comas following ingestion of GHB in 1998 alone.

In March of '98, five young people from Bucks County ingested GHB they had purchased over the Internet; all were hospitalized with life-threatening comas. In May, a 16-year old Centre County girl overdosed on GHB. In July, two Penn State students were rushed to the Emergency Room after ingesting

GHB. Both faced life-threatening side effects including seizure and coma. Last April, police raided a clandestine drug manufacturer near Indiana University of Pennsylvania and seized thousands of doses.

GHB has become the new date rape drug of choice. Because it's a clear, nearly tasteless, odorless drug over half of its victims do not know how it got into their system. It knocks the girl unconscious for four to eight hours, in which time the rape is committed, and she awakens suffering from amnesia and unable to recall what happened.

The DEA is aware of at least nine sexual assault cases involving 19 victims under the influence of GHB. GHB is now the fourth most commonly used drug to commit date rape, surpassing the notorious Rohypnol. Clearly, GHB is highly abused.

Second, there is no accepted medical use of GHB. It's never been approved by the FDA despite having undergone years of clinical tests by Orphan Medical, who you will hear from, I believe later. Orphan Medical believes it should be listed as a Schedule IV. However, it

is the scientists at the FDA who approve drugs for medical use; not executives of drug companies.

Furthermore, if this committee makes GHB a Schedule I controlled substance, it will not take this drug out of the hands of one narcolepsy patient in Pennsylvania or anywhere else. Schedule I will not prevent Orphan Medical from distributing this drug within its clinical trials. So there is still that exception which will be permitted.

The third, GHB has more than limited physical or psychological dependence. We already talked a little bit about that.

A physician asked by Orphan Medical to testify at an earlier hearing stated that my guess was that GHB would probably be unlikely to induce physical dependence because it has a very short half life. He goes on to say, that drugs with a very short half life are not likely to easily produce physical dependence. Actually, some of the most addictive and physically dependent drugs in the world, like crack cocaine, have a very short half life.

Although Orphan Medical has

conducted no tests on GHB's dependence liability, it stated that GHB's half life is about four hours. Well, the half life for crack cocaine is only 30 to 150 minutes. Most crack addicts report intense cravings for the drugs and claim they'll do anything to get it.

I would like to see some more scientific research on the dependence liability of GHB before we should consider allowing this drug to be marketed or sold as a sleep aid. Frankly, we have our hands full treating Pennsylvanians addicted to crack, cocaine, heroin, alcohol and other drugs. We don't need any more.

However, GHB does meet the requirements for Schedule I. A Schedule I drug must have the following: A high potential for abuse; no currently accepted medical use and; a lack of accepted safety for use under medical supervision.

In response to number 1, we know GHB is highly abused. In response to number 2, we know that GHB is not approved for medical use. In response to number 3, there is a potential lack of safety for use under medical supervision

because Schedule IV controls on patients are weak.

For instance, instead of being required to obtain the drug with a physician's prescription on a monthly basis, where the physician can supervise and keep track of the patient's use, under Schedule IV, the patient may simply be mailed large quantities of GHB for as many as 12 months with only one prescription. The company will mail the drug directly to the patient.

In fact, Orphan Medical asserts that it will keep track of patient use, and it will be alerted if there is a danger of a patient overdosing or if the drug is being diverted. In my view, that's not the safe way to distribute and use a drug that is so dangerous and so highly abused.

The patient's doctor should supervise the use of this drug, not the company that wants to profit from its sale. The committee needs to act to control GHB and place it in the appropriate category, Schedule I.

I would like to also make some brief reference to GBL, if I could, Mr. Chairman. The

committee should know that the FDA has banned GHB for medical use and 22 states have criminalized it, but some distributors have turned to selling its central ingredient, GBL. Let me take a few minutes to talk about this other highly dangerous drug.

Although over 80,000 metric tons of GBL are sold every year by chemical companies for use as floor stripper, circuit board cleaners and other legitimate uses, it is now being sold by illicit operators as a substitute for GHB. They are setting up web sites and selling GBL as a dietary supplement, sex enhancement or sleep aid under labels like Blue Nitro, Renewtrient and RemForce.

A woman in Florida overdosed and died from GBL sleep aid, Renewtrient. GBL has caused life-threatening side effects in at least 55 people. In January, the FDA issued a voluntary recall of products containing GBL.

In response, I recommend to this committee that the committee consider legislation to list GBL as a chemical subject to registration under the Non-Controlled Substances Reporting and Registration Act. This act will

require manufacturers and web site operators to register with the Department of Health and to obtain from the buyer a photo driver's license and a signed statement providing a full description of how the substance is to be used.

This will also cause illicit operators to stop selling GBL because they will not want law enforcement to know how they are selling or how we can find them. It will prevent Pennsylvania's children from purchasing GBL over the Internet or at the local hardware store.

Mr. Chairman, I also have provided a list -- provided you with a series of letters from relevant authorities supporting our request on GHB. Each of the following individuals and institutions is calling for GHB to be listed as a Schedule I controlled substance.

They are the Pennsylvania District Attorneys Association, Executive Committee; District Attorney Ray Gricar from Centre County; District Attorney Alan Rubenstein from Bucks County; the Chiefs of Police of State College and Middletown Townships; the Director of the Pennsylvania State University Health Services;

the Medical Director of Poison Control Center at Children's Hospital of Philadelphia; the forensic toxicologist at the National Medical Services; and Mrs. Rumburg, Executive Director of the Pennsylvania Coalition Against Rape.

With that, Mr. Chairman, and members of the committee, I'll be glad to answer any questions that you or the committee members may have.

CHAIRPERSON GANNON: Thank you very much, General Fisher. Any questions from the members of the committee? Brian.

MR. PRESKI: One question, General. If I could play devil's advocate with you. One of the things that we hear from the, I guess not the supporters but the parties that would not like to see this as a Schedule I drug is basically that if we do change this to a Schedule I, we're not going to change the Internet sites available or the recipes that are available to make this drug. Do you have any comment on that, sir?

ATTORNEY GENERAL FISHER: Quite frankly, Counsel, I think that regardless of what schedule we put this drug on, we're going

to have difficulty controlling what is being peddled over the Internet. The fact of the matter is, the problem which we have today is we can't penalize anybody who gets the substances and peddles the drug. That's the real difference.

If somebody is trying to make an argument that Schedule IV is going to make it easier to control the Internet, I can't buy that. But in fact, if we have penalties in place that can penalize those who improperly manufacture, distribute or use this, then I think that we'll control at least the distribution of this drug in Pennsylvania.

MR. PRESKI: Thank you, General.

CHAIRPERSON GANNON: Thank you very much.

ATTORNEY GENERAL FISHER: Mr. Chairman, I'd like to make a couple additional comments. I know that Representative Benninghoff has done a lot of research into this as have the other members. I commend -- I know that he's proposed amending his bill to move it from Schedule II to Schedule 1.

I'd also like to comment, perhaps

this committee is somewhat interested on the process through the Drug, Device and Cosmetic Board, the alternative process by which one can schedule a drug in Pennsylvania. It's interesting to us and I give credit to the Secretary for convening the board and the citizen members on the board who were in attendance that day in January.

The Drug, Device and Cosmetic Board interestingly enough is a board that very seldom meets. It's been, perhaps, years since the Drug, Device and Cosmetic Board actually was brought together to consider any listing, delisting or changes.

But yet, it is a mechanism under the jurisdiction of the Secretary of Health which does provide some flexibility as to when the General Assembly acts. I believe that at this time the preferred way to proceed in this state is for the General Assembly to make a decision on GHB. And then recognizing that there's room for flexibility, to work with the Secretary of Health to determine any changes in the future, whether it be by moving around in the schedule, whether it be this drug or any others.

But, by at least placing this on the schedule, the General Assembly has I think some control to make sure that the Secretary is able to come back to you to say, this is what we find and this is where we should go. It's an alternative to try to get substance scheduled, perhaps, more quickly than the legislative process, but actually as we found through there with necessity for regulations and, perhaps, the unfamiliarity of most of the members of the board, we prefer in this instance the fact that this General Assembly and this committee is the better of the two choices to institute and finalize this process.

I bring that to your attention, because I know as a member and my position as chief law enforcement officer I knew that board was there. Having filed this petition I was never really aware as to how active they have been.

CHAIRPERSON GANNON: Thank you, General Fisher.

REPRESENTATIVE STEELMAN: General, could you expand on your control of GBL, the precursor of GHB through registration? I'm

reading both in your testimony and in the supporting letter from National Medical Services that GBL has as high abuse potential as GHB. Yet, we're proposing, you're suggesting that we should apply much more relaxed controls to it. I understand the problem that this is obviously widely used for commercial purposes.

On the other hand, it appears to be as dangerous a drug as the drug that you're proposing we make a Schedule I, absolutely restrictive drug. Could you expand a little bit on why you think the proposal to acquire that sellers of GBL get a copy of the photo driver's license and a signed statement providing a description of how they are going to use this material is actually going to exercise the kind of controls that we need to?

ATTORNEY GENERAL FISHER: The major difference is that there is an already accepted commercial use for GBL. There are 80,000 metric tons a year sold for various commercial purposes. It's going to be used. We think that this very little used provision of registration, at least based on what we now know about GBL, is an acceptable way to control the illicit

marketing of GBL, while at the same time allowing GBL to remain on the market for its otherwise legitimate commercial use.

We suggest to the committee that this is an acceptable way to try to regulate GBL, while at the same time recognizing, that since it is a precursor to GHB, the criminalizing of the possession of GHB will be the opportunity to penalize those people who try to abuse it, as well as those people who may divert the sale of it to people who aren't, obviously, using it for commercial uses.

REPRESENTATIVE STEELMAN: I understand the problem, but it does seem -- The Schedule I drug requirements don't say no currently accepted commercial use. They say no currently accepted medical use. Am I right in assuming that there is no currently accepted medical use for GBL?

ATTORNEY GENERAL FISHER: Not that we're aware of.

REPRESENTATIVE STEELMAN: So, in fact, GBL also has high potential for abuse, no currently accepted medical use and a lack of accepted safety use under medical supervision.

ATTORNEY GENERAL FISHER: That would be accurate except for the fact that it does have a commercial utilization and it is -- As you say, you can go to various hardware stores and you can buy GBL today, but the problem is, anybody who has it for sale is not required to tell who they are selling it to. At least by schedule using this registration system we would gain that control over it until we learn more about it.

REPRESENTATIVE STEELMAN: If we adopt this registration strategy, does that mean that every retail seller will have to keep the registry of all of the buyers; that is, if you go into your True Value Store and you are looking for a floor stripper that contains GBL, someone behind the counter will take your name, your driver's license number?

ATTORNEY GENERAL FISHER: That's correct.

REPRESENTATIVE STEELMAN: And then who will come around from Harrisburg and look at those registrations?

ATTORNEY GENERAL FISHER: They are required to be filed with both the Secretary of

Health and with my office.

REPRESENTATIVE STEELMAN: Thank you.

ATTORNEY GENERAL FISHER: To make it clear, people aren't walking in -- I know I've never walked into -- I guess that reflects on the amount of floors that I have cleaned, but I don't walk into any hardware stores to buy GBL. Although it has a use, it's not commonly purchased in your hardware stores. So if you saw a run on this, it might be a very good indication that people are using it for other than legitimate purposes. At least this form of registration would require these statutes.

CHAIRPERSON GANNON: Representative Blaum.

REPRESENTATIVE BLAUM: General, I congratulate you on your testimony and your efforts to push this legislation. It seems to me one of the most insidious aspects of this cocktail is the fact that it's odorless and tasteless. Is it unreasonable or at all possible that we could require in the retail sale of Pennsylvania some kind of odor or taste that is not offensive for -- that would not be in conflict with its commercial uses?

ATTORNEY GENERAL FISHER: That is possible. That could also be something that the FDA could require. If the FDA said that there was an acceptable medical use, they could require the manufacturer whether it be Orphan or someone else to add some taste to it to tip people off that it wasn't the normal martini that you were drinking when this particular substance was added.

That's one thing that I think the FDA in approving various marketing techniques would have better control over than one individual state.

REPRESENTATIVE BLAUM: I was once told and I don't know if it's true, that natural gas has no odor. The odor is added so that you know if your house is about to blow up. That's something that we might be able to look into.

ATTORNEY GENERAL FISHER: It's something that could be considered. However, the scheduling system really doesn't give Pennsylvania a qualitative approval process over various drugs. Because a drug like this is sold interstate, across the whole country, that's why I think the FDA is a better entity. Let them do

the testing; let them make some decisions on medical use and if components need to be added for safety purposes.

One thing that you may want to do, this committee may want to do, is in adopting this legislation, take a position recommending to the FDA that that kind of additive be considered before any legitimate medical use be considered by them.

REPRESENTATIVE BLAUM: Very good.

MR. PRESKI: General, one question. Do you have any indication if the Department of Health will act soon, at anytime or whenever?

ATTORNEY GENERAL FISHER: I do not.

MR. PRESKI: Thank you.

CHAIRPERSON GANNON: Thank you very much, General Fisher, for appearing before the committee today and sharing your thoughts on this very important legislation.

Our next witness is Patti Engel, Vice-President of Orphan Medical, and joining her is Matthew Speakman. Welcome, Ms. Engel, and you may proceed when you are ready.

MS. ENGEL: Thank you very much. Mr. Chairman, members of the Committee: My name

is Patti Engel. I work for Orphan Medical, a very small company in Minnesota that specializes in developing medicines for people with rare diseases. In fact, we're the only company in the country who specializes in the treatment of patients with very rare diseases. These are life-threatening rare diseases that most people have probably never heard of.

Life-threatening diseases like Congenital Sucrase-Isomaltase Deficiency, which is a genetic disorder that leaves children unable to metabolize sugars and starches, leading to malnutrition and developmental delays. Diseases like Homocystinuria in which children cannot convert homocystine which becomes toxic material in the blood leading to mental retardation, blindness and death.

Both of these serious medical conditions affect fewer then 1,000 children in the United States, not the size of patient population that typical pharmaceutical companies are interested in. We've developed medicines to help people live a normal life.

I'd like to say that at the outset that we and the Attorney General share an awful

lot of common ground. Home-brewed GHB is poisonous. Young people are dying senselessly. Young women are fearful about leaving drinks unattended. And we agree that illicit use of gamma-hydroxybutyrate or GHB should be severely penalized. We simply have different means of achieving this end, but the end is still the same.

Orphan Medical first heard about GHB back in 1994. The U.S. Food and Drug Administration, the FDA, did something that it rarely does. It asked us, a drug company, to develop a promising new medication. Specifically, it asked us to develop GHB to treat a rare disease called narcolepsy, and an even rarer symptom of that disease called cataplexy.

Narcolepsy is a disabling sleep disorder that affects about 180,000 Americans, about the size of Beaver County, including about 6,000 people here in the State of Pennsylvania. Typically, people with narcolepsy exhibit excessive daytime sleepiness and something called cataplexy which is a sudden and total loss of muscle control. A total cataplectic

attack results in immediate, complete body collapse during which a person appears unconscious. In reality, however, the person is quite awake and alert but unable to walk, talk or move despite the great pain and potential danger resulting from a fall. Cataplexy is often triggered by stress, fatigue or emotion.

Cataplexy affects about 65 percent of narcoleptic patients, and we estimate to around 4,000 patients here in the State of Pennsylvania are affected by cataplexy. Because of unpredictability and frequency of attacks, people with cataplexy are unable to live the life that you and I are accustomed to. They can't usually work outside the home. They can't drive a car, operate machinery and young mothers tell us that they can't hold their babies for fear of dropping them.

While the excessive daytime sleepiness component of narcolepsy is, in fact, treated with a number of medications, including newly-approved medication called Medafinil or Provigil as Attorney General so eloquently described. There is virtually nothing that patients with cataplexy can utilize.

For many years now cataplexy has been treated with tricyclic antidepressants. Unfortunately, they are minimally effective. They cause undesirable side effects, and about ten years ago FDA learned that GHB is, in fact, effective in treating cataplexy. It appears to induce a deep and restful sleep that people with cataplexy don't ordinarily experience. It promotes REM, or rapid eye movement sleep, and does, in fact, reduce cataplexy attacks.

Early on, other pharmaceutical companies attempted to develop this medication. But it does take millions of dollars to develop a drug to FDA requirements, and those companies simply failed.

About five years ago, after being approached by the FDA about developing GHB, I myself had the chance to visit sleep centers where GHB was being used as an experimental treatment for cataplexy. I spoke firsthand to patients who were using this medication. GHB they said had changed their lives. I heard grown men weep as they describe the impact of this medication in their lives. By using GHB, cataplexy attacks in some patients went from as

many as 50 a day to two a month. It gave patients relief they needed to get into the real world and live.

Frankly, these testimonials sound too good to be true. As a pharmaceutical company we are not accustomed to hearing of outrageous results with medications for diseases. We were skeptical and had to scientifically put this to a rigorous test to validate or disprove the claims of the patients and researchers. Under FDA's guidance we initiated rigorous, well-controlled clinical trials of GHB in 1998 at sleep centers in 14 states. In August 1998, we presented the results of our clinical findings to the FDA.

FDA viewed the evidence as so significant that it asked us to consider conducting what is called a treatment IND. The purpose of treatment IND is to increase patient access to experimental medications that have showed strong evidence of safety and effectiveness during the time that FDA is formally reviewing the technical components of a new drug application.

Treatment INDs are granted to only

promising medications used to treat severly debilitating or life-threatening conditions such as cancer, AIDS, severe Parkinson's syndrome, multiple sclerosis, respiratory distress syndrome in infants, diabetes and, of course, now narcolepsy.

In December 1998, FDA formally gave Orphan Medical the go-ahead to conduct the treatment IND. The data collected during this clinical trial will add to the mountain of evidence we've already collected. A new drug application contains volumes of scientific and medical data that FDA needs to evaluate before formally approving the use of a medication. We expect to submit our new drug application this year or early next year.

Representative Steelman described a little earlier the difference between accepted medical use and accepted commercial use. While the FDA will not be allowed to describe the accepted commercial use of the agent GHB until after the formal approval of this drug, the approval of the treatment IND does signify its accepted medical use across the country.

During the time that we've been

quietly developing GHB for the treatment of narcolepsy, interest in GHB's illicit use has certainly grown. As the Attorney General stated, information about how to make and use GHB is readily available on the Internet, and its chemical precursor, gamma-butyrolactone, or GBL, can be obtained easily. It is easy for anyone with a computer, credit card, and the inclination to surf the Net, find the recipe, buy the ingredients, and make a batch of home-brewed GHB right in their kitchen.

It's important to note that no medical-grade GHB has ever been diverted for illicit use, and that's despite its use in clinical trials in 14 states.

Because of the home-brewed nature of GHB through the material purchased on the Internet, the levels of toxicity vary greatly. A capful of one batch may be equivalent or as toxic as a cupful of another.

The newness of GHB and its easy manufacture have caused tremendous problems for law enforcement. We share the concern for public safety that was so eloquently expressed by Attorney General Fisher.

Over the past three years, we have worked with FDA, the U.S. Drug Enforcement Administration and members of Congress to get GHB listed as part of the Controlled Substances Act.

Our goal and message have been extremely consistent: Severely punish those who illegally possess, distribute, or manufacture GHB and its analogs. Severely punish sexual predators who would use it to commit assault. But do so without denying narcolepsy patients access to the only medication that has been proven to be effective for cataplexy.

With that in mind, we wish to urge Representative Benninghoff, Dermody and the committee to improve House Bill 183 or 111 as originally written so that while GHB is listed as a Schedule IV substance, governing its legal and medically appropriate use, Schedule I penalties can be leveled against anyone who illicitly manufactures, distributes or possesses GHB and its precursors.

Specifically, we suggest that a new subparagraph be added to Section 780 dash 113F, paragraph 3 of the Controlled Substance, Drug,

Device and Cosmetic Act. It would say that anyone who violates the act with respect to, quote, gamma-hydroxybutyric acid, any salt, compound, derivative or preparation of gamma-hydroxybutric acid, including any isomers, esters and ethers and salts of isomers, esters and ethers of gamma-hydroxybutric acid whenever the existence of such isomers, esters and ethers and salt are possible within the specific chemical designation, would be guilty of a felony and upon conviction thereof to be sentenced to imprisonment not exceeding 15 years, or to pay a fine not exceeding $250,000 or both, unquote.

A copy of our proposed language is in the information packet, the blue information packet which we have provided to all of the members.

Mr. Chairman, and members of the committee, we maintain that such Schedule I penalties are at the heart of the Attorney General's argument. Knowing that a medication is on Schedule I is no deterrent. Knowing you're going to get 15 years and a quarter-million-dollar fine is.

Attorney General Fisher described earlier horrific instances of abuse throughout the United States. He specifically spoke to instances in both Michigan and Georgia where young women had been raped with GBL. It's important to note that in both Michigan and Georgia GHB is a Schedule I. Schedule I penalties did not stop this in most states at all.

Now, some may argue that our proposal gets too creative with the Pennsylvania statutes, but I would offer that the state Date Rape Act championed by the Attorney General was just as creative. It effectively adds ten years to the rape conviction of anyone who uses any substance to facilitate a sexual assault, any substance, aspirin, alcohol or GHB, controlled or uncontrolled.

Mr. Chairman, and members of the committee, I'm sure you noticed that I did not simply identify GHB in our proposed amendment. In fact, what I identified included GHB and more importantly its chemical precursor, GBL, its esters, ethers and other chemical concoctions that use GBL which some bathtub chemist may

dream up in the future.

Today, GBL is legally used by manufacturers of paints, like PPG Industries; beer manufacturers, like Latrobe; and electronics components manufacturers, manufacturers with experience using regulated chemicals. The key to stemming the illicit manufacture of GHB is to criminalize the illegal use and possession of GBL.

There is absolutely no reason for any individual to have GBL in their possession. If they have it, it's for one reason and that's to make GHB or to use GBL as if it were GHB. GBL is the necessary component to make GHB. Absent GBL, you can't make GHB.

As we discussed earlier, GBL is not difficult to find. You can obtain nearly 100 percent GBL off the Internet for as little as $35 charged to your credit card, or if you looking to run a major GBL trafficking operation, you can obtain GBL in bulk with little, if any, screening.

As a test last summer, our company contacted four reputable chemical suppliers with only a false company name, a false phone number

and a credit card. Two of these suppliers were more than willing to set up an account for us to obtain GBL in huge quantities.

Last year, Florida authorities tell us, illicit manufacturers of GHB learned they didn't have to bother even going to the trouble of buying GHB. GBL is brewing the GHB themselves. They discovered that GBL naturally converts in the body to GHB. So, now they just sell diluted GBL by capfuls. They call it scoop in Florida. It is highly toxic. This bottle that I've been holding up once diluted could make 50 doses of scoop for rave party-goers. And at ten to $20 a dose, that makes a lot of money for the dealer.

A sexual predator could use GBL in this bottle to help him commit at least 15 sexual assaults.

In Florida, GHB abuse is dropping as GBL abuse is increasing. They tell us also that the demographics of the abusers have changed. GHB abuse was occurring among 20 to 30 year olds; GBL abuse is occurring among 15 to 20 year olds. Fifteen year olds. This is an outrage.

Making GHB a Schedule I agent will

do nothing to prevent this as we learned from Michigan and from Georgia.

So, Florida responded by modifying their state statutes using very scientific language to include GBL, its isomers, its esters and any concoction that a scientist might come up with to get GHB. It's the same language that we have proposed to the committee, Mr. Chairman.

The Attorney General is correct that Schedule I drugs can be clinically studied in Pennsylvania, but that's only if you can find doctors and manufacturers who are willing to do so. If GHB were listed in Pennsylvania as a Schedule I agent, the Pennsylvania company that manufactures pharmaceutical-grade GHB for our clinical trials will cease production. That would end the research. We'd have to tell FDA to find someone else to develop GHB all over again. Narcolepsy patients would have to wait at least five more years for GHB to be available to them.

If GHB were listed as a Schedule II substance, a 20,000 square foot vault, the size of a small airplane hangar made of eight-inch concrete would be required to store

pharmaceutical-grade GHB. The cost of construction would be ten to $20 million which would more than double the cost of the clinical trials, and those additional costs, if we could even afford them, would be passed on to the health care system.

And if by some miracle a benefactor were found to build a vault for us, we would face the real problem then and that's diversion. Not at the vault, but in the distribution channel.

Schedule II medications, as the Attorney General stated, cannot be sent directly to patients from single, well-controlled mail-order pharmacies. We would have to distribute pharmaceutical-grade GHB in the same way that highly-prescribed medications are distributed to thousands and thousands of patients; the way a drug like Viagra gets to over three million patients; through every national drug wholesaler, regional distributor, chain-store distributor and retail pharmacy. We would have to produce and ship a whole lot more GHB than is necessary to treat a few patients in Pennsylvania that suffer from narcolepsy.

At every point in the distribution, and there are hundreds of them, every point is an opportunity for diversion. There would be no way of knowing if a patient is over filling prescriptions until after the DEA filings identify it; often months after.

On January 6th of this year, the medical professionals who make up the Pennsylvania Drug, Device and Cosmetic Board, after hearing the medical and scientific information voted five to one that GHB should not be a Schedule I or II, but that this agent scientifically fits into a Schedule IV. That same board recommended control of the precursor chemical GBL to get at the real issues of the abuse of this agent.

If GHB is listed as a Schedule IV agent, it would permit Orphan Medical to ship directly to patients, track the dose that each individual patient around the country is on. We would track their refills. We would manufacture the right amount of GHB, minimizing opportunities for diversion. From our distributor in Ohio to Federal Express directly to the patient door; not on trucks going to many, many wholesalers and distributors

throughout the country.

We could identify any diversion and prevent it before a shipment is made, and we'd call the doctor about it so the patient would not be allowed to get anymore. So who wins; who losses?

Mr. Chairman, members of the committee, we think we have proposed amendments to both Representative Benninghoff's original bill and Representative Dermody's bill that enable everybody to win; parents, children, women, rape crisis advocates, narcolepsy patients and their families, police, prosecutors, and members of the legislation and the Attorney General.

We hope that you will agree with the Pennsylvania Drug, Device and Cosmetic Board that medical-grade GHB should be a Schedule IV agent, and that the criminals that use this and other chemicals to perpetrate crime should be severely punished.

Please approve the original intent of House Bill 183 and 111 with the suggested amendments allowing the continued treatment of Pennsylvanians with narcolepsy.

I'd like to thank you, Mr. Chairman, Representative Benninghoff, Representative Dermody, and the committee members for the opportunity to present this testimony.

Now, I would like to introduce you to Matt Speakman, his father Bill Speakman and his mother Jane Carey of McMurray, Pennsylvania. After Bill, Matt and Jane conclude their comments, I will be happy to answer any questions that you may have.

CHAIRPERSON GANNON: Mr. Speakman.

MR. SPEAKMAN: Thank you. I have narcolepsy. I'm one of the 65 percent of narcolepsy patients who have the excessive daytime sleepiness and cataplexy which she described as being a total lack -- loss of muscle tone and muscle control, which usually results in a collapse.

I had learned about GHB as being a medical treatment for narcolepsy after my mom was desperate to the point where -- I was on Ritalin to treat the sleepiness and one of those tricyclic drugs that's basically a mood elevator to treat cataplexy. It doesn't work, but that's what they give you because it's the best thing

they have.

I was a junior in high school when I was afflicted with narcolepsy. It just kind of happens sometimes. The medical causes aren't quite determined yet. My grades suffered, of course. This cataplexy is what really eats you up. You can maybe can get by with daytime sleepiness by scheduling that throughout the day, like I was allowed to go down to the nurse's office after lunch and take like a 15 or 20-minute nap, which would help me stay awake through my classes which was a difficult thing.

But the cataplexy is not predictable and it happened -- Severe cataplexy attacks would happen to me as many as two and three times a day. It's difficult to try to explain that to your teachers and your friends when your face just hits the desk. They don't know what to do. They don't know if you're in some kind of serious medical trouble, but like she said, I'm fully awake, fully aware. I can hear, see and listen. I just can't move.

After starting on GHB, it was immediately a significant difference in both my daytime sleepiness and my cataplexy attacks. I

have been on it over a year now. I have had only two severe cataplexy attacks in more than a year's time.

Last summer I drove to Maine myself. I got a job as a camp counselor teaching kids how to draw and paint, full time, day and night in the cabin with them, everything. I had no problems whatsoever. I'm happy to say that's a good reference for me. Without GHB that would not have been possible. I honestly wouldn't have attempted it on Ritalin or Vivactil because it doesn't treat the cataplexy.

I can cite embarrassing times as well as scary times. I was a competitive swimmer in high school, and those sudden bursts of emotion and laughter is what triggers cataplexy attacks. When you're in a relay and the guy hits the wall and you shoot off the block and have a cataplexy attack in midair and they have to pull you out of the water, it's embarrassing, but it's also scary being in the water. That can happen, let's be realistic, driving and during a lot of other things that causes emotional responses.

To have only two cataplexy attacks

over a year's time, instead of two or three a day, to me that proves the drug is doing a whole lot more than any of the others. That's what I have to say.

CHAIRPERSON GANNON: Thank you, Mr. Speakman. Any questions?

REPRESENTATIVE BLAUM: Mr. Chairman, I'd like to congratulate the gentleman on his courage in coming before the committee and advocating his position. I think it takes a lot of guts.

CHAIRPERSON GANNON: I can say personally I represented a client who had narcolepsy. It was very revealing how disabling the disease, the illness can be. I had contact with it. I do appreciate -- Representative Steelman.

REPRESENTATIVE STEELMAN: I was just wondering if you could talk a little bit more. We understand in Mr. Speakman's case the drugs that apparently are described in the Merck Manual that Representative Benninghoff referred to weren't effective. Could you give us some idea of how often those drugs are not effective?

Nobody on this panel is a

pharmacologist. We're being asked at this point to judge between one point of view about the pharmacology of narcolepsy and a different point of view. When the Merck Manual says fairly authoritatively, Imipramine is the drug of choice to treat cataplexy, why or why not?

MS. ENGEL: There are two main symptoms of narcolepsy. One is excessive daytime sleepiness and the other is cataplexy. For many years people have attempted to segment the disease in a way where excessive daytime sleepiness is treated with stimulants to keep you awake, if you will, and the cataplexy treated with mood elevators such as Imipramine to not so much control the cataplexy but control the emotions as Matt described with flat effect. With no real highs or lows the incidents of cataplexy will not be experienced by a patient who typically would experience that.

While the Merck Manual states that these drugs are used for cataplexy, Matt spoke to them himself. They are often used because there is nothing else available right now.

MR. SPEAKMAN: It's the drug of choice because there's nothing else. They

think -- They know what certain drugs effect different parts of the brain and to try to level that out so that there aren't -- It's an attempt to make some kind of predictability to cataplexy attacks instead of trying to stop them.

MS. ENGEL: Remember FDA came to Orphan Medical in 1994 and asked us to develop this drug specifically because there were no effective treatments for the cataplexy associated with narcolepsy. Attorney General Fisher described the drug Provigil or Rohypnol that was recently approved by FDA.

I would urge you to look to the PDR, the Physician's Desk Reference, which describes not only where drugs are commonly used but where drugs have scientific evidence and FDA sanction in their practical use. FDA has approved Provigil for the excessive daytime sleepiness associated with narcolepsy. They recognized that Provigil has no impact in cataplexy.

Imipramine has no FDA approval for cataplexy. The other agents that you see in the Merck Manual have no FDA approval for cataplexy because frankly those companies have not been able to prove in scientifically rigorous and

statistically significant manner that those drugs are any more effective than placebo in treating the cataplexy associated with narcolepsy.

With the data presented to the FDA in December of 1998 on the effect of GHB with cataplexy was the first time scientific rigorous statistically significant information had been provided as to a drug that was actually effective in treating the cataplexy associated with narcolepsy. It is for that reason FDA asked Orphan Medical to conduct a treatment on GHB.

Now, we can talk all day long about what is accepted medical use as Schedule I describes, and we believe, as does FDA and DEA, that the sanctioning of a treatment IND for GHB does, in fact, constitute accepted medical use. We're not talking about accepted commercial use.

The FDA and Orphan Medical have squares to fill, if you will, before the FDA's approval for this drug. There are manufacturing issues that have to be finalized, and stability issues on how stable or what is the shelf life of this drug before FDA will approve it for

commercial use or commercial acceptability.

But, in fact, the appearance of Matt and others here who are today using GHB as the only agent that has controlled their cataplexy, and the fact that FDA has approved its use in treatment IND has requested across this country the patients be -- the population of patients be expanded to be allowed to utilize this agent for their cataplexy does speak and speaks very strongly to its accepted medical use.

REPRESENTATIVE STEELMAN: I noticed that several of the states in which you give your trials now have GHB listed as a Schedule I drug. What's that done to your ability to continue to collect evidence.

MS. ENGEL: Well, in some states we have been able to work with the medical boards to get special dispensation to ship product into the states for patients. In other states it has denied patients' access. One example is Alabama, where two clinical sites recently have not been able to continue to provide medication for their patients. The patients are now traveling out of state to obtain medicine for their disease.

The issue here in Pennsylvania centers so much around the issue of the manufacture. Our manufacturing site is based in Conshohocken and with the listing of GHB as a Schedule I, they will not be able to continue to manufacture this agent for clinical trials anywhere in this country.

So, while the law allows for study under a Schedule I as Attorney General Fisher described, the practical implications of a Schedule I would, in essence, shut down the development of this agent for the few people here both in Pennsylvania and across the country who suffer from cataplexy.

CHAIRPERSON GANNON: Representative Benninghoff.

REPRESENTATIVE BENNINGHOFF: I apologize, but I didn't hear where you said it would be manufactured. There was a cough and I couldn't hear over it. My question would be -- Go ahead and tell me where it's manufactured.

MS. ENGEL: It's Conshohocken.

REPRESENTATIVE BENNINGHOFF: You're saying if we were to make this Schedule I here in Pennsylvania, that would shut down the

manufacturing and not allow you to distribute it. What happened in the other states because of them scheduling (drops voice), because it being only manufactured?

MS. ENGEL: As I mentioned, in some states we have been allowed special dispensation to ship products to individual patients, because like Matt nothing else has worked for him. In other states, such as Alabama, we cannot ship at all. We have patients who are, frankly, illegally bringing the drug into the state in order to continue to be treated.

REPRESENTATIVE BENNINGHOFF: But am I understanding, you said that by us in Pennsylvania making this a Schedule I, we're going to shut it down for the whole United States.

MS. ENGEL: Because we manufacture here in Pennsylvania and the code of federal regulations requires the drug manufactured as a Schedule I or Schedule II agent be manufactured and stored in vaults. Perhaps you missed this part of the testimony.

REPRESENTATIVE BENNINGHOFF: Actually, I heard the part of the cost of the

vault.

MS. ENGEL: This drug is a little bit different than others; in that, typically, if you take a medication, an antibiotic or something like that, you take it in milligram quantities. You take a little tiny pill. And the amount that it would take to treat you for a week, a month or a day is not a large bulk. With this agent the amount that is effective for patients with cataplexy ranges anywhere from three to nine grams per day. That's a large bulk.

So the amount of drug that would need to be manufactured for only six months to treat those few patients in the country with cataplexy would require a 20,000 square foot vault. This vault, if you can picture a bank vault in your mind with eight-inch thick concrete walls, television cameras, motion detectors, all the controls that would be necessary under a Schedule I or a Schedule II regulation under the code of federal regulations would cost 500 to $1,000 per square foot.

As I mentioned, ten to $20 million more than doubles the cost of development of

this drug and practically shuts this down. Not only can any company not afford this, because there are very few patients across the country who suffer from the cataplexy associated with narcolepsy, but eventually, when the drug were able, for example, to get approved by FDA, the patients couldn't afford it anyway.

REPRESENTATIVE BENNINGHOFF: My final question, just a clarification of numbers, if I may, Mr. Chairman. In these sentences you are saying a few patients, but in this written testimony you say cataplexy affects 65 percent of the 180,000 Americans. What is the actual number we are talking about, cataplexy patients versus narcolepsy?

MS. ENGEL: There are estimated to be 180,000 narcoleptic patients in the United States. The reason that I say estimated, it is a very difficult disease to diagnose. Many patients who have narcolepsy go through many years of diagnoses and run through the medical system costing us all a lot of money.

Basically, 65 percent of those patients, we believe, have cataplexy, and that's based on population studies done out of Stanford

University Sleep Disorder Center in Stanford, California.

Now, that puts the number of cataplexy patients somewhere around the hundred thousand range. Now, if you compare that to patients who have heart disease, cancer, AIDS, any of the diseases that we hear about so often, you can see that that is a relatively few number of patients. We've estimated that the patient population in the State of Pennsylvania based on your population estimates and the estimates of the incidents and prevalence of cataplexy in the population would be 3,900 patients here in the State of Pennsylvania.

REPRESENTATIVE BENNINGHOFF: Again, just to clarify, these are estimates on the population numbers versus diagnosed cases?

MS. ENGEL: These are not patients in hand. Remember that there haven't been effective treatments for cataplexy. So today there exists no patient registry, if you will, through pharmacies across the country and here in Pennsylvania, as well as to specific patient numbers with cataplexy.

REPRESENTATIVE BENNINGHOFF: Thank

you. Thank you, Mr. Chairman.

CHAIRPERSON GANNON: Mr. Callen.

MR. CALLEN: The issue between Schedule II and Schedule IV, the shipping consideration, if you can ship directly to a patient, can you also ship directly to a pharmacy for the patient?

MS. ENGEL: We could do that. And let me tell me why the company and the federal authorities are very interested in a Schedule IV. Because of the opportunity, frankly, to build a patient registry.

I mentioned earlier that our company has two other drugs that we do for rare diseases. One for a disease called Congenital Sucrase-Isomaltase Deficiency another Homocystinuria which there is less than a thousand kids in the country that have this disease. Because there are so few patients in those diseases, we build what's called a patient registry where we know who every patient is, where every patient is, and what their dose is. In those drugs it's for the reason of manufacturing the right amount of medicine at the right time.

In this case we would be very much in favor of building a patient registry to be able to keep track of who the narcolepsy patients are who utilize this agent, what each dose was for each patient, and to control in a proactive manner its distribution.

In the booklets that I have given you, there's a tab called scheduling and there's some schematics that show you the difference of what happens to an agent that's distributed through the general distribution system in this country versus something through direct distribution. These agents are Orphan drugs. They're used for very, very few patients.

An important fact that the Drug, Device and Cosmetic Board took under consideration when they voted to make GHB a Schedule IV is the fact that there are 57,000 retail pharmacies in United States.

Now, if you sell an arthritis drug or a blood pressure medication or Viagra, it makes an awful lot of sense to put that drug in the national wholesalers, the regional wholesalers, the local wholesalers and down to the drug stores. That includes your CVS chains

and your mom and pop's pharmacy on the corner. But every one of those 57,000 pharmacies and every one of those distributors represents an opportunity for a diversion.

By having a drug that is allowed to be sent from our manufacturer directly to someone like Matt, and I don't mean sat on Matt's doorstep so when he shows up from class five hours later he'll get it, but directly from our manufacturer to Matt's hands, he signs for it and we know exactly what Matt's dose is. And we know if Matt hasn't taken his medication because he's not reordering as often as he should, or we know if Matt is giving some to his friends because he's over-ordered, we can prevent the diversion.

We don't need this stuff traveling on trucks around the State of Pennsylvania or any other state. We don't need this stuff sitting on the loading docks. We don't need to be manufacturing tons and tons of this stuff unnecessarily to fill a distribution pipeline. It's silly.

The ability to put this on Schedule IV allows us to send it right to Matt. It

allows us the ability to keep track of these few patients just like we already keep track of the hundred patients who are suffers of Homocystinuria and take our drug Cystadane, and just like we already keep track of the thousand patients who suffer from Congenital Sucrase-Isolmaltase Deficiency and already have taken our drug Sucraid. This is something that we do. It's our business.

We believe as does the federal authorities that this agent appropriately looked at in a medical and scientific way and be allowed to be controlled in a way that does not harm patients with narcolepsy.

MR. CALLEN: Just one related question. The containment vault that be required on Schedule II, other manufacturers of Schedule I and Schedule II drugs must meet that same requirement in Pennsylvania? How do they --

MS. ENGEL: Yes, they do. Other manufacturers -- There is really -- When you say manufacturers, there is no accepted medical use for a Schedule I, if you will, so that we set aside. But, there are manufacturers who

manufacture Schedule II agents, and some of those agents, in fact, are utilized in sleep disorder centers for narcolepsy. The difference is, they're also used for things like attention deficit disorder, attention deficit hyperactivity disorder. Those agents like Ritalin are used in many, many diseases.

So it makes sense to put those agents in 57,000 retail outlets across this country. They're used enough. They manufacture enough. Those uses, those FDA-approved sanctions and scientically-studied uses of those agents warrant the right amount be manufactured to put in the overall distribution channel.

Today in this country, GHB is being supported by the FDA under FDA-sanctioned clinical trials. This is not, as was described earlier, a company who has been looking at this drug for many years. This is the FDA coming and asking us to develop a drug with scientifically rigorous studies with statistically significant valid medical results and has proven to be the only effective agent for these patients with cataplexy.

So to put this as a Schedule IV and

adopt the amendments to Representative Benninghoff and Representative Dermody's bill that address the real issue, the GBL, is something that we believe leaves a win for everyone, including the Attorney General.

CHAIRPERSON GANNON: Representative Dermody.

REPRESENTATIVE DERMODY: Thank you, Mr. Chairman. Just one question. I was just wondering about side effects.

MS. ENGEL: The most common side effects in our clinical trials -- Why don't I let Matt speak to that first, and then I'll give you the information for the question.

MR. SPEAKMAN: I don't have any side effects. The drug is taken before I go to bed at night. I take two doses which last for about four hours apiece. That's not rigid to the point where I have to take both doses and get eight hours of rest. There have been times where I take -- I'm a college student right now, and I'm doing all right too.

What I'm saying is, like it's a whole lot different from my junior and senior year in high school. I can take a four-hour

dose and go to class, and if I have five or six hours between the next class with nothing I need to do, I can go back to bed and take my second four-hour dose. It's almost like a cumulative amount of sleep that I get to eliminate problems. I don't have any side effects at all.

REPRESENTATIVE DERMODY: How long have you been taking it?

MR. SPEAKMAN: A little over a year.

MS. ENGEL: In our clinical trials the most common adverse experiences included in the trials included headache and nausea. In a FDA-sponsored clinical trial there is a sanction that requires that every adverse effect be documented. That includes, if you are on the drug being studied, if you hiccup we write it down and it gets recorded. So, it's very well documented in hundreds of patients what the adverse experience profile is. The horrific experiences that Attorney General Fisher shared with you earlier happen out there every day.

I'll show you something that we did in our labs. This was a frightening experience. We, as I mentioned earlier, purchased a number of GHB kits off the Internet which frightenly

enough was found in an Internet web site called GHB dot kit dot com. And for about $75 got a little paper box, little corrugated box with gamma-butyrolactone, GBL, or scoop in it with some other chemicals live, frankly, as the solvent and some instructions as to how to make this stuff up in your kitchen.

So, we sent one of our chemists home to his kitchen. In the packet that you'll find, you'll actually find some pictures that we took. The instructions for making the GHB were pretty good, but what we found is that, just simply using a pan that contained aluminum in it didn't give you GHB at all. It gave you -- And I'll give this to the committee to pass around. It's a pretty horrific thing. This is what we came up with. It was a silver gray goop that solidified in the container about ten minutes after its manufacture.

Now, if you were someone who was looking to rape someone with this agent or buy a bottle of this and make a thousand dollars or so selling it out of the cap at rave parties, you probably wouldn't care so much if you followed the right recipe. You probably wouldn't care if

you cooked it too long or too short; or if you added too much lime. What we don't know at the end of the day is what is in that. We don't have any idea.

Medical-grade GHB is manufactured by FDA guidelines. We use good manufacturing practices or GMPs. And manufacturing sites like the site in Conshohocken which we utilized to manufacture this are inspected on an annual basis by FDA and even more often than that by the DEA. If I we make GHB a Schedule I or a Schedule II, people like Matt are going to be forced to buy stuff off the Internet. They are going to go to Canada. They're going to go wherever they need to get this stuff because it helps them live a normal life.

REPRESENTATIVE DERMODY: How expensive is this?

MS. ENGEL: GHB?

REPRESENTATIVE DERMODY: Yeah.

MS. ENGEL: We don't sell it today because it's being studied in a clinical trial. It is likely to be for a patient who suffers severe cataplexy who takes a whole dose of it every day for the rest of their life, would

probably be $3,000 per year range.

We, also as a company, with all of our agents, believe that these are Orphan products. We cannot have people who need these drugs not get them. So we work very closely with patients' insurance companies to make sure that they get coverage and if they don't, we work with the national organization of rare diseases or NOR and we give money to NOR to help provide a product free of charge for people who truly can't afford it.

REPRESENTATIVE DERMODY: Thank you. Thank you, Mr. Chairman.

CHAIRPERSON GANNON: Representative Browne.

REPRESENTATIVE BROWNE: Just real quick, Mr. Chairman. Just a follow-up on Representative Dermody's comment. Under that price schedule of $3,000 for the population this would serve of 180,000 patients, would that make the drug, without expanding into other uses, would it make it commercially viable?

MS. ENGEL: It is commercially viable because of the company that we are. This drug rattled around in the pharmaceutical

industry for many years. A big company, a Pfizer, a Merck, a Bristol-Myers script could never afford to develop this agent. They have huge overheads. In those companies it's typically $20 million at a minimum to get an agent to market.

We are a small Minneapolis-based company. We have 35 employees, and we do our trials along with FDA. The office of Orphan Products assists us in finding clinical trial sites that will work with us and not charge us a lot of money, for example, for the doctor's time.

In many clinical trials when you do the trial the patient gets some money for doing that; not the case typically with these Orphan drugs. We're able to develop this agent, I think by the end of the day it will be for well under $10 million. Yes, for a company like us, the development of GHB is financially feasible.

I'm sorry to say my shareholders probably are not very happy that we are today not a profitable company. This won't change that significantly. This is not a situation where we're going to make $20 billion off this

drug. This is not Viagra. This is not a blood pressure medication. This is not an arthritis drug.

This is a company that's been formed by people from the mainstream pharmaceutical industry who want to go to work every day and make a difference in somebody's life. That's what we're all about.

REPRESENTATIVE BROWNE: Thank you.

CHAIRPERSON GANNON: Representative Benninghoff.

REPRESENTATIVE BENNINGHOFF: I have one quick question. Two actually. One's out of curiosity. You said you're based out of Minnesota.

MS. ENGEL: That's right.

REPRESENTATIVE BENNINGHOFF: Why did they choose Pennsylvania for the manufacturing plant?

MS. ENGEL: There are few manufacturers who are able -- One of the things about this agent, GHB and GBL, it's something called hydroscopic. And what that means is, it takes on water very easily. So the ability of manufacturers to do this right is very small.

There are only a few pharmaceutical-grade manufacturers in the country who can even manufacture very hydroscopic products.

Our manufacturer here in Conshohocken is one of those few. It's very important that this be done right. I think what I showed you here is evident that if it's done wrong, there's problems. Frankly, we don't know, we've never taken this, made it wrong and put it into human subjects.

When we hear about the incidents in the emergency rooms, you know, people coming in in comas; young women coming in confused states; all this kind of thing, we frankly don't know if that's the result of GHB with alcohol or is that the result of incorrectly made GHB; if it was made in somebody's stove or in somebody's bathtub in a way that cooked it too long or too short, or allowed it to be exposed to the open air, took on moisture or something like that. So, the situation with this stuff on the Internet must be shut down.

You see the cases in Michigan. You see the cases in Georgia. Those people thought they were doing the right thing by making this a

Schedule I. I would argue that the young woman who was killed with this in Michigan, her family would probably strongly disagree.

REPRESENTATIVE BENNINGHOFF: Thank you.

CHAIRPERSON GANNON: In your testimony you indicated that both Michigan and Georgia regulate GHB; it's a Schedule I.

MS. ENGEL: That's right.

CHAIRPERSON GANNON: They've had instances where the use of GHB, at least what we have been told, led to some bad results.

You also told us that, apparently, this ingredient GBL is really what is the key ingredient, and some instances GBL by itself is being used.

MS. ENGEL: That's correct.

CHAIRPERSON GANNON: Are there any states that regulate or put GBL as a Schedule I? Well, let me be more specific. Do Michigan and Georgia regulate GBL?

MS. ENGEL: No, they are not, but there is federal legislation that we are party to and working on that will regulate GBL. As was mentioned in Attorney General Fisher's

testimony, GBL is a substance, a very commonly used commercial substance. It's used in the manufacture of plastics, beer, paints, all sorts of things. And if, in fact, you were to make GBL a Schedule I, you may, in fact, have a lot of pressure or defensiveness, if you will, from different industrial sectors.

What we're recommending is that not only -- We've talked in the past and also have recommended some federal legislation that GBL be listed. What that means is that, paint manufacturers, beer manufacturers, reputable chemical manufacturers would need to know how much they produce every year and know exactly who they're selling it to and that, in fact, the people they're selling it to are using it for legitimate purposes.

So, someone like PPG could still get the GBL that they need to manufacture the paint or someone like Latrobe could still get the GBL that they need to manufacture their beer. But that, these people would also need to be able to measure the amount that they buy, the amount that they use, and make some kind of an accounting for the difference. Whatever is left

over today is unscheduled. We don't know where that's going.

GHB is being used today. Medical-grade GHB is being used in less than 300 patients around this country. No medical GHB has ever been diverted for illicit purposes. They are getting this stuff from somewhere. The Internet maybe. The people who sell this on the Internet and repackage in these little bottles get it from somewhere. If it's listed, it will prevent that from happening.

It was horrifying to me -- Myself and an assistant of mine from our company got on the telephone and called four reputable chemical manufacturers. We made up the name of a company; we made up a phone number. And when asked what we were going to use this for, I was purposely very flipped and said, oh, we're going to use it for some research. I had two reputable chemical manufacturers prepared to send me 50 kilos of this stuff to an address that was given just from nowhere. That's really concerning.

Now, if we make this -- As I mentioned, the federal legislation is looking at

not only listing GBL but also putting in these provisions that deal with the very harsh penalties for the manufacture, the possession, and the distribution -- or the distribution I should say of gamma-hydroxybutyric acid, its esters, its ethers, its isomers, its salts. Basically, this is the language that Florida just has adopted.

Because, frankly, as we sit here there will be some bright bathtub scientist out there who figures out some other way to get this covered or to get this around the language so we have to make the language extremely broad. That's why that, unfortunately, somewhat cumbersome but very all in cumbersome language has been recommended.

So that all this stuff, no matter what form they'll figure to put this in, if they have it, if they sell it, if they distribute it, they're in trouble and they're in a lot of trouble. That's what we are trying to get accomplished both here in Pennsylvania and nationally.

CHAIRPERSON GANNON: If someone ingested just a capful of GBL which is this

stuff here, you've told us this converts to GHB in the body. Now, if I took some of this, a capful of this and then later on had a blood test, would that show up as GBL or as GHB?

MS. ENGEL: Yes and no. If you had that blood test within four to six hours of ingesting that, it would show up as GHB. If your blood test was after that, it would not likely show up at all because it has a short half life.

Right now Orphan Medical is working with law enforcement to attempt to obtain grant funding to put together and to develop forensic tests. Part of the issue here, when law enforcement gets ahold of this and maybe they put it in Visine bottle or maybe they put it in a little, you know, who knows what kind of bottle somebody puts it in, it's a pretty clear, harmless liquid. It does have a very salty test which is accurate based on -- which is a bit conflicting with some of the testimonies you heard earlier, but if you were to put this in somebody's margarita, you really wouldn't know what it was.

Law enforcement can't put any kind

of test to this today and really know what it is without sending it off to a chemical forensic lab and doing a lot of very fancy testing, something called HPLC testing, which I think, Representative, you talked about that you are familiar with, so we use an HPLC acid, PCL stat (phonetic; drops voice).

What we're working with is trying to get a forensic test, because frankly, as a commercial company making a medicine for a serious disease, we don't want this hassle either. You know, we don't want someone out poisoning young girls and having a legal liability on our hands, nor do we want to have the development of this drug shut down because law enforcement is so frustrated with their ability to prosecute and figure this stuff out. So, we're working on that.

There was a discussion earlier, could flavor be added, could color be added? Could something be added to make it easier for law enforcement to identify what that is? We're also working on that. FDA has asked us not to do that at this juncture.

REPRESENTATIVE BLAUM: How come?

MS. ENGEL: Because they feel that it would require that the FDA clinical trials for safety and effectiveness would have to start over. They feel like that by adding something else to the medical GHB it may change the result of the GBL. Rohypnol is recently did that.

REPRESENTATIVE BLAUM: That may not prohibit them from recommending something at the end of the trials.

MS. ENGEL: That's exactly right. So, we believe that will happen, but it's unlikely to happen now. The challenge you have with that, however, is, if Orphan Medical works with FDA on the medical-grade GHB to put a color or a flavor or even some kind of a marker in that would be, for example, able to detect it in the blood and the urine hours after someone were slipped this or someone ingested this, that doesn't do anything to GBL. It doesn't do anything to the stuff that's on the Internet, and that's the issue.

We can put controls; we can put markers; we can put flavors; we can put coloring in medical-grade GHB all day long. We're happy to do that. We would be delighted to do that.

Whether or not that will make a bees worth of difference like we've seen in Michigan, in Georgia, and other states, we really doubt it.

We really urge you to look at this issue very openly. It's a very emotional issue. No one is here to say rape is a good thing. No one is here to say that the utilization of any drug, whether it be Aspirin, or alcohol, or GHB, or GBL, or Rohypnol -- it's wrong. It needs to be penalized, and sexual perpetrators need to be able to be really knuckled down on.

By making GHB a Schedule I we're just not going to do that. So, we hope that you'll consider our amendment to Representative Benninghoff and Dermody's bill as originally written with an open mind and one that won't hurt the treatment of Americans with narcolepsy.

CHAIRPERSON GANNON: Representative Dermody.

REPRESENTATIVE DERMODY: I have just one question. Thank you, Mr. Chairman. I was worried about how many doses of Rolling Rock it would take for that GBL? Just kidding. Thank you very much.

MS. ENGEL: That I can't answer.

CHAIRPERSON GANNON: I have another question. I wanted to ask, so would it be fair to say that if a patient was brought into the Emergency Room say in a coma, that a blood test would not show GHB? It would show GHB even if they had only taken this GBL. So the source of whatever they took would have to be either directly from what the patient tells you or from witnesses, but a blood test would not be conclusive if they had only taken GBL as opposed to GHB?

MS. ENGEL: I believe that's correct. I believe on your agenda later this morning you'll be hearing from Doctor Ward Donovan from Penn State-Geisinger, who runs the Poison Control Center there. I think he's best probably to answer that question, but that is my understanding.

CHAIRPERSON GANNON: Thank you very much for appearing before the committee, Ms. Engel and Mr. Speakman, and sharing information about this important legislation.

Mr. William Speakman, Matt's father, has offered written testimony to the committee, and we'll be making that a part of the record.

Thank you, Mr. Speakman.

Our next witness is Doctor David Hawk of the Pennsylvania Medical Society and Doctor Christine Sannerud with the Drug Enforcement Administration. You may proceed when you're ready.

DOCTOR SANNERUD: Mr. Chairman, members of the committee, good morning. My name is Doctor Christine Sannerud. I'm a drug science officer for the Drug Enforcement Administration. I appreciate the opportunity to appear before you to testify, clarify some statements and answer questions regarding GHB, a drug now being discussed for proposed scheduling in the Commonwealth of Pennsylvania.

GHB is a central nervous system depressant which is abused for its ability to produce euphoric states and its alleged role as a growth hormone releasing agent to stimulate muscle growth. Although GHB gained early favor with health enthusiasts as a safe and natural food supplement and was sold in health food stores in the late '80's, the medical community soon became aware of overdoses and related problems caused by its abuse.

In 1990, the FDA issued an advisory declaring GHB unsafe and illicit, except under FDA-approved, physician-supervised study protocols. And FDA has recently reissued its advisory. GHB has not been approved by the FDA for marketing, and it is currently under investigation for treatment of narcolepsy under the Orphan drug program, as you've previously heard.

United States is currently experiencing a problem with the clandestine production, abuse and trafficking of GHB. GHB is not approved for marketing as a medicine in the United States, and that's important to remember. Doctors do not prescribe it; pharmacists do not sell it; and patients do not use it. The abuse of GHB is in the absence of medical supervision.

Although its importation, distribution and use as a drug is not allowed by the FDA, the abuse of GHB has increased. As a drug of abuse, GHB is generally ingested orally after being mixed in a liquid. The onset of action is rapid and unconsciousness occurs in as little as 15 minutes and profound coma can occur

in 30 to 40 minutes after oral ingestion of higher doses.

GHB produces dose-dependent drowsiness, dizziness, nausea, hallucinations, decreased blood pressure, decreased heart rate, hypnotic effects similar to petit mal epilepsy, convulsions, respiratory depression and coma. Overdose frequently requires Emergency Room care, including intensive care for respiratory depression and coma.

In recent years GHB has emerged as a significant drug of abuse throughout the United States and in a number of foreign countries. Since 1993, more than 3,500 GHB-related cases of abuse, overdose, possession, manufacturing, diversion and trafficking have been documented by the federal government and state and local officials.

GHB is frequently taken with alcohol or other drugs that heighten its effects, and it is used at bars, night clubs, rave parties and gymnasiums. The primary users are teenagers and young adults who frequent these establishments. The populations abusing these drugs fall into three major categories: Users who take it as an

intoxicant or euphoriant; bodybuilders who abuse GHB for its role as a sleep aid or as an anabolic agent; individuals who use GHB to commit sexual assault. These categories are not mutually exclusive and abusers can use it for more than one effect.

The GHB encountered by law enforcement has been produced in clandestine laboratories. The GHB synthesis requires no special knowledge of chemistry, and requires only two precursor chemicals, gamma-butyrolactone, GBL, and sodium hydroxide, lye. These precursor chemicals are inexpensive and readily available.

The process is accomplished using a simple one-pot stove top method. GBL currently is a solvent with many industrial uses. It's an unregulated chemical, and it's sold in chemical supply companies. And there are, as you've heard, kits available over the Internet; however, GBL is a precursor chemical to manufacture GHB.

Since 1997, the DEA is aware of at least a hundred cases involving GHB illicit laboratories and over 200 submissions to DEA and

state and local forensic laboratories. GHB has been encountered in every region of the United States in both small, personal use quantities, and large quantities intended for distribution. It is marketed as a legal high or as a substitute for MDMA, or Ecstasy, and is sold in solid and liquid form. Indicators suggest that GHB abuse and trafficking is escalating and pose a serious health and safety risk.

The abuse of GHB is associated with significant adverse effects to the abuser and health risk to the general public. In the last several years there's been an increase in the number of Emergency Room episodes reported to the Drug Abuse Warning Network, or DAWN. From 1992 through June of 1997, there have been over 575 GHB DAWN Emergency Room mentions. There were 257 of them occurring in 1996 and 164 within the first six months of 1997.

Alcohol and GHB mutually enhance each other's toxic effects and many of these mentions in DAWN involved the use of GHB in combination with alcohol. DEA has also collected 32 medical examiner reports from 12 different states involving the detection of GHB

in the biological fluids of deceased individuals. GHB is repeatedly detected in driving-under-the-influence cases which shows the public health and safety hazards associated with GHB abuse. In addition, the DEA is aware of 20 cases of sexual assault involving GHB.

The DEA is currently pursuing measures to administratively schedule GHB under the federal Controlled Substances Act. DEA has been documenting cases of abuse, diversion and trafficking and is currently awaiting the recommendations of the Department of Health and Human Services, including FDA, as required under federal law. Currently there are no sanctions under the Federal Controlled Substances Act for the abuse and trafficking of GHB.

DEA supports the need to make GHB a controlled substance under federal law. Final determination of its placement will have to include the consideration of DHHS's scientific and medical evaluation. Placing GHB in any schedule under the CSA, including Schedule I, should have no adverse impact on the pharmaceutical industry, the medical profession, patients or health care in the United States.

Such control would not adversely affect research of the pharmaceutical industry to conduct studies or develop the drug for marketing.

Control of GHB in the CSA would allow the law enforcement and judicial system to combat the trafficking of GHB in United States. Such control would establish its high potential for abuse and increase awareness of the public to its health risks associated with the abuse to the law enforcement community, the judicial system and the general public.

Although it is not yet controlled at the federal level, 20 states have already controlled GHB, and you can see the map there. Twelve states have placed it in Schedule I; five states have placed it in Schedule II; and three states have placed it in Schedule IV. In addition, two states have criminalized the sale and possession of GHB and placed it in the same penalty group as LSD and marijuana.

Mr. Chairman, in closing, I would like to thank you for providing me with the opportunity to offer the DEA's position and comments on the very serious problem of GHB abuse and the issues of GHB control. I will be

happy to answer any questions you may have.

CHAIRPERSON GANNON: Thank you, Doctor Sannerud. Doctor David Hawk, do you have any testimony to offer?

DOCTOR HAWK: Yes, I do. My testimony has been distributed prior to the meeting.

Thank you, Mr. Chairman, and members of the Judiciary Committee. My name is Doctor David Hawk. I'm the Chairman of the Pennsylvania Medical Society's Commission on Public Health, and I am here this morning as a representative for the society. The Pennsylvania Medical Society appreciates this opportunity to share our thoughts with the Judiciary Committee on legislation concerning the proper scheduling for the drug gamma-hydroxybutyrate or GHB.

At a hearing before the Department of Health's Drug, Device and Cosmetic Board on January 6, 1999, the State Attorney General requested that GHB be classified as a Schedule I controlled substance under the Controlled Substance, Drug, Device and Cosmetic Act. The Attorney General's request was based on his

understanding that the drug is one with high potential for abuse and with no currently accepted medical use and lacks accepted safety standards for use under medical supervision.

The Society believes that there are potentially several medical uses for GHB currently under study. One proposed use is for the condition known as narcolepsy, a condition that results in a recurrent uncontrollable desire for sleep. Another proposed use is for the treatment of depression. GHB has been tested in combination with other central nervous system depressants for surgical anesthesia. Medical research will possibly uncover additional uses for GHB.

On the other hand, classifying GHB under Schedule IV as House Bill 111 and House Bill 183 would do, gives wide and uncontrollable latitude for the use of this drug by prescribing physicians. GHB is known as a recreational drug. It is used for a variety of unproven and unsubstantiated problems such as weight reduction, mood enhancement, athletic performance enhancement, and increased sexual libido.

Wide use in this fashion will also make GHB readily available and, therefore, readily available for abuse and misuse. Even more disturbing is the growing and ready availability of prescription drugs over the Internet with little more control than a valid credit card number. Do we really want GHB to be among those drugs available over the Internet?

A recent Internet search of GHB listings over the past five years reveals approximately 150 published articles on GHB and its uses. A number of potentially beneficial uses are mentioned. However, the large number of harmful uses and effects cannot and should not be ignored.

Some articles discuss the development of physical and psychological dependence to GHB. GHB is known as the date rape drug, easy lay, organic quaalude and grievous bodily harm, to mention a few of its street names. It has been associated with poisoning, blackouts, coma and death, especially when combined with alcohol. Its consequences when used incorrectly or for illegal purposes can be harmful and disastrous.

Seeing Schedule I as being too strict and Schedule IV as too liberal, the Pennsylvania Medical Society would recommend consideration of the designation of GHB as a Schedule II controlled substance.

The Society would also suggest legislation imposing penalties on illegal GHB manufacturers, distributors, sexual predators, and those who would divert the drug for other inappropriate purposes. It is very disturbing to find Internet sites listing the ingredients, the directions for the manufacturing the drug, et cetera. Clearly, some restriction on dissemination of such information is needed.

In closing, the Pennsylvania Medical Society urges your consideration of classifying GHB in a way that will balance the legitimate need to restrict access to GHB while permitting the appropriate use of the drug for medical and research purposes. Thank you very much.

CHAIRPERSON GANNON: Thank you, Doctor Hawk. Any questions? Representative Browne.

REPRESENTATIVE BROWNE: Doctor Sannerud, you probably can anticipate this

question based on your testimony. In one of your paragraphs you mentioned something in direct contradiction to previous testifiers in regards to the fact that classifying this drug as Schedule I substance would not affect the pharmaceutical industry, medical professions, patients or health care in United States; would not adversely affect the research or pharmaceutical industry to conduct studies or develop the drug for marketing in the United States. Could you comment on what the prior testifier said?

DOCTOR SANNERUD: I can comment about what's required under federal law. What's required under the Controlled Substances Act is for researchers who are conducting studies such as are being conducted now, investigational new drug studies--those are considered research protocols--the requirements for researchers under Schedule I is the same as under Schedule II through IV. The requirements are all the same.

Manufacturers, obviously there are heightened requirements for handling of Schedule I and II drugs, but for researchers and patients

who are involved in these clinical trials, there are no differences between the requirements in I versus the other schedules.

REPRESENTATIVE BROWNE: What's mentioned about the pharmaceutical industry, that assumes that something is going to develop that's going to be eventually commercially viable. Does that have any effect in regards to that contradiction?

DOCTOR SANNERUD: At this point, the DEA is the agency that determines accepted medical use based on input from other agencies. At this point, there is no accepted medical use, and there's no established evidence of safety and efficacy. If at some point FDA approves the drug for marketing as a medicine, then that will have to obviously be changed and taken into the scheduling decisions.

REPRESENTATIVE BROWNE: Once it's an approved use, based on your opinion, it would have to go off Schedule I?

DOCTOR SANNERUD: Right. That has been done with several different drugs that have been approved for marketing; were placed in Schedule I during the development and then moved

to Schedule II later, once it was approved.

REPRESENTATIVE BROWNE: Thank you very much. Thank you, Mr. Chairman.

CHAIRPERSON GANNON: Representative Steelman.

REPRESENTATIVE STEELMAN: Thank you, Mr. Chairman. I have a question for both presenters that is related to the previous testimony. What we heard was that, actually, what's available freely over the Internet at this point is gamma-butyrolactone, a precursor to GHB. The suggestion was made that we ought to control the availability of that precursor.

Neither of you mentioned that in your testimony, but I would appreciate hearing your thoughts on that issue.

DOCTOR SANNERUD: What DEA is encountering now is GHB, GHB labs. They may be using GBL, but they're using it to make GHB. GHB is the drug that people are seeking. Once GHB becomes a controlled substance and depending upon where it's placed under the federal law, there's several different options. If it's placed in Schedule I or II, the federal government could control GBL as an analog. It

can be also controlled as a precursor chemical, or it can be listed as what's placed on the list of chemicals called the listed chemicals.

That's similar to what people have talked about here in the State of Pennsylvania, where there's registration requirements, but it's not considered a controlled substance. The federal government has not concluded on what options, what decisions should be made with GBL because it's not -- GHB is not a controlled substance yet, and there is a lot of industrial use of GBL, so that has to be taken into account on what option we eventually use.

REPRESENTATIVE STEELMAN: If GBL were controlled as an analog or precursor, under what standards would it fall? Could you describe how that control would be exercised? This would be by the federal government if this becomes --

DOCTOR SANNERUD: A precursor or an analog is -- An analog is used when it's being -- It's similar to a controlled substance, pharmacologically and chemically, and it's also used for human consumption. When it's listed as a precursor chemical or when the precursor

chemical statutes are used, the penalties -- It's placed in a schedule, but it's not called a controlled substance. It's only called a precursor chemical if it's being used in the manufacture of a controlled substance.

REPRESENTATIVE STEELMAN: Thank you.

CHAIRPERSON GANNON: Representative Benninghoff.

REPRESENTATIVE BENNINGHOFF: I actually have two questions. One, I'm looking over your earlier testimony where you talk about 1990, FDA issued an advisory declaring GHB unsafe and illicit. Here we are in 1999. I assume in those nine years a lot of trials, clinical studies and tests have gone on.

Where's FDA's position? Has it progressed at all? Are they pretty much the same? I mean, nine years is a long time to be researching something. If I was spending money researching something, I'd want to know whether we're making any progress or any kind of --

DOCTOR SANNERUD: I can't speak to FDA's deliberations or FDA's involvement in the product. I know that back in the summer of 1997, DEA sent the Department of Health and

Human Services, FDA and NIDA, a document where we laid out all of our evidence of abuse and trafficking. As required by law, they need to review it, put in their evaluation. And we're still waiting to hear back from them. I know that there's a lot of different parts of FDA working on these issues, but I don't know what their status is.

REPRESENTATIVE BENNINGHOFF: I have a question for the gentleman, and I appreciate your testimony. That's the whole purpose of today's hearing is to hear lots of different opinions and viewpoints.

You're encouraging Scheduling II versus Scheduling I. Any significant -- Or can you list five reasons why you prefer one over the other?

DOCTOR HAWK: I think that Schedule II would be more appropriate because of its use that we heard earlier this morning in narcolepsy, as an example of one of the areas where there's really some research that looks very promising, and I mentioned several other areas that are being looked into as far as this particular compound goes.

Schedule II in my mind, as a practicing physician, falls into the same category as Ritalin. Treating a number of children with attention deficit disorder, I know how tightly Ritalin is controlled. I know that I see people monthly to write their monthly prescriptions. These prescriptions are not taken by phone or by fax. They must be handed to the pharmacist on my written note.

To me this would be the appropriate use. We don't get around faxes and telephone calls and those kinds of mechanisms where people can get refills on their medication. I think that that's the kind of tight control that the Pennsylvania Medical Society is talking about.

REPRESENTATIVE BENNINGHOFF: Just to make a statement. We do know that the half life, if you want to call it, of the GHB is very short and very difficult to trace in the bloodstream.

So, I'm looking at it from a criminology standpoint, investigator's standpoint, that it really frightens me to think we can have people subdued and maybe even have a death occur and no medical reason for that

versus Ritalin we may be able to trace a little easier; that we are not keeping the clinical trial use of GHB from occurring if we were to go to Schedule I. They would still be able to continue to do that. I'm not sure I follow the reasoning for the I to II.

DOCTOR HAWK: Well, I'm saying or trying to say that there is latitude for the flexibility to develop proven medical uses by classifying it as II and bringing drugs aboard as opposed to keeping it in one category which means it's basically banned.

REPRESENTATIVE BENNINGHOFF: Banned from clinical trial. I mean, there's a lot of people that argue different types of drugs that aren't currently -- that are Schedule I should be used for medical purposes as well. Our goal here, obviously, is to decrease or eliminate the illicit behavior of it, the unwarranted and unwanted use of it versus still allowing people to use it for clinical trials.

DOCTOR HAWK: Some of your purposes are already accomplished by bringing it into the controlled substance field. Now, what we're talking about right now is something that is

readily available without a prescription. We're talking about putting significant limits on.

The concern is that we not give it a carte-blanche prescription, open-door kind of approach to it, but to make it the tightest prescription control that we know of in Pennsylvania which is the Schedule II level.

REPRESENTATIVE BENNINGHOFF: Thank you very much.

CHAIRPERSON GANNON: Doctor Sannerud, does the DEA consider ether an analog or precursor for the manufacturer of, say, cocaine?

DOCTOR SANNERUD: I don't know where ether falls, but there are a lot of chemicals that are used in the manufacturing process that are considered listed chemicals. There's two levels. There's a list I and there's a list II. There's various requirements under each listing.

CHAIRPERSON GANNON: The point I was getting at, was that, we have this GBL which is the analog or precursor for GBH (sic), but it appears that GBL apparently has some effect if it's taken just by itself, and then once it gets into the blood can be misidentified as GBH

(sic). I was wondering if any other analogs, precursors that come under regulation that have that same effect?

DOCTOR SANNERUD: There are probably others. I just don't know offhand.

CHAIRPERSON GANNON: I'm sure you didn't come prepared to answer that type of question. But, it just seemed to me that we're focusing on this GBH (sic) issue, which is where they take a combination of drugs, and then this GBL which apparently is going to have the same effect as the GHB.

DOCTOR SANNERUD: DEA has received reports of GBL abuse, but they've been scattered. It's been more sporadic. It's a lot of self-report. There were the three nutrients in the other products which FDA just recently band. But, the majority of the GBL is used in the plastics, preliminarization process and other industrial uses, so the majority of it--I don't know what percent--is used in industry and is not out there for sale to the individual person.

CHAIRPERSON GANNON: Do you know whether or not -- Maybe Ms. Engel could answer

the question. Can GBH (sic) be manufactured without GBL?

DOCTOR HAWK: No.

MS. ENGEL: You need a necessary component.

CHAIRPERSON GANNON: Are there any other questions?

(No response).

CHAIRPERSON GANNON: Thank you very much, Doctor Hawk and Doctor Sannerud, for appearing before the committee and offering testimony on this important issue.

Our next witness is Doctor Ward Donovan, Director, Central Pennsylvania Poison Center, Penn State College of Medicine. Welcome, Doctor Donovan, and you may proceed when you are ready.

DOCTOR DONOVAN: Good morning. I'm not going to in the interest of time -- actually it's afternoon now, and that's why for the interest of time I'm not going to read my entire statement. What I'd like to do is focus on just what this problem is in Pennsylvania.

I'm not here to represent a special interest group. I'm not here to represent the

pharmaceutical industry. I'm here to give you the facts about the abuse and extent of abuse in Pennsylvania of GHB and GBL and also then, based on those facts, to render my opinion as a medical toxicologist as to what I would urge this committee to do.

I am reminded as I make that decision of the risk benefit ratio that we all in medicine use to decide whether an agent is useful to use on a patient. By that I mean, what are the risks to this patient versus the benefits to that patient, and what are the risks to society versus the benefits to society? I think that's what you're dealing with in this issue.

Let me turn my attention to the facts. I'm not going to repeat all the uses of GHB and the street names of GHB and GBL. I think you all have become experts on that already in here this morning.

I'm the Director of the Central Pennsylvania Poison Center. I am also a Board certified medical toxicologist. I also direct the only regional poison treatment center in Pennsylvania. What that means is that, we see

some of the more serious poisonings in the state, and this is, of course, at the M.S. Hershey Medical Center which is now part of the Penn State-Geisinger Health System.

In 1998, the Central Pennsylvania Poison Center was contacted about ten individuals exposed to GHB. All of these were intentional cases of abuse for a purpose of achieving a high. Three of these ten had hallucinations and another three were unconscious and required admission to an intensive care unit. One of the patients was critically ill enough to require transfer to our regional poison center at the Hershey Medical Center.

Seven cases of GHB exposure requiring hospitalization were also reported during the last six months of 1998 by the Philadelphia Poison Center.

I'd like, however, to place the extent of abuse of GHB in context. Before that you might want to turn to the third page of my testimony which is a graph that we prepared to show some drugs of abuse in Pennsylvania, and specifically in Central Pennsylvania.

Our poison center of the Penn State-Geisinger Health System provides poison and drug information services for 3.6 million Pennsylvanians in 34 counties. During 1998, we had over 34,000 human drug or toxin exposure managed by our center and a total of over 42,000 inquiries. Of these over 34,000 human exposure cases, there were 570 due to drug abuse, and 332 were due to product tampering or for some malicious use.

Thus, GHB accounted for only .03 percent of our total human exposures and only 1.8 percent of the abuse cases. I'd also like to point out that we had no reported cases of tampering or malicious use of GHB.

I would also say, however, that many cases of GHB probably were undoubtedly not reported to our center. But, our extensive network of participating member hospitals assures us that most cases of GHB exposure requiring an Emergency Department visit would have been captured by this system.

Now, particularly I turn your attention to the graph to point out that in contrast to the small number of reported cases

of GHB during 1998, there with 250 cases of abuse of stimulants such as Ritalin and Fenfluramine. Doctor Hawk previously testified about Ritalin and the fact that it's a Schedule II agent.

There were 25 cases of Benzodiazepines abuse. Benzodiazepine, a class of drugs -- The best known representative of that is Valium. And there were 130 cases of inhalant abuse of household products of aerosols, products in all of our homes and readily available at any supermarket.

As these figures demonstrate, abuse of some drugs and products will continue to occur by those inventive individuals mentioned earlier here today whether these agents are restricted or they are readily available.

There is a promising legitimate use for GHB as you have heard here this morning, and I will not repeat that, other than to point out I would disagree, or at least qualify the statement previously made by the representative from the DEA.

There is, in fact, an accepted clinical use of GHB for narcolepsy. The

qualification I would add is, in the United States and the terminology, accepted use. It is not yet an accepted FDA drug. However, as you have heard from the testimony of a narcolepsy patient, I think that individual would say this is an accepted use in his mind. It's an accepted use, by the way, in Europe.

I would also add that I'm currently using at least three new antidotes for overdose patients that are widely used in Europe and have been for decades and only recently were approved in United States for use because of our somewhat cumbersome and prolonged process of approving drugs for use in the United States.

Therefore, in summary, I urge support of legislation to make GHB a controlled substance in Pennsylvania, to reduce its potential for abuse and in some rare cases of use for malicious purposes.

At the same time, however, I certainly do not agree that this drug warrants classification as Schedule I. I would point out Schedule I again says, by law that the drug has no accepted purpose. To state that this drug is a Schedule I is to deny the fact that this drug,

indeed in the medical community, has an accepted purpose.

I would accede to our pharmaceutical representatives to explain to you the limitations of a Schedule I and even possibly a Schedule II classification would have on the uses of this drug.

Finally, I would point out that even strict restrictions, unfortunately, will not eliminate this drug's availability for illicit purposes. Thank you for your time.

CHAIRPERSON GANNON: Thank you, Doctor. Representative, Steelman, any questions?

REPRESENTATIVE STEELMAN: Would you comment on the suggestion made earlier that we should also be looking at regulating GBL as a precursor to GHB?

DOCTOR DONOVAN: Yes. I certainly would agree with that. That goes to my comment about inventive persons finding a way to have this drug available. If we are going to control GHB, and I agree with the Pennsylvania Medical Society and my colleague Doctor Hawk in his statement, I also then would suggest that GBL be

placed under some control as well.

There was a question I will answer, incidentally, about the testing in the laboratory and in Emergency Departments for GBL and GHB. We are probably missing some cases of GHB and possibly GBL use as well because this standard drug screen in any emergency department, in fact in every emergency department in Central Pennsylvania, except for our poison center at Hershey, only tests for drugs of abuse, and that standard screen does not include GHB or GBL.

And, in fact, a comprehensive drug screen which is done in very few patients by very few hospitals also does not screen for GHB or GBL. These screens are available and relatively easy to do, but you have to ask for that test to be done. You can find it for a prolonged period of time in the urine if you know to look for it.

REPRESENTATIVE STEELMAN: That does put an interesting perspective on it to look at your chart to see that you have fewer people admitted to poison control with GHB poisoning than for abuse with mouthwash containing

ethanol?

DOCTOR DONOVAN: Yes, that's correct. I would use this graph as a relative graph rather than an absolute graph. By that I mean, these probably do no represent the total number of cases in Central Pennsylvania.

But, in relative terms you can see that amphetamines, such as Ritalin, but also included in amphetamines is cough and cold medicines, is our greatest reason for abuse. That's the tall blue column on the far left. That includes not just standard amphetamines but cough and cold medicines.

And, yes, as you point out, even your mouthwash with alcohol is abused more commonly than GHB. Although not a significant difference actually, just one case in this small series.

CHAIRPERSON GANNON: Representative Benninghoff.

REPRESENTATIVE BENNINGHOFF: On that same note, I don't want to dispute your graph, but I don't generally get too excited about graphs because they sometimes are relative.

I would be curious as to what

percentage the cold and cough medicine might be part of those numbers, because you could make a graph jump significantly and not necessarily tell people that we are talking about cold and cough. But, I'm not trying to disclaim it.

I think we have to also understand that accessibility factor is probably an issue with all these different things you list on this graph. As GHB becomes more prominent and more accessible, via the Internet or however you get it, I would suspect that those statistics are going to change. If we have this here in five years from now, this graph is going to look significantly different.

DOCTOR DONOVAN: If GHB was not a controlled substance, I certainly would agree. That's an absolutely excellent point. People abuse and take an intentional overdose of whatever is available to them. GHB should not be available to them.

Your first comment about the amphetamines, I actually did try to look at that in our very complex data collection system and was not able over these past few days to separate that out. I can, therefore, only

anecdotically tell you as one who handles most of these cases, the great majority of those 250 cases were in fact in Central Pennsylvania cough and cold medicines; not the standard (drops voice).

REPRESENTATIVE BENNINGHOFF: The reason I ask this question, it's well known in the Emergency Room, an alcoholic that you can't get alcohol will drink mouthwash. They have to hide it in the hospital all the time. They can make statistics go really wild. I have two other questions.

One, you said about antidotes. I'm curious. Are you aware of the toxicology of any antidotes to GHB? And again, I'm asking this from an E.R. and EMS perspective because, with a lot of narcotics you get a narc in we can treat something and reverse it very quickly, where I'm concerned, we can't do that with GHB.

DOCTOR DONOVAN: There are no antidotes, unfortunately, for most poisons. There's specifically is not an antidote for GHB other than supportive care. Until very recently there was no antidote for Valium, for example, and there now is. There still is no antidote

for a barbiturate overdose or phenobarbital overdose. In this particular case, no. There is no antidote other than to make sure they continue to breathe. If so, they will survive.

REPRESENTATIVE BENNINGHOFF: I have one last question, and I'll skip my second one. What schedule is cocaine?

DOCTOR DONOVAN: Cocaine we still -- It certainly has an accepted medical purpose. I believe it's a II. It certainly isn't a I because there's an accepted purpose for it.

REPRESENTATIVE BENNINGHOFF: That's why I ask you that because it is medicinally --

CHAIRPERSON GANNON: What about heroine?

DOCTOR DONOVAN: Heroine I believe is Schedule I. I'm not quite sure of that. Our DEA representative could confirm that. I believe it's a Schedule I.

REPRESENTATIVE BENNINGHOFF: Thank you. Thank you, Mr. Chairman.

CHAIRPERSON GANNON: Thank you. Would it be fair to say from what you told us about the fact that there's very little drug screening occurring with GHB or the GBL; that

most of the data is based upon what the person tells you or what witnesses tell you as opposed to any objective test that would be performed?

DOCTOR DONOVAN: That's right. That too is a good point. Most of these reporting systems depend upon what the patient tells us.

As I stated earlier, most hospitals and emergency departments do not do comprehensive screening. Even when they do, there are other drugs that they don't include in that screen. GHB reporting is almost strictly by what the patient tells us.

CHAIRPERSON GANNON: Thank you very much, Doctor Donovan, for appearing before the committee today and offering testimony on this very important issue.

Our next witness is Ms. Diane Moyer, Pennsylvania Coalition Against Rape. Welcome, Ms. Moyer. You may proceed when you are ready.

MS. MOYER: Thank you. Thanks everyone for sticking around. I know it's tough to sit through three hours of testimony.

I'm Diane Moyer. I'm Public Policy Director for the Pennsylvania Coalition Against Rape. We represent 53 rape crisis centers

throughout the Commonwealth. We provide technical assistance, advocate for legislative initiatives and otherwise advise our centers.

I'm here today to convey PCAR's support for the Attorney General's recommendation for Schedule I for GHB. Although we have spoken with the Governor's Office and we agreed that should GHB become approved by the FDA for medical use, that it would be sensible for it to be scheduled as a Schedule II drug.

GHB is one of several substances known to be used as the Representative pointed out, just one of many that's used in the commission of drug-facilitated rape. What is of concern about GHB is, of course, as been mentioned, the availability of the kits over the Internet. I agree that it is salty, but it can still be concealed in drinks because it's colorless and odorless.

Rohypnol now is -- The manufacturer has agreed to make a blue pill for Rohypnol. So that, if it's put in somebody's drink, it is discoverable.

The problem with GHB is, of course, that it produces sedative effects. I,

unfortunately, had to speak with a victim just last week who was a drug-induced rape. She woke up unconscious -- She was unconscious. She woke up. She found herself naked and condoms all over her bedroom floor. She can only surmise that it was as a result of a substance.

It may or may not have been GHB, but it was certainly GHB, Rohypnol or Ketamine or one of the drugs used to be known as drug-facilitated rape. She had absolutely no memory of leaving the party. She had no memory of what happened to her. It's the amnesiac-like effects of these drugs that are particularly a concern to us in the rape crisis field because it makes it so difficult to testify.

The credibility issue is questioned there. Well, why did you leave the party with him, or often in these cases what happens is, the perpetrator slips the drug into someone's drink and then is seen to help the victim out of the -- being taken away from the party.

It looks as if the victim herself became intoxicated and then the perpetrator can actually be seen to help the victim. It's really kind of an insidious situation.

I did an informal survey of our centers to see how many of them knew of suspected cases of drug-facilitated rape and particularly GHB because I know everybody wants to get the numbers. But, what they could only come up with is suspected cases and seven here, five here, four here.

The problem is, as I understand it, the drug metabolizes very quickly in the system. If someone is going to lay unconscious for eight hours and then wake up, questioning whether or not something happened, they're generally not going to get into an Emergency Room situation and perhaps even know to request a blood test or urinalysis. So, there's quite a bit of problems associated with these cases.

I agree with the Attorney General that the best way to approach this is to schedule a drug. Also, I think it's worth noting that in the Violence Against Women Act 1999, within the House bill is a proposal to schedule GHB and Rohypnol as a Schedule I drug along with Ketamine which is another date-rape drug on the Schedule IV.

I have spoken with people from

Orphan Medical and I'm sympathetic to clinical use of GHB and treatment of narcolepsy, but as I agree with the person, the doctor from DEA that it is my understanding that in FDA clinical trials, the GHB is, in fact, available.

So, until such time as the FDA approves it for general distribution, I would recommend -- I'm in agreement with the Attorney General that it be a Schedule I drug. I'm happy to entertain any questions.

CHAIRPERSON GANNON: Any questions?

(No response).

CHAIRPERSON GANNON: Thank you very much --

MS. MOYER: Thanks for bearing with me.

CHAIRPERSON GANNON: -- for wrapping this up and waiting so long for us to get to you. We do appreciate your testimony on this important issue. Thank you for being here.

Unless there is any further questions or comments from the committee --

MR. PRESKI: Two things for the record. A letter from Charlie Artz from the Pennsylvania Academy of Family Physicians. They

requested this be scheduled as a Schedule IV controlled substance.

Also a letter from Charles Zogby, Z-O-G-B-Y, of the Governor's Office. He's Director of the Governor's Policy Office. They are requesting it be Schedule I with a provision that will allow for Schedule II if DEA and FDA so approve. That's it.

CHAIRPERSON GANNON: With no further business before the committee, this public hearing is adjourned. Thank you very much.

(At or about 12:30 p.m., the hearing concluded)

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C E R T I F I C A T E

I, Karen J. Meister, Reporter, Notary Public, duly commissioned and qualified in and for the County of York, Commonwealth of Pennsylvania, hereby certify that the foregoing is a true and accurate transcript of my stenotype notes taken by me and subsequently reduced to computer printout under my supervision, and that this copy is a correct record of the same.

This certification does not apply to any reproduction of the same by any means unless under my direct control and/or supervision.

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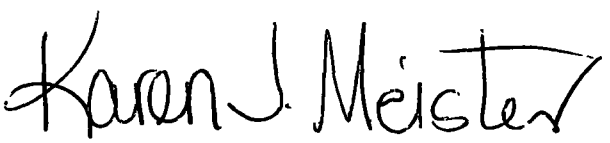

Karen J. Meister - Reporter
Notary Public

My commission
expires 10/19/00