









*United States.* 43779476

**CONTROLLED AND UNCONTROLLED SUBSTANCES  
USED TO COMMIT DATE RAPE**

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**HEARING**

BEFORE THE

SUBCOMMITTEE ON CRIME

OF THE

COMMITTEE ON THE JUDICIARY

HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTH CONGRESS

SECOND SESSION

ON

**H.R. 1530**

JULY 30, 1998

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# **CONTROLLED AND UNCONTROLLED SUBSTANCES USED TO COMMIT DATE RAPE**

**THURSDAY, JULY 30, 1998**

**HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON CRIME,  
COMMITTEE ON THE JUDICIARY,  
*Washington, DC.***

The subcommittee met, pursuant to call, at 2:08 p.m., in Room 2237, Rayburn House Office Building, Hon. Bill McCollum [chairman of the subcommittee] presiding.

Present: Representatives Bill McCollum, Steve Chabot, Bob Barr, Asa Hutchinson, Howard Coble, and Sheila Jackson Lee.

Staff Present: Paul J. McNulty, Chief Counsel; Daniel J. Bryant, Counsel; Nicole R. Nason, Counsel; Veronica Eligan, Clerk; and Melanie Sloan, Minority Counsel.

## **OPENING STATEMENT OF CHAIRMAN McCOLLUM**

Mr. McCOLLUM. The Subcommittee on Crime will come to order.

In the 104th Congress we addressed the devastating and cowardly crime of drug-induced rape when we passed the Drug-Induced Rape Prevention and Punishment Act. By increasing the penalties for the abuse and use of flunitrazepam, I hoped we had given some measure of protection to young women, particularly college students, who were unaware of the dangers of drug-induced rape. Despite our best efforts, however, new drugs which have similar properties as the old flunitrazepam formula are popping up at nightclubs and college campuses nationwide. Unfortunately, they are beginning to gain real popularity.

The Associated Press reported yesterday that two Penn State students were rushed to a local hospital after intentionally ingesting gamma hydroxybutyrate, popularly known as GHB. The director of the University's Office of Student Health Services was particularly upset, since Penn State's students are warned about potential date rape drugs at orientation. GHB is one of the drugs discussed at that orientation, and yet the message clearly did not get through.

In its liquid form, GHB is sold by the capful for about \$10. It can also be ingested in powder form. Either way, it dissolves quickly in alcohol and can take effect within 15 minutes. GHB can cause vomiting, dizziness, tremors and seizures, and victims frequently lapse into unconsciousness and require hospitalization. Although it was banned in the United States by the FDA in 1990, the Drug Enforcement Administration has received reports of GHB being used to incapacitate victims before the commission of a sexual assault.

How then are young students getting their hands on a drug which is banned in the United States? The answer is the Internet. Once again, the Internet is being manipulated by those who would take advantage of its wide accessibility and protections of anonymity.

The instructions for concocting GHB abound on the web, which is extremely dangerous since the drug can be manufactured at home with a few simple products available from hardware stores and specialty foods stores. Some sites even offer the visitors an opportunity to purchase any items which they may not be able to obtain locally. Unfortunately, this information is usually inaccurate and misleading. One particularly sinister web site even noted that GHB was very effective as a precursor for sex since it lowered a woman's inhibitions. To me this sounds like a direct invitation for date rape.

Like flunitrazepam, I am certain that GHB does have some valuable medical uses. I am aware that the FDA allows certain physician-supervised GHB studies to continue in the United States, and we certainly do not want to overreact to the issue.

The same is true of other drugs which we may be discussing here today, such as the drug ketamine hydrochloride, known on the street as "Special K". The abuse of ketamine is clearly on the rise. It has been coupled in the media with the crime of drug-induced date rape, but little evidence exists thus far to associate it with that hideous act. There may be persons who could benefit greatly from the use of GHB or ketamine, and, as I always hope, this hearing will provide us with some opportunity to learn more about these drugs.

We all know rape is a crime of power in which the aggressor tries to exert control over the victim through the sexual assault. It is one of the worst crimes which can be committed, and yet, astonishingly, the criminal element in our society has found a way to make it even worse. Rape becomes even more cowardly when the victim is incapacitated through the surreptitious use of drugs.

Today we will hear some tragic stories about the misuse of GHB and ketamine. We will also discuss the abuse of flunitrazepam in the United States since the passage of our legislation in the last Congress. I certainly hope that the DEA has some good news to offer regarding what effects the passage of that act had on the incidents of drug-induced rape.

I want to particularly thank the gentlewoman from Texas, Ms. Jackson Lee, for her unyielding commitment to this important issue. She is a dedicated member of this subcommittee, and I know this hearing is very significant for her.

I also appreciate all of the witnesses being here today, to help us think through what response would be the most effective and appropriate for Congress to take to resolve this continued and apparently very aggressive problem.

Miss Jackson Lee, would you like to make opening remarks?

Ms. JACKSON LEE. I thank you very much, Mr. Chairman. And first of all, let me thank you for working so evenhandedly and so closely with me on this particular legislation, and particularly the dedication of your staff, Paul McNulty, and the willingness that you expressed in holding this hearing today.

The legislation we are introducing here today has a great personal importance to me. We are here to discuss legislation which focuses on the use of controlled and uncontrolled substances to commit date rape. Violence against women is a social evil that we must address.

Drug facilitated date rape is just one manifestation of this complex issue. As legislators, parents, brothers, sisters, and aunts and uncles, mothers and fathers, we must work to protect our loved ones from the insidious harm resulting from the use of these mis-used drugs.

Like you, Mr. Chairman, I recognize that there are those who will argue for the medical prowess, if you will, of both the drugs we are concerned with today. But I hope this hearing will help explore those questions, and that we will have a full understanding and we will come down on the side of protecting the innocents.

This issue, and this legislation, is a result of a tragedy which has been carried out in many States and cities in our country. The bill I have introduced, H.R. 1530, is named for a young woman, Hillory Janine Farias, from LaPorte, Texas, who died on August 5th, 1996 at age 17 from an overdose of GHB. I think it was this picture of her on the television screen, showing her as a lovely young teenage girl, that got my attention that evening.

On the night she died, Hillory and two girlfriends went to a dance club. Witnesses said that Hillory consumed only soft drinks while at the club. Not long afterwards, she complained of feeling sick and having a severe headache. A friend took her home and she went to bed. The next morning Hillory's grandmother discovered her lying in bed unconscious and not breathing. She rushed her to the hospital, but Hillory never regained consciousness.

Hillory Farias was going to be a senior at LaPorte High School. According to those who knew her, Hillory was neither a drinker nor drug user. In fact, she was a clean-cut girl, a model student, a varsity volleyball player, and I remembered that most, and a talented overall athlete.

Unfortunately, this story is the not so unusual. The Los Angeles County Sheriff's Department recently successfully prosecuted a man and two accomplices for drugging and raping 10 women and poisoning six others. Numerous photographs depicting sex between the men and unconscious women were found in the defendant's van. On New Year's of 1996, 30 to 50 people collapsed from ingesting a GHB analog. Luckily, all of them received medical attention and survived, including a 17-year-old who suffered a heart attack.

The DEA has been working on placing this drug on Schedule I of the Controlled Substances Act at the Federal level. Many of our districts have already assigned GHB to Schedule I or II, including Georgia, Rhode Island, Illinois, Alaska, Louisiana, Tennessee, Hawaii, and Nevada.

After the death of Hillory, in my own State, I decided something must be done at the Federal level to combat the use of these dangerous drugs as a tool of date rape. H.R. 1530, the Hillory J. Farias Date Rape Prevention Drug Act, directs the Attorney General to schedule GHB as a Schedule I drug and ketamine as a Schedule II drug.

It also directs the Attorney General to establish programs throughout the country and disseminate materials to provide young people in high school and college with education about the use of controlled substances in the furtherance of rape and sexual assault, and as well in using it at all.

Both GHB and ketamine have been used as date rape drugs, rendering the victim helpless to defend herself against the attack and even obliterating memory of the attack. It is responsible for as many as 60 admissions in the past 6 months to emergency rooms in Houston alone. To date, there have been 16 deaths officially attributed to GHB use. However, many more deaths have undoubtedly gone without notice, since GHB is not part of a standard toxicology screen.

Although GHB is not produced legally in the United States, much of it is either smuggled across United States borders—and by the way, Mr. Chairman, there are 16 sites in Mexico that are now making these drugs—or else is illegally created in home labs and bathtubs by those who can easily access this date rape drug recipe through the Internet.

Scheduling a drug on the Federal Controlled Substances Act allows prosecutors to all punish anyone who uses scheduled drugs in any sexual assault crime to suffer penalties under the Drug-Induced Rape Prevention and Punishment Act of 1996. If we fail to schedule GHB as a level I or level II drug covered by the Controlled Substances Abuse Act, drug analogs of GHB, which are those chemical substances which have almost exactly the same chemical makeup as the drug itself, will take its place on the market, leaving law enforcement without legal recourse.

Finally, my legislation, unlike that of my colleague, Representative Stupak, will ensure that those who illegally possess and/or produce GHB, or any closely-related compound with the same effects, can be and will be prosecuted to the full extent of the law.

When we balance the pros and cons of this legislation, and I know as a lawmaker and a parent of two children that there is always more than one way to look at an issue, we can only conclude that we do whatever is necessary to stop both the illegal production and illegal use of this dangerous drug.

My legislation also schedules ketamine in Schedule II of the Controlled Substances Act. And as you said, ketamine is used as an anesthetic, primarily for veterinary use. It will be able, under Schedule II, to be used properly. Ketamine is only available to physicians and not commonly sold as an illicit drug, but is only scheduled in several States. And like GHB, ketamine also is used as a tool of sexual assault against unsuspecting girls and women. And like GHB, it is equally as important to schedule that drug federally so that we can limit the abuse of this drug.

I believe we must do whatever we can to stop the abuse of these harmful drugs. I hope my colleagues will support this legislation and our efforts to protect girls and women from the violent crime of sexual assault through these date rape drugs. I would really prefer to have Hillory alive today, but I hope we can do something in tribute to her life and that of her family, and young girls and young boys across the Nation.

Mr. Chairman, I thank you very much for the holding of this hearing.

[The bill, H.R. 1530, follows:]

105TH CONGRESS  
1ST SESSION

## H. R. 1530

To schedule Gamma y-hydroxybutyrate in schedule I of the Controlled Substances Act and to schedule Ketamine in schedule II of such Act and for other purposes.

### IN THE HOUSE OF REPRESENTATIVES

MAY 5, 1997

Ms. JACKSON-LEE of Texas (for herself, Ms. MCKINNEY, Mrs. MEEK of Florida, Mrs. TAUSCHER, Ms. KILPATRICK, Mrs. LOWEY, Mrs. MORELLA, Ms. VELAZQUEZ, Ms. MILLENDER-MCDONALD, Mr. BISHOP, Mr. PALLONE, Mr. WEXLER, Ms. STABENOW, Ms. MCCARTHY of Missouri, Ms. ROYBAL-ALLARD, Mr. BENTSEN, Ms. DELAURO, Mr. HINOJOSA, Mr. RODRIGUEZ, Mr. REYES, and Mr. SERRANO) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

### A BILL

To schedule Gamma y-hydroxybutyrate in schedule I of the Controlled Substances Act and to schedule Ketamine in schedule II of such Act and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Hillory J. Farias Date Rape Prevention Drug Act".

#### SEC. 2. DRUG SCHEDULING.

The Attorney General shall schedule Gamma y-hydroxybutyrate in schedule I of the Controlled Substances Act (21 U.S.C. 812) and shall schedule Ketamine in schedule II of such Act.

#### SEC. 3. EDUCATION AND DRUG ABUSE PREVENTION.

The Attorney General shall establish programs throughout the United States and disseminate materials to provide young people in high school and college with education about the use of controlled substances in the furtherance of rape and sexual assault and shall assist law enforcement personnel in the prevention of abuse of controlled substances for such purpose.

○

Mr. MCCOLLUM. Thank you, Ms. Jackson Lee.

Does anyone on this side wish to make an opening statement?

Mr. Hutchinson.

Mr. HUTCHINSON. Thank you, Mr. Chairman. I will try to be brief, but I do commend you for holding this hearing, and there have been a couple of recent Arkansas cases that dramatize the serious nature of the crimes in question and the difficulty of prosecution.

In both cases that I am thinking of, memory was a very serious problem for the prosecutors in handling the case. In one case six

women testified that they had been drugged and raped by the same man. Samples taken during subsequent physical exam proved crucial to the case, which was otherwise hindered by the victims' lack of memory as a consequence of the drug.

The many legal and emotional problems faced by victims and the difficulties associated with prosecution point up the need for serious penalties for mere possession. The use of drugs such as Rohypnol, which was used in the Arkansas cases, make these cases even more difficult because of the memory loss. Like the women from Arkansas, victims lose control of their faculties and cannot remember the events leading up to the rape.

Another Arkansas case was successfully prosecuted because the rapist videotaped his encounters, and the tapes were obtained and used by prosecutors to demonstrate the effects of the drug and the subsequent sexual assault. Few victims are able to present such convincing evidence, and that is why, Mr. Chairman, it is so important that the mere possession of such drugs carries severe penalties. In the case that I just mentioned, the victim would not even have been identified without the discovery of the videotape.

But it is equally important that we extend our discussion of date rape drugs to others that the chairman has mentioned, not just Rohypnol but GHB and ketamine as well. Neither of these drugs is currently controlled or scheduled in the United States, and this I hope will be discussed during this hearing.

So I look forward to the testimony today. I thank you for this hearing, and I think we also ought to look at greater education and preventive efforts on our college campuses because of the dangerous nature of these drugs. Thank you, Mr. Chairman.

Mr. MCCOLLUM. Mr. Coble.

Mr. COBLE. Briefly, Mr. Chairman, I thank you for having this hearing. Schedule I may or may not be the appropriate course to pursue. Hopefully we will know more about this after this hearing. If in fact the drug at issue does have some value for medicinal purposes, and I have been told that studies are underway to either confirm or refute that, I think we need to be careful in charting this course toward Schedule I, given the possibility of that.

I thank the chairman.

Mr. MCCOLLUM. Thank you, Mr. Coble.

Mr. Chabot.

Mr. CHABOT. Thank you, Mr. Chairman. I also will be brief. I want to thank you for holding this important hearing. I share your concern about the dangers of these drugs, and I share your concern for the safety of women who have been victimized by these dangerous drugs.

These date rape drugs present a real danger to women across the country. In fact, there is currently a case in my hometown of Cincinnati where a man allegedly used date rape drugs to attack at least eight women. It is vital that we take strong steps to protect them and women like them from these deranged acts.

Mr. Chairman, as you know, Federal, State and local law enforcement agencies, drug abuse prevention organizations, independent studies and media reports have raised serious concerns about the trafficking of controlled substances, including, in particular, date rape drugs from Mexico. While Rohypnol has been banned in

the U.S., many other dangerous controlled substances have taken its place.

For example, Texas law enforcement officials, in undercover videotape, have discovered that since Rohypnol was banned, Mexican pharmacies have been offering other drugs, such as Rivotril substitutes. While this problem is most notable in communities along the U.S.-Mexican border, it impacts communities well outside the Southwest. A study in Laredo found that residents of 39 States crossed the border and returned to the U.S. with a variety of drug products.

Mr. Chairman, Congress has and is continuing to fight the war on drugs to protect our children, our communities and our families. It is important that we highlight the danger of these drugs and take significant steps to stop them. I know that you share this concern, and I appreciate your leadership and commitment in stopping these dangerous drugs.

Mr. MCCOLLUM. Thank you.

Mr. Barr, do you have any opening comments?

Mr. BARR. Just to the chairman for convening these hearings. I would like to also thank my colleague from Texas, Ms. Sheila Jackson Lee, for introducing the legislation and providing a great deal of support for moving these hearings forward.

As all of us here know, we began looking at this matter a couple of years ago, and while there has been some progress made with regard to some changes in the drug Rohypnol, it still remains a serious problem.

I am looking forward to the testimony today and to continuing to remain in contact both with our colleagues that support legislation to address this, and I count myself among that group, but also to continue to hear from our colleagues at DEA, which has spent a great deal of time over the past year in conducting a very extensive study of this matter; and also maintaining contact with those in the industry itself, which I think are, in large part, taking a very responsible attitude toward trying to address these problems and, where possible, to make changes to the composition of and the properties of some of these drugs so that it makes their unknowing ingestion by other people much less likely.

And while all of these things are important, the problem remains for us that there are innocent people being harmed and, in some instances, killed in this country through these sorts of drugs such as GHB. So I think through these hearings and the additional work that we will be doing, I have every confidence that we will be able to craft a piece of legislation that follows on the legislation that we passed in the last Congress that continues to fine-tune the concerns that we have to provide for whatever level of criminal penalties are appropriate based on sound scientific and medical analysis.

This hearing today, particularly focusing on the legislation by Ms. Jackson Lee, I think is very appropriate and will be very, very beneficial, and I commend the chairman for holding these hearings.

Mr. MCCOLLUM. Thank you, Mr. Barr.

We are now ready for our witnesses, and the subcommittee's first witness is Mr. Raul Farias, I believe is the correct pronunciation. He may come forward and take a seat.

Mr. Farias is from LaPorte, Texas. He is the uncle of Hillory Farias, who, as you heard from Ms. Jackson Lee, was tragically killed by the date rape drug known as GHB. Mr. Farias and his wife, Maria, are the proud parents of four children. They have been active in speaking out against the drug GHB since Hillory's death and have established a scholarship in memory of Hillory. Commendably, they have turned their personal tragedy into a commitment to educate communities on the dangers associated with GHB.

Our second witness is Dr. Joye Carter. Dr. Carter is the chief medical examiner of Harris County. She served as the chief medical examiner for the District of Columbia for 4 years, while also serving as assistant clinical professor in the Department of Pathology at Howard University and as associate professor in the Department of Forensic Science at George Washington University.

Dr. Carter is currently assistant clinical professor in the Department of Pathology at Baylor College of Medicine and assistant clinical professor in the Department of Pathology at the University of Texas. She has been published in many medical journals over the years and is a recognized expert in pathology. Dr. Carter received her doctorate in medicine from Howard University.

Our next witness on this panel is Detective Michael Stevens from the Orlando Police Department's Drug Enforcement Division. Detective Stevens has been extensively involved in undercover investigations of the Rave drug scene and has conducted training courses regarding the Rave trend and designer drugs for the Orange County, Florida Corrections Department and the Florida Department of Probation and Parole.

He has testified before the Tampa, Florida City Council regarding Rave activities, designer and club drugs, as well as groups selling and distributing them. He has received an Orlando Police Department Award of Commendation for his work associated with having ketamine classified as a controlled substance in the State of Florida.

Detective Stevens is a graduate of the Brevard County Law Enforcement Academy and served for more than 5 years in the United States Marine Corps as a military police officer. I have to especially say I am proud of the fact he is from my home, Orlando.

Our fourth witness is Mr. Paul Doering, distinguished service professor in the Department of Pharmacy Practice at the University of Florida College of Pharmacy. Professor Doering is also co-director of the statewide Drug Information and Pharmacy Resource Center. He is a frequent speaker to on-campus groups, helping to educate college students about the risk of using drugs for recreational purposes.

Professor Doering has been recognized four times as Teacher of the Year for the College of Pharmacy, and in 1995 was named to his present position, making him the first distinguished service professor in the College of Pharmacy's history to be awarded this high honor.

Professor Doering received his B.S. Degree in pharmacy from the University of Florida and his M.S. in clinical pharmacy. It is a distinct pleasure to welcome a fellow Gator.

You have one constituent and I only have one constituent, but I did go to the University of Florida so I claim two of panel. You can claim Dr. Carter and we will be even. How about that?

Ms. JACKSON LEE. Yes, and Mr. Farias.

Mr. MCCOLLUM. Let me say I first of all want to welcome each of you here. Your complete statements will appear in the record, without objection, and I would request that you summarize for us, hopefully as briefly as 5 minutes or so, as we have limited time this afternoon.

Secondly, I want to say before you commence that I am grateful, as all the committee members are, for your understanding today. We moved this hearing, if anyone here in the room didn't know, from this morning to this afternoon because of the funeral services for one of the police officers slain here in the Capitol, Detective Gibson, and we really appreciate your indulgence in that regard.

I will go in the order in which I introduced you, so we will start Mr. Farias. Did I get that right?

Mr. FARIAS. Farias.

Mr. MCCOLLUM. So I actually had that right. So, Mr. Farias, please proceed.

#### STATEMENT OF RAUL FARIAS, LaPORTE, TX

Mr. FARIAS. First, I want to thank the chairman, Bill McCollum, and Ranking Member Charles Schumer for holding this hearing on this use of controlled substances used to commit date rape. I would especially like to thank Congresswoman Sheila Jackson Lee of Houston, Texas, for sponsoring H.R. 1530, in which, with the permission of my family, she most appropriately named the bill the Hillory J. Farias Date Rape Prevention Drug Act. I would like to thank her and her entire staff for their tireless efforts, for bringing this legislation forward. We appreciate that very much.

Again, my name is Raul Farias, uncle of Hillory Farias, who was murdered August 5th, 1996, by a date rape drug called GHB which was slipped into her Sprite.

The week before Hillory's death she had attended a volleyball camp held at Southwest Texas State University at San Marcus, Texas, sponsored by the University of Texas. This was the first time Hillory had ever gone away by herself. It was a week-long camp, and Hillory got homesick pretty quickly. She started calling two or three times a day, and then we called her also, so it was a very difficult time for all of us.

Saturday, my brother, my mother and my father went to go see her perform, and I remember my brother Rubin telling me that as soon as Hillory saw them she broke into tears. It was pretty evident that she missed everyone.

When Hillory returned on August 4th, my family went to my mother's house to go see how she was doing. My son, 5 years of age, and my daughter, 3 years of age at the time, really had missed her. Hillory loved my children in a very special way. She always made time to spend time with them almost every day.

And our visit that Sunday was about 2 hours. We played, we talked, then it was time for us to go back home. We all gave Hillory a kiss good-bye. I was the last to leave. I leaned over and I told her that I loved her and I would see her the following day.

I was real happy for her. She came back with a great outlook for her senior year. She had won a lot of awards at camp. She was very proud. I had never seen her so happy and confident, and she told me that she was ready for the upcoming volleyball season and was praying for a scholarship, hopefully from the University of Texas. She was looking forward to the homecoming, the prom, graduation, and her first date. She was full of life.

The next day, August 5th, I was at work when my mother, Hillory's grandma, called. She could not wake up Hillory. My mother sounded rather shaky. Then mom told me she was cold, and I told her to call 911. Then she hung up the phone. And at that moment I knew Hillory was in trouble. I had a gut feeling that Hillory had just died.

I drove from work to the hospital. It was a 30-mile trip, and all the way up there I prayed to God to spare her life and take mine. When I arrived, my brother met me outside and he told me that Hillory didn't make it. I couldn't believe it. The previous day I had just told Hillory I would come by and see her. Now, I am seeing her lying peacefully and breathless. She looked like she was just sleeping, and I told the nurses to come and revive her because she looked fine, and the nurses just told me that she was gone. She's gone.

The baby that came into our lives 17 years ago, the one that used to cry for me when she was in trouble, I wasn't there to protect her. I wasn't there to protect her from the evil that took her life away.

This all happened the night she came back from volleyball camp. Hillory and a friend went to a night spot, it was a teen night, to see all her friends from high school. It was like a school gathering before school started. Hillory came home around midnight. Grandma was waiting for her, as usual, and she told Hillory to go brush her teeth and go to bed for the following day, and Hillory complained of a headache. She took some aspirins, went to sleep and never woke up. Someone had slipped GHB into her Sprite. She was murdered.

Hillory never drank alcohol, never smoked, and was drug free. The investigation has proved all of this, and what is so honorable about the investigation, the one thing that stood out in the investigation is that Hillory's character was recognized by all that were interviewed. We already knew Hillory was special, but to hear from hundreds of other people, it was just something very special and something very meaningful to the family.

Hillory will never get the scholarship she dreamed of. She will never go to the prom. She will never experience her first date. She will never graduate. My children, every night they pray to God so God can play volleyball with her so she won't be alone. I am just telling you how I am feeling. I can't even start telling you how Hillory's grandparents are feeling. They are the ones that raised her.

Yes, our family has been through a very difficult time, but what happened to Hillory also has touched the community, the Nation and the world. Hillory's death tells the story of what is wrong with this world today. The alleged killer to have done this to Hillory is one of her best friends.

We teach our children to be aware of strangers. Well, we have gotten to the point to where we cannot trust anyone, including friends or even family. Accountability has gone away from our society. Children are being raised with no morals. Our Nation has followed the same path. It is one thing to be a willing participant of drug use, but it is another when you are participating unwillingly or unknowingly.

Please put this bill into action. We need to protect our youth; need to protect our daughters, sons, nieces and nephews, and hold people accountable for their actions, especially when it comes to defenseless rape and murder.

Before I close, I know there are some people that want this drug to be a Schedule III, and the problem with that is the damage has been done. You can get the information, the recipe on how to make GHB, on the Internet. Therefore, if it becomes Schedule III, then no one will ever be held accountable for any type of murder or defenseless rape.

And I do want to thank you very much for having me here, and I leave this up to God's hands. Thank you.

Mr. MCCOLLUM. Thank you very much, Mr. Farias, for telling us a very touching and very emotional story through your own testimony.

Dr. Carter, you are recognized.

**STATEMENT OF JOYE M. CARTER, M.D., CHIEF MEDICAL EXAMINER, JOSEPH A. JACHIMCZYK FORENSIC CENTER, HOUSTON, TX**

Ms. CARTER. Good afternoon, Mr. Chairman and members of the Subcommittee on Crime. As a physician and forensic pathologist, my responsibilities include investigating deaths due to natural and unnatural causes, as well as promoting social change and improved health care through information gained by close examinations of the dead body. And I consider it an honor to speak on behalf of the dead, who can no longer tell their story.

Substance abuse is a very broad category encompassing addiction to alcohol, prescription drugs, illicit drugs, and naturally occurring chemicals such as sugar, caffeine and fats. It is the leading cause of death when we investigate accidents, suicides, homicides, and even natural cases.

In the Harris County experience, 25 percent of all accidental deaths are due to drug ingestion. The most common drug, of course, is ethyl alcohol. Other drugs detected with frequency in the dead body include cocaine, marijuana, codeine, morphine, methadone, PCP, also things such as aspirin and Tylenol. Other drugs are detected with less frequency. Those include ketamine, inhalants, which can encompass many household chemicals, LSD, and date rape drugs. I would like to focus my comments on this latter category of abused substances.

Date rape drugs is a very complex entity which has been highlighted by the media in recent years. The two most notable drugs, gamma hydroxybutyrate, known as GHB, and Rohypnol are the most frequently discussed. Rohypnol is in the category of benzodiazepines. Other drugs also in that category come under Valium, Atavan, Xanax, Halcion or Librium. Other preparations which

should be considered are Benadryl, even things such as Nytol, which can be purchased over the counter. The "date rape" phrase suggests these drugs are unknowingly consumed and a sexual encounter takes place after the victim has been intoxicated.

GHB is in the category of a CNS, or central nervous system depressant. Its first phase is to reduce inhibitions, just like alcohol. The common denominator of the different drugs I previously mentioned is they interfere with memory, some even cause amnesia, thereby making sexual assault all the more difficult to document.

The Harris County Medical Examiner's Office set a precedent in 1996 when a case was ruled homicide due to gamma hydroxybutyrate toxicity. You have already heard about the life of Hillory Farias, certainly well-known in southeast Texas. She had gone to a dance club. She complained of a severe headache and, indeed, she never woke up.

The medical examiner was notified of a sudden death in a teenager, and Ms. Farias' family had made a conscious decision to give the gift of life. The diagnosis working at that point had been a sudden death due to an accidental hemorrhage in the brain. At autopsy no abnormalities were found. Repeated drug testing finally revealed the presence of GHB in her blood and in the fluid from the eye. It took us 2 months to detect this chemical.

The investigation, indeed, did not suggest any experimentation previously with drugs. The blood level was low, by our forensic standards, but we must take into consideration the half-life of GHB is as little as 1 hour. It may disappear from the body fluids in 12 hours. Our tests were performed on urine.

GHB can be naturally occurring but also is easily manufactured by simple chemicals which are available at your local hardware store. You don't need a degree in chemistry to manufacture this drug. It is, indeed, sold on the black market. The instructions are, of course, listed on the Internet. It was originally marketed to health food stores for body builders and as a diet and sleeping aid.

Its central nervous system activity, that of a depressant, and numerous complaints that ranged from nausea to seizure activity and coma were recognized, and in 1990 the FDA removed it from public consumption. It is important to recognize that there is no known antidote for GHB toxicity.

Besides the nomenclature of date rape, these drugs should also be considered as something that is now being abused by young people, particularly high school and college age. These drugs in the category of date rape can produce hallucinogens and certainly depress the central nervous system, more severe when used with alcohol. The effects are dose and time related.

There are very few written procedures to document GHB in a person's blood. When used for recreational purposes, the person can expect perhaps to have a high, to feel good, euphoria, increased libido, especially dangerous with date rape, weight control or steroid supplement.

Problems exist in documenting the presence of date rape drugs in the body. First of all, these drugs are not included in the routine drug screening panel. The scene of death or injury must be thoroughly investigated because GHB can be found mixed with other substances, such as water, soft drinks, ice tea, even mouthwash.

Laboratory analysis is critical in documenting the presence of GHB. What is more important is that with the potential for amnesia or memory distortion, date rape may be difficult to prosecute due to the passage of time and the need to document the presence of the drug in the victim's system.

Congresswoman Sheila Jackson Lee introduced the Hillory Farias Date Rape Prevention Drug Act in May 1997 for purposes of including GHB in Schedule I of the Controlled Substances Act, and I do support this. This is important for those that investigate cases of substance abuse in death, due to the complex nature of detecting the chemical in the body fluids. It would certainly remove a misdemeanor offense charge and place it in the same category for possession of narcotic substances. It is important to have a means available for those persons who suspect they have fallen victim to date rape, and allow for more timely and selective drug detection methods.

I want to emphasize date rape drugs do cover a broad category, and I have focused on only one in the interest of time.

Since GHB and other drugs may produce an altered state of consciousness and memory loss, that victim of sexual assault becomes an unwilling participant in this criminal activity. There is no doubt there is some limited activity under the medical value for GHB, but there is also limited activity for cocaine and morphine, yet these are Schedule I.

I conclude my remarks at this time and I thank you for your interest in this topic.

[The prepared statement of Dr. Carter follows:]

PREPARED STATEMENT OF JOYE M. CARTER, M.D., CHIEF MEDICAL EXAMINER,  
JOSEPH A. JACHIMCZYK FORENSIC CENTER, HOUSTON, TX

SUMMARY:

The category of Date Rape drugs is very broad. The media frequently discusses Gamma-hydroxybutyrate and Rohypnol, but other drugs must be considered such as: alcohol, Benadryl and over-the counter medications that contain diphenhydramine.

A common feature of "Date Rape" drugs is their ability to be ingested without knowledge and the inducement of an altered state of consciousness or memory loss. These drugs are not easily detected nor considered regularly as the causative agent in a death or sexual assault. Further, these drugs are not all categorized as level one or two under the current Controlled Substance Act.

In addition to being utilized in sexual assaults many of these "Date Rape" drugs are being abused with alarming frequency among young people.

OFFICE OF THE MEDICAL EXAMINER OF HARRIS COUNTY,  
JOSEPH A. JACHIMCZYK FORENSIC CENTER,  
Houston, TX, July 27, 1998.

Hon. HENRY J. HYDE, *Chairman,*  
*Committee on the Judiciary,*  
*House of Representatives, Washington, DC.*

CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE ON CRIME: Thank you for the opportunity to address our national legislators on such an important issue as substance abuse.

My name is Dr. Joye M. Carter, and I am a forensic pathologist and the Chief Medical Examiner for Harris County, Houston, Texas. I am a private citizen and do not represent any federal programs or subcontractors awardees.

As a physician and forensic pathologist my responsibilities include investigating deaths due to natural and unnatural causes, as well as promoting social change and improved health care through information gained by close examinations of the dead

body. I consider it my honor to speak on behalf of the dead, who can no longer tell their story.

Substance abuse is a broad category; incorporating addictions to alcohol, prescription drugs, illicit drugs and natural occurring chemicals. Substance abuse is a leading cause underlying motor vehicular accidents, suicide, homicides and yes, natural deaths.

In the Harris County, Texas experience approximately 25% of all accidental deaths investigated by the medical examiner's department are due to overdosing on alcohol and other drugs. The most frequently detected drug is ethyl alcohol. Alcohol has been recognized world wide as the most common drug involved in violent deaths as well as naturally occurring deaths such as cardiovascular disease, liver failure, various types of cancer, infectious process and malnutrition. Other drugs detected in the dead with frequency are Cocaine, Marijuana, Codeine, Morphine (Heroin), Methadone, Salicylates, Acetaminophen, PCP, Benzodiazepines, anti-depressants. Other drugs are detected with less frequency in the dead bodies, as well as those individuals arrested on suspicion of driving while intoxicated. These drugs include Ketamine, inhalants, LSD and Date Rape Drugs. I would like to focus my comments on this latter category of abused substances. Date Rape Drugs is a complex entity which has been highlighted by the media in recent years. This category includes Gamma hydroxybutyrate (GHB) and Rohypnol as the most frequently discussed, but also the other benzodiazepines, which may be recognized by brand names of Valium, Ativan, Xanax, Halcion or Librium. Other preparations, such as Benadryl or even Nytol, may be considered in the "Date Rape" category. Please be mindful that alcohol may be consumed without knowledge. The Date Rape phrase suggests that these drugs are unknowingly consumed and a sexual encounter takes place after the victims have become intoxicated. The common denominator of the different drugs previously listed is that they interfere with memory, some even cause amnesia, thereby, making a sexual assault all the more difficult to document.

The Harris County Medical Examiner Office set precedent in 1996 when a case was ruled homicide due to Gamma-hydroxybutyrate (GHB) toxicity.

The death of Hillory Janean Farias is well known in Southeast Texas. Ms. Farias was by all accounts a healthy and well-adjusted seventeen years old girl about to enter her senior year of high school. She had gone to a teen dance club where she may have consumed a soft drink. Upon returning home she complained of a severe headache and went to bed. She never woke up. The Medical Examiner's Office was notified of a sudden death in a teenager and the family had made a conscious decision to donate her organs. The working diagnosis had been cerebral hemorrhage secondary to aneurysm. At autopsy, no abnormalities were found. Repeated drug testing finally revealed the presence of GHB in her blood and ocular fluid. The investigation into Ms. Farias death did not demonstrate any willing experimentation with drugs. The detected blood level was low, by forensic standards, however, the metabolism and half-life of this drug should be taken into consideration.

GHB (gamma hydroxybutyrate) is a naturally occurring substance found within our bodies and also is easily manufactured by simple chemicals, which are available at the local hardware store. No degree in chemistry is needed to produce "black market" GHB; in fact the instructions are available over the Internet. GHB was originally marketed in health food stores to body builders and as a diet and sleeping aid. Its central nervous system activity, that of a depressant and numerous complaints of symptoms ranging from nausea to coma were recognized. In 1990, the Food and Drug Administration removed it from public consumption. The death of Hillary Farias is now one of many examples of the dangerous properties of GHB.

Besides the nomenclature of "Date Rape" these same drugs should be considered as abused substances from the standpoint that they can act as central nervous system depressants and mild hallucinogens in individuals. The effects are dose and time related. Gamma hydroxybutyrate and other drugs in this category have been detected in persons admitted to area hospitals for unusual behavior or coma induced states. Numerous cases are cited in the recent literature of abuse by purposeful ingestion of the compound either in liquid form, mixed or consumed as a powder. If used as an abused substance, the findings might include getting a "high", increasing libido, weight control by suppressing the appetite and steroid supplement for bodybuilding.

Problems exist in documenting the presence of date rape drugs in the body. First of all these drugs are not included in the routine drug screen panel. The scene of injury or death must be investigated thoroughly because GHB in particular has been found in spring water bottles, ice tea and even mouthwash. Both GHB and Rohypnol used to be white powder or tablet form. Now manufactures of Rohypnol include a blue dye, at least in this country. Laboratory analysis is critical in documenting the presence of GHB since we know that it also occurs naturally. What is

more important is that with the potential for amnesia or memory distortion, date rape may be difficult to prosecute due to passage of time and the need to document the presence of the actual drug in the victims system.

Congresswoman Shellie Jackson Lee introduced the Hillory J. Farias Date Rape Prevention Drug Act in May of 1997 for purposes of including Gamma-hydroxybutyrate in Schedule I of the Controlled Substance Act. This is important for those that investigate cases of substance abuse and deaths due to the complex nature of detecting those chemicals in body fluids. It would remove the misdemeanor offense charge and place it with the same category of possession of narcotic substances, which is important for those who minimize the serious complications that occur and I make reference to the internet recipe. Lastly, it would make a means available to those person who suspect that they may have fallen victim to date rape drugs and allow for more sensitive and selective drug detection methods.

I want to emphasize that Date Rape Drugs cover a broad category and I have focused on only one of these drugs in the interest of time. Other drugs to be considered include alcohol, chloral hydrate (Mickey Finn), other Benzodiazepines, Ketamine, Marijuana, D-Lysergic Acid (LSD), and phencyclidine. Along with GHB these drugs may produce an altered state of consciousness and memory loss, making the victim of a sexual assault that ensues an unwilling or unknowing participant.

I will conclude my remarks at this time, thank you for your time and interest in this topic.

Mr. MCCOLLUM. Thank you very much, Dr. Carter, for that enlightening testimony.

Mr. Stevens, you are recognized.

**STATEMENT OF MICHAEL STEVENS, DETECTIVE, UNDERCOVER DRUG INVESTIGATIONS, ORLANDO POLICE DEPARTMENT, ORLANDO, FL**

Mr. STEVENS. Good afternoon. I would like to thank the chairman and the committee for having me here today. I would like to start my remarks by stating simply that I am not an administrator, I am a street detective. Therefore, some of my remarks will be very straightforward.

Two days ago I was buying GHB in a club in Orlando. Three days ago I was buying 100 Rohypnol pills. And, a week ago I was buying two bags of ketamine.

In 1995, the Orlando Police Department started having trouble with what we call the Rave subculture. Officers were finding drugs they had no experience with: MDMA, methylene, dioxymethamphetamine. Pills were popping up—that none of the officers who had been trained to fight crack cocaine, powder cocaine and marijuana had any idea what it was.

In early 1996 we started establishing a unit that worked primarily the new Club/Rave scene that was coming up. We started getting officers trained for undercover work in it and started putting people inside these clubs and inside these Raves. We began finding a smorgasbord of drugs, everything from prescription drugs to drugs that we didn't even have a way of identifying. We ended up calling pharmacies at our hospitals, trying to ask them what kind of drug is this, what pill is this. The drugs ran the gamut, everything from depressants to stimulants to hallucinogens. You name it, they had it.

Through 1997 we continued to target dealers. The trend became worse. What started out as small amounts of drugs were becoming bigger and bigger. Two drugs in particular began to get a very nefarious reputation with them. One was flunitrazepam, under the trade name Rohypnol. In 1996 we were buying Rohypnol any time

we wanted it; 30, 40, 50 pills at a time. These were the 2 milligram pills. Fairly cheap, easy to get, most of it being sold by females.

Again, this is the central Florida area, is what I am speaking for, and that is all I can.

Rohypnol at that time was very popular as what is called a landing gear, something that brought people down from their MDMA high. It is actually a stimulant. They were using Rohypnol to bring them down so they could go home at night without their hearts racing a mile a minute.

Unfortunately, when they were taking Rohypnol, they didn't know the dosages they could take. They didn't know how much they could take, and we were having a lot of overdoses, a lot of people just passing out, a lot of people going into respiratory arrest. All the overdoses in my department go pass my desk, and we were seeing an average of 15 to 20 in downtown Orlando a night out of nowhere.

Most of the Rohypnol we were seeing was coming from Mexico up through Miami and South Beach area.

Sometime during early 1997 the State of Florida passed a trafficking law for Rohypnol, flunitrazepam, making it 4.0 grams and over would be trafficking. Within about 3 months the dealers in flunitrazepam knew about that, knew the trafficking, knew the minimum mandatories through the Internet. The information was passed on from dealer to dealer to dealer through the Internet and E-mails. Rohypnol sales dropped markedly. It cost us a lot of money to buy "ruffies" at that point in time, which is the street name for them.

But a new drug, just when we thought we had that drug worked out, a new drug popped up and that was GHB. GHB right now in Orlando is battling Ecstasy, or MDMA, for the number one Rave/Club drug, without a doubt. Two days ago I was watching kids as young as 17 shrugging down capfuls of GHB in a club and out in the parking lot, money changing hands left and right.

GHB right now is taking over the date rape drug moniker that ruffies did. A lot of these people here have more degrees than I do to tell you about the pharmacology and they will explain why it is, but I can tell you honestly from a drug cop's point of view it is out there and it is everywhere, and we are talking kids as young as 14 and above.

There is no control. There is a complete lack of knowledge on the kids' part. Most of these kids are 18, 19, 20. They cannot afford to drink, so they take GHB because they think it mimics the effects of alcohol without the hangover. They have no understanding of what it does or what it is. All they know is their friend took it and they lived, so I will take it and it is okay.

One of the things we started seeing with Rohypnol was the organized groups that were conducting sexual assaults with it. That has been documented by informants that work for me. Groups would go in with what is called the distractor, a guy who would meet a woman inside a club, keep her busy while another drugged her drink.

GHB has become the same way, and it is a lot easier to do with GHB. GHB can be carried in a Visine bottle, whereas ruffies had to be carried at least as pills. If a cop searched you at the door and

he found pills, he knew what he had. We don't know what we have. We have a kid with a Visine bottle. We don't know if it's GHB or not. It can't be field tested. It has to be sent to a lab. It is very easy to be put in a drink. It is clear. It is odorless. It takes no time for it to dissolve in a drink. The only thing you might get is a salty tasting liquid. If you mix that with a Coke or something, you will not notice it.

The other thing we are getting with GHB is they are making it in people's bathrooms. They are getting it off the Internet. They are paying \$80 for a kit. Comes in the mail from whatever State allows it. It comes across the mail, boom, it is in the guy's house and he is making pounds of GHB, and we cannot control it. We can't find it. All we know is it is getting into the clubs, usually in a liquid form in Orlando. It is probably now the most popular drug in Orlando right now on the club scene.

As I said before, I can't tell you what is happening in the other States, but I guarantee you it is going to be darn similar to Orlando. In 1997 we had the dubious distinction of being voted by Rolling Stone as the number one techno music city, so we have a pretty good edge on the Rave culture and what goes on. These drugs are out there, your kids are in them, they are using them, and I think it would benefit law enforcement, and this whole country if the Federal Government would put some backing behind it, give us something to work with to where we can do something with these drugs, and I thank the committee.

[The prepared statement of Mr. Stevens follows:]

PREPARED STATEMENT OF MICHAEL STEVENS, DETECTIVE, UNDERCOVER DRUG INVESTIGATIONS, ORLANDO POLICE DEPARTMENT, ORLANDO, FL

**DRUGS OF ABUSE  
CENTRAL FLORIDA RAVE/ CLUB  
SCENE**

**DETECTIVE MIKE STEVENS  
ORLANDO POLICE DEPARTMENT  
DRUG ENFORCEMENT DIVISION**

**HISTORY IN ORLANDO**

Since 1996, our agency has been actively and aggressively investigating drug distribution groups frequenting and involved in the Rave and club culture here in Central Florida.

Our investigations have identified two primary drugs used in the Rave/Club scene that are used by some to commit sexual assaults against incoherent or incapacitated victims. These drugs are Gama Hydroxy Butyrate (GHB) and Flunitrazepam (Rohypnol®).

# Flunitrazepam (Rohypnol®)

- **Ruffles**

- Street name for flunitrazepam (Rohypnol®)
- Schedule I
- Central nervous system depressant
- Ten times more powerful than Valium
- Not legally available in the United States

- **History**

- Used in several foreign countries as a pre-surgical sedative and for the treatment of severe sleep disorders
- Some doctors in foreign countries administer flunitrazepam (Rohypnol®) to psychiatric patients
- First documented as an abused drug in the United States in the early '90's
- Gained national attention as a "date rape" drug

- **Production of Flunitrazepam (Rohypnol®)**

- Chemical analog of diazepam
- Marketed by Roche Pharmaceuticals
- Legally available in Mexico, Europe, South America and Asia

- **Appearance**

- White-colored tablets
- Single or doublecross scored line on the back of tablet
- R.H., Roche, or Ruffies on front of tablet
- The #1 or #2 scored on front of tablet indicating milligrams.

When dissolved in a drink, flunitrazepam (Rohypnol®) is odorless and tasteless.

- **Packaging**

- Wrapped in bubble pack with clear front and silver peel-away backing with Roche and the number of milligrams written on it

- **Methods of Ingestion**

- Swallowed
- Inhaled (crushed into powder)
- Injected
- Smoked (in Central Florida generally by Ravers)
- Dissolved in drink

- **Duration of Effects**

- Onset - 15 to 20 minutes
- Peak - 1 to 2 hours
- Duration - 8 hours
- Hangover - 12 to 24 hours .

- **Detection in Urine**
  - Standard drug testing may not detect flunitrazepam
  - An advanced test targeting flunitrazepam is available
- **Physical and Psychological Effects**
  - **Moderate Doses**
    - Loss of inhibition
    - Drunken state
    - Dizziness
    - Tranquility
    - Slurred speech
  - **High Doses/Overdoses**
    - Slowed breathing
    - Headaches
    - Affects judgement
    - Memory loss
    - Death
    - Confusion
    - Hallucinations
    - Blackouts
    - Comas
- **Withdrawal Symptoms**
  - Headaches
  - Tension
  - Irritability
  - Hallucinations
  - Muscle Aches
  - Confusion
  - Delirium
  - Convulsions

- **Slang Terms and Street Names**

- Ruffie
- Dulcita
- Wheel
- "R-2"
- Shay
- Roach 2
- Landing gear
- Mind eraser

- **Prices**

- \$5 to \$25 per tablet in Rave clubs

Prices have escalated due to strict sentencing guidelines recently passed by the Federal Government. Dealers have raised their prices to compensate for the increased risk factors involved in selling flunitrazepam (Rohypnol®).

# GHB

- **GHB**

- Stands for Gama Hydroxy Butyrate
- Controlled substance in some states
- Central nervous system depressant
- Causes euphoria, hallucinations and deep sleep
- Called the "date rape" drug of the '90's

- **History**

- Synthesized in 1961
- Developed for use as an anesthetic
- Used as a treatment for sleep disorders
- Aided in the treatment of alcoholism
- Used by bodybuilders as a growth hormone stimulant
- Banned by the Food and Drug Administration in 1990 due to several acute poisonings

- **Production of GHB**

- Legally produced in Europe
  - Legitimate laboratories
  - Good quality control of product
  - Accurate dosing levels
  - Qualified chemist

- **Production of GHB (continued)**
  - **Illegally produced in the United States**
    - Made in kitchen laboratories
    - Unstable quality of product
    - Inaccurate dosing levels
    - Local drug dealer acts as chemist

The two main ingredients in GHB manufactured in the United States:

1. Industrial engine degreaser
2. Caustic acid

- **Internet Connections**
  - Information available on producing GHB
  - Home-cooking kits can be ordered for GHB production
  - Offers safety tips on consuming GHB
- **Appearance**
  - **Clear Liquid**
    - Odorless
    - Salty taste
    - Slightly thicker than water
  - **White Powder Form**
    - Similar to powder cocaine
  - **Attempts to Avoid Detection**
    - Adding artificial flavoring and coloring to GHB
    - Mixing GHB in bottled water and drinks that have a salty taste

- **Packaging**
  - Tin foil
  - Plastic baggie
  - Kid's "bubbles" jar
  - Capsule
  - Water bottle
  - 35mm film canister
- **Method of Ingestion**
  - Inhaled
  - Injected
  - Swallowed
- **Effects of GHB**
  - Onset - 10 to 20 minutes
  - Duration - 1 to 3 hours
  - After effects - 2 to 4 hours
- **Internet Recommended Dosing Levels**
  - Low doses - .5 to 1.5 grams
  - Moderate doses - 1 to 3 grams
  - High doses - 3 to 8 grams
- **Testing for GHB**
  - In Humans
    - Routine drug screen will not detect GHB
    - You must request a test that specifically targets GHB
    - GHB can be detected in both blood and urine
    - Urine testing should be used since GHB leaves the bloodstream within 4 to 7 hours after consumption

- **Testing for GHB (continued)**
  - **Field Testing**
    - There is no specific field test for GHB
    - Specimen must be sent to laboratory for testing
- **Physical and Psychological Effects**
  - **Low Doses**
    - Euphoria
    - Anxiety
    - Increased sexual pleasure
    - Impaired judgement
    - Loss of inhibition
    - Loss of coordination
    - Nausea
  - **High Doses/Overdoses**
    - Dizziness
    - Slowed breathing/heart rate
    - Memory loss
    - Respiratory depression
    - Muscular fatigue
    - Passing out
    - Coma
    - Death
- **Withdrawal Symptoms**
  - Insomnia
  - Anxiety
  - Tremors
  - Depression

- **Slang Terms and Street Names**
  - Liquid "E"
  - Georgia homeboy
  - Scoop
  - Grievous bodily harm
  - Liquid "X"
  - "G"
  - Easy lay
  - Gamma 10
  - Salty water
- **Paraphernalia**
  - Water bottles
  - Flavored food coloring
  - 35mm film canisters
  - Cut-off straws
- **Prices**
  - \$10 per dose (1/2 teaspoon) in Rave clubs

- **Drug Interaction and Use**
  - MDMA
    - Used with Flunitrazepam or GHB to come down from the high
- **GHB Kits From Internet (Mail Order)**
  - Cooking directions
  - Ease of making

**There is a lack of trafficking laws for GHB (as opposed to Flunitrazepam)**

Mr. McCOLLUM. Thank you very much, Detective Stevens.  
Professor Doering.

**STATEMENT OF PAUL DOERING, PROFESSOR, DEPARTMENT OF PHARMACY PRACTICE, UNIVERSITY OF FLORIDA**

Mr. DOERING. Good afternoon, Mr. Chairman and members of this committee. It is a privilege and honor to address this group on the subject of GHB, the dreadful drug of abuse that is wreaking havoc in communities all over our country. I come here today to express the concerns that I share with my colleague, Dr. Michael Okun, a neurologist at Shands Hospital at the University of Florida.

Exactly what is GHB? Well, as you have heard, GHB is shorthand for a chemical called gamma hydroxybutyrate, known on the street by a variety of slang names, including Liquid Ecstasy, Nature's Quaalude, Zonked, and the particularly offensive name Easy Lay.

GHB is a simple molecule related to one of the chemical messengers in the brain. GHB depresses the central nervous system, and when combined with alcohol or other tranquilizing or sedating drugs there is a resulting chemical overload in the brain that may lead to cessation of breathing. In addition, heart rate can slow, blood pressure can drop, coma can set in and deaths have occurred.

The problem of GHB is nationwide, from St. Petersburg to Sacramento, Dallas to Detroit, from Orlando to Omaha, reports of deaths, near deaths, sexual assaults and other problems pouring in. New reports of toxicity are appearing with increased frequency in the medical literature as well.

In June 1998 an article appeared in the Annals of Emergency Medicine reporting a series of 88 patients seen in a San Francisco emergency room. We have seen 10 cases in our hospital alone, and this does not account for the numerous problems that never come to the attention of medical personnel. We have had to place five patients on breathing machines, one of whom developed a complication and remained hospitalized for 9 days. Luckily, we have had no GHB-related deaths at our hospital, but without some swift action it is just a matter of time until we do.

Prior to 1990 GHB was available as an over-the-counter pill or powder sold mostly in health food stores, but the FDA pulled it from the shelves because of deaths and serious illnesses related to its use. Today the major source of GHB sold on the streets is homemade from cheap kits obtained over the Internet. It is mixed largely by nonchemists from recipes that are often flawed or incomplete, and this leads to finished products of questionable purity and, more importantly, unknown potency. Because there is no way to tell the strength of homemade GHB, what might be a safe dose today, for example, one capful, could produce a toxic dose tomorrow.

The misinformation surrounding GHB is most troubling. Proponents of GHB often appeal to the anti-government, anti-establishment mentality of potential users. One seller calls GHB, "Not only very safe, but also extremely beneficial," and brazenly offers, "a \$10,000 reward for any scientifically documented permanent harm" from the drug. He finishes his message by stating, "It appears that the only true danger associated with GHB use is the loss of billions of dollars of revenue to the alcohol, tobacco, legal and illegal drug pushers and the AMA malpractitioners of the world when GHB gains widespread acceptance and use."

Our impression, after interviewing many of GHB's victims, is that they are truly Internet educated and honestly believe this drug is a safe over-the-counter vitamin. Dr. Okun and I decided to fight back with an information campaign of our own, using the same tools to spread the truth as others used to spread lies. We set up a web site with the title "University of Florida declares WAR on MISINFORMATION on GHB."

GHB has been and is being studied for a number of legitimate medical uses, including its use as an anesthetic, for the treatment of narcolepsy and the treatment of drug addiction. One must remember this research is done using precise doses of carefully manufactured products under close medical supervision. Ultimately this drug may prove to have some therapeutic usefulness, but it should not be available for use as a party drug.

GHB has gained a reputation as a date rape drug. To me, nothing is more despicable than using a chemical to disable a person so that she can be raped. We often visualize the perpetrator slipping the drug into the victim's drink. Let us not forget the person who willingly takes the drug for purposes of partying, only to have the drug incapacitate them. This makes them an unsuspecting target for the rapist who might seize the opportunity to take advantage of the drugged partier when she is unable to resist.

Unscrupulous sellers of the dangerous chemicals used to make illegal drugs are very creative, and will use whatever loophole they can find to peddle their deadly wares. One site claims they sell their kits only for purposes of demonstrating a type of heat-producing chemical reaction called an exothermic reaction. Here is part of their disclaimer:

"This experiment is for lawful use in research and study only. Purchase of this kit does not give permission to the buyer to perform this experiment. It is meant to provide an educational experience in an exothermic reaction as well as showing properties of molecules when reacted."

With the new school year rapidly approaching, we hope to intensify our war on misinformation. Needless to say, we have received some interesting electronic mail messages in response to our web site. Some are open and honest exchanges of perspective, while others are attacking. Some will break your heart. I would like to close by reading you an excerpt from one message received by Dr. Okun from a grieving sister of a young whom who died from GHB.

"I just want everyone to read and understand how dangerous GHB is. My sister who was only 22 died. My sister is gone now, and we can never see her beautiful smile nor hear her wonderful laugh, but through the words of people like yourself, maybe 1 day people will stop, listen and learn."

Thank you for your kind attention to these comments.

Mr. MCCOLLUM. Thank you very much, Professor Doering.

We will now proceed to a period of questioning by the Members of Congress who are here today under the 5 minute rule, and I will recognize myself for 5 minutes.

Detective Stevens, in your experience out on the street, is GHB known just as that; do kids call it that? Is that what they call it, "GHB"?

Mr. STEVENS. We have heard it called "G", Liquid X, Grievous Bodily Harm, and what they are calling it now is "water" because that seems to be the common way they are carrying it. They are carrying it in some kind of water bottle, Evian, Zephyr Hills.

To understand GHB and how it fits into the club scene, you have to understand exactly what the Raves are. The primary drug in the Rave is MDMA, the stimulant. When they rave and they dance, they get hot and dehydrated; they drink a lot of water to rehydrate themselves. They also drink the water with the GHB in it to bring them back down from their stimulant.

Mr. MCCOLLUM. The stimulant is to get them to be able to dance a lot?

Mr. STEVENS. From like 9 o'clock at night to 7 in the morning. I tried it sober. It is not a pleasant experience. You just can't do it. That is why they take the Ecstasy, to give them the continual energy. But at 7 in the morning or so, when they need to come down, Ecstasy doesn't just shut off, and that is why they use this "landing gear" to bring them down from their flight so that they can go ahead and come back to normal, usually "ruffies", flunitrazepam, or GHB or some other prescription drug like Valium.

But that is what they are doing. They are combining it with water and drinking it. Unfortunately, they don't know the purity levels or how much.

Mr. MCCOLLUM. Is that combined with the water before they get there? Is it like a Zephyr Hills water bottle they have already mixed up, or is it something they mix there at the club?

Mr. STEVENS. The dealer, I watched doing it, had a large—probably a liter water bottle that he had already premixed. He was serving capfuls. One capful cost probably \$25. And they were either dropping it into the water when they approached him or they were taking it right there at the car.

That is what makes it difficult for us to buy GHB at that level, at a street level. They want you to take the GHB right there at the

car. Obviously we are not going to use the drug, so we are left with either to arrest the person right there and destroy whatever undercover operation we are using, or to go ahead and simply watch him and try to follow him. Most of them, like with LSD, they make you take it right there at the scene.

Mr. MCCOLLUM. And it is out on the street literally, not in the club itself but on the street usually, where this is happening: Somebody walks out the door and goes to the parking lot.

Mr. STEVENS. Right. Most of the clubs in Orlando have very vigilant security, especially with all the pressure that has been applied to them. A lot of the stuff that we are seeing now is occurring in parking lots where there are not enough police officers, and security to cover it. They are in and out of the club all night long. If they get customers, they take them out to the car, serve them, and go back to the club.

Mr. MCCOLLUM. Mr. Farias, is this the type of setting you think your niece was involved with the night she encountered GHB?

Mr. FARIAS. Well, yes, sir. It is a club. And I believe, supposedly someone slipped it into her drink at the club. But at that time no one was aware of GHB except for the youth.

Mr. MCCOLLUM. Was it a dancing type of club like the Rave scene Mr. Stevens is talking about?

Mr. FARIAS. No, it is a regular night spot. A country western.

Mr. MCCOLLUM. So the way she got it may be a little different than the way he is describing a lot of it being used in the Rave scene?

Mr. FARIAS. That is correct.

Mr. MCCOLLUM. Professor Doering, what was the purpose and what was the use of GHB back before it was banned? What was it being used for?

Mr. DOERING. Well it was sold in health food stores as a powder or as a pill and principally used by body builders to improve their muscle gain. It seems that while the patient is under the effects of GHB their levels of growth hormone increase, and if that is combined with a vigorous workout program it can result in increased muscle mass and weight gain and so forth.

Mr. MCCOLLUM. Is there any downside to that, like you see with some other drugs used among ball players and so forth?

Mr. DOERING. Certainly it has its own downside risk. People were passing out, they were combining it with alcohol, they were nearly dying from the drug, and the FDA decided, whoa, wait a minute, this isn't something we want to have sold over the counter. I think that is half the reason why the myth about it being an over-the-counter vitamin has sort of stayed with it, because it was once used in that regard.

Mr. MCCOLLUM. Today you have told us there is research ongoing about possibly constructive uses of GHB. If we reschedule this drug as Schedule I, would that in any way affect the research that is going on or the possible use of it for these more constructive purposes?

Mr. DOERING. In my opinion, it would not. If it did become a recognized drug under the guidelines of the Food and Drug Administration, then it would be scheduled differently. But unless and

until it is recognized as a medicinal drug in this country, Schedule I, in my opinion, is the appropriate place for it to be.

Mr. McCOLLUM. Dr. Carter, you have expressed concern over how difficult it is to detect this drug in autopsies and so forth, and the way Mr. Stevens is describing it, Detective Stevens, it is very hard to even catch up with who is doing it.

What is the specific test, can you tell us? Is it a chemical test? How do you find it? And in the case of Mr. Farias' niece, how much time had passed? You said a lot of this goes away and you cannot figure it out, and yet I think you said you found it around the eye or some specific locations. How did that happen?

Ms. CARTER. It can be difficult to detect. It is not on the usual schedule with cocaine, morphine, phencyclidine. It can be detected by chemical means and advanced technology. We call it a mass spectrometer, which is an advanced way of screening fluids. Usually GHB will disappear from the body, from the urine, within 12 hours.

Because the Farias family had made the donation, a gift of life, we had that first specimen of blood and urine retained, and we were able to test that. But we went through numerous drug screens, and it took us 2 months to finally decide that this was a drug that was involved in this young girl's death.

Mr. McCOLLUM. Wow. Well, thank you very much, all of you. I will recognize Ms. Jackson Lee for 5 minutes of questioning.

Ms. JACKSON LEE. Thank you very much, Mr. Chairman. And let me thank my colleagues as well for their comments.

Congressman Hutchinson from Arkansas mentioned the problem of amnesia, which is a real problem. Even if Hillory had lived, there might have been some impact, I would imagine, on her memory; is that correct, Dr. Carter?

Ms. CARTER. That is correct.

Ms. JACKSON LEE. And as well, my colleague from Georgia mentioned the issue of education, and I would like to note that the legislation does have a provision to help educate young people and everyone about the detriments of GHB, I think that is extremely important, and other forms of drugs.

Let me just briefly thank Dr. Carter for her persistence, Mr. Chairman. It was the persistence of her County Medical Examiner's Office, that felt the passion of Hillory's family that kept pressing the issue that our teenager, our Hillory, was not someone who willingly or did take drugs. And it came to my attention because the normal response when teenager dies suddenly, the images in the press were a drug overdose. But this family was extremely persistent, and for that I do thank them.

Mr. Stevens, I would like to ask you a question. You captured my thought processes with the definition of this drug as battling, or as being number one, as one of the more popular drugs.

Mr. STEVENS. Yes, ma'am.

Ms. JACKSON LEE. Your representation, and I thank you very much, was that it may be only in Florida, but just listen to this out of Los Angeles:

"The widely publicized June 26, 1996, incident in the 400 block of Fairfax Avenue in Los Angeles, when four males between the ages of 16 and 20 were found unconscious on a public street after

consuming GHB, is powerful testimony to the need for control of this substance.”

Mr. Chairman, this is from an article on GHB, “Old Drug-New Tricks”, from Detective Trinka Porrata, Los Angeles Police Department, dated May 11, 1998, and I would ask permission of the chairman to submit this into the record.

Mr. McCOLLUM. Without objection, so ordered.

[The information referred to follows:]

GAMMA HYDROXY BUTYRATE  
OLD DRUG—NEW TRICKS  
BY TRINKA PORRATA

Gamma hydroxy butyrate (GHB, also called G, Liquid X, Liquid Ecstasy, Grievous Bodily Harm, Georgia Home Boy, Scoop, Great Hormones at Bedtime, Salty Water, Water, Everclear, Aminos, GH Buddy, Blue Monster) has become a growing problem for law enforcement. On September 28, 1997, GHB became a Schedule II drug in California (the original legislative proposal, initiated by the LAPD, requested Schedule I placement). At least 20 other states have scheduled GHB, three more states have criminalized it with stiff penalties, and federal legislation to control GHB (Schedule I) is now pending in both the House and the Senate.

More than fifty-eight deaths (plus about 30–40 more pending), including twelve in California (plus seven or more California cases pending review), are listed as GHB-related deaths and more are being researched by the Drug Enforcement Administration. Many more deaths have undoubtedly gone without notice since GHB is not part of a standard toxicology screen. Many of those deaths are individuals under the age of 30. Far too many of the deaths, especially those within the past few months, have involved individuals between 15 and 20 (See attached document re GHB related deaths). More than 5,500 overdoses have been documented (with more occurring during the last few months). In Toms River, New Jersey, more than 24 people were treated for GHB overdoses Memorial Day weekend. An additional 13 overdoses were reported Fourth of July weekend in Toms River, plus one death on June 1, 1999. Nationwide, multiple overdoses are swamping the emergency rooms. Recent incidents include five teens overdoses in a Michigan community and three 13-year-olds frothing blood through their noses (evidence of pulmonary edema) at a party in Louisiana.

The widely publicized June 26, 1996, incident in the 400 block of Fairfax Avenue in Los Angeles, when four males between the ages of 16 and 20 were found unconscious on a public street after consuming GHB, is powerful testimony to the need for control of this substance. The young men, who reside in Woodland Hills, Westlake Village, Berkeley and Agoura, were in various stages of respiratory arrest and at least two had to be resuscitated. In truth, far more than four were seriously impacted by this drug that night. One of the first officers to arrive described it as one of the most eerie scenes he had ever witnessed. With ghostly fog as a backdrop, they were confronted by dozens of people in various stages of overdose and/or under the influence, running (but in slow motion) or staggering or lying around. They asked for paramedics, and more paramedics and finally requested, “Clear the station, we need some people out here.” Most of them, however, had disappeared before assistance arrived.

The 16-year-old later stated that he had consumed 12 beers, several Dexatrim (diet pills) and then took two “swigs” of GHB, which was offered to the large group in a gallon water jug, and literally dropped dead. Paramedics brought him back. He stated that the substance tasted like “cow manure” and that he recalls nothing from that moment until he awoke in a hospital bed, grateful to be alive. He said that his friends advised him that after drinking GHB he was grinning ear to ear with his eyes rolling in opposite directions, and he became “flirtatious” with the females in the crowd. And then he collapsed and literally died until medical assistance saved him. He has been in drug rehabilitation and doing well.

A 19-year-old participant, the only one of the foursome who did not lapse into a coma, stated he had used GHB before. He noted that, depending on how much is consumed and what other drugs are consumed, you feel good for a period of time, up to about two hours, and then you sleep. He added, “It’s easy to get. There’s no punishment if you get caught, so it’s cool.” It was never really cool, and now it is illegal.

Incidents of GHB overdose occurred repeatedly throughout 1996, including multiple incidents in the Hollywood area, plus Orange County (at the Rhino Room), and

in Australia (ten collapsed, five on life support). It is important to understand that in each of these incidents, one third to one half of those who collapsed actually "died" and were revived by drastic measures by paramedics and/or sustained on life support until the danger passed. These are witnessed overdoses. If they had occurred inside a van in the parking lot, for example, or at home alone, there would have been no one to summon paramedics and reverse their date with death.

A behavioral depressant and a hypnotic, GHB is being used in conjunction with alcohol or other drugs, with detrimental effects in an increasing number of cases. It is difficult to isolate the impact of GHB ingestion since it is so typically taken with an ever-changing array of other drugs and especially alcohol, which potentiates its impact. Furthermore, no one tests for this drug unless the patient history indicates GHB or the circumstances dictate a search beyond routine drug testing. GHB is an anesthetic (sleep inducer) without analgesic (pain relieving) properties that has been found naturally occurring in minute quantities in brain and other tissues in the human body.

NOTE: The fact that GHB occurs naturally in the human body does NOT make it safe; it appears naturally in tiny quantities. Ask any rattlesnake if it would like to have its own venom injected into its body! After all, poison ivy is "naturally occurring."

GHB has no nutritional value. Side effects from ingested doses include high levels of intoxication, nausea, coma (sometimes abrupt and profound), uncontrollable seizures and respiratory depression.

While the objective symptoms reflect a CNS depressant (from a law enforcement perspective), according to Dr. Wallace Winters, who researched GHB 30 years ago and in 1997 retired as a Medical Officer with the Food and Drug Administration, the brain wave pattern of GHB users reflects various stages of epileptic seizure (dose related). This is at least true of research cats, though some aren't so sure that it transfers over to humans. If so, it may in reality be a CNS excitant, but external symptoms shut down and appear depressed, especially with higher dosages. In fact, 30 years ago, Dr. Winters predicted that this would become a horrible drug of abuse; his only surprise is that it took so long to happen.

Frankly, law enforcement was first seeing only the attention-drawing, collapse-level overdose cases and did not initially get much experience with less than overdose levels until more recently. During my early research on GHB, I found some documents saying yes, GHB produces nystagmus and others which said no, it doesn't produce nystagmus. Based on recent research by Dr. Alex Stalcup of the New Leaf Treatment Center in the Bay Area, it appears that nystagmus may not be seen in very low dose usage, but will likely appear at higher doses and overdose levels.

Because GHB takes the same path as alcohol, processed via alcohol dehydrogenase, its symptoms at lower levels of intake and as impact builds are comparable to alcohol ingestion/intoxication. The "happy" alcohol drunk will more likely be a "happy" GHB drunk; the "mean" alcohol drunk will likely be a "mean" GHB drunk. Thus, aggression and violence can be expected in some individuals. Because GHB reduces inhibitions and seems to stimulate sex-oriented behavior, you may encounter someone on GHB running through a crowd grabbing the breasts of females as they pass, for example (as the 16-year-old described).

During June of 1997, one male at a Hollywood Club ran around grabbing females in the crotch area and was booked for battery on a security guard who tried to intervene. People in the crowd later stated he had been seen taking GHB. His belligerent and sexual behavior both are indicative of GHB. Since he neither vomited nor went comatose, it can be assumed that the dose taken was relatively moderate. Two hours later a second individual became aggressive in the Club, fighting police officers, who were at the scene for another incident, and being pepper-sprayed by them. His girlfriend stated he had taken GHB 30 minutes prior and advised me where he had the container in his pocket. His prescription pill bottle (no pills—contained a small quantity of liquid) was booked and tested. The contents were positive for GHB and no other drugs were present (GHB is on occasion laced with MDMA, crystal meth, or other uppers).

Users claim it to be an aphrodisiac. Many say, "It makes you want to have sex." It clearly releases inhibitions. It also makes most people vomit. Undercover film, shot by news crews with hidden cameras, show users getting wildly giddy and then vomiting as casually as one might spit tobacco in a spittoon!

While that aspect seems less than "sexy" conduct, it must be understood that the user, at that time, may not feel ANY sensation of being ill. Users commonly describe a feeling of security and sleepiness and no recall of being nauseated, though they may wake up to indications of having vomited repeatedly. One overdose victim stated, "I just felt so safe and secure. I just wanted to go to sleep. I thought I was just

nodding off. I couldn't understand why the 50 people around me were screaming and hysterical. It was like I was outside, watching myself and them. I could hear them, but couldn't understand their reaction. I couldn't seem to communicate my feelings of security to them. Finally, I did become a little anxious, realizing that they must know something I didn't know." What he thought was "nodding off" were seizures.

He said he realizes now that if he had been alone or with people used to the experience who did not get excited at his condition, he would not have had any idea of how dangerously impaired he was. Without that reality check, abusers wake up with a false sense of security and use again and again.

GHB users on the Internet are now stressing use of very low doses of GHB to intensify the spiritual, euphoric, out-of-body experience that they crave; trying to avoid the dangers of overdose seems to be of secondary concern. This will likely translate into law enforcement seeing more and more GHB driving under the influence cases. Both New Jersey and California (Los Angeles County) have DUI traffic deaths where other parties were killed by a driver under the influence of GHB. The Los Angeles Sheriff's Department case recently resolved with the suspect pleading to vehicular manslaughter (11 years plus three years enhancements and will do 85 percent of that time, plus he waived time served, 14 months). He admitted in court to alcohol, GHB, driving and killing someone.

Unfortunately, during Spring Break of 1998, GHB users in Florida discovered the secret we had hoped no one would learn. We had known for some time that drinking GBL, the primary precursor of GHB, by itself is the same, or worse, than drinking GHB. Panama City was one of the cities absolutely rocked by GBL overdoses. Users suffered severe body tremors and psychotic episodes, according to news accounts. Medical and law enforcement personnel swear the effects and recovery from GBL is far worse than GHB. GBL is an analog of GHB and should be treated as such, at least in states with analog laws, such as California. Florida, unfortunately, did not have their statute re GHB written to cover analogs, and GHB has several. GBL, a floor stripper or degreaser, was brought into the area in 55 gallon drums.

GHB is available in Europe as an anesthetic; in actuality, it is used primarily only in France and requires giving the patient other medications to block pain and stop the nausea which so often occurs. While this drug has been around for many decades, it is not widely respected and used in any medical community. GHB is currently legitimately available in the United States SOLELY on a restricted basis as an "Orphan Drug" for experimental treatment of narcolepsy. GHB encountered in California is illicitly produced and is primarily distributed as a liquid.

NOTE: Placing GHB in Schedule I, in any state or federally, would NOT alter its availability to those now using it in LEGITIMATE research and treatment. On the other hand, placing it in Schedule II, for example, will technically NOT make it legitimately available to anyone not already authorized by the FDA.

GHB is a behavioral CNS depressant that was originally abused by bodybuilders who believed it stimulated the body's production of growth hormone. It is still being heavily used by body builders and their associates, though it appears its use by them now is as much for deliberate abuse as it is for any dreamed-of body gains. It has now become the drug of choice on the Los Angeles party scene, primarily in Hollywood area, the West San Fernando Valley, and in the Newport/Laguna Beach area. It is widely used from San Francisco to Santa Ana and San Diego. It is common in some gay communities. GHB was allegedly involved in the drug abuse cycles of both Billy Idol (who overdosed in a Hollywood Club) and River Phoenix (who died), both reportedly experiencing seizures.

More than fifty eight deaths, including about twelve in California, (plus 30-40 more pending review) are now listed as GHB related deaths. On August 4, 1996, a role-model teenager in La Porte, Texas, died mysteriously after GHB was slipped into her soft drink. On September 11, 1996, that death was ruled to have been a homicide, caused by GHB. This was an unwitnessed overdose—she went home and went to sleep and died. Many more deaths have undoubtedly gone without notice since GHB is not part of a standard toxicology screen. When the first of three bills to criminalize GHB hit the California Legislature on February 25, 1997, a father came forward on behalf of the bill because his son had died from GHB ingestion; he held the coroner's autopsy report stating GHB as the cause in his hand. This was yet another death previously uncounted and another unwitnessed overdose—he was drunk, took GHB and passed out and was left to sleep it off, but died during the night.

Fortunately, drug analogs (drugs which are primary precursors or are designed for use in lieu of the drug) are covered in both Schedule I and II. GHB has several analogs of grave concern, including 1,4 Butanediol which surfaced in Los Angeles on New Year's Eve (December 31, 1996) in a vial called FX and labeled as kava kava. Within an hour, 30-50 individuals collapsed from ingesting the substance, in-

cluding a 17-year-old who had a heart attack but survived. There was no kava in the product, just an incredible blast of caffeine and the 1,4 Butanediol, which is converted into GHB by the body adding an oxygen molecule. This analog of GHB has now surfaced in Northern California as a Russian herbal product, in the state of Washington and possibly in Canada. The manufacturer of FX has now plead guilty in federal court to charges of mislabeling and misrepresenting a product.

The Los Angeles County Sheriff's Department recently successfully prosecuted a Lawndale party disc jockey and two accomplices for drugging and raping ten women and poisoning six others (knocking out their dates, in some cases). The primary suspect was found guilty on 44 counts; the second suspect was guilty on seven of 15 counts; and the third worked a deal. The primary suspect was then sentenced to 77 years. Photographs depicting sex between the men and unconscious women were found in the disc jockey's van. The victims in this case were enticed into drinking unusual mixed drinks (such as the "Oatmeal Cookie" drink) as a method of covering up the unpleasant, salty taste associated with GHB. Some victims noted nothing unusual about the taste of the drinks; some reported it tasted bad or salty; and one stated that it burned (probably indicating a very high PH level in that batch). GHB was identified in margarita salt. It should be noted that there were no positive toxicology tests in this case partly because sexual assault kits at that time did not include urine (they do now for all of Los Angeles County) and partly because of the time factor (victims reporting beyond the possible time limit of 12 hours for getting a GHB positive)

"Goldschlager," a cinnamon flavored liquor, (or comparable product) has come up in GHB investigations several times, used to mask the salty taste. Long island ice teas or margaritas are also sometimes used.

Unlike the use of Rohypnol, where the victims are more likely to be totally unsuspecting and unable to taste the drug slipped into their drink, victims of GHB sexual assaults or overdoses are typically convinced to try GHB as an "energy drink" or are talked into trying an unusual concoction. The salty taste is still noticeable, but the victim may simply not sense the danger.

NOTE: This problem was much LIKE the Rohypnol (flunitrazepam) issue in that it was NOT under the California Controlled Substances Act (Rohypnol became controlled as of January 1, 1997), and it is in fact also used in a number of rapes since it does induce sleep. Law enforcement has, until now, been unable to deal effectively with issues of possession, transportation or sales of GHB.

It is UNLIKE the Rohypnol issue in that Rohypnol is almost exclusively manufactured in quality controlled labs, albeit outside the United States, and is smuggled into this country, while GHB is primarily manufactured in "bath tubs" with little regard for proportions and cleanliness. This results in increased danger from contamination and excessive PH level ("drain cleaner") and more unpredictable reactions. GHB powder from Switzerland and liquid in bottles marked "For research only" and presumed to have come into the U.S. via Mexico (as per statements by suspects) have been encountered.

While Rohypnol is known for its paralyzing effect and anterograde amnesia, obvious benefits to an attacker, GHB (which also causes amnesia) is perhaps best known for its intense intoxication and enhancement of sexual interest. Thus, GHB provides a different set of advantages to an attacker and a different level of nightmare for both the victim of sexual assault and for the law enforcement agency seeking to prosecute.

Sexual assault investigators are reporting an increasing number of cases involving the use of drugs such as GHB, Rohypnol, Flunitrazepam, Ketamine (behavioral analog of PCP and an animal tranquilizer), Halcion (controversial sleeping pill from which Rohypnol was derived), Xanax (another benzodiazepine), or Ambien, etc.

NOTE: Ketamine (Special K), MDMA (Ecstasy) and GHB are not "street drugs" at this time, but flow most freely in the RAVE crowd. They are the drugs of preference because they are what I call "soft hallucinogens." Granted, that's my own descriptive term. The real stuff (LSD, PCP) take one beyond reality, hearing colors, feeling sounds. These three drugs are credited by their proponents with intensifying reality, letting one see one's inner self, giving a spiritual, out of body experience, etc.

All officers should be aware of all above mentioned drugs and their potential use in sexual assaults or other crimes such as robberies. These drugs also present officer safety issues, especially for those working in undercover assignments. Most of these drugs must be identified through urinalysis by current technology and within a relatively short time span, while blood has been the common item associated with evidence testing for sexual assault cases in the past. GHB presents special problems re testing. This has created a need for law enforcement to re-think and re-write protocols for handling sexual assault cases, at least where drug use is a possible factor.

Newly formulated sexual assault evidence collection kits (now countywide in Los Angeles) include urine samples. Officers should be alert at the crime scene for any loose pills, vials, empty blister pack fragments, drink glasses, milk jugs or sports-type bottles, for example, that might harbor important evidence of drug use.

We have recently been getting an increasing number of sexual assaults in which multiple drugs are found in the victim's urine, or stimulants are found, but perhaps no "rape drugs." When pretext phone calls are utilized, the suspect may comment about her use of various drugs. Listen closely, he may be telling you what drugs he employed, and is just trying to put them off on her as voluntary. First and foremost, get to know your victim; the credibility of your victim is important. If you believe her, dig deep. Do not write it off just because stimulants are present. Consider now the timing and testing issues. Was the urine sample taken AFTER GHB and/or other drugs would have been eliminated? Did the symptoms she experienced and described match with a drug that could have already been eliminated?

Here is where the expert witness testimony becomes critical. She may have been enticed to ingest the other drugs while highly intoxicated by alcohol and GHB, for example; OR she may have involuntarily ingested the additional drugs. The suspect may have blown meth or cocaine or ketamine (Special K—stimulant but with paralyzing effects for at least a brief period) or MDMA (Ecstasy) literally up her nose (or in some other manner). Remember, you have to REQUEST testing for unusual drugs. And, can you trust your testing source? Do NOT base your handling of the case based on a preliminary screen for drugs. The benzodiazepine screen does NOT pick up on Rohypnol and many other benzos (such as lorazepam). NOTE: There are about 15-20 benzo's approved for use in the U.S. and numerous other foreign benzo's such as Rohypnol.

Every possible piece of evidence from witnesses is important as to her normal condition, normal drink tolerance, normal or abnormal behavior prior to or at the time of the incident, etc. Do a thorough interview as to timing involved (between drinks and incident, etc.), what she does and doesn't recall, and feelings she experienced. Does she articulate an out of body phase when she watched it happen to herself as if on TV, but couldn't control the action? This symptom could be induced by a variety of drugs. Don't "lead" your victim with questions like, "And then did you feel this way.....?". Let the drugs talk to you and then see what drug(s) fits the pattern that develops.

There have also been a couple of recent rapes involving "booting." This is a sexual practice, heterosexual or homosexual, involving putting cocaine or methamphetamine on the penis or in the vagina or rectum. Both parties get some drug effect from this practice, though not the "rush" associated with other forms of drug use. I've heard of some apparently unrelated cases which have also involved the practice of shaving the victim's pubic area.

Several crime labs in the State may be able to determine if a substance is GHB, but may not be prepared to perform analysis on bodily fluids for the presence of GHB. Blood is the primary sample for analysis, ONLY if there is reason to believe the victim ingested the GHB within the past four hours, as it remains in the blood for only four to five hours. If the victim dies, it will remain in the blood. Fortunately, the Los Angeles County Coroner's Office is now among those capable of testing for GHB, joining the Orange County and San Francisco Coroners and others.

GHB is rapidly absorbed, with peak plasma concentrations occurring 20-60 minutes after oral administration. At a dose of 12.5 mg/kg, half life is 20 minutes. GHB is almost completely oxidized to carbon dioxide. Only around five percent is eliminated in urine. Quality of testing and availability of testing for GHB in both body fluids (blood and urine) are progressing rapidly in response to this health danger being recognized throughout the country. Work on a field test for law enforcement is underway.

Since 1990 it has been a federal felony, under the Food and Drug Administration (FDA) rules, to manufacture GHB and transport it across state lines for purposes of sales. You may wish to contact the FDA in some manufacturing cases where you have indications of crossing state lines with the precursors or the final product. The FDA will prosecute manufacturing and transportation cases involving appropriate quantities and circumstances. At this point, no GBL (the primary precursor) is made in California, indicating that interstate commerce has indeed already occurred. Even prior to GHB becoming controlled here, California laws relating to food and cosmetics (consumer fraud type sections) could be employed to deal with suspects selling GHB, providing the local prosecutor was willing to deal with the unusual case.

It is important to stress that though it has been placed in Schedule II, normally reserved for triplicate prescription drugs, GHB is NOT available for prescription in California since it is a federally banned drug.

GHB is being manufactured throughout the State. It is easily made and involves just two basic ingredients, available at any chemical supply house: Gamma butyl lactone (a solvent used for degreasing engines or cement or stripping floors, for example) and sodium hydroxide (lye). Muriatic acid or vinegar may also be present; these may be used to "back down" the PH level after initial processing, just as you control your pool's PH level. A clear liquid, only slightly thicker than water and with only a mild odor and usually transported in rather common or subtle containers, GHB is going to be difficult to verify "on scene." The PH level would be one indicator, but not definitive. In many cases the PH level will be 11-14, but not necessarily and not if it is a properly manufactured version.

Kits to make GHB are sold over the Internet. A GHB liquid lab is the easiest lab operation you will ever encounter. Some recipes involve using acetone in the process (if trying to powder it), and some labs have exploded. The U.S. Attorney General's Office is now pursuing some cases against Internet dealers.

It has been reported that some meth operations may run a cook of GHB between meth runs. Agencies experiencing problems with GHB abuse should establish contact with local chemical supply houses to determine who is making regular, quantity purchases of these items.

The LAPD Clandestine Lab Squad in late October arrested eight at a crash pad maintained solely for the purpose of producing GHB. Charges were filed on two. Most of the people present had ties to Hollywood promoters, recording companies, etc., including the two members of the RAVE band called "The Crystal Method." The band members have been bragging about their experience, but failed to mention in their press release or on MTV that they were the two guys found hiding on the rooftop (in the vicinity of some brew that was cooling). This proves the point that much of the GHB is coming into the clubs via the back door. The Hollywood Athletic Club began searching incoming patrons, but the flood of GHB continued. They now need to look at their bands and promoters. Labs have also been encountered, since the law took effect, in San Francisco and Mono County.

The actual number of deaths from GHB will never be known since no one was testing for it until recently and usually only when GHB is given in the patient history. Additionally, there is no formal reporting system in place, leaving it to word of mouth (DEA officials counted only those they "heard" about that they could verify with an autopsy report). While early in 1997 only six or seven deaths were officially counted by DEA, that figure is now rapidly climbing as the coroner's reports are starting to filter in and as more and more agencies come on line to test for this drug. If Jeffery Fraga (Contra Costa County—California), for example, had gotten into a car and driven away prior to lapsing into a coma, his death would have been written off as a DUI fatal accident. A blood alcohol level of .17 (I originally had been told .12, but .17 is correct in the Fraga case) would justify such an assumption. But a healthy 25-year-old dying while asleep isn't explained by a .17 blood alcohol level, resulting in further investigation and the diagnosis of GHB.

Om 1998 I learned of the death of a 15-year-old in the cold night air of the high desert near Landers during January 1996. This young man attended an all-night RAVE party with 40-50 others. Despite a variety of drugs available, he chose to go with GHB. While everyone sipped GHB, he foolishly took a big drink. Frothing blood and obviously in need of medical help (with the nearest phone many miles away), he was placed near the campfire. They continued their worshiping of drugs and realized he was dead hours later. No other drugs were found in his body. GHB was found at the scene and statements supported GHB ingestion. Hypothermia finished him off. Unfortunately, tests for GHB in the blood weren't as readily available then, and its presence was not ascertained. Arrangements were made for the LA Coroner to test his remaining blood samples. The results were positive, a high level of GHB. That case is now being handled as a murder case with a federal conviction (for manufacturing and for supplying a misbranded drug) obtained against the man who supplied GHB to that party. State charges against him relating to the murder are pending. Sadly, the victim had struggled with a drug problem and was doing better. His mother had gotten a job in Arizona and they were moving. This was to be his last night in California. Instead, it was his last night on this earth.

His situation mimics that of a young woman in Georgia, featured on a CNN documentary. While everyone else sipped GHB, she boldly took a big gulp and immediately frothed blood. The supplier commented that she might as well lay down and die, that she had just killed herself by drinking so much. Another person complained that she was getting blood on the carpet. Her roommate and her sister took her to a hospital where she has remained brain dead and comatose since October 1996. Georgia officials have stated they intend to file murder charges. The frothing of blood through the nose and mouth are indicative of pulmonary edema, left heart valve failure.

On April 30, 1998, a 27-year-old San Diego man, who regularly used GHB, accidentally grabbed a water bottle containing GHB when he meant to retrieve a bottle of real water. He poured a glassful and took a big drink, realizing too late what he had done. He called his girlfriend to say he loved her, had taken too much GHB and was going to pass out. His "friend" took the phone and said not to worry, he would sleep it off. When a roommate arrived and suggested calling 911, the "friend," aka drug dealer who had made the stuff, said not to worry, just check on him now and then. Four people left the apartment, leaving the roommate to check on him occasionally. Three hours later he was not breathing and medical assistance was too late. There is NO antidote for this drug, people need to be put on life support until the effects pass. Calling 911 would likely have saved him. His family was stunned and turned to the Internet to find out what this drug was all about. They were horrified to find that all over the Internet it says this drug is totally safe, news reports aside. The chat rooms say NOT to call 911, it's a waste of a trip to the emergency room, and you'll just sleep it off. His stepmother created a web page, [ashesonthesea.com/ghb/](http://ashesonthesea.com/ghb/), devoted to getting valid information out there to those surfing the Internet and hopefully to make a difference for future victims. There is also now a death in Santa Barbara. His girlfriend witnessed him drinking an orange concoction of GHB (it also contained methaqualone and methadone) after a night of partying on stimulants. He suddenly vomited and lost control of his bodily functions, collapsing on the bed in a coma. She dressed and left for work, later calling a friend to "check" on him. He was breathing but also "snoring" (classic of GHB overdoses). While his friend was reading in the other room, he died. In April 1999, a California Lutheran University student died in his sleep; he had taken GHB as a sleep aid after reading on the Internet that it was very safe.

Despite what the Internet gurus say, GHB is addictive and it is now known that withdrawal from GHB for those addicted is life endangering. The bodybuilder types are most susceptible to becoming addicted, since they take it regularly from the beginning. There are documented cases of people dying from the actual withdrawal. Furthermore, we have seen cases where these young men try to detox on their own, suffered months of tortured existence and then end up overdosing and dying from the painkillers and tranquilizers they self-prescribe in an effort to avoid taking GHB. Hospitals often mistake their withdrawal symptoms for overdoses. Addiction treatment centers have no idea how to treat this drug, resulting in 3-5 day detox efforts that fail to help them. Long-term addiction counseling is needed.

#### CONCLUSION

GHB poses a serious challenge for law enforcement. Every officer should make an effort to become familiar with this drug. It is an officer safety hazard, especially to those working undercover, and should be of concern to every officer in terms of family and friends. It is simply the hardest drug to recognize and identify because it simply looks like water and is transported in water bottles or colored to look like other liquids. This is now complicated even further by the appearance of ILLEGAL analogs of GHB being sold over the counter as "herbal" or "legal" GHB, under names such as Blue Nitro, Firewater, Renewtrient, Revivarant, Serenity, Enliven, Revitalize Plus and Remforce. In any state where GHB is a controlled substance and where GHB is in a schedule that is covered by an analog law, these products are simply illegal. Ingredients will be listed as 2,3H furanone dihydroxy or 1,4 butanediol or tetramethylene glycol.

While drugs such as cocaine, heroin and methamphetamine certainly represent the massive side of our drug problem, GHB especially presents a unique high-risk personal danger. Many people successfully smoke rock cocaine often and for prolonged periods without dying. The addiction level and devastation to a functional lifestyle of those primary drugs are certainly well known. With GHB, one-time use of a small quantity, especially when mixed with alcohol or other drugs, represents a stunning risk of death. Much of the information on GHB on the Internet (more than 3,000 sites talk about GHB, according to the French police) is dangerous and invalid. We are now learning that this drug is much more addictive than previously known and, in fact, the withdrawals from this drug are worse than those of heroin. Standard addiction programs do not work safely for those addicted to GHB; withdrawal requires constant medical supervision by someone familiar with GHB.

Does the issue of these two drugs seem remote to your personal life? If so, consider the fact that the 16-year-old who literally died and was revived by paramedics from the June 1966 GHB overdose in Hollywood is the son of a retired police officer, who didn't even know his son had tried alcohol, much less a variety of drugs.

For more information about GHB, see [www.ashesonthesea.com/ghb/](http://www.ashesonthesea.com/ghb/). The "viewers comments" section is particularly enlightening.

Ms. JACKSON LEE. Would you describe for us the kind of impact that would happen to those of you who fight this battle, if this was made a Schedule I, from the law enforcement perspective?

Mr. STEVENS. For us, from the law enforcement perspective, ma'am, the reality is that the average drug dealer, he fears the Federal Government. He might fear the State, but the reality is that the Federal Government, when you bring up names like DEA into any type of work with an informant or someone, we get their attention. The Federal Government commands their respect. A lot of our State governments and our State laws they know are lax. They know our systems are overcrowded. They know they are not going to serve a whole lot of time in jail, whether they are ordered to or not.

This drug has been referred to as "kiddie dope" by many of my peers in the business. I don't believe it is kiddie dope. It is drugs to me. People are dying from it. I make no difference between this and crack cocaine. Different substance. People are still dying.

But it is interesting to note our first contact with GHB was much like the information you just provided. We were having officers stopping, finding vehicles stopped at intersections where all four occupants of the vehicle were passed out, with glass vials, which is originally what GHB was coming in, laying over the steering wheel. Initially, we thought they were intoxications, DUIs, DWIs. Later we began to realize, after about the fourth or fifth one we were encountering, that this was not a drinking or an alcohol problem. This was a drug problem that we had not yet learned about.

Schedule I would make life for us at our street level, I think, very easy. I do not know what it would do for the DEA as far as extra work, but for us it would make it better. The more power, the more teeth we have, the better it is. And it will take them probably a month to realize over the Internet that it would be scheduled.

Ms. JACKSON LEE. Thank you, Mr. Stevens.

Professor Doering, I thank you for your work. It has been brought to my attention that there are pharmaceutical companies that are manufacturing GHB, in fact, overseas. And they make the argument that someday we are going to make this a useful drug. Would you give me a response to that, please?

Mr. DOERING. I am glad you offered me the opportunity to comment on that. On the Internet that mantra is repeated over and over again: It is a legitimate pharmaceutical drug in Europe; it is one of the most popular sedative and sedating drugs.

To check that, I E-mailed, using electronic means, my counterpart in Frankfurt, Germany. There is a German product called Somniset, which is a commercially prepared and pure quantitated dosage form. And I asked my colleague, in fact, is it true, is this drug used in popular medical practice, or is it more of a pharmacologic curiosity? He said as an anesthetic it is not used much any more because it has too many side effects, so that if this drug disappeared tomorrow, I don't think it would really put a big dent on our pharmaceutical industry or the way people are treated.

Mr. MCCOLLUM. We will come back if you need more questions, Ms. Jackson Lee, but we have more members we need to go to.

Mr. Coble, you are recognized for 5 minutes.

Mr. COBLE. Thank you, Mr. Chairman, and I want to thank the panelists for their time and their contribution to this.

Let me think aloud for a minute. It is my belief that for a drug to be placed in Schedule I it must pass muster, if you will, of a three-part test: A, it must have a high potential for abuse, that is, addiction. B, it must have no currently accepted medical use in treatment in the United States. And, C, there must be a lack of accepted safety for use of the substance under medical supervision.

Now, having said that, that is why I made my opening statement that I think we should probably proceed very cautiously toward Schedule I.

Now, I don't want to take any sort of action that would make it possible for Hillory's assailant, Mr. Farias, to walk away. But it is my belief, Mr. Chairman, and if I am wrong I will stand corrected, that a person who is found guilty of unlawfully manufacturing or dispensing, say, a Schedule III or Schedule IV drug, could he or she not be penalized just as severely as if he or she had been found guilty of dispensing or manufacturing a Schedule I drug?

Anybody want to weigh in on that?

Mr. DOERING. Let me give it from the pharmaceutical point of view. The big difference between III, IV and V are essentially the penalties. As you go up the scale from III, IV and V, the penalties get greater.

Schedule II drugs are those that are recognized with some medical purpose but have the highest degree of controls. The prescriptions cannot be phoned in, it has to have a new prescription each time; there are greater degrees of supervision.

Schedule I are those, as you correctly said, which pass that three-part test. However, the penalties of a Schedule I are much more severe than a Schedule II, and I think that is why the detective was asking, give us some muscle to do something if people are apprehended.

Mr. COBLE. Well, Mr. Chairman, it was my belief that there was a provision in the law whereby that could be inserted, and I will stand corrected if I am wrong about that, Professor. And I will back off if I am wrong.

But Schedule I drugs simply—well, strike that. For a drug to be in Schedule I, any clinical development is prohibited. Am I correct about that?

Mr. DOERING. I don't believe so. Heroin, for example, is a Schedule I controlled substance, whereas in England it is recognized as an analgesic agent.

Mr. COBLE. This may be subject to interpretation, Mr. Chairman. But I think I'm right, Professor. We will talk about this over a cold drink one time, perhaps. And maybe the DEA rep can add to that, too.

But, Mr. Chairman, I thank you for your time, and I thank you all for your contribution.

Mr. MCCOLLUM. Thank you very much, Mr. Coble.

Mr. Barr, you are recognized for 5 minutes.

Mr. BARR. Thank you, Mr. Chairman.

Mr. Stevens, I know you mentioned that you felt that the experience that you had seen in the Orlando area would be replicated in other communities all across the country. And I ask not just your-

self but other members of the panel, are there any studies that indicate differences in demographic usage of GHB or the other drugs that we are talking about here, that indicate particular availability or predisposition to use it in certain parts of the country, in certain metropolitan areas?

Mr. STEVENS. The information I provided, I believe to the chairman's counsel today, was some information we had received at the Orlando Police Department. It was from the Great Lakes intelligence network, some information they had on GHB usage. Their compilation of stuff from Los Angeles, from California, from Texas, all pretty much shows the same thing.

Rave scenes are held differently in the West than they are in the East, which is much more urbanized. They have Raves out in the middle of the desert that draw 3,000 to 4,000 people. And please, don't misunderstand me, GHB is not simply a Rave drug. It is in the mainstream clubs, Top 40, country, it is everywhere.

Mr. BARR. Take just a moment and very succinctly describe exactly what a Rave is.

Mr. STEVENS. Our definition of the Rave, which actually began in Europe and several large cities in the United States in the mid-'80's, the Rave scene is basically a dance party, if you will. Very loud music, mostly techno, lot of synthesizers, a lot of bass, colored lights, flashing lights, strobe lights.

They originally started out as spontaneous parties. They were passed out by hand flyers, word of mouth, Internet, and they would spring up overnight in a field. Kids would dance from 5 o'clock to 8 in the morning. A smorgasbord of drugs if you wanted them.

As they became more commercialized, in Orlando we saw clubs, mainstream clubs that used to not cater to that, they usually danced Top 40, suddenly start getting into the Rave look; colored lights, mushrooms up on the wall, things going back and forth, strobe lights, more techno music. As they became mainstream, more and more of the drugs started flowing into Orlando. A lot of the DJ production companies that make these type records and music started springing up in the central Florida area.

Right now the Rave is very commercialized. You will not see the spontaneous Raves like you see out in the West, where if we had people from California they could attest to people appearing on public land, and overnight there is a production stage up and they are going to 7 in the morning with park rangers out there. We don't see that, but we do see clubs now opening up catering to this going to 7 in the morning dance-till-you-drop attitude.

So that is basically what the Raves are right now. They were all-night dance parties, which, as far as we are concerned at the Orlando Police Department, exist to get the drugs out. The drugs exist because of the Rave; the Rave does not exist because of the drugs.

Mr. BARR. Dr. Carter, if I could ask you, please, in addition to any experience or studies that you have seen with the distribution of these drugs varying in different parts of the country, Rohypnol, there have been some adjustments made to the physical characteristics of Rohypnol, the insertior of dye into the pill so that it is more apparent when it has been put in a drink. The dissolution

time has been extended. I am not sure how that is done but I think the manufacturers have done that.

Is that possible to do this with GHB, or feasible? And does the fact that there have been changes made to the physical properties of Rohypnol, in your opinion, diminish the attention that it deserves when we are looking at this problem?

Ms. CARTER. Well, with GHB, it is a totally different drug form. And since you can make GHB in your home, you really can't add that dye. They are adding a blue dye to Rohypnol pills. Of course, it is not really used in this country. But you can, with very simple chemicals, manufacture GHB at home, so that would really not make any change.

We are seeing increasing frequency in the forensic literature finding GHB. But, again, there is a lot of education that needs to be done to detect it, to educate the investigators and those that perform the tests.

Mr. BARR. How about the first question I asked, in terms of do you have any knowledge of any studies that have been done—and this may be a better question to ask DEA in the next panel—but are you aware of any studies that have been done that indicate a larger percentage of usage or appearance of these particular drugs in different parts of the country?

Ms. CARTER. Yes, there have been increasing reports in not only major cities but small areas where they are detecting GHB. There have been increased reports of fatalities, as well as performing tests for hospitals and local law enforcement. It is increasing, no doubt.

Mr. BARR. May I ask one more quick question, Mr. Chairman?

Mr. MCCOLLUM. Yes, Mr. Barr.

Mr. BARR. Are we seeing any of these, and which ever one of you might be in the best position to answer this, are we seeing the appearance of these drugs at high schools as opposed to just Rave scenes or whatnot? Are the drugs appearing in schools in America?

Ms. CARTER. I believe they are. And, again, it is difficult to detect.

Mr. STEVENS. One of my purchases of 173 grams of GHB was from a 17-year-old high school student. So I would assume—

Mr. BARR. At school?

Mr. STEVENS. Yes, he was still in school. So I would assume, if he is selling it out there, he has probably got a very large customer base in schools.

Mr. BARR. Thank you.

Thank you, Mr. Chairman.

Mr. MCCOLLUM. Thank you, Mr. Barr.

Mr. Hutchinson.

Mr. HUTCHINSON. Is there great profit motivation in the selling of GHB, or is it mainly just party and social?

Mr. STEVENS. I just got done with the City of Tampa discussing this, sir. A lot of people in the club scene state that it is about transcendence and experiencing a new—it is about money. It is dope.

These guys are selling capfuls of what is a little bit of GHB, maybe 20 percent GHB, 80 percent water, at \$25 a pop. It takes them \$80 to make 7 or 8 pounds of it. I am not sure exactly how much. You can figure if he is serving, if he goes to a Rave with a

thousand people, he might be selling 700 capfuls at \$25. His overhead is nothing.

Mr. HUTCHINSON. That is not Internet sales or motivated, it is simply a drug dealer out there?

Mr. STEVENS. It is a drug dealer that has realized, hey, I have a drug that the cops really don't know a heck of a lot about. It is easy to hide. It is easy to get rid of. When a cop walks up, I pour it on the concrete.

Mr. HUTCHINSON. Rohypnol or flunitrazepam you indicated went down in its usage and its desirability because of enhanced penalties; did I understand that correctly?

Mr. STEVENS. Yes, sir, we went from being flooded with ruffies, shays, that is their street name, Rohypnol, to where we couldn't get any, unless you paid a very high price. Now, as I say that, a week ago I bought 100 of the new pills. I have been told they are the new dye pills.

I can attest to my experience in nightclubs that a blue dye, in my opinion, as a police officer working these, is not going to have any effect in a night club. It is not well lit in a night club. Nobody is checking their Jack Daniels and Coke for blue dye.

Mr. HUTCHINSON. Let me work through this a little bit. They went to GHB because of the enhanced penalties and the fear?

Mr. STEVENS. Right, because we make 4 grams or above on Rohypnol trafficking.

Mr. HUTCHINSON. Which is a Florida law?

Mr. STEVENS. Right.

Mr. HUTCHINSON. So the State legislature addressed that in Florida and that had a significant impact.

Mr. STEVENS. Yes, sir.

Mr. HUTCHINSON. But they have not done anything yet with GHB?

Mr. STEVENS. GHB is Schedule II for the State of Florida, sir.

Mr. HUTCHINSON. And it did not have the deterrent effect as the trafficking law that they passed in Florida on Rohypnol?

Mr. STEVENS. Correct. We have not seen a downward spiral yet. In fact, we have continued to see it up. We are hoping to get something passed in a trafficking venue, which has a strict minimum mandatory penalty if you are caught with a certain amount.

Mr. HUTCHINSON. Then despite what Florida has done, you see the need, even as a street officer, of a Federal response to this problem?

Mr. STEVENS. Yes, sir, I do.

Mr. HUTCHINSON. Now, if we hammer GHB, and they move away from that, are the odds going to be that there is going to be another date rape drug that is going to come along that will have the same properties that will be a substitute for GHB or ruffies?

Mr. STEVENS. I would like to say no, sir, but in my professional opinion, yes, they will find a way around it. That is what they did with GHB.

Mr. HUTCHINSON. I yield back, Mr. Chairman. Thank you.

Mr. MCCOLLUM. Thank you very much.

Ms. Jackson Lee, do you want to have a follow-up question with this panel? We don't want to take another full round, because we

need to get to the other panel, but you may, if you wish. You are the only one on your side and the author.

Ms. JACKSON LEE. I thank you for your kindness, Mr. Chairman. Let me try to hurry on, but I did have a couple of follow-up questions.

First, I wanted to again thank Hillory's family, and I wanted to ask Raul a question, because I know, in his generosity, he provided life for others. But I would like you to tell us what made you angry about Hillory's death or the way she died or this finding of this GHB?

Mr. FARIAS. It was administered to my niece for no reason. The only thing that can be done when you do this to someone is rape or death. That is what upset the whole family in the first place. There was no sense in it. And that is the answer to that question. But I would like to comment on another thing that this gentleman said over here, if you don't mind.

Ms. JACKSON LEE. Go ahead.

Mr. FARIAS. There will be another date rape drug after GHB, but that does not mean that we cannot make this a Schedule I. And that is what we are here for. Because no matter what, there is going to be drugs out there for the rest of our lives, and it is our job to go out there and make people accountable. And that is what upset our family, is that there is no law that is holding anybody accountable.

Ms. JACKSON LEE. Thank you.

And Dr. Carter, I appreciate your overview of the detriment of many drugs, and you noted alcohol and others. I think people in hearing your testimony, who would want to oppose the legislation that we are presenting today would raise that question, frankly; that alcohol abused may result in the same reactions.

Would you help distinguish, by assessing the potency of GHB in its certain amounts, whether or not GHB in a small amount can be potent, or used as it is presently used and abused raises a higher level of concern.

Ms. CARTER. Well, certainly GHB is dose-related. When you are given GHB, you don't know what the concentration is, like other illicit drugs that have been mapped out somewhat for alcohol. Certainly GHB is more easily concealed in a soft drink or other liquid. Usually, alcohol certainly has a taste to it. And the whole idea is the concealment.

But from the legal standpoint, GHB will disappear more rapidly from the body than alcohol does. You are literally looking at 12 hours in order to document—there is an unknown chemical in the person's blood or in the person's urine and, therefore, making it very difficult to preserve the chain of custody and to record evidence that a crime has been committed.

Ms. JACKSON LEE. So it helps if we have, and I know you are not a lawyer, to have it as a Schedule I to immediately give police and others the evidentiary tools they may need in order to begin looking for it?

Ms. CARTER. Yes, certainly for the educational environment, and also for those who have to detect the drug, to have the proper equipment available it will demand, because there is so much out

there. We are seeing the tip of the iceberg. It is almost a tandem analysis in performing for the known illicit drugs.

This will not be found from doing an illicit drug screen that would detect cocaine and morphine. It has to be done in a different method. And we do feel, as forensic pathologists, we are missing a majority of cases.

Ms. JACKSON LEE. Dr. Doering, you made an important point. You said that the FDA, and you correct me if I have misinterpreted your words, took it off the market. It was on the market; took it off the market. Could you just, for the record, restate that for me, please?

Mr. DOERING. Yes, it was on the market not as a drug but as a nutritional supplement. Now, that is another story, because there are a lot of dangerous drugs, in my opinion, masquerading as nutritional supplements. But even this one before the Dietary Supplement Health Education Act of 1994, before that it was sold as a nutritional supplement. And FDA was very, very concerned, and has reissued its warning that this is not a drug, has never been approved as a drug in this country, but is readily available.

And if you don't believe me, try this web site: WWW.GHBKIT.COM, and you will get all you want of the ingredients to manufacture this drug.

Ms. JACKSON LEE. Do you consider it potent, GHB?

Mr. DOERING. Oh, absolutely, very potent medication.

Ms. JACKSON LEE. Do your attackers attack you for being way off the mark and providing misinformation?

Mr. DOERING. Oh, no question about that. We are public enemy number one for the purveyors of misinformation. But the problem with street level samples of this drug, you don't have any idea what the potency is. It would be a lot like going to the pharmacy and getting a prescription for penicillin and them handing you a scoop and saying scoop out what you think is the right dose. That is the difference between medical GHB and street level GHB.

Ms. JACKSON LEE. Thank you very much, Mr. Chairman, and I thank all the witnesses very much.

Mr. MCCOLLUM. We are not going to go to a second round, as I said. I recognized Ms. Jackson Lee because of the two reasons I mentioned.

But we want to thank this panel for being here today. You have all contributed a great deal, and several of you have come quite a distance, so thank you again for coming.

I will now introduce our second panel, which really consists of only one witness, but a very important witness, Mr. John King who is the Deputy Assistant Administrator in the offices of Diversion Control of the U.S. Drug Enforcement Administration.

Prior to his appointment as the Deputy Assistant Administrator, he was the Assistant Special Agent in charge for DEA's St. Louis field division. During his time in Washington, D.C., he served as the Associate Deputy Assistant Administrator in the Office of Information Systems, as an inspector with the Office of Inspections, and as the senior narcotic enforcement advisor to the Assistant Secretary of State on International Matters. Mr. King also served overseas as the country attache in New Delhi, India. Mr. King re-

ceived his Bachelor of Arts degree from Randolph Macon College in Virginia.

I want to thank you, Mr. King, for being with us today. Your entire testimony will be submitted into the record. Without objection, it is so ordered. And if you would please summarize your statement for us and give us your thoughts, if you can, in 5 minutes or so. We might be a little flexible if you need more time. I know I have read your statement, and perhaps others have too, so it would be helpful to us for you to be relatively brief.

So, please proceed as you see fit.

**STATEMENT OF JOHN H. KING, III, DEPUTY ASSISTANT ADMINISTRATOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, U.S. DEPARTMENT OF JUSTICE**

Mr. KING. Thank you, Mr. Chairman. Thank you members of the subcommittee. I appreciate the opportunity to appear before the subcommittee today on the subject of use of drugs in sexual assault cases.

I have already submitted my prepared statement. I will try to summarize that prepared statement with just a few quick pages here.

There are three unique substances the DEA is reviewing for possible control for their emergence in trafficking and abuse patterns. These drugs, flunitrazepam, ketamine, and gamma hydroxybutyrate, or GHB, have also been associated with reports of sexual assault. It is important to note that all three of these substances also have been abused for their psychoactive effects.

Flunitrazepam belongs to the benzodiazepine class of drugs. Its pharmacological effects include sedation, muscle relaxation, and a reduction in anxiety. Flunitrazepam has never been approved for medical use in the United States. However, it is legally prescribed in over 50 countries outside of the United States.

It was placed in Schedule IV of the Controlled Substances Act in 1984 due to international treaty obligations. At that time there was little abuse of flunitrazepam in the U.S. More recently, with the increase in trafficking and abuse, DEA began to consider the merits of transferring flunitrazepam into a more restrictive schedule.

As part of the administrative scheduling process, the DEA submitted data on the abuse and trafficking of flunitrazepam to the Department of Health and Human Services in April 1996. In January, 1997, HHS provided DEA with a scheduling recommendation which stated that although flunitrazepam had no accepted medical use in the United States, that its abuse potential was the same as other benzodiazepines, consistent with Schedule IV control.

Flunitrazepam is abused by high school and college students, gang members, Rave party attendees, heroin and cocaine abusers. The drug produces profound intoxication, boosts the high of heroin and modulates the effects of cocaine. It is also commonly used in combination with alcohol, which potentiates its toxic effects.

Flunitrazepam abuse may cause drowsiness, dizziness, loss of motor control, lack of coordination, slurred speech and confusion. It also causes anterograde amnesia, and is particularly problematic when flunitrazepam is used to aid in the commission of sexual as-

sault. Chronic use of flunitrazepam can result in physical dependence and withdrawal symptoms when the drug is discontinued.

Although it is difficult to estimate the magnitude of the problem, the DEA has identified 20 flunitrazepam facilitated rapes between 1994 and 1997. If flunitrazepam exposure is to be detected, the screening must take place within 72 hours of ingestion. This problem is compounded by the onset of the amnesia after ingestion, which causes the victim to be uncertain about the facts surrounding the rape.

The DEA has documented approximately 4,500 Federal, State, and local law enforcement investigations involving the distribution or possession of flunitrazepam in 38 different States. The majority of these cases are in Florida and Texas. Data from the Drug Abuse Warning Network shows that there were 88 emergency room episodes involving flunitrazepam from 1994 to 1996. Our report to Congress on the abuse and trafficking of flunitrazepam expressed our concern over problems associated with the drug and its use in sexual assault encounters.

DHHS, Department of Health and Human Services, as part of their administrative process, recommended that flunitrazepam remain on Schedule IV. After a careful analysis of the relevant data, as well as the DHHS recommendation, the DEA concluded that we did not have sufficient grounds administratively to reschedule flunitrazepam as a Schedule I substance. Legislative rescheduling, however, remains an option.

A number of other actions have been taken to address this problem. The Drug-Induced Rape Prevention and Punishment Act of 1996 made it a crime to give an unconsenting individual a controlled substance with the intent of committing a violent act, including rape, against that individual. It also established Schedule I penalties for possession and distribution of flunitrazepam.

In addition, the United States Customs Service has been seizing all flunitrazepam at border points of entry in response to the growing abuse and trafficking problem. Several States have rescheduled flunitrazepam on Schedule I. Hoffman-LaRoche, the manufacturer of the trade name of Rohypnol, has also cooperated with law enforcement in several areas to target the use of this drug in rape cases. The trafficking and abuse of flunitrazepam continues and is a serious concern.

The current uncontrolled substance associated with drug-induced rape is GHB. It is also being abused for its psychoactive effects, and we believe it should be controlled under the CSA. We are currently waiting for scientific and medical evaluations from HHS on the scheduling recommendation of GHB, as required by law.

GHB is abused for its ability to produce euphoric states and alleged role as a growth hormone. In 1990, the Food and Drug Administration became aware of the overdoses and related problems with its use and issued an advisory declaring GHB unsafe and illicit. It currently has not been approved for marketing but is under investigation for the treatment of narcolepsy.

Ingestion of GHB produces dose-dependent drowsiness, dizziness, nausea, amnesia, visual hallucinations, hypnotic effects, convulsions, severe respiratory depression and coma. Medical examiners

have reported 26 fatalities in which GHB was detected, and in many of these deaths GHB was used in combination with alcohol.

Over 1,000 GHB-related cases have been documented by Federal, State, and local law enforcement officials. GHB abuse often occurs in bars, nightclubs, Rave parties and gyms by teenagers and young adults who frequent these locations. During 1995 and 1996, there were 411 emergency room episodes involving GHB. The DEA is aware of at least 9 sexual assault cases with 19 victims involving GHB.

GHB does leave the body very quickly and it makes detection of this very, very difficult in the sexual assault cases. Almost all of the GHB encountered by law enforcement has been clandestinely manufactured. Although GHB is not controlled at the Federal level, 17 States have controlled GHB in either Schedule I, II or IV.

Ketamine is the only drug of the three discussed that has been approved for marketing in the U.S. Though not controlled, it is primarily used in the field of veterinary medicine as a fast-acting general anesthetic. The pharmacological profile is essentially the same as phencyclidine, or PCP, which leaves the individual anesthetized, detached or disconnected from their pain and environment. It has both analgesic and amnesic properties.

As a drug of abuse, ketamine has become common at Rave parties. It produces a dose-related progression of effects from a state of dreamy intoxication to delirium, accompanied by the inability to move, feel pain, or remember what has occurred while under the drug's influence.

There has been no reported clandestine manufacturing of ketamine, and to date it has been diverted primarily from distributors and veterinarians. From 1993 to 1996, 82 emergency room episodes have been reported with a detection of ketamine. The DEA is aware of one incident in which ketamine was used to facilitate rape. This drug, like flunitrazepam and GHB, may be used by individuals intent upon committing sexual assault due to its effect on victims.

HHS has recommended, on two occasions, that ketamine be placed in Schedule III of the CSA, based largely on the pharmacological profile of the drug. On both occasions the DEA determined that the incidence of actual abuse was not sufficient to sustain the proposed scheduling. Ketamine's recent emergence as a drug of abuse has prompted the DEA to reevaluate our position.

I would like to conclude with some general observations.

Due to the nature of the crime of rape, for a variety of reasons a significant percentage of rapes go unreported. These problems are compounded in drug-induced rape.

The DEA supports the rescheduling of flunitrazepam in the control of both GHB and ketamine. These drugs are being abused for their psychoactive effects and used by rapists to incapacitate their victims. This abhorrent activity makes Federal control action critical.

I would like to thank the subcommittee for the opportunity.

[The prepared statement of Mr. King follows:]

PREPARED STATEMENT OF JOHN H. KING, III, DEPUTY ASSISTANT ADMINISTRATOR,  
OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION, U.S. DE-  
PARTMENT OF JUSTICE

Mr. Chairman and Members of the Subcommittee: I appreciate the opportunity to appear before you today on the subject of controlled substances used to commit date rape. One controlled substance that has been associated with sexual assaults, including date rape, is flunitrazepam. Flunitrazepam, commonly known as Rohypnol, is currently a Schedule IV controlled substance, which is manufactured by Hoffman-La Roche. I will also provide comments on two other drugs, gamma hydroxybutyrate (GHB) and ketamine, that DEA is reviewing for possible control. It is also important to note that all three of these substances are abused for their psychoactive effects. However, the abuse of these drugs is not comparable to the abuse of cocaine, heroin and methamphetamine.

Flunitrazepam belongs to the benzodiazepine class of drugs. Like other benzodiazepines (such as Valium, Librium, Xanax and Halcion), flunitrazepam's pharmacological effects include sedation, muscle relaxation, reduction in anxiety and prevention of convulsions. With respect to its sedative effects, flunitrazepam is approximately 7 to 10 times more potent than diazepam (Valium). The effects of flunitrazepam appear approximately 15 to 20 minutes after administration, and last approximately 4 to 6 hours. Some residual effects can be found 12 hours or more after administration.

Flunitrazepam has never been approved for medical use in the United States, therefore, doctors cannot prescribe it and pharmacists cannot sell it. However, flunitrazepam is legally prescribed in over 50 other countries, and is widely available in Mexico, Colombia and Europe where it is used for the treatment of insomnia and as a preanesthetic medication.

Flunitrazepam was placed into Schedule IV of the Controlled Substances Act (CSA) in 1984 due to international treaty obligations. At that time there was little abuse of flunitrazepam in the U.S. However, over the last several years, DEA has been concerned with the problem of flunitrazepam abuse and approximately three years ago, began to consider the merits of transferring flunitrazepam to a more restrictive schedule which would result in increased penalties. Currently, flunitrazepam remains in Schedule IV of the Federal CSA, which also contains such drugs as Valium, Librium, Xanax and Halcion. As part of the administrative scheduling process required under the CSA, the DEA submitted its data on the abuse and trafficking of flunitrazepam to the Department of Health and Human Services (DHHS) in April, 1996. Along with DEA's document was a request to DHHS for a scientific and medical evaluation and a scheduling recommendation. In January, 1997, after the appropriate scientific and medical review, DHHS provided its scheduling recommendation to DEA which stated that flunitrazepam has no accepted medical use in the United States (consistent with Schedule I placement) but that its abuse potential was no different than other benzodiazepines, a finding which is consistent with Schedule IV control. The recommendation of DHHS was that flunitrazepam remain in Schedule IV.

Several different populations that abuse flunitrazepam have been identified in the United States. Flunitrazepam is abused by high school students, college students, street gang members, rave party attendees and heroin and cocaine abusers. It is abused to produce profound intoxication, to boost the high of heroin, and to modulate the effects of cocaine. Flunitrazepam is primarily abused orally. To a lesser extent, it is also abused by crushing, the tablets and snorting the powder. It is commonly abused in combination with alcohol.

The abuse of flunitrazepam, like other controlled substances, is associated with clear risk to the abuser and to the safety of the surrounding community. Flunitrazepam abuse causes a number of adverse effects in the abuser, including drowsiness, dizziness, loss of motor control, lack of coordination, slurred speech, confusion, and gastrointestinal disturbances, which may last for 12 or more hours. Higher doses produce respiratory depression. Chronic use of flunitrazepam can result in physical dependence and the appearance of the withdrawal syndrome when the drug is discontinued. Flunitrazepam impairs cognitive and psychomotor function which affects reaction time and driving skill. The use of flunitrazepam in combination with alcohol is a particular concern because they both potentiate each other's toxic effects.

Data from the Drug Abuse Warning Network (DAWN) shows that there were 88 emergency room episodes involving flunitrazepam during the period January 1994 through December 1996. All but eighteen of these episodes occurred in the Miami area. Most of the episodes also involved other drugs, including alcohol.

Flunitrazepam causes anterograde amnesia in which individuals are unable to remember certain events that they experienced while under the influence of the drug. This anterograde amnesia is particularly problematic when flunitrazepam is used to aid in the commission of sexual assault; victims may not be able to clearly recall the assault, the assailant, or the events surrounding the assault. Since 1994, at least eight individuals have been convicted of sexual assault in five state court cases in which there was evidence that flunitrazepam was used to incapacitate the victim. There are at least an additional 14 other sexual assault cases, from 1994 to 1997 in which there is evidence to suggest that flunitrazepam was used in committing sexual assault. These cases have not gone to trial.

For a variety of reasons, it is difficult to estimate just how large a problem flunitrazepam-facilitated rapes are across the country. One problem is the documentation of the use of flunitrazepam in sexual assault cases. Very often in these cases, biological samples are taken at a time when the effects of the drug have already passed and only residual amounts remain in the body fluids. These residual amounts are difficult, if not impossible, to detect using standard screening assays available in the United States. If flunitrazepam exposure is to be detected at all, urine samples need to be collected within 72 hours and subjected to sensitive analytical tests. The problem is compounded by the onset of amnesia after ingestion which causes the victim to be uncertain about the facts surrounding the rape. This uncertainty may lead to critical delays or even reluctance to report the rape and to provide appropriate biological samples for toxicology testing.

In recent years, the increased popularity of flunitrazepam has led to an escalation in the smuggling and illegal distribution of flunitrazepam into various parts of the United States. Flunitrazepam has most often been smuggled into the U.S. from Mexico, primarily at border crossings located in Texas, Arizona and California. In addition, approximately 25 other countries have been identified from which flunitrazepam has been directly smuggled into the U.S.

DEA has documented approximately 4,500 Federal, state and local law enforcement cases involving the distribution and/or possession of flunitrazepam in 38 states. The largest number of cases is concentrated (1,600) in Texas and Florida (1,500). Significant numbers of cases also occurred in Louisiana, Oklahoma and Arizona with the majority of these cases occurring between January 1994 and December 1996.

An examination of both DEA case files and the DEA System to Retrieve Information from Drug Evidence reveals 170 cases involving over 530,000 flunitrazepam tablets for the period of January 1, 1993 to April 30, 1998. Most of these investigations were conducted in Texas and Florida. There were 34,000 tablets of flunitrazepam seized in 1994, 227,199 tablets seized in 1995, 165,000 tablets in 1996, and 35,000 seized in 1997. The decline in seizures in 1996 and 1997 was primarily the result of increased Customs enforcement action at the points of entry from Mexico. While the number of tablets seized declined during 1996 and 1997, during the first quarter of 1998, 52,000 tablets were seized. This is more than were seized in all of 1997.

The two milligram (mg) pharmaceutical tablet had, until recently, been the most frequently encountered form of flunitrazepam seized by law enforcement officials. However, the manufacturer, Hoffman La Roche has discontinued production of the two mg tablet. As a result, there has been a significant reduction in encounters with the pharmaceutical two mg tablets but increases in encounters with the one mg pharmaceutical tablets and with counterfeit tablets containing two mgs of flunitrazepam. The appearance of the counterfeit tablets demonstrates that there is an established illicit market in the U.S. for the two mg tablet.

A special review of the appropriate schedule for the control of flunitrazepam was initiated as required by the Drug-Induced Rape Prevention and Punishment Act of 1996. DEA prepared a report to Congress on the abuse and trafficking of flunitrazepam and the appropriateness and desirability of rescheduling it into Schedule I of the CSA. The report expressed concern over the problems associated with flunitrazepam, particularly its use in sexual assault incidents. It also noted that the DHHS provided a scientific and medical evaluation of the available data on flunitrazepam and, based on this evaluation, recommended that it remain in Schedule IV. After careful analysis of the relevant data, as well as the DHHS recommendation, the DEA concluded that we did not have sufficient grounds to reschedule flunitrazepam as a Schedule I substance administratively. Legislative rescheduling at the Federal and state levels, however, remains an option. Some individual states, such as Florida, have decided that current controls are inadequate to address the abuse and trafficking of flunitrazepam within their jurisdictions and have rescheduled it into Schedule I either through an administrative process or by legislation. Schedule I at the state level is comparable to Schedule I at the Federal

level. In our report to Congress on flunitrazepam, we confirmed our support for such legislative action at both the state and Federal level.

Even though DEA has been unable to reschedule flunitrazepam, there have been a number of other actions taken to deal with this problem. Congress passed The Drug-Induced Rape Prevention and Punishment Act of 1996 which made it a crime to give any unconsenting individual a controlled substance with the intent of committing a violent act, including rape, against that individual. In addition, the law established stricter Federal penalties for the possession and distribution of flunitrazepam without changing the schedule of the drug. In implementing these new penalty provisions, the United States Sentencing Commission established sentencing guidelines for flunitrazepam that were above those generally applicable to Schedule I and II depressant drugs. These guidelines became effective on November 1, 1997. Also, since March 5, 1996, the U.S. Customs Service has been seizing all flunitrazepam encountered at border points of entry in response to the growing abuse and trafficking problem and the fact that it is not approved for use in this country.

At the state level, Florida, Idaho, Minnesota, New Hampshire, New Mexico, North Dakota, Oklahoma, and Pennsylvania have rescheduled flunitrazepam into Schedule I and some states have increased the penalties for illegal distribution.

The manufacturer of Rohypnol, Hoffman-La Roche, has cooperated with law enforcement in several areas to target the use of this drug in rape. The firm has changed their production from two mg tablets to one mg tablets and has developed a new formulation which contains a dye that will make it easier to detect that the drug has been placed in a victim's drink. However, the dye will be much less effective if the drink is served in an opaque container or if the drink itself is dark in color. In addition, this new formulation has only been approved in a few countries and the company is still seeking approval in other countries, including Mexico. Hoffman-La Roche has also launched a public information campaign concerning the potential use of its product in the commission of criminal acts and has made available a drug testing service for law enforcement agencies in the U. S. to assist authorities in investigating cases in which flunitrazepam is suspected of being used in a criminal act.

Since our report to Congress on this issue in November, 1997, the trafficking and abuse of flunitrazepam have continued. There is no doubt that the abuse of this drug is a serious concern. However, in light of the DHHS recommendation, we believe that there is still insufficient relevant data to support rescheduling flunitrazepam into Schedule I administratively.

Flunitrazepam is not the only substance which has been associated with drug-induced rape. A currently noncontrolled drug, GHB, has been used for this purpose. GHB is also being abused for its psychoactive effects and, in our opinion, should be controlled under the CSA. DEA has conducted the analysis required under the CSA for control, and we are waiting for completion of the scientific and medical evaluation and scheduling recommendation from the DHHS. However, the administrative process to control new drugs of abuse is lengthy, and it is not known when GHB will be controlled.

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 sold in health food stores in the late 1980'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. GHB has not been approved by the FDA for marketing, but it is currently under investigation for use in treating narcolepsy under the FDA's Orphan Drug program.

Although its importation, distribution and use as a drug are 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 can occur in as little as 15 minutes and profound coma can occur within 30 to 40 minutes after-oral ingestion. Emergency room patients often regain consciousness within 2 to 4 hours. GHB produces dose-dependent drowsiness, dizziness, nausea, amnesia, visual hallucinations, reduced blood pressure, decreased heart rate, hypnotic effects resembling petit mal epilepsy, convulsions, severe respiratory depression and coma. Overdose frequently requires emergency room care, including intensive care for respiratory depression and coma. In addition, Medical Examiners have reported 26 fatalities in which GHB was detected in the decedent. Many of these deaths involved the use of GHB in combination with alcohol.

In recent years GHB has emerged as a significant drug of abuse throughout the United States and a number of foreign countries. Since 1993, more than 1,000 GHB-

related cases of abuse, overdose, possession, manufacturing, diversion and trafficking have been documented by Federal, state and local officials. GHB is frequently taken with alcohol or other drugs that heighten its effects, and it is often found at bars, night clubs, rave parties and gyms. The primary users are teenagers and young adults who frequent these establishments. The populations abusing this drug fall into three major groups: (1) Users who take GHB as an intoxicant or euphoriant or for its alleged hallucinogenic effects; (2) bodybuilders who abuse GHB for its alleged utility as an anabolic agent or as a sleep aid; and (3) individuals who use GHB to commit sexual assault. These categories are not mutually exclusive and an abuser may use the drug illicitly to produce several effects. Abuse of GHB has led to an increasing number of emergency room episodes reported to DAWN. From 1992 through 1996, there have been 411 GHB-related DAWN emergency room mentions, with 257 of them occurring in 1996. Alcohol and GHB mutually enhance each other's toxic effects and most of the mentions involved the use of GHB in combination with alcohol.

The DEA is aware of at least nine sexual assault cases involving 19 victims under the influence of GHB in Florida, Texas, Louisiana, Wisconsin, California, Michigan and Maryland. In seven of these nine cases, GHB was detected in the urine of the sexual assault victims. However, like flunitrazepam, GHB's involvement in rape cases may go unreported or unsubstantiated. GHB is quickly eliminated from the body making detection in body fluids unlikely, and its fast onset of depressant effects may render the victim helpless to recall details of the attack.

Almost all of the GHB encountered by law enforcement has been produced in clandestine laboratories. GHB synthesis requires no special knowledge of chemistry, the precursor chemicals (gamma-butyrolactone and lye) are inexpensive and readily available, and the process can be accomplished without special equipment by a simple "one-pot" stove top method. In fact, GHB "kits" containing the precursor chemicals are available for sale on the Internet. DEA is aware of at least 43 illicit laboratories seized since January 1997 in which GHB was being synthesized. GHB has been encountered in every region of the United States and both small (personal use amounts) and large (intended for distribution) clandestine laboratories have been encountered. It is marketed as a "legal high" or a substitute for MDMA (Ecstasy) and is sold in solid and liquid forms. Indicators suggest that GHB abuse and trafficking is escalating and poses a serious health and safety risk.

Although it is not yet controlled at the Federal level, seventeen states have already controlled GHB: Rhode Island, Georgia, Hawaii, Illinois, Louisiana, Nevada, Wisconsin, Michigan, Delaware, Idaho in Schedule I; Florida, California and Indiana, New Hampshire in Schedule II; and Tennessee, Alaska and North Carolina in Schedule IV. In addition, Texas and New Jersey have criminalized the sale and possession of GHB and placed in the same penalty group as LSD and marijuana.

The final drug I want to discuss, ketamine, also is not controlled. It is the only one of the three which has been approved for marketing in the U.S. and it is primarily used in veterinary medicine. It is a rapidly acting general anesthetic whose pharmacological profile is essentially the same as phencyclidine (PCP). Like PCP, individuals anesthetized with ketamine feel detached or disconnected from their pain and environment. In addition, ketamine has both analgesic and amnesic properties. The use of ketamine as a general anesthetic for humans has been limited due to its adverse effects including the delirium and hallucinations which some experience when awakening from anesthesia. However, it does have some utility for emergency surgery in humans and surgery of short duration in children and the elderly, groups which experience delirium and hallucinations less frequently.

As a drug of abuse, ketamine (street name "Special K") has become common at dance parties or "raves." It produces a dose-related progression of effects from a state of dreamy intoxication to delirium accompanied by the inability to move, feel pain or remember what has occurred while under the drug's influence. The "Special K" trip is touted as better than that of LSD or PCP because it lasts only 30-60 minutes as opposed to several hours. Ketamine is less potent than PCP: 25 mg of PCP can produce a full psychedelic experience whereas it would require at least 100 mg of ketamine (depending on body size) for the same effect.

"Special K" is prepared by evaporating the liquid from the legitimate pharmaceutical injectable product and grinding the residue into a powder. There has been no reported clandestine manufacture of ketamine. All of the ketamine encountered by law enforcement to date has been diverted from licit sources, primarily distributors and veterinarians. The "Special K" powder is snorted like cocaine or to a lesser extent smoked in tobacco or marijuana. In addition, the liquid form has been added to drinks. A typical dose would be 20 mgs snorted in each nostril, repeated at 5 to 10 minute intervals (usually 3 or 4 times) until the desired effect is achieved. It is

distributed as powder in small bottles, ziplock bags, capsules, paper, glassine or aluminum "folds", or as a liquid in small vials or bottles.

Since 1993, the frequency of law enforcement encounters as well as emergency room and medical examiner's reports has increased, indicating that the abuse of ketamine is growing. Abuse of ketamine is reflected in the 82 emergency room episodes reported to DAWN during the period 1993-1996. Alcohol, cocaine and marijuana were the most frequently reported substances identified in the DAWN reports as being used in combination with ketamine. This drug can be used by individuals intent on committing sexual assault due to its effect on victims who become extremely compliant and later may not be able to remember what happened. However, we are aware of only one documented case in which it was demonstrated that ketamine was used to facilitate a rape. Of course, the same factors which lead to under-reporting the use of flunitrazepam and GHB in rape apply to ketamine as well.

The Department of Health and Human Services has, on two occasions, in 1981 and 1986, recommended that ketamine be placed in Schedule III of the Controlled Substances Act (CSA) based on a scientific and medical review. These recommendations were based largely on the pharmacological profile of the drug. On each occasion the DEA determined that the incidence of actual abuse was not sufficient to sustain the proposed scheduling. Ketamine's recent emergence as a drug of abuse has prompted the DEA to reevaluate its placement in the CSA, and we have requested a new scientific and medical evaluation and scheduling recommendation from DHHS. At least 14 states have already controlled ketamine; California, Connecticut, Delaware, Florida,, Hawaii,, Illinois,, Louisiana, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, and Wisconsin have placed it in Schedule III and Missouri has placed it in Schedule IV.

I would like to conclude with some general observations. The Subcommittee's concern with the use of these drugs in rape cases is important and certainly timely as their abuse and trafficking trends continue to be on the rise. DEA shares this concern. Some individuals are using these drugs to take advantage of helpless victims. This use is abhorrent and cannot be tolerated by society. Unfortunately, DEA's task of evaluating and determining the level and extent to which these drugs are used to facilitate rape is almost impossible. Due to the nature of the crime of rape, it is frequently stated that, for a variety of reasons, a significant percentage of all rapes go unreported. This problem is exacerbated in the instance of drug-induced rape. The very qualities which make these drugs attractive to the rapist, for example: amnesia, loss of inhibitions, inability to control what is happening, make it less likely that this type of rape will be reported and documented. A more fundamental problem is the lack of data base information on drug-induced sexual assaults and the need to protect the privacy of victims.

This presents us with a situation in which we do know that these drugs are clearly capable of facilitating rape. For example, in the recently publicized Spitzer case, there was evidence that one of the rapes was facilitated by using flunitrazepam.

We support the rescheduling of flunitrazepam and the control of both GHB and ketamine. These drugs are being abused for their psychoactive effects and both flunitrazepam and GHB are being used by rapists to incapacitate their victims. Certainly ketamine can also be used for this same purpose. This makes the need for Federal control action critical. Unfortunately, in light of the DHHS recommendation regarding flunitrazepam, we believe that we do not have the data to support rescheduling the drug through the administrative process. In the case of GHB and ketamine,, we have collected the data and are waiting for the recommendations of DHHS. However, it may well be several years before these drugs are brought under control. Until that happens, there" will be no sanctions under the CSA for the abuse and trafficking of GHB and ketamine and they will continue to be readily available for use by rapists.

Mr. Chairman, in closing, I would like to thank you and the Subcommittee for your continued support for the DEA. I also thank you for providing me with the opportunity to offer the DEA's position and comments on the very serious problem of drug-induced rape. I will be happy to answer any questions you may have.

Mr. McCOLLUM. Thank you very much for coming and being with us today, Mr. King. I will yield myself 5 minutes in the question period.

Back in 1996, we basically passed a bill that gave the same penalties for trafficking in flunitrazepam as would be the case had it been a Schedule I drug. And I would suggest that we could do the same thing with GHB, even if it were not rescheduled, if it were

important to the continued research that Dr. Doering said is being done on narcolepsy and other aspects of that possible use for a constructive purpose.

Yet you have testified today that you think even flunitrazepam ought to be moved on up to Schedule I, even with those tough penalties that are present for it. Under the law, it now reads Schedule I and II drugs and specifically the names flunitrazepam get these increased penalties.

What would be the significance? Why does DEA feel that even though flunitrazepam already has the tougher penalties, it needs to be rescheduled as Schedule I? And, number two, what would be the distinction here with respect to scheduling GHB, or rescheduling it somewhere with respect to how that would affect the research that Dr. Doering was discussing? And could we solve the potential problem of not being able to do that narcolepsy research by simply increasing the penalties as we did with flunitrazepam?

Mr. KING. There are many drugs that are investigative, that are new drug registrations, like marijuana, like LAAM, initially. Now, they start at Schedule I, and as they are approved for use by the FDA—we will talk about Marinol and LAAM right now—they move down the schedule. They suggest a schedule, we agree upon it, and then it is done that way. LAAM was once a Schedule I; now it is a Schedule II. Used in methadone clinics. Marinol, once a Schedule I, now it is a Schedule II, used for people that have a problem with—

Mr. MCCOLLUM. Whatever. That's all right.

Mr. KING. But I do not think that would affect—the research could go on with no problem whatsoever. All you would have to do is upgrade security and the reporting requirements, that is all. But the research could continue. And if it was approved by the FDA for narcolepsy, they could move it down to the appropriate schedule.

Mr. MCCOLLUM. Let's ask it the reverse way, then. If there is no harm to research in scheduling a Schedule I, what harm is there in law enforcement if, instead of rescheduling it to Schedule I, we just zap the same penalties on that particular drug and leave it where it is? What is the significance of getting it scheduled higher or to a I level, if you will, except for penalties?

Mr. KING. Well, there is penalties and there is perceptions. And the perceptions are that the higher the drug is, or the lower the drug is on the schedule, the more harmful the drug is, which is absolutely true.

In addition to that, most States mirror the Federal system, and it is very easy for them to move a drug into a Schedule I, like Florida. They can move a drug, any drug, or GHB, into Schedule I very easily if the Federal Government schedules it as Schedule I.

Mr. MCCOLLUM. As you know, Rohypnol, the flunitrazepam drug that is most commonly discussed, Mexico has just decided to make it available chemically only in an altered state, which causes it, if it is put in a drink, to turn blue, as I understand it. First, what is your reaction to that? Might that be done in other countries? Would it be helpful?

I heard Detective Stevens say something to the effect that he didn't think that would make any difference at all, as far as the date rape Rave scene is concerned, because people couldn't see that

it was blue. Is this a significant thing Mexico has done? Is it something you would encourage other countries to do? Is it significant at all?

Mr. KING. Actually, sir, it is a company, Hoffman-LaRoche, that did this. We have been in negotiations with them for some time to do certain things, and they have been extremely helpful to law enforcement. This was one of the things that they came up with.

It is not going to work every time. Obviously, if you put it in a dark drink, you can't see it. You cannot put it in white wine in a lighted bar that I might go to. It is just one of the things that they tried to do to not convey that their drug is a date rape drug.

Mr. MCCOLLUM. So you would say it is a positive thing, but it is not a fully effective mechanism for alerting people to the fact that this is in their drink?

Mr. KING. Yes, sir.

Mr. MCCOLLUM. So the fact that Mexico has made it available only in the altered state, you would hope that others might follow suit, I assume, other countries where Rohypnol is legal? Is that something you would encourage?

Mr. KING. I don't think it has been approved for use in that altered state in Mexico yet, sir.

Mr. MCCOLLUM. Oh, it hasn't been yet?

Mr. KING. No, sir, I think it is only in certain other countries.

Mr. MCCOLLUM. My staff was saying last week it was, but I don't know. We will find out sooner or later. It matters not at this point, I suppose, for the purpose of this hearing.

Ms. Jackson Lee, you are recognized for 5 minutes.

Ms. JACKSON LEE. Thank you very much.

Thank you, Mr. King, for your testimony. It seems, in your testimony, that there is some collaboration between the DEA and the FDA. You are not at odds. You can work together.

And I think there are two themes running through this hearing and typically running through any hearing that deals with rescheduling of drugs. You want to be fair and balanced. You want to have all the facts. You want to ensure that if there is something meritorious that someone should see and look for that you take that into consideration and weigh the pros and cons.

In listening to the testimony, I wish to pose this question. One is, simply, do you all work together? And can you state again the kind of actions that might occur if in the long run FDA, in its research, determined some meritorious use for GHB? What then would be the process if this drug had been rescheduled or scheduled as Schedule I?

Mr. KING. Well, we do work together. And even though we work together on mutual problems, when it comes to scheduling, we are supposed to do it independent from each other.

Ms. JACKSON LEE. I understand that.

Mr. KING. On a substance like GHB, when it has this tremendous abuse potential, if it was moved to Schedule I and then FDA approved it for use, I think a Schedule II would be appropriate.

Ms. JACKSON LEE. But what I glean from that is this is not a forever, forever bar. If out of this hearing and the ultimate wisdom of this committee and this body that it was moved to a Schedule I, we know that there are measures upon which it could be consid-

ered something else if there was some meritorious argument to be made by the FDA. You have seen this occur?

Mr. KING. Oh, absolutely.

Ms. JACKSON LEE. Do you think the scheduling of GHB to Schedule I would save lives?

Mr. KING. Absolutely.

Ms. JACKSON LEE. There was a point that Mr. Stevens made that I found very interesting. I think he has done, in his area, a very good job. But he said something that caught my attention. "When you hear the Feds are involved, people get pretty serious."

You are in DEA. You are all over the country. You are in my southern district of Texas. What is your impression, in working with local law enforcement, when a drug is Schedule I, and dealing with it as it relates to the impressions by those who use it and sell it or traffick it? How does the Schedule I help in law enforcement?

Mr. KING. Most of the time the Federal sentencing guidelines are much heavier than the State and local guidelines. In most of my experience in DEA for the last 29 years, it has been working with State and local law enforcement officials. DEA does not have enough agents just to continue to do investigations by themselves, so in just about all the divisions we have multiple task forces. They enjoy having those kind of powers; they enjoy getting somebody with an ounce of crack cocaine and watching them really squirm when they walk into a Federal Courthouse rather than a State courthouse. It makes a big difference.

Ms. JACKSON LEE. Does it help make the case, as well?

Mr. KING. Oh, absolutely.

Ms. JACKSON LEE. One of the points of my legislation, and I think noting the age of some of the participants or the users of this drug, it seems it may be prevalent among teenagers, I think part of our responsibility is prevention, educating people not to use it. Does the idea get on the street?

Because a lot of people argue against that. Nobody cares whether or not cocaine is at its level, or crack. But in the kind of population that is using GHB, do you think it could get on the street, hey, this is a Federal crime? Do you think it would bring down the usage of it or frighten people away from it?

Mr. KING. Well, we in DEA think that demand reduction is very important. But education, getting the word on the street, like the detective said, it would be on the street immediately that DEA, or like when Florida raised their scheduling to Schedule I with Rohypnol, it was difficult to find Rohypnol. Price went way up. We saw that in 1996. That is when Florida did their thing, and Customs started stopping all the Rohypnol on the border. It was very, very effective. In 1997 we saw very little Rohypnol, and now we are starting to see it creep back up again.

The idea of educating the criminals is one side, but the idea of educating the children is much more important, and we have a lot of those programs going on. My staff, we deal with rape crisis centers. We are helping DOJ right now do a videotape concerning concerning sexual assaults.

Ms. JACKSON LEE. Let me read one question into the record and I think you can answer this yes or no.

If GHB is not scheduled as I or II, then drug analogs will remain prevalent. Drug analogs of GHB are just as potent and dangerous as GHB itself. Do you believe this drug and its analogs are dangerous enough so that they should be removed from the illegal market in every way possible?

Mr. KING. The drug analogs of GHB?

Ms. JACKSON LEE. Yes.

Mr. KING. I do not have an answer for that question.

Ms. JACKSON LEE. Would you research that question for us, please?

Mr. KING. Yes, I will, and I will get back to you.

Ms. JACKSON LEE. Thank you.

Mr. MCCOLLUM. Thank you, Ms. Jackson Lee.

Mr. Barr, you are recognized for 5 minutes.

Mr. BARR. Thank you.

Mr. King, is either GHB or Rohypnol approved by the FDA for use in this country?

Mr. KING. Rohypnol has never been brought forth to the FDA to be manufactured or distributed in the United States by Hoffman-LaRoche. GHB, no. It is only in a research grant right now.

Mr. BARR. We talked a little bit about some changes that have been made to Rohypnol, its physical properties, the way it dissolves, the coloring, and so forth. How would that change the scheduling of a drug? Would that relate to its potential for abuse? Why is that relevant, or is it relevant?

Mr. KING. I think back in 1997 we were having discussions with Hoffman-LaRoche, not only here in Washington but also in Switzerland, over the concern of their product. They were trying to find ways to get rid of that title as a date rape drug. They were going out of their way to do education courses, drug samplings, urine testing free for police officers and, in addition, they wanted to try this new compound so that you couldn't put it in a glass of water like this and you could detect it very easily. So I think what they were trying to do was responsible.

As I told the chairman, it is not 100 percent effective but it is responsible.

Mr. BARR. What is the relevancy of that, if any, to where a drug ought to be scheduled?

Mr. KING. None, sir.

Mr. BARR. Do either GHB or Rohypnol, or its chemical name, flunitrazepam, have any currently accepted medical use for treatment in the United States?

Mr. KING. No, sir.

Mr. BARR. That being the case, is there any reason why these drugs should not be properly scheduled under the controlled substances schedule?

Mr. KING. In which way, sir? I'm sorry. They should both be Schedule I?

Mr. BARR. I am not saying any particular schedule, that is my next question, but is there any reason that both of these drugs should not be considered controlled substances under 21 U.S.C. A(12) 1, the Schedule of Controlled Substances? Is there any reason why they both should not be there somewhere?

Mr. KING. Well, flunitrazepam is scheduled, sir.

Mr. BARR. I understand that. GBH is not.

Mr. KING. That is correct.

Mr. BARR. I am saying in your opinion is there any reason why both of them should not be scheduled there? Should both of them be somewhere in the schedules of controlled substances?

Mr. KING. Yes, sir.

Mr. BARR. That being the case, in your best opinion, and you might have covered this in various ways with other questions and in your testimony, but just as sort of a final question here, given the various characteristics that place a controlled substance in one of five schedules, where would the best place to place GHB and flunitrazepam be, in which schedule?

Mr. KING. Schedule I.

Mr. BARR. Both of them?

Mr. KING. Yes, sir.

Mr. BARR. And that is based on your concerted expert opinion and your knowledge of the different factors, the potential for abuse, the lack of medical use in this country, and the effects of the drugs?

Mr. KING. Administratively, we could not put flunitrazepam into Schedule I. It would have to be done legislatively. We could not meet all the criteria. But if I had my druthers, I would put them both in Schedule I.

Mr. BARR. Okay. Thank you, Mr. Chairman.

Mr. MCCOLLUM. Thank you, Mr. Barr.

Just one point of clarification, before we end, Mr. King. The pharmaceutical companies, in their memoranda to us,—and this is probably a little unfair because we did not have them here on the panel, maybe we will have to have them here—have indicated that, whereas technically there could be some research done on a Schedule I drug, as a practical matter, it is rare that it is done.

It is difficult getting grants for it. Money doesn't flow into this. People are scared away from it, and therefore it diminishes the chance that the research will actually be accomplished. And they are, therefore, very much opposed to any scheduling of a drug as Schedule I that might have medical potential, particularly GHB, because of the potentially good results it may have on narcolepsy.

Do you have any comment on that? Is there a gradation here we are missing? I just want to be as honest and open as I can about the subject and thought I ought to at least lay that on you.

Mr. KING. I could research that question and get back to the committee.

Mr. MCCOLLUM. It would be very helpful if you would. Because while we are the tough law and order committee, we have to be fair about. If it really interferes with—I mean narcolepsy is a pretty serious matter, and if, indeed, GHB is potentially very useful for that, as I think Dr. Doering indicated and some of the pharmaceutical concerns have indicated, whatever we do, we don't want to mess up the option there and miss out on something potentially beneficial.

Thank you very much.

[The information referred to follows:]

DRUG ENFORCEMENT ADMINISTRATION,  
U.S. DEPARTMENT OF JUSTICE,  
Washington, DC, August 31, 1998.

Mr. DAN BRYANT, *Counsel,*  
*Subcommittee on Crime,*  
*Committee on the Judiciary,*  
*House of Representatives, Washington, DC.*

DEAR MR. BRYANT: Enclosed are the responses to the questions on GHB from the July 30 hearing on Controlled Substances Used to Commit Rape. If you have any questions, please contact me at the number above.

Sincerely,

KEN RONALD, *Chief, Congressional Affairs.*

On July 30, 1998, the Subcommittee on Crime of the House Judiciary Committee held a hearing on Controlled Substances Used to Commit Rape. During the Question and Answer session following the testimony of John King, Deputy Assistant Administrator, Drug Enforcement Administration (DEA), there were two questions for which Mr. King stated he would provide a detailed response in writing. Both of these questions concerned gamma hydroxybutyrate (GHB).

As a preface to our responses, we wish to state that the Drug Enforcement Administration supports placing GHB in Schedule I of the Controlled Substances Act (CSA). This action would establish the high abuse potential of GHB and the public health risks associated with its abuse to the law enforcement community, the judicial system and the general public. In addition, such an action would increase the priority given by law enforcement and the judicial system in combating the trafficking of GHB in the United States.

1. SHOULD ANALOGUES OF GHB BE COVERED AS SCHEDULE I OR II SUBSTANCES UNDER H.R. 1630? (QUESTION BY REP. SHEILA JACKSON LEE)

Yes. However, specific language in the legislation is not necessary to accomplish this if GHB is controlled as a Schedule I or II substance under the CSA. In this case, GHB analogues which meet the definition of a controlled substance analogue (see definition at end of this response) would be treated as Schedule I controlled substances for purposes of criminal prosecution. Gamma butyrolactone (GBL), a precursor in the illicit synthesis of GHB, and 1,4- butanediol, could be considered analogues under the current CSA definition. However, GBL is our greater concern at the present time. It should be emphasized that control of GHB in another schedule (i.e., III, IV or V) would not automatically cover analogues for purposes of criminal prosecution.

*Gamma Butyrolactone Problem*

The clandestine manufacture of GHB involves the use of two non-regulated chemicals: (GBL), the primary precursor as well as an analogue, and sodium hydroxide (lye). GBL is a solvent with many industrial uses. As an unregulated chemical, GBL is sold in chemical supply companies and is available for sale over the Internet as a component of a GHB "kit". Several DEA field offices are receiving information on suspicious GBL orders from chemical supply companies for use as a precursor for GHB.

In addition, there are reports of the abuse of and dependence on GBL. These are self-reports from abusers, with no toxicological evidence, that GBL is being used as a substitute for GHB. Most of these reports have come from states that have controlled GHB under state laws. GBL, once absorbed orally, is rapidly converted into GHB in the body and produces the same profile of behavioral effects as GHB.

*In view of the above, it is clear that any control action involving GHB must include or be followed by GBL control.* If GHB is placed under the CSA, there are several options for the control of GBL. If GHB is placed in Schedule I or II, as discussed above, GBL can be treated as an analogue for purposes of criminal prosecution, if it is intended for human consumption (i.e., abused for its psychoactive effects). If GHB is controlled in any schedule, GBL could also be controlled as an immediate precursor in that same schedule. GBL could also be made a listed chemical. While GHB remains uncontrolled, we cannot initiate any control action regarding GBL unless the Department of Health and Human Services (DHHS) provides a scheduling recommendation specifically for GBL. The level of control of GBL must be weighed against its current industrial use.

There have been a few reports of 1,4-butanediol being abused as a GHB substitute. Its chemical structure and pharmacology are such that it could be treated

as an analogue and production and distribution for human consumption would be covered under the analogue provision of the CSA.

*Definition of controlled substance analogue 21 U.S.C. 802(32)*

A controlled substance analogue is defined as a substance which:

- (1) has a chemical structural substantially similar to that of a controlled substance in Schedules I to II;
- (2) has a stimulant, depressant or hallucinogenic effect on the central nervous system that is substantially similar to or greater than that of a controlled substance in Schedules I or II; or
- (3) a particular person represents or intends to have a stimulant, depressant, or hallucinogenic effect substantially similar to or greater than that of a controlled substance in Schedules I or II.

The term "controlled substance analogue" does not include controlled substances; drugs or substances with approved new drug applications; substances which have an exemption for investigational use under the FDA's Federal Food Drug and Cosmetic Act; or substances not intended for human consumption.

2. WHAT IS YOUR COMMENT ON THE PHARMACEUTICAL INDUSTRY'S CLAIM THAT SCHEDULE I CONTROL OF A SUBSTANCE HINDERS ITS DEVELOPMENT AS A LEGITIMATE PHARMACEUTICAL? (QUESTION BY CHAIRMAN MCCOLLUM)

Some members of the pharmaceutical industry have alleged that control of a substance in Schedule I impedes legitimate research and the development of medications. Certainly, placing GHB in Schedule I would impose additional regulatory requirements on those who handle it. These requirements, however, are minimal, particularly for the researcher, and were determined to be necessary to establish a closed system of distribution to prevent the diversion of abusable substances, while providing for the legitimate research and development needs of the pharmaceutical industry.

The GHB manufacturer would be required to obtain a Schedule I registration (21 U.S.C. 823(a)), establish adequate security, obtain quotas if material is manufactured in bulk (21 U.S.C. 826), maintain records and provide reports (21 U.S.C. 827).

Researchers, including practitioners, conducting the studies would be required to obtain a Schedule I researcher registration from DEA (21 U.S.C. 823(h)), keep records of the material obtained and used, and store the Schedule I substance in a securely locked, substantially constructed cabinet. In general these requirements are similar to FDA regulations for research conducted under an Investigational New Drug Exemption (IND). Individuals applying to conduct research with Schedule I controlled substances must have their qualifications and competency as well as their research protocol reviewed for scientific merit by DHHS. The DEA must determine whether there are effective procedures to safeguard against diversion of controlled substances from legitimate medical or scientific use. The record keeping and security requirements for a Schedule I researcher are no different than those for a researcher with any other controlled substance. Currently, there are 478 Schedule I researchers registered with DEA and authorized to conduct research with Schedule I substances.

Schedule I controls should not prevent or preclude the development of GHB as a new pharmaceutical product. There are, for example, other drugs, including alfentanil, sufentanil, etorphine hydrochloride, difenoxin, LAAM, and dronabinol ( $\Delta^9$ -THC) that were in Schedule I while they were undergoing research for development and eventual marketing in the United States. If a company decides to submit a New Drug Application (NDA) to the FDA to market a Schedule I controlled substance, sufficient and appropriate data will be generated to support placing it in a schedule other than Schedule I. In regard to the substances listed above, once each was approved for marketing, the DEA expeditiously moved it to a lower schedule, generally Schedule II. The same process would apply to GHB. Schedule I control should not prevent any patient population in the United States from receiving adequate medical treatment. It is important to note that currently there are 11 states which have controlled GHB in Schedule I of their Controlled Substances Acts. Schedule I controls at the state level are analogous to Schedule I controls at the federal level and DEA is not aware of any impediments to research and development efforts for GHB in these states.

Ms. JACKSON LEE. Would the gentleman yield for a moment?

Mr. MCCOLLUM. Be happy to to yield.

Ms. JACKSON LEE. Let me first of all thank you very much, and I think that certainly I made the remark that we must balance the pros and cons. I would hope that Mr. King, in his answer, and maybe as we proceed for additional information with hearings that we will have a DEA representative when the pharmaceuticals are here, but the point being that it is not foreclosed.

If, for example, the drug was a Schedule I, it would not be foreclosed from either further research and/or determined ultimately that it has some valuable use in being rescheduled. And I think you made that point. I don't want to put words in your mouth, but I think that is an important point, Mr. Chairman.

Mr. MCCOLLUM. That was the point he had made, Ms. Jackson Lee. I wasn't trying to diminish it. I was just trying to make a point that there is some gradation of gray, apparently, if the pharmaceutical companies are right, and I was just asking if he knew about it.

Ms. JACKSON LEE. And I welcomed his input on that.

Mr. MCCOLLUM. At any rate, thank you, Mr. King, for being here today. We are going to adjourn this hearing; we have a vote on. I think everybody has asked their questions. Thank you so much for being here.

The subcommittee hearing is adjourned.

[Whereupon, at 3:55 p.m., the subcommittee was adjourned.]

## A P P E N D I X

### MATERIAL SUBMITTED FOR THE HEARING RECORD

Orphan Medical  
Minnetonka, MN

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to provide testimony for the record of the Crime Subcommittee's July 30, 1998 hearing on date rape drugs.

Orphan Medical supports the intent of the hearing. Sexual predators who use GHB to facilitate their crimes should suffer severe federal penalties.

Orphan Medical, however, opposes HR 1530's proposal to list GHB as a Schedule I controlled substance. A Schedule I or Schedule II designation for GHB would have the unintended consequence of shutting down the promising development of GHB for the treatment of a rare disease called narcolepsy which incapacitates as many as 180,000 Americans.

GHB is not a narcotic, nor is it similar to any of the other controlled substances currently designated as a Schedule I or Schedule II. GHB's appropriate medical use and current evidence of psychological and physical dependence is comparable to controlled substances already listed in Schedule IV.

Orphan Medical proposes that GHB be designated as a Schedule IV substance. This would both permit the continued development of this drug to treat narcolepsy and provide harsh federal penalties as defined by the "Drug-Induced Rape Prevention and Punishment Act of 1996." That act, which was approved by overwhelming bipartisan support in the House and Senate, provides for up to 20 years imprisonment for anyone convicted of using a controlled substance to facilitate a sexual assault—any controlled substance, no matter what schedule it falls under.

Additionally, Orphan Medical proposes that the subcommittee use the "Drug-Induced Rape Prevention and Punishment Act of 1996" as a model to impose Schedule I and II penalties on anyone convicted of possessing, distributing and manufacturing any amount of GHB or its analogues.

Many pharmaceutical companies choose medicines to develop because they are interested in a certain therapeutic area or see a large market opportunity. Orphan Medical chooses new medicines to develop in a very different way. As a company dedicated to patients with uncommon diseases, Orphan Medical develops medicine for patients whose conditions are so rare there is *no other* therapeutic alternative available.

One such condition is narcolepsy. Narcolepsy patients experience profound sleepiness in the daytime—so severe that they often find it difficult to drive, hold a job or perform other seemingly "normal" tasks. In addition to excessive daytime sleepiness, some narcoleptic patients also experience cataplexy, which is a sudden loss of muscle control which may cause the patient to collapse. Some patients find themselves virtually unable to function as they may collapse from 25–50 times in one day.

One promising drug therapy for narcoleptic patients is gamma hydroxybutyrate (GHB). After the passage of the Orphan Drug Act of 1983, an Orphan Drug Research Grant was awarded to a scientist who uncovered scientific evidence that GHB may be an effective and safe medicine for patients with narcolepsy. Based on this work other scientists became interested, and along with the National Organization for Rare Disorders (NORD), many pharmaceutical companies were approached about development of GHB as a treatment for narcolepsy. Due to the rare nature of this condition and the low revenue potential all but one company declined. In 1989, NORD and FDA were successful in convincing Biocraft to commence development of GHB for narcolepsy. However, in 1994 the GHB; development program was abandoned when Biocraft was acquired by a large pharmaceutical company.

In that same year, Orphan Medical was formed as a company dedicated solely to the development and commercialization of medicines for rare diseases. At the urging of the FDA's Office of Orphan Products, NORD, and the scientific community, Orphan Medical commenced development of GHB for narcolepsy with full knowledge that GHB would be listed as a controlled substance.

Orphan Medical recommends scheduling GHB; immediately as a Schedule IV for the following reasons:

*Schedule I and Schedule II are inappropriate.*

Schedule I is reserved for those drugs that have no current accepted medical use and a high abuse potential; two examples are heroin and LSD. Schedule II is reserved for drugs that have a high abuse potential, a serious psychological dependency and a serious physical dependence liability; two examples are morphine and secobarbital. GHB has a well documented current medical use and clinical data do not suggest a profile similar to agents in Schedule I or II.

*Schedule I or II would halt the development of QHB as a narcolmsy treatment.* If GHB; were classified as Schedule I for the remainder of development, Orphan and its suppliers, would be "shut down." This is evidenced by the fact that only last week, our manufacturer in Illinois was contacted by the Illinois Department of Professional Regulation and enjoined from producing further product. This happened, despite the fact that the Controlled Substance Act (CSA), *specifically allows for medical research.* As it stands today, many patients in clinical trials are at risk of not being able to obtain their much needed medication, due to the actions of the state.

A Schedule II listing would require the additional expenditure of millions of dollars. That's small change for a big pharmaceutical company; it's commercially devastating for a tiny company like Orphan Medical.

Contrary to its intended purpose, the scheduling of GHB as a II would actually increase the potential points of diversion. Far more product would have to be manufactured in order to fill a 50,000 pharmacy "pipeline" versus what is needed by a small number of patients. It would be shipped through numerous levels of distribution providing hundreds, if not thousands, of potential sites for diversion. Schedule IV would allow for manufacture of the exact amount of drug needed for the patient population and minimize potential sites of diversion. Direct shipment to the patient would also permit Orphan Medical to track the use of GHB patient-by-patient, prescription-by-prescription and to quickly and easily identify if a patient was attempting to divert the drug. Records would be available to quickly identify in a proactive manner, patients attempting to divert drug.

Orphan Medical understands and agrees with the basic principle that the Scheduling of GHB would be in the public's best interest and would aid law enforcement's ability to prosecute GHB abetted crimes to the fullest extent. Orphan Medical believes that legislation should be amended to accomplish these objectives and we believe it can be done without jeopardizing this important medication.

In conclusion, we recommend consideration of the following actions:

Amend the Controlled Substances Act to make GHB and its analogues schedule IV.

Amend the '96 Date Rape Act to provide stiffer penalties for general possession of any amount of GHB (precedent has been set with Rohypnol).

Mr. Chairman and Members of the Subcommittee, we urge you to consider the recommendations as put forth.

Sincerely Yours,

PATTI A. ENGEL, Vice President,  
ORPHAN MEDICAL, INC.

SCHEDULING GHB WITHOUT HURTING THE TREATMENT OF AMERICANS WITH NARCOLEPSY

- The key to punishing GHB-aided date rapists under the "Drug-Induced Rape Prevention and Punishment Act of 1996" and imposing the maximum penalty of 20 years imprisonment is to list GHB as a controlled substance.
- Illegally manufactured GHB has been implicated in some heinous sexual assaults. The perpetrators should be put behind bars. However, it is not necessary to list GHB as a Schedule I substance to ensure appropriate punishment for illegal use.
- Listing GHB as a Schedule III or IV drug would provide prosecutors with the tools to seek the harshest punishment of the law—up to 20 years unprisonment—under the "Drug-Induced Rape Prevention and Punishment Act of 1996."

- The Controlled Substances Act may be further amended by imposing the general penalties of Schedule I and H substances on anyone who illegally possesses, distributes or manufactures any amount of GHB and its analogues, and by directing the US Sentencing Commission to appropriately amend the sentencing guidelines.
- Scheduling GHB as a Schedule I or II substance would have the unintended consequence of halting the clinical development of GHB as a prescription drug used for the treatment of narcolepsy, a disabling sleep disorder affecting 180,000 Americans.
- GHB used to facilitate sexual assaults has been cooked up on a stove using legally-obtained materials. It is not pharmaceutical-grade GHB.
- In 1995, FDA and the National Organization of Rare Disorders patient advocacy group asked Orphan Medical to undertake the development of GHB as an orphan drug. Orphan Medical is a small Minneapolis-based developer of drugs used to treat rare diseases.
- Results of FDA-sanctioned clinical trials at 16 sleep centers were recently submitted to FDA. Narcolepsy patients from California, Colorado, Florida, Georgia, Kentucky, Maryland, Michigan, Missouri, New York, Obdo, Oklahoma, South Carolina, Tennessee and Washington participated.
- The clinical trials prove that pharmaceutical-grade GHB safely and effectively restores natural sleep for people with narcolepsy and prevents sudden episodes of cataplexy.
- No other drug therapy provides the therapeutic benefits that GHB has demonstrated in people with narcolepsy. GHB restores natural sleep, allowing patients to live a normal life. Absent GHB therapy, they suffer daily episodes of cataplexy? the sudden and total loss of muscle control.
- A New Drug Application for GHB and its use in the treatment of narcolepsy is expected to be submitted to FDA as soon as possible.

DEPARTMENT OF HEALTH & HUMAN SERVICES,  
OFFICE OF ORPHAN PRODUCTS DEVELOPMENT,  
FOOD AND DRUG ADMINISTRATION,  
*Rockville, MD, March 6, 1998.*

BERT SPILKER, Ph.D., M.D.,  
*President, Orphan Medical,  
Minnetonka, MN.*

DEAR BERT: In response to your letter of February 15, 1995, I will be happy to meet with you in my office on March 23, 1995 at 1:45 PM to discuss general orphan drug development issues. I understand Dayton T. Reardon, Ph.D., Orphan Medical Regulatory Affairs Coordinator, will accompany you.

You may feel free to report that Betaine, Gamma hydroxy butyrate and several other orphan products are being developed by your firm at the suggestion of FDA's Office of Orphan Products Development (OPD). You may publicize this information in annual reports, regulatory documents or at public meetings. I hope this clarification answers your question.

I am looking forward to seeing you and Dr. Reardon on March 23.

Sincerely,

MARLENE E. HAFNER, M.D., M.P.H. *Director,*  
OFFICE OF ORPHAN PRODUCTS DEVELOPMENT.

DEPARTMENT OF HEALTH & HUMAN SERVICES,  
OFFICE OF ORPHAN PRODUCTS DEVELOPMENT,  
FOOD AND DRUG ADMINISTRATION,  
*Rockville, MD, March 6, 1998.*

Senator DONALD C. SULLIVAN, M.D.,  
*Chairman, Senate Ways and Means Committee,  
Florida Senate Office Building, Tallahassee, FL.*

DEAR SENATOR SULLIVAN: My office understands that you are interested in some affirmative indication that FDA continues to support the clinical investigation and development of gamma-hydroxy butyrate (GHB) as a potential treatment for narcolepsy. I can assure you that we strongly support clinical investigation of GHB for narcolepsy and anticipate that this drug may have additional legitimate medical uses in other rare diseases. GHB is designated as an orphan product for narcolepsy under the Orphan Drug Law which my office administers.

Over nearly two decades, the Office of Orphan Products Development, along with many patient groups and their families, has made consistent and persistent efforts to enlist a sponsor to develop the clinical data on GHB for narcolepsy and obtain FDA approval for this drug. We are delighted that we now have a committed sponsor; we continue to give full clinical evaluation to this therapy as very high priority.

FDA supported some early GHB research with its grant funds. As physicians, we know narcolepsy is a serious condition for tens of thousands of patients who have no adequate treatment today. And as physicians, we know that substances like GHB may have potential for abuse and harm. FDA has and continues to support strong penalties for those who abuse GHB for non-medical uses.

Please call upon me if I can be of any further assistance.

Sincerely,

MARLENE E. HAFFNER, M.D., M.P.H.  
Rear Admiral, United States Public Health Service,  
Director, Office of Orphan Products Development.

#### Members of the Subcommittee:

I appreciate the opportunity to provide testimony for the Subcommittee's July 30th hearing on H.R. 1530, the Hillory J. Farias Date Rape Prevention Drug Act, which is designed to ban drug substances that have been used for "date rape" purposes. The Subcommittee is addressing the issue of designating GHB and other substances Schedule One; effectively banning the drug for any purpose. *The banning of GHB would be a HUGE mistake.*

I have a chronic disease called Narcolepsy. Although it is uncommon, approximately 150,000 people in the U.S. suffer from this disorder. Along with the more commonly known symptom of overwhelming fatigue, another symptom of Narcolepsy is Cataplexy. Cataplexy is the sudden and complete loss of muscle control usually triggered by emotion. The cataplexy leaves one unable to move or talk for as little as a few seconds up to 30 minutes or more with each episode. A person may go days between attacks or may have many (30-50+) episodes in a day. I have the more serious degree of symptoms. Currently, the only available treatments for cataplexy consist of effectively removing all emotions. I have been on various anti-depressants for over ten years. The anti-depressants have enabled me to function, have a job, and care for my daughter.

For the last fifteen months I have been fortunate to be involved in a medical study by Orphan Medical investigating new treatments for Cataplexy. The new substance that I have been taking through the medical study is WONDERFUL! Not only have my cataplexy attacks been greatly controlled, but I am much less tired. All this AND I have my feelings back. I can feel joy as I listen to my daughter excitedly tell me a story about her life. I can feel touched by a sad story. I can simply feel again. *The substance that I have been taking that has really improved the quality of my life is GHB.*

We've all heard the cliché "get a life". I feel like I have gotten a chance to have a life. One where I don't need to be afraid that I will fall and hurt myself or simply make someone else uncomfortable or afraid. Although compared to a "normal" person I am still very, very tired, relatively I feel better than I have felt for over ten years. I'm almost afraid to say it . . . I feel good.

The hearing on Thursday, July 30th addressed making GHB a Schedule One substance. This would effectively ban the drug for any purpose. The drug trial I have been involved in would be stopped and, sadly, the first help for Narcolepsy patients would be shelved. PLEASE DO NOT DO THIS! GHB has made a tremendous improvement in my life. Narcolepsy is so misunderstood. The other Narcolepsy patients I have met through the years have had sad, lonely lives. Please help! I couldn't bear to go back to the treatment regime I had been sentenced to before.

If GHB is made a Schedule One substance, no patient could ever get this life-saving drug. While this might seem to be the only answer to prevent the terrible use of GHB in date rape, it is not the only answer. GHB could be scheduled as a Schedule Four drug. Its distribution would be highly controlled, but it would still be available to the very sick patients who need it. If the Subcommittee believes something is needed, please do not "help" some people while terribly hurting others.

As a female and single mother of a young teen daughter, I know that banning GHB will not stop victimization of women. People will find other substances, or ways of making current substances whether banned or not. Nice boys don't decide to rape girls with the aid of drugs because there is a prescription use for those drugs. I would guess that a ban of GHB will not prevent a single rape. BUT THE BAN OF GHB WILL AFFECT THE LIVES OF MANY NARCOLEPSY PATIENTS

**WHO CAN FINALLY HAVE A BETTER TREATMENT FOR A QUIET, DISABLING DISEASE.**

Thank you for your time and attention.

MALI A. EINEN, EINEN@MSN.COM

NATIONAL ORGANIZATION FOR RARE DISORDERS, INC.,  
New Fairfield, CT.

Mr. Chairman and Members of the Subcommittee:

My name is Abbey Meyers. I am President of the National Organization for Rare Disorders (NORD), an organization formed fifteen years ago to represent patients and families of patients with rare disorders often called "orphan" diseases. Today, NORD represents over 5,000 rare diseases affecting an estimated twenty million Americans. For the vast majority of these people, there is no effective therapy or treatment for their conditions. Many of these conditions are life-threatening and disabling; all of them are life-altering and accompanied by terrible costs in physical and emotional suffering as well as frequently frustrating and ineffective health care.

NORD appreciates the opportunity to provide testimony for the subcommittee's hearing on potential legislation that would result in scheduling, as a Schedule I controlled substance, the drug product gamma-hydroxy butyrate (GHB), which is currently being developed as a treatment for the most debilitating symptom of narcolepsy. We are interested in this issue because of our belief that such legislation, if enacted, would halt the development of this critically important drug, prevent its marketing as an FDA-approved safe and effective therapy, and deprive thousands of desperately ill people of the best chance they have of living normal lives while afflicted with the mysterious and as yet incurable illness, narcolepsy.

NORD began its work to help people with orphan diseases by uniting patient organizations, medical professionals, patients and families together in an effort to encourage Congress to pass, and President Reagan to sign into law, the *Orphan Drug Act of 1983*. That Act provides financial incentives to entice pharmaceutical companies into conducting research and development needed to produce safe and effective medicines for small populations of patients. Because of the small potential markets for these drugs, there was little potential for profit and therefore pharmaceutical companies did not want to manufacture them.

There were fewer than ten orphan drugs developed during the decade before 1983. Now there are more than 850 designated orphan drugs and 170 of them have been approved by the FDA for marketing in the United States. But we still have a long way to go. It is a huge challenge for us to reach the ultimate goal of providing hope for patients and families facing the tragedy of a little known incurable disease; an anguish made worse because the disease is rare and thus is much less likely to draw the interest and attention of researchers and companies who might develop a therapy. That challenge is only manageable if we believe we can reach our goal one drug and one disease at a time; we cannot ever hope to meet the challenge if truly insurmountable obstacles fall into the path of drug developers.

We have been advocating for commercial development of GHB for more than fifteen years. Indeed, the federal government recognized the significance of GHB during the 1980's when it awarded an Orphan Drug Research Grant to a narcolepsy scientist who launched a clinical trial showing it is a safe and effective therapy. Based on the success of that trial, we begged pharmaceutical companies to develop the drug, particularly because the only current therapies for narcolepsy are amphetamines, which are habit-forming controlled substances. Because the government rations the annual manufacturing of amphetamines, there are often shortages of these drugs during which narcolepsy patients are left with no treatment at all. One can only imagine how difficult it must be to hold a job or drive a car when you cannot stop yourself from falling asleep. It is as serious as suffering from epileptic seizures.

We truly believe that scheduling GHB as a Schedule I or II controlled substance would be an insurmountable obstacle for a small drug manufacturer and a nightmare for patients and doctors. The is that the security, registration, reporting, and other requirements a company would have to meet to manufacture the drug, or even to continue ongoing research on it, would be so costly as to make the investment prohibitive. Keep in mind that the patient population for this drug is extremely small—it will be prescribed primarily for a subset of narcolepsy—those who suffer from cataplexy. (They can literally become unconscious and fall to the floor triggered by an emotional reaction such as laughter, excitement, or anger, and they become paralyzed during sleep, as if in a coma.) This means the market for the drug is very limited, and the ability of a company even to earn a return on its research invest-

ment is extraordinarily limited. Moreover, such restrictions would make the cost of the drug unaffordable to many narcolepsy patients, and it would encourage doctors not to prescribe it.

There are only a few companies willing to commit to manufacturing a product with such a small possibility of profit. FDA's Office of Orphan Products Development expends enormous effort to find and work with companies that might do this kind of work, when that office believes there is a real possibility for helping patients with an orphan disease. That was the case for GHB.

FDA recognized that GHB offered a real medical advancement for narcolepsy patient with severely disabling cataplexy symptoms. It funded the first American clinical trial of the drug through an Orphan Drug Research Grant. They also recognized the abuse potential of this chemical and took steps to prevent its being sold over-the-counter in health food stores. But this left only one option for patients: get an approved prescription version of GHB on the market as soon as possible. FDA sought out and found one company willing to do the studies necessary for FDA approval: Orphan Medical in Minnesota is a small company dedicated solely devoted to development of orphan drugs. If action were taken now that would stop or impede this progress, the consequences would be disastrous for people with narcolepsy. First and most tragic, if this company does not complete its development of the drug, or does not accomplish the costly and difficult manufacturing requirements, narcolepsy patients will never have access to this treatment.

There is also another consequence that is equally troubling. That is other companies will watch this disaster and learn that even if FDA "recruits" them to develop an orphan drug, and even if they are well along in the development process, their investment or resources may be at risk. If one arm of the government encourages you to develop the product, while another discourages you without regard to the valid medical need for the product, this could be disastrous for the future of all orphan drug development.

Some might ask: "Why is this a problem? If a company can develop one product to treat a disease, it can develop another. There are so many possibilities for new drugs. It just isn't possible that there is only one compound that works." I want to assure the members of this Subcommittee that, for orphan diseases, nothing could be further from the truth. The reality for patients with orphan diseases is that if there is *one* possible therapy, it is almost miraculous. To think they have a choice, or that companies are out there competing to put a variety of products on the market for narcolepsy, is simply unrealistic. In short, for patients with severe and debilitating narcolepsy, GHB is their only hope for a non-habit forming treatment. Making GHB a Schedule I controlled substance destroys that hope.

But that does not mean that we believe this drug should be on the market without control of any kind. We know, as you do, that this chemical has been used illegally and is being abused, and this should be prevented. We agree that the strongest possible penalty should be in place for those who commit crime utilizing this drug, or for those who possess this drug with no other reason than to use it improperly and illegally. However, just as Congress has not made guns illegal simply because some people commit crimes with guns, neither should the government prevent very ill people from having access to a drug that has a valid medical use only because some criminals might abuse it.

We urge the Subcommittee and the Congress to work with the DEA to ensure that proper controls are placed on the distribution of GHB and that those who abuse the drug receive the strongest penalties. But this can be done *without* placing the drug under Schedule I. Placing GHB under Schedule III or IV, but providing the authority to the Department of Justice to levy the maximum penalty for abusing the drug, strikes the right balance. It gives law enforcement officers the ability both to deter and to punish wrongdoers, but it does so without penalizing patient who need access to a proven safe and effective medication they desperately need.

*The first and most important step that Congress can take is to regulate the Internet and get the formula for GHB off of the World Wide Web!* None of the crimes involving GHB have been caused by the medical version of the drug. They have all been caused by criminal amateurs who make the compound themselves. To make GHB a Schedule I drug would be tantamount to scheduling Aspirin as Schedule I simply because some people (7,000 per year) die from Aspirin.

We stand ready to provide the Subcommittee with any additional information you may need regarding orphan diseases, the Orphan Drug Act, or the importance of GHB for patients with narcolepsy. We urge you not to take an action which, while it may seem to help some people, will certainly harm others. Thank you for the opportunity to present our views.

NATIONAL SLEEP FOUNDATION,  
Washington, DC, August 10, 1998.

Hon. BILL MCCOLLUM, *Chairman,*  
*Subcommittee on Crime,*  
*Committee on the Judiciary,*  
*House of Representatives, Washington, DC.*

DEAR CHAIRMAN MCCOLLUM: I am writing on behalf of the National Sleep Foundation (NSF) regarding H.R. 1530, the "Hillary J. Farias Date Rape Prevention Drug Act" which was recently discussed at hearings before the Subcommittee on Crime. This legislation is of great concern to the National Sleep Foundation because it would place Gamma hydroxybutyrate (GHB) in Schedule I of the Controlled Substances Act and greatly hinder research and clinical trials currently being conducted by a small drug company and sleep disorders clinics for the treatment of narcolepsy.

The National Sleep Foundation is a nonprofit organization, founded in 1990, dedicated to promoting public understanding of sleep and sleep disorders through education, research and advocacy initiatives in order to improve public health, safety and productivity. Our board of directors consists of some of the nation's top sleep experts who have years of research and clinical experience in the treatment of sleep disorders including narcolepsy.

Narcolepsy is a chronic neurological disorder that affects the central nervous system and causes excessive daytime sleepiness, cataplexy, sleep paralysis, and hypnagogic hallucinations. This rare genetic disorder affects approximately 250,000 people in the United States, most of whom are undiagnosed due to the lack of awareness of primary care physicians. It is estimated that about 30,000 people with narcolepsy suffer some form of cataplexy (the sudden loss of muscle control ranging from slight weakness to total collapse). The usual age of onset is during the late teens or early twenties when young people are attending high school, college or beginning employment that will shape the rest of their lives. People with narcolepsy suffer from irresistible sleep attacks throughout the day, during business meetings, social events, during conversations, and while driving. The disorder causes enormous disruptions in patient's lives that can become debilitating if not carefully managed and treated.

Because little is known about narcolepsy by the general public and most primary care physicians, the average person with narcolepsy sees at least five doctors and suffers for some 15 years before they are properly diagnosed. At this time, there is no cure for narcolepsy and treatment options are limited. Medications are the only treatments available to minimize the affects of this disorder. Excessive daytime sleepiness related to narcolepsy is treated with stimulants while cataplexy is treated with antidepressant medications. Unfortunately, medications only reduce symptoms of narcolepsy, they do not alleviate them all together. All drugs currently available for narcoleptics were developed for other disorders.

While Narcolepsy is just one of eighty sleep disorders, the NSF has recognized the severe effects the disorder has on people, especially young adults, and has taken actions to promote research and treatment regiments. In September of 1996, the NSF founded the National Narcolepsy Registry (NNR) which is housed at the Montefiore Medical Center in the Bronx, New York. The NNR was developed to provide a major resource for researchers who wish to study the cause of narcolepsy. The Registry has been overwhelmingly supported by patients and patient support groups such as the Narcolepsy Network. The NNR is the primary source of genetic material for a new fouryear study being funded by the National Institutes of Health that will help identify the genes responsible for the disorder. The NSF is committed to finding effective and safe treatments for narcolepsy, its related symptoms and eventually a cure.

Due to the effect H.R. 1530 would have on the development of GHB, the NSF cannot support moving this promising treatment to Schedule I status. As you may know, several organizations, including the Food and Drug Administration's (FDA) Office of Orphan Products Development and the National Organization for Rare Disorders, Inc., underwent a lengthy search to find a company to further investigate GHB for the treatment of narcolepsy. It appears that no drug companies other than Orphan Medical showed any interest in GHB because narcolepsy remains a relatively rare disorder. Orphan Medical specializes in developing drugs that other companies will not manufacture due to the low profit potential. The development of GHB for narcolepsy has been enthusiastically supported by the FDA over the years.

Because Orphan Medical remains a relatively small company, the NSF is concerned that listing GHB as a Schedule I substance would place an undue burden on the company and possibly hinder further development. Additionally, we are told

that the labs currently taking part in clinical trials would be faced with increased administrative and security concerns that would be extremely time consuming and costly; placing their research in jeopardy. The NSF is encouraged by the primary data and anecdotal evidence provided by patients and physicians associated with clinical trials using GHB.

One point that was made very clear by the Drug Enforcement Administration and representatives from the Orlando police department during testimony before your Subcommittee was that the GHB being sold at clubs and over the Internet is not coming from drug companies or medical labs, but almost entirely from "clandestine laboratories." Therefore, it seems that enforcement measures should be aimed at the sources which allow people to illegally manufacture GHB at home rather than drug companies that are manufacturing it for legitimate medical research and clinical trials. If the dealers are as young as law enforcement officers say, will they really be paying attention to whether GHB is a scheduled drug or not? If so, will it really make a difference to these criminals whether GHB is a Schedule I drug rather than a Schedule IV?

The National Sleep Foundation believes that there are strong measures (some of which were already mentioned by members of the Subcommittee) that can be taken to see that police officers have the necessary tools to get GHB off the streets without affecting people who suffer from narcolepsy. The NSF supports the following:

1. Placing GHB in Schedule III or IV of the Controlled Substances Act. This would properly place GHB under the jurisdiction of the Drug Enforcement Administration without adding unnecessary burdens on Orphan Medical, drug manufacturers who contract with Orphan, and the 16 clinical labs currently conducting trials. While placing GHB in Schedule I would not legally prohibit Orphan from continuing its research and development of this compound, it would, in effect, create large financial and administrative barriers that would put further research in real jeopardy.

2. Amend the "Date-Induced Rape Prevention and Prevention Act of 1996" to add criminal sanctions for the illegal possession or distribution of GHB similar to those currently in place for Rohypnol. As you suggested during the hearing, this would place the most severe criminal sanctions on those people caught manufacturing, possessing or distributing GHB—treating GHB as a Schedule I drug while actually listing it as a Schedule III or IV. The NSF believes that this measure would give law enforcement officials what they need to stop the flow of homemade GHB while not affecting the promising research that is currently taking place for the treatment of narcolepsy.

3. Add GBL, a major component needed to make GHB, as a "listed drug." As we understand it, this would place significant hardship on the operations which currently sell GBL to people who make GHB themselves or sell "GHB Kits" over the Internet. This would make it more difficult for people to import GBL from Mexico which accounts for much of the GHB production. It would also put stricter sanctions on the people directly responsible for the abuse of illegal GHB production rather than medical professionals seeking legitimate treatments.

Additionally, the NSF asks that Crime Subcommittee hold additional hearings to hear from narcolepsy patients, sleep experts conducting the trials, representatives of Orphan Medical, and the Food and Drug Administration's Office of Orphan, Product Development before it moves forward with any legislation affecting legitimate GHB production. The National Sleep Foundation strongly believes that the measures proposed in H.R. 1530 will do little to stop the illicit manufacture, sale and abuse of GHB while hindering further development of it for legitimate medical purposes.

Unfortunately, people and organizations in the health community are constantly faced with the realities of the market economy when looking to conduct research or develop new drugs or treatments. An overwhelming factor in seeking new drugs for relatively obscure disorders or diseases is whether a drug company will be able to allocate sufficient resources to properly develop and test a drug that will provide an economic return. Simply put, the bottom line is if a company cannot reasonably profit from the enormous effort they put in to the development of a new drug, they will not manufacture it leaving a potentially life-saving alternative out of the reach of those who desperately need it. We hope that you and the Crime Subcommittee will help us find alternative solutions to those put forth in H.R. 1530 and see that criminals are dealt with severely and that people suffering from narcolepsy are provided the best treatment available as quickly as possible.

Thank you for your time and consideration.

Sincerely,

WILLIAM DEMENT, M.D., PH.D., *Director*,  
STANFORD UNIVERSITY SLEEP DISORDERS CLINIC  
GOVERNMENT AFFAIRS COMMITTEE CHAIR,  
NATIONAL SLEEP FOUNDATION



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