

DATE RAPE DRUGS

HEARING
BEFORE THE
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
OF THE
COMMITTEE ON COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

MARCH 11, 1999

Serial No. 106-7

Printed for the use of the Committee on Commerce



U.S. GOVERNMENT PRINTING OFFICE

55-638CC

WASHINGTON : 1999

COMMITTEE ON COMMERCE

TOM BLILEY, Virginia, *Chairman*

W.J. "BILLY" TAUZIN, Louisiana	JOHN D. DINGELL, Michigan
MICHAEL G. OXLEY, Ohio	HENRY A. WAXMAN, California
MICHAEL BILIRAKIS, Florida	EDWARD J. MARKEY, Massachusetts
JOE BARTON, Texas	RALPH M. HALL, Texas
FRED UPTON, Michigan	RICK BOUCHER, Virginia
CLIFF STEARNS, Florida	EDOLPHUS TOWNS, New York
PAUL E. GILLMOR, Ohio	FRANK PALLONE, Jr., New Jersey
<i>Vice Chairman</i>	SHERROD BROWN, Ohio
JAMES C. GREENWOOD, Pennsylvania	BART GORDON, Tennessee
CHRISTOPHER COX, California	PETER DEUTSCH, Florida
NATHAN DEAL, Georgia	BOBBY L. RUSH, Illinois
STEVE LARGENT, Oklahoma	ANNA G. ESHOO, California
RICHARD BURR, North Carolina	RON KLINK, Pennsylvania
BRIAN P. BILBRAY, California	BART STUPAK, Michigan
ED WHITFIELD, Kentucky	ELIOT L. ENGEL, New York
GREG GANSKE, Iowa	THOMAS C. SAWYER, Ohio
CHARLIE NORWOOD, Georgia	ALBERT R. WYNN, Maryland
TOM A. COBURN, Oklahoma	GENE GREEN, Texas
RICK LAZIO, New York	KAREN McCARTHY, Missouri
BARBARA CUBIN, Wyoming	TED STRICKLAND, Ohio
JAMES E. ROGAN, California	DIANA DEGETTE, Colorado
JOHN SHIMKUS, Illinois	THOMAS M. BARRETT, Wisconsin
HEATHER WILSON, New Mexico	BILL LUTHER, Minnesota
JOHN B. SHADEGG, Arizona	LOIS CAPPS, California
CHARLES W. "CHIP" PICKERING, Mississippi	
VITO FOSSELLA, New York	
ROY BLUNT, Missouri	
ED BRYANT, Tennessee	
ROBERT L. EHRLICH, Jr., Maryland	

JAMES E. DERDERIAN, *Chief of Staff*

JAMES D. BARNETTE, *General Counsel*

REID P.F. STUNTZ, *Minority Staff Director and Chief Counsel*

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

FRED UPTON, Michigan, *Chairman*

JOE BARTON, Texas	RON KLINK, Pennsylvania
CHRISTOPHER COX, California	HENRY A. WAXMAN, California
RICHARD BURR, North Carolina	BART STUPAK, Michigan
<i>Vice Chairman</i>	GENE GREEN, Texas
BRIAN P. BILBRAY, California	KAREN McCARTHY, Missouri
ED WHITFIELD, Kentucky	TED STRICKLAND, Ohio
GREG GANSKE, Iowa	DIANA DEGETTE, Colorado
ROY BLUNT, Missouri	JOHN D. DINGELL, Michigan,
ED BRYANT, Tennessee	(Ex Officio)
TOM BLILEY, Virginia, (Ex Officio)	

(II)

CONTENTS

	Page
Testimony of:	
Adatsi, Felix, Toxicology Unit, Michigan State Police	39
Bane, Paul, Drug Enforcement Command, Maryland State Police	38
Dyer, Jo Ellen, Assistant Clinical Professor of Pharmacy, University of California at San Francisco Bay Area Regional Poison Control Center ..	34
Engel, Patti, Orphan Medical, Inc	88
Faistenhammer, G. Mark, Detective, Grosse Ile Police Department	26
Jackson-Lee, Hon. Sheila, a Representative in Congress from the State of Texas	13
Maher, Patricia L., Civil Division, Department of Justice	54
Porrata, Trinka, D., designer drug consultant	29
Pruett, Candace, accompanied by Lugene Pruett, Commonwealth of Vir- ginia	24
Reuter, Nicholas, Associate Director, Domestic and International Drug Control Office of Health Affairs, Food and Drug Administration	66
Snyder, Denise, DC Rape Crisis Center	42
Woodworth, Terrance W., Deputy Director, Office of Diversion Control, Drug Enforcement Administration	58
Zukin, Stephen, Director, Clinical and Services Research, National Insti- tute on Drug Abuse, National Institutes of Health	73
Material submitted for the record by:	
Meyers, Abbey S., President, National Organization for Rare Disorders, prepared statement of	99
Plaisier, Melinda, Interim Associate Commissioner for Legislative Affairs, Department of Health & Human Services, letter dated April 27, 1999, enclosing response for the record	100

DATE RAPE DRUGS

THURSDAY, MARCH 11, 1999

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON COMMERCE,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:30 a.m. in room 2322, Rayburn House Office Building, Hon. Fred Upton (chairman) presiding.

Members present: Representatives Upton, Burr, Whitfield, Bryant, Bliley (ex officio), Klink, Stupak, Green, McCarthy, Strickland, DeGette, and Dingell (ex officio).

Staff present: Alan Slobodin, majority counsel; Chuck Clapton, majority counsel; Jason C. Foster, legislative clerk; and Chris Knauer, minority investigator.

Mr. UPTON. Welcome, everyone. Today this subcommittee will hear testimony and gather facts on a growing public health and safety problem, so-called date rape drugs.

I want to particularly thank full committee Chairman Tom Bliley for supporting this hearing. I also want to recognize and thank our colleagues Sheila Jackson-Lee and Bart Stupak for their early leadership that they have shown on this issue, and our ranking member, Ron Klink, for his genuine concern that I know he shares about this growing problem.

The reality of this problem hit me hard several weeks ago when I heard about what happened to two young women in my home State of Michigan. While they were at a party, their beverages were laced with GHB, probably without their knowledge. Tragically, 15-year-old Samantha Reid and her friend lapsed into a coma, and Samantha died.

I am the father of an 11-year-old daughter, and I can only imagine what Samantha's family and friends have endured, and I want to join with Sheila Jackson-Lee and Bart Stupak for what I hope every member of this subcommittee today will do in committing themselves to doing whatever they can to prevent tragedies like this from occurring in the future, for I cannot imagine a worse nightmare for any parent.

What are date rape drugs? Date rape drugs are a popular reference to lethal street drugs that people may use to get high or to incapacitate women and make them utterly vulnerable to sexual assault. These drugs can induce a deep, anesthetic-type sleep.

We know many drugs are used to facilitate rape, but the most commonly encountered drugs in drug-facilitated rapes are GHB, Ketamine, and Flunitrazepam. The victim blacks out, experiences

amnesia, and by the time the victim wakes up and gets to the hospital, it may be too late to detect even the presence of the drug because the drug moves so rapidly through their system.

I want to clarify that date rape drugs are in many cases a misnomer. They may be used by near strangers or others to incapacitate young women.

A few years ago, Rohypnol, a prescription anesthetic drug sold in many foreign countries, was the leading date rape drug. Thanks to restrictions on its import, Federal controls and changes that the manufacturer made to it makes it less easy now to abuse it as a date rape drug. Rohypnol no longer is a big part of the problem. Now it is GHB, and to some extent Ketamine, which are the leading date rape drugs.

What makes GHB a particularly fast-growing problem is the availability of its ingredients: hundreds of Internet sites. In fact, we have an example here, a demonstration. Maybe if we can just dim the lights? Darlene, can you just—thanks.

Hundreds of Internet websites promoting GHB and others offer ingredient kits and recipes for making it and the difficulty in detecting this drug. Neither GHB nor Ketamine is under Federal control.

The DEA has documented over 3,500 overdoses in law enforcement encounters with GHB and more than 32 GHB-related deaths since 1990. According to the Drug Abuse Warning Network, GHB-related hospital emergency department episodes increased from 20 in 1992 to 629 in 1996. Clearly the status quo is entirely unacceptable.

In today's hearing, I want us to focus on what additional steps should and could be taken at the Federal and State levels to protect our vulnerable young people from the vile misuse of these substances.

We have impressive witnesses to assist the subcommittee with its fact finding. We will hear first from Sheila Jackson-Lee, our colleague from Texas, who has introduced legislation in response to the death of a 17-year-old girl in her district who died as a result of unintentionally drinking GHB, which was poured into her soft drink. I look forward to working with Congresswoman Sheila Jackson-Lee on this issue and others.

We will then hear from a panel of witnesses offering various perspectives on the problem. Those perspectives will be those from victims, victim advocates, law enforcement and the medical community. We will hear from experts representing the Department of Justice, DEA, the Food and Drug Administration and the National Institute on Drug Abuse.

Finally, we will hear from Orphan Medical, Inc., a company developing a GHB derivative drug in clinical trials for the terribly debilitating symptom of narcolepsy. They are concerned that if GHB was scheduled as a I or II drug, it would be impossible for them to continue their research.

I appreciate the support of my colleague, Ron Klink, for holding this hearing, and I look forward to working with him and everyone else on this issue, and I will, in his stead as acting ranking member of the subcommittee, recognize Bart Stupak for an opening statement.

[The prepared statement of Hon. Fred Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON, CHAIRMAN, SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS

Today, the Subcommittee will hear testimony and gather facts on a growing public health and safety problem: so-called “date rape” drugs. I want to thank full Committee Chairman Tom Bliley for supporting this hearing. I want to recognize and thank our colleagues Sheila Jackson-Lee and Bart Stupak for the early leadership they have shown on this issue and our ranking member, Ron Klink, for the concern I know he shares about this growing problem.

The reality of this problem hit me hard when several weeks ago I read about what happened to two young women in my home state of Michigan. While they were at a party, their beverages were laced with GHB, probably without their knowledge. Fifteen-year-old Samantha Reid and her friend lapsed into comas, and Samantha died.

I am the father of an eleven-year-old daughter, and I can only imagine what Samantha’s family and friends have endured. I want to join with Sheila Jackson-Lee and Bart Stupak and what I hope will be every member of this Subcommittee today in committing ourselves to doing whatever is necessary to prevent tragedies like this from occurring in the future.

What are “date rape” drugs? “Date rape” drugs are a popular reference to lethal street drugs that people may use to get high or to incapacitate women and make them utterly vulnerable to sexual assault. These drugs can induce a deep, anesthetic-type sleep. We know many drugs are used to facilitate rape, but the most commonly encountered drugs in drug-facilitated rapes are GHB (gamma hydroxy butyrate), ketamine (a veterinary drug), and flunitrazepam (trade name “Rohypnol”). The victim blacks out, experiences amnesia. By the time the victim wakes up and gets to the hospital, it may be too late to detect the presence of the drug because the drug moves so quickly through the bloodstream or urine. I want to clarify that “date rape” is in many cases a misnomer. They may be used by near strangers or strangers to incapacitate young women.

A few years ago, Rohypnol, a prescription anesthetic drug sold in many foreign countries, was the leading “date rape” drug. Thanks to restrictions on its import, federal controls, and changes that the manufacturer made to make it less easy to abuse as a date rape drug, Rohypnol is no longer a big part of the problem. Now, GHB, and to some extent, ketamine, are the leading “date rape” drugs. What makes GHB a particularly fast-growing problem is the availability of its ingredients, the hundreds of internet web sites promoting GHB and offering ingredient kits and recipes for making it, and the difficulty in detecting the drug. Neither GHB nor ketamine is under federal controls. The Drug Enforcement Administration has documented over 3,500 overdoses and law enforcement encounters with GHB and 32 GHB-related deaths since 1990. According to the Drug Abuse Warning Network, GHB-related hospital emergency department episodes increased from 20 in 1992 to 629 in 1996.

Clearly, the status quo is entirely unacceptable. In today’s hearing, I want us to focus on what additional steps should and could be taken at the federal and state levels to protect our vulnerable young people from the vile misuse of these substances.

We have impressive witnesses to assist the Subcommittee with its fact finding. We will hear first from Congresswoman Sheila Jackson-Lee, who has introduced legislation in response to the death of a 17-year-old girl in her district who died as a result of unintentionally drinking GHB which was poured into her soft drink. I look forward to working with Congresswoman Jackson-Lee on this issue.

We will then hear from a panel of witnesses, offering various perspectives on this problem. Those perspectives will be those from victims, victim advocates, law enforcement, and the medical community.

We will hear from experts representing the Department of Justice, the Drug Enforcement Administration, the Food and Drug Administration, and the National Institute on Drug Abuse.

Finally, we will hear from Orphan Medical, Inc., a company developing a GHB-derived drug in clinical trials for a terribly debilitating symptom of narcolepsy. They are concerned that should GHB be made a schedule 1 or 2 drug, it will be impossible to continue their promising research.

I appreciate the support of my colleague, Congressman Ron Klink, for holding this hearing. I looking forward to working with him and everyone else on this issue.

Mr. STUPAK. Thank you, Mr. Chairman, and thank you for holding this hearing.

I was interested when I read the subject of this hearing in the briefing memo because it says, and I quote, "The subcommittee will examine the problem of date rape drugs and considering whether the Federal Government is adequately responding to this serious problem."

Mr. Chairman, I agree the Federal Government is not responding to this problem in an adequate fashion, but I believe much of the blame falls on Congress. As my colleagues know, I have taken a special interest in law enforcement issues due to my background as a Michigan State police trooper. This interest has led me to chair both the Law Enforcement Caucus and the Democratic Crime Task Force.

On May 21, 1997, I introduced H.R. 1699, the Families First Juvenile Offenders Control and Prevention Act of 1997. This bill was co-sponsored by Ms. Jackson-Lee, as well as a number of other members. The bill included a provision that would have scheduled GHB and Ketamine as Schedule III controlled substances.

Then again on June 8, 1997, I introduced a provision on date rape drugs as a stand-alone bill because of the attention that this issue needed. Ms. Jackson-Lee introduced her own bill in May that would have also scheduled these drugs as Schedule I.

Mr. Chairman, I know that you were not the chairman of this subcommittee last year, and if you had, many subcommittee priorities would have been different. But I feel compelled to point out that I believe that the legislation would not have languished in the committee since mid-1997, and I wish the majority would have done things differently to hasten its passage. In fact, I am told that the Judiciary Committee was willing to move Ms. Jackson-Lee's bill last year, but this committee refused to allow the bill to the floor.

Mr. Chairman, I understand that you became aware of this issue because of the tragic death of a girl in the district of our colleague, John Dingell of Michigan. While we cannot be sure her tragic death could have been prevented, actions on these bills, my bill or Ms. Jackson-Lee's bill, may have prevented some of the tragedies that have occurred over the last 2 years.

Yesterday I reintroduced the Date Rape Prevention Act of 1999. We have worked with industries and others to move this bill along. This bill would require the Drug Enforcement Agency to schedule both GHB and Ketamine as Schedule III controlled substances.

Second, it would increase the penalties for illegal possession and illegal import or export of these drugs to the Schedule I level, similar to the congressional treatment of Rohypnol.

Third, it allows the tracking for GBL, the precursor chemical for GHB, to ensure that it is not being used to manufacture GHB. Congress has required similar tracking with Ephedrine, a bill that I introduced and was passed and signed into law in 1993, and that was with the drug Methcathadone or "Cat" as we knew it back then. We have basically wiped that drug out.

Finally, it would require the Attorney General to conduct a drug awareness campaign about the dangers of date rape drugs.

Mr. Chairman, I look forward to working with you, and I urge you and the members on your side of the aisle to work with Representative Jackson-Lee and myself to pass our legislation quickly.

After this hearing, I would ask that we circulate a letter among the members of the subcommittee to urge Chairman Bilirakis on the Health Subcommittee to mark up our legislation as quickly as possible.

I want to thank my colleague, Ms. Jackson-Lee, and others for all their work on this issue. I look forward to working with her and you, Mr. Chairman, on quick action on my proposed legislation or any other legislation that would address this dangerous, growing problem. Let us not wait another 2 years.

Thank you, Mr. Chairman.

Mr. UPTON. At this point I recognize the chairman of the full committee, Mr. Bliley.

Chairman BLILEY. I thank you, Mr. Chairman. I thank you for holding this hearing. I will put my statement in the record, but I would like to respond to the remarks of the gentleman from Michigan.

Yes, we did oppose putting this on the omnibus bill because the ranking member of the full committee, the gentleman from Michigan, Mr. Dingell, contacted me about many proposals that were being suggested for the omnibus bill last fall that fell in the jurisdiction of this committee and urged me to oppose all of them.

Therefore, I thought I was carrying out the wishes long held by this committee in the 19 years I have been on here, 14 of them in the minority.

Mr. STUPAK. Would you care to—

Chairman BLILEY. I will not at this time. I will not. I listened with great dismay to the gentleman's remarks, and he can listen to mine. Thank you.

We have traditionally refused. I wanted to bring the satellite bill up last week at full committee, but at the insistence of the ranking member, who insisted on regular order, we went through the subcommittee.

We need to know more about this bill. We had had no hearings. Therefore, I felt that it was the right thing to do, and I am happy to be here today, and I will do what I can to encourage the chairman of the subcommittee to schedule hearings and bring the bill for mark-up as soon as possible.

Thank you. I yield back the balance of my time.

[The prepared statement of Hon. Tom Bliley follows:]

PREPARED STATEMENT OF HON. TOM BLILEY, CHAIRMAN, COMMITTEE ON COMMERCE

Mr. Chairman, thank you for holding this hearing today to expose the growing national problem of the abuse of certain drugs to facilitate sexual assaults on unsuspecting victims. By holding this hearing, this Committee can hopefully bring greater public attention to this abuse, and educate potential victims of the dangers posed by substances that can be easily slipped into an unsuspecting person's drink which will leave that individual unconscious a short time later. The hearing will also focus on what the response of the Federal government has been to the emergence of these drugs as a serious public health concern, and what else can be done.

GHB, flunitrazepam and ketamine are all powerful sedatives, which in certain dosages can induce unconsciousness or even death. In addition to the risk that is posed by the misuse of these drugs by sexual predators, misuse of these drugs for recreational abuse is also a growing danger. The numbers of emergency room admissions for overdoses, drunk driving accidents, and other injuries which are related

to these drugs are all increasing. In addition, some of these drugs and their precursors can be obtained readily at local hardware stores, gyms, or over the Internet.

I am particularly troubled by the difficulties that have been encountered in prosecuting the abuse of these drugs. Because of the unique characteristics associated with these drugs, including memory loss, and the rapid breakdown of the drug in the body which makes it especially difficult to detect, prosecutors have found it particularly difficult to obtain convictions for those who abuse these drugs. In response, many state and local law enforcement officials have lobbied to have these drugs listed as controlled substances under their state drug control laws.

To date the Federal government has not scheduled either GHB or Ketamine. I look forward to hearing from the agency administrators who will testify about what actions have been taken to date, and when we can expect final actions to be taken on these drugs. Anecdotal evidence certainly indicates that this is a growing problem which is putting more of America's youth at risk every day. We will need to review the adequacy of the federal government's response to this problem, including their continuing efforts to assess the scope and severity of this particular issue. If this review indicates that the government's response has been insufficient, we should then consider what steps Congress should take to address this problem.

I would like to welcome all of our panels here today to testify. I would especially like to welcome Candace Pruett, who is from Northern Virginia. Candace was the victim of a sexual assault when she was fifteen years old. Her attacker had given her a soda laced with Rohypnol, which rendered her unconscious for several hours and enabled him to assault her. She went through a very difficult trial where she had to recount these painful memories. I commend her courage in testifying about this troubling event before the Subcommittee today, which we all hope will help to educate other potential unsuspecting victims and prevent similar assaults in the future.

Mr. UPTON. The Chairman yields back the balance of his time.
The gentlelady from Colorado?

Ms. DEGETTE. Thank you, Mr. Chairman. I would like to thank you for calling this hearing today also, and I would like to thank all of my colleagues who have introduced legislation to address this problem, specifically Congresswoman Jackson-Lee and my colleague, Mr. Stupak, from the committee.

The problem of date rape drugs is real and must be addressed. The alarming incidence in reports of these drugs being slipped into the drinks of unsuspecting women in order to render them defenseless for sexual exploitation is disturbing.

In Colorado, for example, my home State, a woman was raped in May of last year. Testing confirmed that someone had slipped GHB into her drink while in a bar. Two other women reported similar assaults within 2 months of that incident, and that is just in one State.

GHB and similar substances are odorless, tasteless, colorless, and they induce serious impairments in functioning, such as drowsiness, dizziness, confusion and memory loss.

Although they are not marketable in this country for prescription purposes, the common ingredients and recipes for making GHB are now available on the Internet, and reports indicate that these substances are widely available because of the Internet availability at fraternity parties, bars and other social gatherings.

This is a complex issue that demands an intelligent response. When Congress passed the Drug Induced Rape Prevention and Punishment Act of 1996, Congress made a strong statement it wanted to find such a solution. With this law, Congress amended the Controlled Substances Act, imposing penalties for distributing these substances with the intent to commit a violent or sexual crime.

We also directed the DEA to study the appropriateness of re-scheduling Rohypnol as a Schedule I drug. After analysis and consultation with the Department of Health and Human Services, the DEA decided there was not sufficient rationale to reclassify Rohypnol as a Schedule I drug.

Indeed, the company that produces that drug has made changes in the product to prevent it from being used as a drug for sexual assault. For example, the drug turns blue when it is put into a drink, and it has a salty taste so that people can tell it is being put into the drink.

We applaud such steps to try to address the crisis, but it is pretty clear with the increase of these drugs being used that more needs to be done. That is why we are here today.

There are other drugs that are misused to rape women; as I discussed, GHB, and Ketamine. Representative Jackson-Lee introduced a bill to reschedule these substances I believe under the Controlled Substances Act as Schedule I substances. The bill was referred to committee, but died, as Congressman Stupak said.

I think it is time for this Congress to act. I think it is time for this Congress to act swiftly because with the Internet availability, more and more young women are becoming subject to date rape for this reason, and we need to do something to figure out how we can stop the illegal distribution of these drugs and we can stop these practices.

With that, Mr. Chairman, I will yield the balance of my time to our acting Chairman, Mr. Stupak, who would like to follow up on his previous statement.

Mr. STUPAK. Thank you, and thank the gentlelady for yielding.

I want to make it very clear. The Jackson-Lee bill was not, nor was it ever requested to be, part of the omnibus bill that we were working on in late October. It was a freestanding bill.

We requested it to be a freestanding bill while we sat here for 2 weeks twiddling our thumbs while they put together the omnibus bill, and we had Judiciary to sign off. There was not a request to Mr. Dingell that this bill be part of the omnibus bill.

We wanted to do a freestanding bill while we were here. As everyone on this side of the dais knows, we did plenty of bills in the 2 weeks while we were waiting for the omnibus bill.

The point is there has been plenty of time to move our legislation. We get people to sign off, and it gets bottlenecked here. I want the bottleneck to stop, and I want to move forward so we can move this legislation.

Ms. Jackson-Lee has worked with industry and others to get her bill in good shape. My bill was in good shape. We introduced it last night after we got the last of industry to sign off. We are ready to go. Let's move these bills forward.

I would yield back to the gentlelady and thank her for the time.

Ms. DEGETTE. And I will yield back the balance of my time, Mr. Chairman.

Mr. UPTON. The gentlelady's time has expired.

Vice-Chairman of the committee, Mr. Burr, from North Carolina?

Mr. BURR. Mr. Chairman, I thank you, and my colleague, Ms. Jackson-Lee, thank you for committing your time to come up. Hopefully we have gotten the name blame out of the way, and now

we can all look forward to learning more about the problem, but, more importantly, more about the solution.

I think it was in 1996 that Congress responded to an imminent problem of date rape. I appreciate my colleague from Colorado pointing out the fact that some companies have been responsive. Hoffman LaRoche did everything they could to help tighten controls over certain products.

Congress also passed legislation at that time that I am convinced today, after reading back on it—I was here, but the intent was to eliminate this problem, and it did not. I think that is one of the reasons that hopefully this oversight hearing might be just the start of some additional hearings on what is the appropriate answer.

I think one of the things that alarms me, and I hope that Mr. Stupak will be as vicious with his questions to the FDA, is that they made a recommendation for scheduling to FDA in 1997 to set a scheduling change at that time for GHB. Unfortunately, I do not think that that has taken place yet, Mr. Chairman. If it did, it is only recently.

We have a system that we thought would be responsive. Clearly there are areas of it that have been not effective or have broken down. I hope that through the efforts of some of our colleagues like Ms. Jackson-Lee and others who are passionate about this that in fact we can ensure all Americans that Congress has done everything within its power to make sure that this is not a problem and that the system does work.

I thank the chairman for these hearings. I yield back.

Mr. UPTON. The gentleman from Pennsylvania, the ranking member of the subcommittee, Mr. Klink?

Mr. KLINK. I thank my friend, Mr. Upton, and I apologize. I had another meeting this morning, so I am delayed a little bit. I thank my friend, Mr. Stupak, for filling in. I know how important this issue is in his legislative office because he has seen the problems up in Michigan. I know he has been working very hard on this.

I want to thank the chairman, Mr. Upton, for realizing that this was such an important issue and for conducting this hearing. It has been a pleasure to work with him on this. We think that something really should have been done earlier, but I am glad that the chairman has really taken the bull by the horns and moved forward on this, and we look forward to working with him.

Can I ask you, my dear colleague, Ms. Jackson-Lee? In your opinion, what is more dangerous, the—

Mr. UPTON. Mr. Klink, we are doing opening statements.

Mr. KLINK. We are doing opening statements? I am sorry. You are going to have to really bear with me. I thought we were actually on questions.

I was listening to the engaging way in which Mr. Burr was responding, and I thought that we were at a question time.

Mr. Chairman, I, too, want to applaud you for having this hearing on date rape drugs. Sadly, the manufacture and use of GHB has recently become a problem for law enforcement authorities in my own State of Pennsylvania where authorities seized enough chemicals and packaging for thousands of doses of GHB, only to discover the drug is not illegal under Federal or Pennsylvania law.

The sooner we take action to make these date rape drugs more difficult to obtain, the better, and I hope that this hearing will help us do that.

There are two drugs under question for today's hearing: Ketamine and GHB. Both have been scheduled by a number of States, but have not been scheduled by the Federal Government. In that regard, today's hearing is more than about date rape drugs. It is also about what actions we in Congress should be taking to control these drugs.

While I fully support the efforts of the Oversight and Investigations Subcommittee to look into this important matter, I wish that we could do it jointly with the Subcommittee on Health and Environment so we could mark up one of these bills that have been introduced so that we could schedule Ketamine or GHB as quickly as possible because I think they are very dangerous.

The fact is that this issue is not entirely new. During the past Congress, no fewer than seven bills were submitted by Democrats to schedule Ketamine and/or GHB. In fact, two of those bills were referred to this committee. One, authored by my good friend Sheila Jackson-Lee, who is with us, and the other by my good friend Bart Stupak, was referred to the Commerce Committee almost 2 years ago. We did not take any action.

I am glad that we have both of these people here today, and I look forward to working with both of them and with Chairman Upton on this issue. I cannot really blame any inactivity on my dear friend, Mr. Upton. He in fact is the reason that we are here today. He realized the importance of this. He was not at the helm of this subcommittee during the last Congress, nor were you in charge of determining, my friend, Mr. Chairman, what bills would be scheduled by the full committee.

If anything, I have to applaud your willingness and your conviction to shed light on a matter in which a serious discussion by our committee is long overdue. Hopefully, this hearing will help us move closer to taking action on either Mr. Stupak's bill or Ms. Jackson-Lee's bill. In fact, maybe both of our colleagues will be able to work together to come up with a consensus bill. I would enjoy working with them on that effort if that is what they decide to do.

I think we already realize that these drugs have been a problem and that there must be a Federal response. Whether they get scheduled as I, II, III, or IV is an issue that is worthy of debate. The important thing is that we do what we have to do to protect people from the misuse of these substances.

For today's discussion, we must understand that the Federal scheduling of any drug is a slow process because it is a deliberative one. To make a recommendation to schedule a substance, the Food and Drug Administration must go through a multitude of investigational tests. The process is highly procedural. It requires significant data gathering and allows for the public input by those that might be affected by the decision.

Mr. Chairman, we may not like how long it takes the FDA or NIDA or HHS or the DEA to do this, but that is what the law requires. While I look forward to hearing testimony from the FDA, so far we have seen no evidence suggesting that the FDA or our

friends at HHS have been derelict in their effort to evaluate either GHB or Ketamine for the scheduling purposes.

Some many wonder why many States have already scheduled these drugs when the FDA has not. The answer is a simple one. Like our colleagues, Mr. Stupak and Ms. Jackson-Lee, have attempted to do, most States that have scheduled these drugs have done so through legislative fiat. That, Mr. Chairman, is the debate that we need to have.

I am not saying that either of these bills is perfect, but they are an excellent place for us to start. I am hopeful we can join together and commit ourselves to moving this debate forward.

Mr. Chairman, I will conclude by saying that because Mr. Stupak is a former law enforcement official and has already been very active on this issue, I intend to turn the reins of this subcommittee ranking leadership over to him for today's hearing. I thank him in advance for his hard work.

I also thank Ms. Jackson-Lee. She has shown extraordinary leadership on this matter, and we are privileged to have her here from the Judiciary Committee today.

Finally, Mr. Chairman, again I thank you for your willingness to have this hearing. You have made a commitment to work with us together in this new Congress to solve serious policy matters, and I think that today's hearing, the way you have handled it, is a great start.

This appears to be a reasonable starting point, and I look forward to something good coming out of today's hearing.

[The prepared statement of Hon. Ron Klink follows:]

PREPARED STATEMENT OF HON. RON KLINK, A REPRESENTATIVE IN CONGRESS FROM
THE STATE OF PENNSYLVANIA

Thank you Mr. Chairman.

Mr. Chairman, I want to applaud you for having this hearing on date-rape drugs. Sadly, the manufacture and use of GHB has recently become a problem for law enforcement authorities in my own State of Pennsylvania where authorities seized enough chemicals and packaging for thousands of doses of GHB only to discover that the drug is not illegal under Federal or Pennsylvania law. The sooner we take action to make these date-rape drugs more difficult to obtain the better, and I hope this hearing helps us do that.

There are two drugs under question for today's hearing: ketamine, and GHB. Both have been Scheduled by a number of states, but have not yet been scheduled by the federal government. In that regard, today's hearing is about more than date-rape drugs. It is also about what actions Congress should take to control them.

While I fully support the efforts of the Oversight and Investigations Subcommittee to look into this very important matter, I wish we were doing it jointly with the Subcommittee on Health and the Environment so that we could mark-up a bill to schedule ketamine and GHB as quickly as possible. The fact is that this issue in not entirely new. I would be remiss if I did not point out that during the past Congress alone, no fewer than *seven* bills were submitted by Democrats to schedule ketamine and/or GHB. In fact, two of those bills, were referred to this Committee. One, authored by my good friend Sheila Jackson-Lee and the other by my good friend, Bart Stupak, were referred to the Commerce Committee almost two years ago without any action being taken. I am glad to have them both here today and I look forward to hearing their testimony.

Mr. Chairman, I don't blame the inactivity of the Committee on your leadership. You were not at the helm of the Oversight Subcommittee during the last Congress, nor were you in charge of determining what bills would or would not be scheduled by the full Committee. Rather, if anything, I applaud your willingness and conviction to shed light on a matter in which a serious discussion by our Committee is long overdue.

Hopefully this hearing will help us move closer to taking action on either Mr. Stupak's or Ms. Jackson-Lee's bill. I think we already realize that these drugs have been a problem, and that there must be a Federal response. Whether they get scheduled as I, II, III, or IV, is an issue worthy of debate. The important thing is that we do what we have to do to protect people from the misuse of these substances.

For today's discussion, we must understand that the Federal scheduling of any drug is a slow process because it is a deliberative one. To make a recommendation to schedule a substance, the Food and Drug Administration must go through a multitude of investigational tests. The process is highly procedural, it requires significant data gathering, and allows for public input by those that might be affected by the decision. Mr. Chairman, we may not like how long it takes the FDA, NIDA, HHS or the DEA to do this, but that's what the law requires. And while I look forward to hearing testimony from the FDA, so far, we've seen no evidence suggesting that FDA or our friends at HHS have been derelict in their efforts to evaluate either GHB or ketamine for scheduling purposes.

Some may wonder how many states have already scheduled these drugs when the FDA has not. The answer is simple: like our colleagues Mr. Stupak, and Ms. Jackson-Lee have attempted to do, most of the states that have scheduled these drugs have done so through legislative fiat. That, Mr. Chairman, is the debate we need to have. I am not saying that either of these bills is perfect, but they are an excellent place to start, and I am hopeful that we can join together and commit ourselves to moving this debate forward.

Mr. Chairman, let me conclude by saying that because Mr. Stupak is a former law enforcement official and has already been very active on this issue, I intend to turn the reins of ranking member over to his leadership for today's hearing. I thank him in advance for his hard work. I also thank Ms. Jackson-Lee. She too has shown extraordinary leadership on this matter and we are privileged to have her here today. Finally, Mr. Chairman, I want to again thank you for your willingness to have this hearing. You and I have made a commitment to work together in this new Congress to solve serious policy matters. This appears to be a reasonable starting point and I look forward to working with you to follow it to its conclusion.

Mr. UPTON. Thank you.

Mr. Whitfield from Kentucky?

Mr. WHITFIELD. Mr. Chairman, thank you. I am particularly excited that you decided to have this Oversight hearing today on this important issue as we address the continuing problem of date rape drugs in general and the abuse of GHB and Ketamine in particular.

The Controlled Substances Act requires the Drug Enforcement Agency to submit data to the Department of Health and Human Services and to request that HHS conduct a medical and scientific evaluation of the substance in question.

GHB has no medical use, and the FDA has issued an advisory declaring GHB unsafe and illicit. The DEA finished its evaluation and submitted its report to HHS in 1997, and still HHS has not come up with its findings. HHS' findings as to scientific and medical matters are binding on DEA, so DEA cannot move unless HHS completes its responsibility, which it has not done.

I hope that today's hearing will provide some answers as to why we are not taking advantage of the one aspect of the fight against drug use in our society that is within our control, the ability to schedule dangerous drugs.

I would like to make one more comment. This administration, over the last 3 or 4 years, has been in the forefront of a well-coordinated campaign to protect children from tobacco use. We all recognize that tobacco use is damaging to children over the long term, but as I go around my district and my State and I talk to educators, as I talk to law enforcement people and others, the most direct, the most immediate threat to young people today is the pro-

liferation of dangerous drugs, which are easily available and readily available around the country.

I am delighted that we are focusing on some serious drug problems facing young people in America today, and I commend the chairman for having this hearing.

Mr. UPTON. Thank you.

I would like to announce that all members of the subcommittee by unanimous consent will have an opportunity to insert their opening statements as part of the record.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. Chairman, I am pleased this hearing has been called on a very important issue. Let me preface my remarks by welcoming Mr. Upton to the Chair. I look forward to cooperating with him on many issues in the future.

“Date rape” or “acquaintance rape” is a new name for an old and terrible problem. More often than not, rapists are not strangers. Two thirds of all victims of rape and sexual assault know their assailants—their husbands or relatives, boyfriends or acquaintances. Most appalling, the use of drugs by rapists to incapacitate their victims may not only expedite a violent sexual assault, but also deprive the victim of her memory of the assault.

In seeking an answer to this terrible problem, I want to associate myself with the remarks of my colleague from Pennsylvania. Almost two years ago, bills were introduced by our colleagues, Congresswoman Jackson-Lee and Congressman Stupak, to help solve this problem.

Last year, the Judiciary Committee acted on Congresswoman Jackson-Lee’s bill. I think it is deeply regrettable that the Commerce Committee did not consider Congresswoman Jackson-Lee’s bill. If the full Committee had acted as decisively as the Judiciary Committee last year, law enforcement would probably *already* have an effective Federal law at its disposal.

Let me make a final point about the substances to be discussed today. The Food and Drug Administration will testify today. They may be criticized for not acting more quickly or decisively to restrict access to two of the substances being discussed today, GHB and its chemical precursor, GBL.

I want my colleagues to understand that GHB and GBL are or were marketed as dietary supplements. Five years ago, this Congress placed very significant restrictions on the FDA and its ability to act against unsafe supplements. FDA does not approve supplements or supplement ingredients before they are marketed. FDA bears the burden in showing a supplement is unsafe. And FDA lacks the resources to effectively police the supplement marketplace.

Before we throw stones at FDA, I caution my colleagues that we in Congress may live in a glass house. If anything, the problems with GHB and GBL suggest that the FDA needs more authority and more resources from Congress to evaluate dietary supplements and enforce the law against unsafe supplements. I would be happy to work with all of my colleagues on this problem in the future.

I welcome Congresswoman Jackson-Lee and the rest of our witnesses. I look forward to their testimony.

Mr. UPTON. Ms. Jackson-Lee, before you begin I have some subcommittee business to do. You are aware that this subcommittee is an investigative subcommittee. As such, we have always had the long practice of taking testimony under oath. Do you have any objection to testifying under oath?

Ms. JACKSON-LEE. No, Mr. Chairman.

Mr. UPTON. We also advise you per se that you are allowed to be advised by counsel. Do you have any desire to be advised by counsel as well today?

Ms. JACKSON-LEE. Not as we begin. Maybe as we continue.

Mr. UPTON. We do not reimburse for that, by the way. In that case, would you please rise and raise your right hand?

[Witness sworn.]

You are recognized. Your statement will be made part of the record in its entirety, and you are recognized for 5 minutes.

**TESTIMONY OF HON. SHEILA JACKSON-LEE, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Ms. JACKSON-LEE. Thank you very much, Mr. Chairman, and good morning to all of my colleagues.

This morning I would say how do you spell relief? You spell it by the Subcommittee on Oversight and Investigations, chaired by Chairman Upton, and ranking member Klink, and with the leadership of Bart Stupak and the many, many talented members who are here this morning who have a great interest in this area.

I am comforted by the expertise that you offer. I note particularly the leadership of Congresswoman DeGette on women's issues, and I am appreciative of both Chairman Bliley and ranking member Dingell coming together on this very important issue.

This is the day that we should move forward, and I hope Chairman Bilirakis will move forward under your leadership in collaboration, Chairman Upton, on this very important point.

Why am I here today? To save lives. To save young people and to commit to the promise that we have given to all young people to lead a healthy life.

Let me acknowledge LPD retired police officer Trinka Porrata, who you will hear later on, who has dedicated her life to fighting against this unknown killer of which so many people have not been able to get a handle on.

I would also like to acknowledge that I chair the Congressional Children's Caucus, and we have as a mission to promote children as a national interest.

This morning's hearing is extremely important. I do want to acknowledge that Bart Stupak and myself have worked together on many issues. He has a bill to schedule GHB as Schedule III. I look forward to working with him.

As you will note, I filed in January 1997 in the 105th Congress and now again on January 6, 1999, a G.H. bill named after Hillary J. Farais to schedule GHB as a Schedule I drug.

I look forward, of course, to working with Mr. Stupak on his leadership to come together. Hopefully this is a party that will bring us all together to ultimately allow our young people to have parties that are safe. My bill, named after Hillary J. Farais, is a bill that would ask the Attorney General to schedule this at Schedule I and Ketamine at Schedule II.

Particularly let me emphasize that my drug legislation also asks the Attorney General to establish programs throughout the United States and to 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.

Let me just tell you that I had my bill pulled off the Internet. I would hope that the only thing we can pull off the Internet would be legislation and other positive instructions to our young people, not the instructions on how to make GHB, which can be found, as you have so noted, on the Internet. We note that young people will

make GHB in bathtubs for these rave parties that have been very popular around the country.

As a legislator and a mother, I believe we must work to protect our loved ones from the insidious harm resulting from the misuse of potentially dangerous drugs. We must schedule this drug effectively to limit the abuse of GHB and to more efficiently prosecute those who use it for illicit purposes.

I will move quickly, but I must tell you about Hillary J. Farais and this drug that killed a young woman, as I know many of you have experienced in your community. I have named it after her, H.R. 75, the Date Rape Prevention Drug Act, and I want to tell you about her story.

Her death occurred in my home State in 1996 when Hillary J. Farais of La Porte, Texas, died as a result of unintentionally drinking GHB, which was poured into her soft drink at a teenage club on August 5, 1996. On the night she died, Hillary and two girlfriends went to a club where she consumed only soft drinks.

Our immediate response to young people is were they on drugs? Were they drinking? We wish to sort of group them together. She was not a drinker. She was an athlete, a volleyball player, well loved and living with her grandmother.

Soon afterwards, as I complete my remarks, I guess, she complained of feeling sick and having a severe headache. She went home to bed, and the next morning her grandmother was unable to wake Hillary. The grandmother contacted Hillary's uncle, Raul, and she was rushed to the hospital where she later died.

Hillary, a 17-year-old high school senior, model student and varsity volleyball player, had died during the night as a result of the GHB slipped into her drink. As I said, she was not a drinker. She did not use drugs.

This is a drug that attacks the central nervous system. It is detrimental, Mr. Chairman. It is one that has been called by the pharmaceutical offering with a medical use.

Let me just conclude by saying that I worked extensively with DEA. We had the support of Chairman McCullum of the Crime Subcommittee. We worked with FDA. We started out this morning saying that we have relief so that I will not offer to finger point, but I will say that it is time that the Government agencies come up to the bar, if you will and work together.

This is a deadly drug, and I would hope that we could move FDA expeditiously to work with those of us who have sought a compromise, and I would hope that if there is a compromise that we would ensure that the criminal penalties for the illicit use and selling and possession to do harm of GHB has a 20-year penalty. We must let America know we are serious not only about good health care, but as well in protecting our young people.

I know the other witnesses will document for you, Mr. Chairman, the various incidents that have occurred in the use of this drug and rapes that may not have occurred or resulted in death. This is a tragedy. America must do something about it.

I thank the chairman for his kindness and his indulgence and this committee for its leadership. Thank you very much, Mr. Chairman.

[The prepared statement of Hon. Sheila Jackson-Lee follows:]

PREPARED STATEMENT OF HON. SHEILA JACKSON-LEE, A REPRESENTATIVE IN
CONGRESS FROM THE STATE OF TEXAS

Thank you Chairman Upton and Ranking Member Ron Klink for inviting me to testify this morning. I would also like to say that I look forward to working with Congressman Stupak who has a bill to schedule GHB in Schedule III. We must work together on this national problem. This legislation has great personal importance to me. As a legislator and a mother, I believe we must work to protect our loved ones from the insidious harm resulting from the misuse of potentially dangerous drugs. We must schedule this drug to effectively limit the abuse of GHB and to more efficiently prosecute those who use it for illicit purposes.

H.R. 75, the Hillory J. Farias, Date Rape Prevention Drug Act amends Section 401 of the Controlled Substances Act. (21 U.S.C. 841) to make it a federal crime to possess, distribute or manufacture GHB, and adds up to 20 years imprisonment when the use of this drug causes serious bodily injury or death.

This legislation is a direct result of a tragedy which occurred in my own home state of Texas in 1996, when Hillory J. Farias, of Laporte, Texas, died as a result of unintentionally drinking GHB (gamma hydroxybutyrate) which was poured into her soft drink, on August 5, 1996.

On the night she died, Hillory and two girlfriends went to a club where they consumed only soft drinks. Soon afterwards, she complained of feeling sick and having a severe headache. She went home to bed, and the next morning, her grandmother was unable to wake Hillory. The grandmother contacted Hillory's uncle, Raul and she was rushed to the hospital where she later died.

Hillory, a 17 year old high school senior, model student and varsity volleyball player had died during the night as a result of the GHB slipped into her drink. She was not a drinker and she did not abuse drugs.

GHB is a central nervous system depressant that is abused for its ability to produce euphoric states. It also acts 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. The FDA has not approved GHB for marketing, but it is currently under investigation for use in treating narcolepsy under the FDA's Orphan Drug program.

Although the FDA has made it illegal to import, distribute and use GHB, the abuse of this drug 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. Profound coma can occur within 30 to 40 minutes after ingestion. GHB has also been used by drug abusers for its alleged hallucinogenic effects and by bodybuilders who abuse GHB for an anabolic agent or as a sleep aid.

GHB is known to be responsible for as many as 19 deaths and innumerable rapes throughout this country. In seven of these cases, GHB was detected in the urine of the sexual assault victims.

However, GHB's involvement in rape cases often goes unreported or unsubstantiated because little is known about how to detect the presence of the drug in victims rushed to hospitals and police stations. GHB has been widely used as a party drug and most horrifyingly, by those intending to drug and then rape their victims. In California in 1996, 2 men were eventually brought to trial and convicted of 43 counts of rape, attempted rape and conspiracy to commit rape. These men gave their dates drinks spiked with GHB and then brutally raped and sodomized them.

During preparation for trial, prosecutors discovered nearly 2000 photographs in one of the accused rapist's home. One of the police officers testified that some of the women looked obviously comatose in the pictures.

Unfortunately, this terrible story is not an anomaly. Women who are drugged and raped using GHB, often do not remember the rape until much later, making the evidence scarce, and prosecution of these cases a legal nightmare.

GHB has the greatest potential for abuse as a date-rape drug because it is more easily obtained than other drugs and can be manufactured by amateur "basement chemists." Many of young people mix the drug with a home kit and with chemicals available at chemical supply and hardware stores. The recipe is readily available on the Internet.

GHB comes in liquid form and is often slipped into drinks with eye droppers or bottle caps. Dizziness, confusion, overwhelming drowsiness, and unconsciousness are

common. GHB is colorless and odorless, but may be detected by its slightly salty taste.

During testimony last July, law enforcement officers, doctors and researchers agreed on the importance of scheduling GHB under the Controlled Substances Act. I would like to thank former Detective Trinka Poratta, of the Los Angeles Police Department; Detectives Mike Stevens and Toni Moreschi from Orlando, Florida; and Dr. Joy Carter from Houston, Texas for their help and encouragement in working to schedule GHB.

This drug is currently controlled at the state level in 17 states, including Tennessee, Alaska and North Carolina which have scheduled it as a level 4 drug under the state controlled substances act.

I believe we must do whatever we can to protect our young people from GHB when used improperly. I hope my colleagues will support my efforts in preventing date rape and lethal drug overdose. Thank you.

Mr. UPTON. Thank you very much. We appreciate—all of us—your leadership on this issue.

I know you spoke on the floor again yesterday or the day before with regard to this issue, and I just want to commit as chairman of this subcommittee, and as a Member of Congress representing my good State of Michigan, that we do want to see changes made.

The purpose of this hearing is to identify some of those abuses, find out whether legislation is needed, whether FDA can act on its own. Those will be some of the tough questions that we will be asking later this morning.

We just appreciate your testimony today, and with that I will yield for purposes of questioning to Mr. Stupak.

Mr. STUPAK. Just a quick question, and I am sure the sponsor of the legislation knows while FDA has been working with us, I am sure you understand there are two ways we can do this.

We can either do it through the FDA and have them pass rules or regulations, or we can do it legislatively. Is there any preference you prefer?

Ms. JACKSON-LEE. Congressman, I would relish the opportunity for us to work together in the Congress and to move swiftly and to do this legislatively. I think in doing so, we would not in any way injure or damage the relationship between the Congress and the Executive.

I think that the Congress is asked to deal with crises, and I think we now have a point where we can assess the GHB use and its proliferation as a crisis. I would welcome doing this through the legislative process.

Mr. STUPAK. In our conversations we have had on this issue, it was your hope and our belief and hope, much like I did in 1993 when we did Ephedrine to wipe out the Cat problem, that we could introduce this legislation, move it legislatively and get it done within 6 months, as I did in 1993. I know that was your understanding.

When we got it cleared through Judiciary Committee, it was your hope, was it not, that you wanted your bill to be passed as a free-standing bill in October in the waning days of the 105th, or were you looking for it to be part of an omnibus bill?

Ms. JACKSON-LEE. I did file it as a freestanding bill, and as I worked through the process, Mr. Stupak, and got the support of Chairman McCullum and Chairman Hyde, I certainly wanted to collaborate with the appropriate jurisdictional committees, but I wanted it to be a freestanding bill.

Mr. STUPAK. Do you know of any reason why or have you had any objections from any pharmaceutical manufacturers, from anyone who would object to either your bill, my bill or any of these passing as a freestanding bill?

Ms. JACKSON-LEE. I would think with the intent of pharmaceuticals to do good that there would certainly seem no reason why they would not want to see this bill passed inasmuch as, and you are the experts, this would not preclude a medicinal use if it could be determined.

We want to see if that is the case, but at this point I cannot imagine why there would be opposition, and I would hope there was not opposition.

Mr. STUPAK. You have worked on this—and especially with the tragic circumstances in your district, in your opinion, what is more dangerous, the use of GHB and its analogs as a tool to facilitate rape or the use of GHB as the party drug of choice for young people?

Ms. JACKSON-LEE. Well, you have me between a closed door and a brick wall. I would simply say that we know that the GHB in young people resulted in deaths. We know that the rape use of it has resulted in immobilization of the victim, who then cannot help law enforcement to even find the perpetrator.

Death obviously will take the lead, but as a woman let me tell you that I have experienced or seen victims and heard stories from victims as we did our research, and it is an enormous tragedy on all counts.

Forgive me for not trying to choose, but I think it is a tragedy. Maybe you were giving me the rhetorical question to say it is a dangerous drug that should be made criminal.

May I just add my appreciation to my counsel, who did not have to sit here, but my staff person, Leon Buck, for the work that he and our staff did on this particular matter.

Mr. STUPAK. Leon does a good job, and I think he would agree with you that both are equally dangerous facets of GHB.

Ms. JACKSON-LEE. Absolutely.

Mr. STUPAK. Let me ask you one more. I understand that your bill, the Hillary J. Farais Date Rape Prevention Act, as it currently reads asks that GHB to be placed on Schedule I of the Controlled Substances Act.

Are you open to other solutions that would provide law enforcement with additional tools for fighting the illicit use of this drug?

Ms. JACKSON-LEE. I think there is a great opportunity, Mr. Stupak, for us to work together, and, yes, I am.

The only point that I would like to emphasize is the consideration of the criminal penalty of 20 years or some compromise thereof, but as well that we have an educational and prevention piece in it because I really want to have young people be aware themselves of the danger of the utilization of these kinds of drugs.

Mr. STUPAK. In fact, I believe both your bill and my bill ask the Attorney General to put forth some education process throughout the country as to the dangers of GHB and Ketamine—

Ms. JACKSON-LEE. Absolutely.

Mr. STUPAK. [continuing] and the precursor.

If we place GHB on Schedule III, but if we put the penalties for Schedule I, which is I think \$250,000 and 20 years—

Ms. JACKSON-LEE. Yes.

Mr. STUPAK. [continuing] you have no objection with that?

Ms. JACKSON-LEE. We can work together, yes. Thank you.

Mr. STUPAK. Thank you, Mr. Chairman, and I would yield back my time.

Mr. UPTON. The gentleman from Virginia, Mr. Bliley?

Mr. BLILEY. I just have one question. My mind sometimes gets rusty. Did you not call me and ask me to allow your bill to be put on the omnibus bill at the end of the session?

Ms. JACKSON-LEE. I called and indicated that I had a freestanding bill and whatever the procedures might be to help get it in these last moments.

My original request was a suspension bill, and staff instructed and staff was working on other aspects and so whatever they may have guided us to do, if it was possible, that may have been the case, but my bill was a freestanding bill that I asked to get on the suspension document at that time, Mr. Chairman.

Mr. BLILEY. Thank you.

Mr. UPTON. Mr. Klink, do you have questions?

Mr. KLINK. Yes, I sure do. Your testimony, I am intrigued by it, and I just have to laud you for moving forward with your bill.

I have to tell you. As the father of an 11-year-old daughter, and not only your testimony, but I have read the testimony of the other witnesses we are about to hear. I am going to tell you something. We have to do something.

Mr. Chairman, I thank you for holding this hearing. This action must be taken as immediate as we can take it. I just really think that the kind of protections that we have the ability to offer are certainly deserving by the young women of this country and by their parents that will need the peace of mind when they start to understand that these kinds of things are happening.

I have to ask you, though. Are the punitive aspects of this bill, do you think, enough that will stop the misuse of GHB?

Ms. JACKSON-LEE. I think that if we utilize the 20 years' penalty that is associated with Schedule I and the fine that is associated that we will have a sufficient deterrent, along with, ranking member Klink, the idea of the preventative and educational aspects.

That is extremely important, and so I want to be very sure that we have a combination, the criminal penalties that are strong enough and the educational aspects.

Mr. KLINK. We have to realize up front, though, that Orphan Drug is telling us there are legitimate uses for GHB; for example, the treatment of narcolepsy. Are you sensitive to that use, and how would you deal with that?

Ms. JACKSON-LEE. I am sensitive to the representation made by Orphan Drugs, and I am sensitive to those who suffer from that disease.

I believe that we will be able to have provisions that would acknowledge the medicinal use of that drug and have this defined in illicit use, possession and selling or utilization of, and we separate it from the legal use of it.

I mean, we have a variety of drugs that fall in that category that have medicinal purposes, and yet their illicit use have a penalty at that level.

Mr. KLINK. I do not want to speak for Orphan Drug, but I think it is counsel's understanding that they are willing to support Schedule III with very tough penalties, and I think there are some other things that we might want to be able to work some of this, I think.

Are there any other steps that might be taken to combat the dangers of GHB?

Ms. JACKSON-LEE. Absolutely. We must wage a massive educational campaign because, as I said earlier, GHB by teenagers—and who wants to speak for teenagers?—is a fun drug, if you will, made in bathtubs, made for rave parties.

I do not think the point has gotten out how devastating and deadly—just think of the examples. I think the chairman gave his example of the victims in his community. These youngsters have this drug the night before, and they are gone the next morning.

There seems to be no way, because it attacks the central nervous system, of getting them in there and bringing them back, if you will, or using emergency medical devices because it has no odor, it has no telltale immediate signs, and so you cannot rush immediately to the hospital. They go home, and tragically the next morning or maybe hours later they have died.

I think that is the tragedy of what we are here. It is extremely dangerous.

Mr. KLINK. Have you been contacted by others besides the Farais family who have had to deal with tragedies like this involving GHB?

Ms. JACKSON-LEE. In working with Officer Porrata, I know that there have been occasions in California. There have been incidents in Florida. Chairman McCullum is aware of them.

So, yes, we are aware of incidents of death that have occurred because of the utilization of GHB and the immobilization of those rape victims I think as well.

Mr. KLINK. Again, when you read the stories that we are going to hear today, just reading the testimony I cannot imagine what it is going to be like to hear from these victims and the parents of these victims who have gone through this unbelievable experience.

I will tell you, Congresswoman Jackson-Lee, as I said, as a father of a daughter that is about to enter that dating age, I am pleased to work with you, Mr. Stupak, Chairman Upton, and anyone else. We have to act very quickly. We cannot let this threat out there in the public another day than is necessary.

I said in my opening statement and I realize our friends at the FDA have limits because they have to go through procedures. Congress has the ability to act, and I think with what Chairman Upton has scheduled here today, with your help and guidance and that of Congressman Stupak we can move very quickly and protect the children of this country and also give the parents some peace of mind that they deserve.

Ms. JACKSON-LEE. Thank you very much, Mr. Ranking Member.

Mr. UPTON. Mr. Whitfield, do you have any questions?

Mr. WHITFIELD. Thank you, Mr. Chairman.

Representative Lee, are you aware of any jurisdictions in the U.S. today where it would be illegal to possess GHB?

Ms. JACKSON-LEE. Pennsylvania and California. I am sorry. I had to be refreshed.

Mr. WHITFIELD. Well, I did not have any idea, so I am glad you did.

Ms. JACKSON-LEE. We had all of this piled-up information. I wanted to be accurate.

Mr. WHITFIELD. So in Pennsylvania and California, those are the only two States in which it is illegal to possess GHB?

Ms. JACKSON-LEE. That is why I think the congressmen and myself have recognized this as a national issue deserving of legislative attention.

Mr. WHITFIELD. So the only other way that someone that used GHB illegally could be prosecuted criminally today would be if the victim died or suffered some sort of permanent injury or would be subject to a civil action? That would be the only—

Ms. JACKSON-LEE. That is correct, or in an instance in our State, in Texas, of course, there would be State criminal laws, of course, causing the death of another.

Mr. WHITFIELD. Right.

Ms. JACKSON-LEE. As to how that would be determined, it could be manslaughter, et cetera, et cetera. You would be subject to that, but it would never end the dissemination and the making thereof of that drug and selling it for that purpose.

Mr. WHITFIELD. So in 48 States, there is just nothing out there?

Ms. JACKSON-LEE. Nothing there, Congressman.

Mr. WHITFIELD. You and Mr. Stupak had a conversation about Schedule I and Schedule III. Schedule I has a more severe criminal penalty, I guess you said up to 20 years.

Ms. JACKSON-LEE. Yes.

Mr. WHITFIELD. Is that correct?

Ms. JACKSON-LEE. And \$250,000 in fines, I believe.

Mr. WHITFIELD. I do not want to speak for Mr. Stupak, but he seemed to be talking about Schedule III. What is the penalty on Schedule III?

Ms. JACKSON-LEE. Mr. Stupak?

We are now working. As he gets his answer, I will say to you that I think in that instance that minimally at best, but we are working in collaboration with Mr. Stupak to see how we could combine the criminal penalties. That is the key for getting the message out that we are serious.

I know that the criminal penalties for Schedule III did not, in my opinion, fit the level of the crime.

Mr. WHITFIELD. Is there any difference?

Mr. STUPAK. If the gentleman would yield? While we may schedule it as Schedule III, we want the penalties as Schedule I.

Mr. WHITFIELD. Okay.

Mr. STUPAK. We had done that with Hipynol, which was another one we did earlier, so we are following that same track because the criminal intent here is so heinous when you can put a person unconscious so they cannot help in the rape case, or just by the use of it, as in this case here, people die.

While it may be scheduled under III because of the chemical make-up, we want the penalties to be criminal penalties under Schedule I, the maximum.

Mr. WHITFIELD. You would prefer that it be scheduled as III, but have the penalties as I? Is that correct?

Mr. STUPAK. Correct. Correct.

Mr. WHITFIELD. Is that—

Mr. STUPAK. Because of the legitimate uses involved in these drugs.

Mr. WHITFIELD. Okay.

Mr. STUPAK. There are legitimate uses. It is when it is used illegally or concocted illegally that we have the problem.

Mr. WHITFIELD. Okay. So, Representative Lee, you would not object to that in scheduling it as a III and penalty as a Schedule I?

Ms. JACKSON-LEE. No. I am very happy to work with Congressman Stupak on that collaboration.

Mr. WHITFIELD. Now, are you aware of any funds that would be available at HHS or the Department of Justice or FDA or Drug Enforcement Agency that could be used to educate young people today about this problem?

Ms. JACKSON-LEE. When we first looked at this question, we looked to the Department of Justice, who indicated, or at least let me not represent their indication, but that there would be a revenue stream within the Justice Department for educational and preventative information disseminated that would already be included in their existing appropriations.

Let me not conclude or at least foreclose the need for targeted funds for this legislation on the educational aspect.

Mr. WHITFIELD. Are you aware which particular program the funds are already available at Justice for this purpose?

Ms. JACKSON-LEE. I think they would come, and let me not mispeak, maybe under the community relations aspects, which is an outreach program which might be helpful.

Mr. WHITFIELD. Okay. Now, I know you have been in the forefront on this issue.

Thank you, Mr. Chairman.

Mr. UPTON. Ms. DeGette?

Ms. DEGETTE. Chairman, I think Ms. Jackson-Lee has made a compelling case, and so I will let her off of at least my hot seat.

Thank you. I have no questions.

Mr. UPTON. Okay. The gentlelady from Missouri?

Ms. MCCARTHY. Thank you, Mr. Chairman, for calling this hearing.

Thank you, Representative, for coming forward with testimony. I look forward to working with you toward successful completion of legislation.

I am anxious to hear from the law enforcement panelists who will follow you so that I can better understand while we do change the schedule and the penalties how out in the States we will actually enforce this new law so that it is more than just merely a national intention and a Federal initiative, but within our local law enforcement agencies and within our State government we can make sure that your intentions are carried out.

Thank you, Mr. Chairman.

Mr. UPTON. Thank you.

The gentleman from Texas?

Mr. GREEN. Thank you, Mr. Chairman, and I again will not belabor it because we have a long number of panelists.

I would like to congratulate my colleague from Houston. It is my impression in Texas the State law is possession of GHB is a Class A misdemeanor. Is that correct?

Ms. JACKSON-LEE. It has that level. It is not a felony, which is what we are trying to do.

Mr. GREEN. But selling it obviously is a State jail felony time.

I agree that we need to do something on a national basis, and so, Mr. Chairman, with that I will yield back my time so we can go on, but congratulations.

[The prepared statement of Hon. Gene Green follows:]

PREPARED STATEMENT OF GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE
STATE OF TEXAS

Thank you, Mr. Chairman, for holding this hearing. We must never let down our guard in the fight against drug abuse.

Mr. Chairman, we are here today to talk about drugs that are being horribly misused, these so-called "date rape" drugs. While none of these drugs should be easily available, I think that Congress needs to act to insure that our young people do not have access to these dangerous substances.

In my hometown of Houston alone, there have been numerous cases of young people becoming ill or dying from the abuse of one of the most popular of these drugs, GHB.

In late 1996, a young woman from the Houston area, Hillory Farias, died after someone laced her drink with a lethal quantity of GHB.

GHB, which is an unapproved drug, is currently under investigation as a treatment for narcolepsy. A number of states have already scheduled this drug. Currently, the Federal Drug Administration (FDA) has GHB under consideration for scheduling and the Violence Against Women Act, which I am a cosponsor of, would make this a Schedule I drug.

More recently, the FDA has acted to remove GBL, a chemical "cousin" to GHB, from the shelves of gyms and health food stores, where it was being sold as a nutritional supplement.

GBL is an organic solvent used in, among other things, paint thinner. However, it was easily transformed through simple chemical reactions to GHB.

Mr. Chairman, the FDA has been reviewing scheduling these drugs. I would like to commend them for being proactive in addressing the dangers of these and other drugs.

This Committee, though, has questions to answer. Where the FDA is deliberate, and rightfully so, we have the power to act quickly, swiftly and decisively on these issues.

In our first panel, we will hear from Ms. Jackson-Lee, my colleague and friend from Houston. In 1997 and again this year, she has introduced legislation that would make GHB and other "date rape" drugs, like ketamine, schedule I or II drugs.

Previously, her legislation, for whatever reason, died after being referred to the Commerce Committee. No action was taken on her bill. This is after the Judiciary Committee waived a full hearing for her bill, based on its bipartisan support.

Also, my colleague and friend on this Committee, Mr. Stupak of Michigan, introduced similar legislation, which would have made these drugs schedule III drugs. His legislation, after being referred to the Commerce Committee, died without action at either the Subcommittee or full Committee level.

Mr. Chairman, if these drugs are as dangerous as I think everyone here knows them to be, then why should we wait? Why has our Committee not scheduled these bills for hearings or markups? Why have we not moved these bills to be voted on by the House?

We know that these drugs are powerful sedatives with dangerous side effects. Let's get together and put aside our differences to protect America's youth.

We need to make it as difficult as possible for our children to get their hands on these drugs. Sitting around and doing nothing is irresponsible and dangerous to our children.

Ms. JACKSON-LEE. Thank you very much, Mr. Green.

Mr. UPTON. The gentleman from Tennessee, Mr. Bryant?

Mr. BRYANT. I thank the chairman, and I would say that it is disappointing having to be here to hear this testimony and the fact that this is a subject that we do need to act on and probably should have acted some time ago.

I know all sides on this issue—it is certainly not a partisan one—agree that this is a serious problem, and we have attempted to address portions of this previously, but there is I guess a continuing problem that we are going to hear more about today. I look forward to doing that.

I simply want to close my remarks by thanking my colleague from Texas for the outstanding work that she is doing in this, and also I would add a compliment to her staff. Having lived next door to them for 4 years now, going on our fifth year, we have a great relationship.

Ms. JACKSON-LEE. Thank you.

Mr. BRYANT. Again, I appreciate very much your efforts, as well as your office. Thank you.

Ms. JACKSON-LEE. Thank you very much. Thank you for your help.

Mr. UPTON. The gentleman from Ohio, Mr. Strickland? Do you have questions for—

Mr. STRICKLAND. No opening statement. Thank you.

Mr. UPTON. Do you have questions? Your opening statement, if you want, will be—

Mr. STRICKLAND. No questions.

Mr. UPTON. Okay. Ms. Jackson-Lee, thank you for coming. We appreciated your testimony and your answers.

Ms. JACKSON-LEE. Thank you very much, Mr. Chairman.

Mr. UPTON. We look forward to working with you.

Ms. JACKSON-LEE. Mr. Chairman, let me thank you for this hearing.

My legal mind wants to just conclude by simply saying that this bill, we hope, will go forward as a freestanding bill as I wanted in the last Congress, and any questions to suggest its inclusion in omnibus, let me make sure that we clarify and say that if we were advised by staff to do anything that might have added it to that at that point that might have been the action, but it did not occur so I want to be very clear that we did not have it in that legislation, and we hope that we will move forward in a freestanding bill this session. I want to clarify.

Mr. UPTON. Thank you. Thank you.

Ms. JACKSON-LEE. Thank you very much.

Mr. UPTON. Okay. We are ready for Panel 2.

You are excused.

Ms. JACKSON-LEE. Thank you.

Mr. UPTON. The next panel will be Dr. Felix Adatsi from Michigan State Police; Ms. Jo Ellen Dyer, Assistant Clinical Professor of Pharmacy at the University of California-San Francisco; Lieutenant Paul Bane from the Drug Enforcement Command from the Maryland State Police; Ms. Denise Snyder from the Rape Crisis Center here in Washington, D.C.; Ms. Trinka Porrata from Pasa-

dena, California; and Sergeant Mark Faistenhammer from the Grosse Ile Police Department.

We are hoping that Mrs. Lugene Pruett and her daughter, Candace, from Virginia will be here as well.

MALE VOICE. They are here.

Mr. UPTON. They are here. Okay. Good. Terrific.

If all of the witnesses would take an appropriate seat at the table? If you were here at the beginning, you heard me tell Ms. Jackson-Lee that the common practice in this subcommittee historically has been to take your testimony under oath. Do any of you have an objection to that?

[No response.]

Mr. UPTON. We also have the practice if you would like to have counsel, which you need to let us know about in advance. Anyone have a problem not having counsel?

[No response.]

Mr. UPTON. Okay. If you would stand with me and raise your right hand?

[Witnesses sworn.]

Mr. UPTON. All right. Ms. Pruett, we will start with you.

By the way, for all the witnesses I had the luxury of looking through some of your testimony last night because you complied with our committee rules. Your testimony will be made entirely a part of the record.

We would like you to limit your remarks to 5 minutes. I know for some of you you will either have to read very, very fast, or you will have to summarize it in quite a fashion.

We appreciate your testimony, but we would like to stick to the 5 minute rule.

Ms. Pruett, thank you for coming.

TESTIMONY OF CANDACE PRUETT, ACCOMPANIED BY LUGENE PRUETT, COMMONWEALTH OF VIRGINIA; G. MARK FAISTENHAMMER, DETECTIVE, GROSSE ILE POLICE DEPARTMENT; TRINKA D. PORRATA, DESIGNER DRUG CONSULTANT; JO ELLEN DYER, ASSISTANT CLINICAL PROFESSOR OF PHARMACY, UNIVERSITY OF CALIFORNIA AT SAN FRANCISCO BAY AREA REGIONAL POISON CONTROL CENTER; PAUL BANE, DRUG ENFORCEMENT COMMAND, MARYLAND STATE POLICE; FELIX ADATSI, TOXICOLOGY UNIT, MICHIGAN STATE POLICE; AND DENISE SNYDER, DC RAPE CRISIS CENTER

Ms. PRUETT. Thank you, Mr. Chairman and members of the committee.

Mr. UPTON. If you would not mind, all the witnesses, putting the mike fairly close to you? That would be terrific. Thank you.

Ms. PRUETT. Thank you for inviting me to appear before you today. My name is Candace Pruett, and I am an 18-year-old senior in high school.

Three years ago, I was raped after someone gave me a soft drink laced with Rohypnol, which left me unconscious for several hours. I am appearing here today to warn other potential victims about the dangers of date rape drugs and how they can be misused. I

hope that by telling my story I can help prevent other unsuspecting victims from being assaulted like I was.

One of the most difficult things I had to cope with after I was raped was not knowing what happened to me that night. One of the symptoms associated with the so-called date rape drugs is that you remember very little, if anything, after being given the drug.

Afterwards, I did not know what happened to me. I did not know what I had been given, that I had been given a drug or that I had gone into a coma and could have died. I did not remember being raped, nor did I even know who raped me. The only things that I knew were that something was very wrong, and I wanted to go home. I do know these questions should never have to be faced by any 15-year-old girl.

Luckily, my parents had notified the police, who found me the next morning. I was taken to a hospital where they were able to perform a test which revealed that I had been given Rohypnol.

Additional tests indicated that I had been raped by a 19-year-old man while I was unconscious. The police were able to apprehend this person and later bring him to trial, but it was not until he made two separate attempts, one fleeing the State and one fleeing the country, to avoid his prosecution.

The most frustrating part of the trial was that I could not remember what he had done to me. I wanted to be able to tell the Judge and jury what happened that night, but I could not because of the drug that was given to me.

The forensic evidence, including the tests the police had given me, showed that I had been given Rohypnol and that someone had raped me. The drug, unfortunately, had robbed me of my memories and what happened that night. What he did to me also robbed me of my childhood. Going through the trial took away my innocence and forced me to become a grown up.

I hope that by appearing today, I can let other people know about the danger that exists because of the sick people who use these drugs to assault unsuspecting victims. I also want to reassure other girls who may have been drugged and assaulted to immediately get help.

An entire network of people, including counselors, police and prosecutors helped me during the trial. By seeking such assistance, other victims can get the help they need and hopefully work to put their rapists in jail.

I want to thank the chairman for giving me the chance to tell my story today and hope that the committee can find some way to prevent what happened to me from ever happening again.

Thank you.

[The prepared statement of Candace Pruett follows:]

PREPARED STATEMENT OF CANDACE PRUETT

Mr. Chairman and Members of the Committee, thank you for inviting me to appear before you today. My name is Candace Pruett and I am an eighteen year old high school senior. Three years ago, I was raped after someone gave me a soft drink laced with Rohypnol, which left me unconscious for several hours. I am appearing here today to warn other potential victims about the dangers of date rape drugs and how they can be misused. I hope that by telling my story, I can help prevent other unsuspecting victims from being assaulted like I was.

One of the most difficult things I had to cope with after I was raped was my not knowing what had happened to me that night. One of the symptoms associated with

the so-called date rape drugs is that you remember very little if anything after being given the drug. I did not know that I had been given a drug, or that I could have gone into a coma and died. I did not remember being raped, nor did I even know who raped me. The only things that I knew were that something was very wrong and that I wanted to go home. I do know that these questions should never have to be faced by any fifteen year old girl.

Luckily, my parents had notified the police, who found me the next morning. I was then taken to a hospital where they were then able to perform a test which revealed that I had been given Rohypnol. Additional tests indicated that I had been raped by a nineteen year old man while I was unconscious. The police were able to apprehend this person, and later bring him to trial, but not until after he made two separate attempts to flee the state to avoid prosecution, once getting as far as London, England before being brought back to stand trial.

The most frustrating part of the trial was that I could not remember what he had done to me. I wanted to be able to tell the judge and jury what happened that night, but I could not because of the drug that I had been given. The forensic evidence, including the tests that the police gave me, showed that I had been given Rohypnol, and that someone had raped me. One of the scariest things about date rape drugs is that they are absorbed very quickly by your body. If a test for the drug is not performed right away, it may only detect very small traces of the drug or it may not even show up at all. Another problem is that not all laboratories even know how to test for date rape drugs. Before I went to the hospital that morning, my mother had called several labs, but could not find any labs who were willing or knew how to test for date rape drugs.

The drug I was given unfortunately had robbed me of my memories of what happened that night. What my attacker did to me also robbed me of my childhood. Going through that trial took away my innocence and forced me to become a grown-up.

I hope that by appearing today, I can let other people know about the danger that exists because of the sick people who use these drugs to assault unsuspecting victims. I also want to reassure other girls who may have been drugged and assaulted to immediately get help. An entire network of people, including counselors, police and prosecutors helped me during the trial. By seeking such assistance, other victims can get the help they need and hopefully work to put their rapists in jail.

I want to thank the chairman for giving me the chance to tell my story today and hope that he and the Committee can find some way to prevent what happened to me from ever happening again.

Mr. UPTON. Thank you very much.
Sergeant Faistenhammer?

TESTIMONY OF G. MARK FAISTENHAMMER

Mr. FAISTENHAMMER. Good morning. I am a Detective/Sergeant with the Grosse Ile Police Department assigned to a Michigan State Police managed drug unit known as DRANO.

DRANO is a consortium which is made up of 19 member communities, and we police south of Detroit, Michigan. The unit is administered and managed by the Michigan State Police. My role there is an assistant crew leader and an investigator of controlled substance distribution in the metro Detroit area.

During the past 2 years, the unit itself has noted an increase in the illegal distribution of GHB and GBL, a component of GHB. We often refer to it out on the street as scoop. Unit members are aware and have assisted in several investigations in the area 19 member departments, one of them being Brownstown Police Department, where they have had in the last year and a half 13 complaints of persons being scooped out of bars; that is, given GHB without their knowledge in the bar, someone pouring it in their drink, either by rescue runs or complaints the following morning.

One of the people involved was a 15-year-old who was given GHB without her knowledge in May, 1997. Sex acts were done to her in

an unconscious state, and the offender has been successfully prosecuted in Michigan and is in jail currently.

The Riverview Police Department, another member of our consortium, has reported three confirmed suspicious deaths from GHB. The persons involved were body builders. Laying on the floor next to them were bottles of clear liquid. At the time, neither the officers involved in the case nor did the Wayne County Prosecutor's Office know to even look at GHB as the culprit. Although it is not the listed cause of death, information that the DRANO unit has been able to develop makes it more than just the suspected culprit in the cases.

Cases that officers have investigated have been hampered by the fact that the body actually produces GHB; that in our bodies GHB is contained in there at all times. Additionally, it has been reported that GHB dissipates from the body within 24 hours, making it tough to find on autopsy.

At the same time, the DRANO unit has numerous cases that are open, but one of which currently has 12 suspects that just in our 19 member community has been mixing and distributing GHB in the area bars.

Investigations from Woodhaven Police Department, as well as Gibraltar and Southgate Police Department, all describe deaths, people being scooped out of bars. Again, I refer to scoop as the act of placing it without your knowledge.

The Michigan State Police DRANO unit, through investigations, believes that GHB is a drug of abuse that we need your assistance on. We have been finding it in our gyms. Body builders utilize scoop as a fat-burning process, as well as a method for getting high without the calories of alcohol.

We also find it inside the dancers at many area bars who use it because they in turn can get high. They will place one capful of this clear liquid, and they report that it equals approximately 12 beers.

Users report that they become extremely addictive to the drug. We have arrested people who we have had a great deal of problems in incarceration in that they have had to be woken up and actually needed to take GHB four or 5 hours into their sleep. They report to being addicted to GHB 24 hours a day.

The biggest problem for us at the Michigan State Police is that there are no test kits available. Since it is not an illegal drug, companies are not pursuing the test kit. When we run into it on the street, we cannot develop probable cause. There is no immediate way to test for GHB in the containers that we are running into.

When I say just GHB, I also mean GBL. In addition, officers have been buying large quantities of GBL. We have learned that GBL is manufactured by the body into GHB. GBL is a component in making GHB, so what has been occurring with us is that we have a group of attorneys in the metro Detroit downriver area who have been advising their clients to not sell GHB, but to distribute GBL and a person's body will make it for you, so the analog statute is very important. We fell a bit short in Michigan State law on that.

As a member of the Grosse Ile Police Department, we have been working in conjunction with the Wayne County Prosecutor's Office in the investigation of the death of a girl who came to Grosse Ile

in the middle of the night and with her friends was also scooped out. This girl recently died in January of this year.

[The prepared statement Sergeant G. Mark Faistenhammer follows:]

PREPARED STATEMENT OF G. MARK FAISTENHAMMER, DETECTIVE SERGEANT, GROSSE ILE POLICE DEPARTMENT, MICHIGAN STATE POLICE, S.E.C.I.D. DRANO UNIT

I am a D/Sgt. from the Grosse Ile Police Dept., assigned to the Michigan State Police, Downriver Area Narcotics Organization (DRANO). DRANO is a consortium made up of 19 member communities, which is located south of Detroit, MI. The unit is administered and managed by the Michigan State Police. My role at DRANO is that of Assistant Crew Leader and an investigator of controlled substance use and distribution in the metro Detroit area. During the past two years the DRANO unit has noted an increase in illegal use and distribution of GHB which is BUTYRO-LACTONE (GBL) plus SODIUM HYDROXIDE equals GHB, with the street name of "scoop". Unit members are aware and have assisted in investigations with several members of other departments to include the Brownstown Twp. Police Dept. who, through investigations, have at least 13 "scooped" victims in the past one and a half years. "Scooped" is what is referred to as the placing of GHB in someone's drink without their knowledge. Example: If you were at a bar and someone did place GHB in your drink, people on the street refer to you as being "scooped". One of Brownstown Twp. cases involved a 15 year old girl who was given GHB without her knowledge and therefore was "scooped" in May 1997, and sex acts were done to her in an unconscious state. The offender has been prosecuted and is currently in jail.

The Riverview Police Dept., an additional member of the downriver community, reports at least 3 confirmed suspicious deaths where GHB is the suspected culprit. The persons involved were body builders, and lying on the floor next to them was a bottle with a clear liquid inside. At that time, neither officers knew about GHB nor did the Wayne County Medical Examiner. The cases were not noted GHB deaths, however information received by DRANO officers makes GHB more than the suspected culprit.

Cases that this officer has investigated have been hampered by the fact that the body produces GHB, not only after death, but contains some GHB in it at all times. Additionally, it is reported that GHB will dissipate from the body within 24 hours, making it impossible to find during an autopsy. At this time, in just one of the DRANO units open cases, there are at least 12 suspects that are responsible for the transportation, mixing and distribution of GHB into our area. Investigators from the Woodhaven Police Dept., another downriver community, reports five unexplained deaths. In the past year at least two juveniles have been "scooped" in Woodhaven and admitted to the hospital for an overdose. Gibraltar Police Dept. and Southgate Police Dept. also reports incidents of "scoop" in their area.

The Michigan State Police DRANO Unit, through their investigations, have learned that GHB is a drug of abuse, which has been on an increase in the area gyms. Body builders utilize "scoop" to assist them in their fat burning process, as well as a method of getting high without adding the calories of alcohol. Body builders seem to equate one pop bottle cap full of GHB equaling the high of approximately 12 beers. DRANO officers have located GHB mostly in pop bottles, however numerous water bottles and containers have been discovered. This same formula has been utilized by dancers in adult bars. The dancers abuse GHB because it gives them the alcohol high without the calories. This officer has been involved in investigations where persons utilizing the GHB have been severely addicted to the drug. Users report that they will take GHB, go to sleep at night, and approximately four to five hours later wake up with a severe need to utilize GHB again and remain on the drug throughout the day and night (24 hours a day). In spite of the fact that these abusers have been in drug rehabilitation, they continue to come out and go right back to utilizing GHB.

One of the biggest problems for the Michigan State Police DRANO Unit has been the fact that there are no test kits available and that the Michigan State Police lab is having problems with the analysis of GHB. Most any material the lab would use to break down and test the GHB also manufacturers it. In addition, officers on the street brought in numerous bottles and containers from inside vehicles, which have a possible odor of being GHB; but have no method of testing the liquid on the street. Therefore, we have established a great need to develop a field test kit. DRANO officers have also run into a major problem in that GHB components are legal. An example would be GBL, which is one of the major components needed to make GHB. It has been learned that if GBL, is consumed by itself the body will then produce

GHB and the same high will be accomplished. Officers have seized multiple gallons of GBL and cases cannot be brought against the culprits because it is not GHB, but in fact GBL. DRANO officers are finding abuse of GHB and GBL in various locations such as the local bars, adult dancing bars, gyms, high schools, therefore by persons from all walks of life. Information from confidential sources, as well as defendants themselves, have stated that lawyers are advising persons engaged in sales of GHB to only deal in GBL, a GHB component. The attorneys are advising their clients that there is no federal law prohibiting GBL and that state law in the State of Michigan does not cover GBL only GHB. Officers in the DRANO unit have several cases where only GBL has been acquired from the suspects. I have been a party to an investigation assisting the Grosse Ile Police Dept. in an incident where juvenile girls were "scooped" or possibly given GBL without their knowledge. The suspects in this particular case admit that they deliberately gave the girls GBL, knowing that their bodies would convert it into GHB and did so without the knowledge or consent of the girls. Both of the juvenile girls given the drug were admitted to the hospital in an unconscious state. The outcome was one of the girls was eventually pronounced dead at the hospital and the second recovered from a severe overdose. The Grosse Ile Police Dept., working with the Wayne County Prosecutor's Office and the Michigan State Police, should be acquiring warrants within a couple of days but word from the prosecutor's office is that it will be a death by poisoning charge as opposed to a charge involving GHB or GBL.

In the prospective of officers investigating these types of cases at the MSP DRANO unit, the inadequate laws, as well as the nature of GHB interacting with the body, makes them difficult if not impossible to prove. Our crime labs are having a difficult time analyzing GHB, the fact being if you take GBL and place it in the body, the body itself will manufacture GHB and the person will get high anyway. The fact that there are no test kits available for officers on the street who may encounter GHB or GBL, and that the drug dissipates in the body, blood, or urine samples within 24 hours whether the subject is alive or deceased, makes the investigator's task to be more than just cumbersome. Officers can only rely on assistance from the FDA as opposed to being able to call the Drug Enforcement Administration, FBI, or United States Customs and get the assistance needed from agencies set up to deal with illicit drugs.

Mr. UPTON. Thank you.

Folks here in the room know the buzzer has sounded, which means we have a vote in progress. Mr. Burr has gone over to vote. He will relieve me soon, but we will continue with the testimony since the witnesses have started.

Ms. Porrata, you are recognized for 5 minutes.

TESTIMONY OF TRINKA D. PORRATA

Ms. PORRATA. Thank you. I have waited a long time to be here for this day. I normally teach an 8-hour class, so I will try to condense it.

I brought these because I want you to see just how easy it is to hide GHB. This is all that a rapist needs to commit a rape with GHB; nothing more than a little eyedropper full. The guy who just got 77 years in California for rape with GHB started his career with just an eyedropper in his pocket.

We see it now in little Bianca bottles, food coloring and vanilla bottles. They are nice, flat bottles. They fit in a man's pocket nice and easy when he goes to the club. A videotape of suspects in Hawaii were using food coloring bottles for that purpose.

Any container that will hold a liquid. It seems like an empty container. No. He just drank the GHB out of it. Mouth wash bottles, water bottles. I commend the officers who found this one. It was a woman's hair spray bottle, purse size, full of GHB, taken into a club, and we have seen it in kids' bubbles.

There is not any container that is not fair game. It is a clear liquid. It can be colored to look like the mouth wash or the Gatorade

bottle that it is in. It does not matter. It is just that easy to hide, and law enforcement is missing it.

You have absolutely no clue how big this problem is. The rape statistics are minute compared to what really is going on. For every rape victim out there, there are hundreds of overdoses that were caused by voluntary ingestion. There are dozens and dozens of kids deeply, deeply addicted to this drug. It is much more harder to get off of than heroin.

I get e-mails from kids who say I shook heroin on my own. I shook cocaine on my own. I shook nicotine. Why can't I get off of GHB? It is that hard for them to get away from.

It is hard to believe that if your kid is running around, if you have a 15-year-old son, a 25-year-old son. A 30 year veteran of the Los Angeles Police Department, his son walked around the house sipping from a water bottle. He thought it was kind of odd that he sipped from it. You normally drink from a water bottle. His son had a deep, deep, serious addiction to GHB right in front of him, and he knew nothing about it until he read my training bulletin.

The scope of this problem is humongous. If you really look at it, it is far bigger than rape. Rape is a serious issue, but we are missing the boat. This is a serious drunk driving issue. We have had at least a couple of deaths from it. You have to understand that for every death that occurs, there are more that just were not caught by the coroner. For every drunk driving case, there are hundreds more that were not caught.

In California, a young man made it two and a half times through the criminal justice system without GHB surfacing. He was convicted for drunk driving with actually a very low blood alcohol, but his aggression was so intense that he did get convicted. They thought it was alcohol only.

The second time he had a very low BA, and he got through as a reckless driver because again a very low BA, a negative for any other drugs in the standard drug screen, and yet the third time when he killed somebody he got through the prelim as a drunk driver only, alcohol only, but the word GHB came up during the investigation, and we were able to get it tested and determine that he was a chronic GHB user. We had testimony to that effect. He pled guilty. He is doing 14 years in California.

There are hundreds more cases like that out there, but the officers did not notice the water bottle on the car seat or the mouth wash bottle on the floor of the car. They would have no way of knowing. The training is totally inadequate. Every single place that I teach—every single place—within 2 weeks they are arresting people for GHB.

I want to stress the biggest problem I have had in doing the legislation in California and other States is the total misunderstanding and confusion. This drug has no approved medical use. There is no approved medical use for GHB.

Your action, if you put this in Schedule III, does not make this drug available as a prescription drug. Orphan Medical would like to get their foot in the door by you doing that, but by making it Schedule III you are not approving this drug. The FDA still has to do that.

The failure of the Federal Government to take action on this drug has caused additional confusion in the States. The States, too, when they look at this drug go whoa. We have this drug company here telling us it is like a good drug, and they have these people that want to come and take this drug.

That is not what determines what schedule you put it in. I am personally bothered as an officer who just retired and as a citizen that the drug scheduling concept is now being violated based on what the drug companies want.

Rohypnol. There is no approved medical use for Rohypnol, yet it is in Schedule IV. I plead with you to put these drugs where they belong. These are unapproved drugs. There is no medical use. If and when there is ever a medical approval, then you can move them down.

[The prepared statement of Trinka D. Porrata follows:]

PREPARED STATEMENT OF TRINKA D. PORRATA, DESIGNER DRUG CONSULTANT

Law enforcement is literally drowning in the "standard" drugs of abuse—cocaine, methamphetamine, heroin and marijuana. Law enforcement is now *only beginning* to realize that we are far behind in accessing the depth and breadth of the current drug problem. As a whole, law enforcement has failed to notice that 13 of the top 20 drugs of abuse are prescription medications. Very few agencies have *any* resources assigned to pharmaceutical diversion issues. Meanwhile, street drug "news" (whether accurate or inaccurate) now travels as fast as the click on an icon. Crime laboratory statistics re seizures of trendy drugs like MDMA (Ecstasy), gamma hydroxy butyrate (GHB), ketamine (Special K) and flunitrazepam (roofies or Rohypnol) are minute compared to statistics for the old standard drugs. But, after 25 years as a police officer, seven years as a narcotics officer and three years fully immersed in the issues of these trendy drugs, it is my opinion that those figures do not reflect reality. The trendy drugs have been considered to be off in some small segment of society, such as the RAVE crowd or the wildest and highest echelon of the Hollywood set, and thus not a big issue.

But, while we weren't looking, those trendy drugs have become mainstream. The truth is, the *average* police officer, the *average* narcotics officer, knows very little about prescription drug abuse and even less about violations by the doctors and pharmacists who knowingly feed this market. The *average* police officer/narcotics officer knows very little about ketamine, flunitrazepam, GHB and MDMA.

These now mainstream drugs circulate in subcultures and environments where law enforcement either has limited contact or doesn't expect to deal with drug abuse issues, such as: 1) in RAVE/Goth gatherings, college/high school gatherings, on any beach, 2) in health clubs/gyms and on the high school playing field and in after-game activities of the athletes and cheerleaders, 3) now predominant in many restaurants and clubs catering to 21-35 year olds with college degrees, driving fancy cars, 4) in any stripper or exotic dance club, and 5) in the hands of sexual predators.

None of these environments are the focus of narcotics enforcement efforts. In fact, most agencies avoid RAVE gatherings like the plague unless called in to handle the aftermath of civil disturbances or medical emergencies.

These drugs are becoming more common in drunk driving and sexual assault cases, though our standard drug screening does not include many of them. Some present unique testing issues, yet we have not adequately responded by modifying our testing and rape investigation protocols and improving our testing capabilities.

One would expect the federal Food and Drug Administration (FDA) to take the lead, providing prompt and accurate information regarding existing and developing drugs and to be definitive as to current/potential licit status of any drug and its abuse potential.

One would expect the Drug Enforcement Administration (DEA) to be cutting edge on issues of illicit trafficking, manufacturing and abuse as it develops. But in my experience, their roles have been quite passive, not active. Thus, we are here today talking about drugs that are in reality 25-30 years old and have all been abused to varying degrees throughout that existence. GHB is perhaps the youngest in terms of discovery by abusers, though it is now literally exploding around the world.

Many people do not understand the difference between state and federal laws; it is particularly confusing when it comes to drug scheduling. Many do not understand

how a drug can be scheduled in a state, but not federally, and vice versa. There is a logical pattern for how drugs are to be scheduled. This is defined by terms such as “approved medical use” and “abuse risk.” I don’t see the term “drug company’s desires” in the formula, though I have seen clearly that their desires do drive much of what happens in recent drug scheduling efforts.

In actuality, there have been several dedicated FDA and DEA agents, chemists and doctors working on these specific drug issues. But, they have not had full support from management and/or issues become lost in the tangle of bureaucracy and politics.

KETAMINE

Ketamine clearly has legitimate medical uses and has endured in the legitimate medical world far beyond PCP, its chemical cousin. But we have known for decades that it has a high abuse factor, with flashbacks worse than PCP. One year ago, while trying to upgrade mere possession charges for ketamine in California, I was told that the volume of legitimate medical use of ketamine had not changed significantly, but manufacturing of ketamine was up 40 percent. If that is true, that should be a dramatic indicator of the abuse level of ketamine in this country at this moment. Yet ketamine is not federally scheduled. DEA has someone “tracking” ketamine abuse, but it is a rather passive role to date. I’ve personally seen nothing on this abuse issue actively emanating from the FDA.

FLUNITRAZEPAM

Flunitrazepam (Rohypnol, aka roofies) is already federally scheduled (Schedule IV), and from a law enforcement viewpoint, I can force myself to “settle” for that since at least something can be done when this drug is encountered. But philosophically, it bothers me because it violates the drug scheduling concept and is a clear case of where big money has won, and the poor folks (victims and law enforcement) have lost. Even the American medical community has no interest in this drug. Flunitrazepam *is* a Schedule I drug by definition. It is not approved for medical use in the United States and has a very high abuse factor. There is really nothing this drug does that other drugs don’t do as well and with less side effects. It seems from my exposure that much of the worldwide *use* of flunitrazepam is *abuse*, especially by those addicted to other drugs who merely use it as a facilitator (to extend their heroin) and/or as a transitional drug (to cushion the crash from stimulant abuse). I’m not concerned that the manufacturer doesn’t want to give up this drug worldwide since it generates more than \$100 million per year for them. I’m not concerned with their fears that Schedule I in the U.S. might cause a domino effect and cause other countries to gradually drop it. So be it. The money spent on flunitrazepam would most likely transfer to other benzodiazepines. It is my personal opinion that flunitrazepam is Schedule IV for purely political reasons.

GAMMA HYDROXY BUTYRATE (GHB)

Thirty years ago, a doctor researched GHB for a major drug company and found that it caused virtually all lab animals to vomit and many to convulse. Brain waves went into an epileptic seizure mode. That drug company walked away from it, and that doctor predicted that GHB would become a horrible drug of abuse. He is only surprised that it took so long to happen. Ironically, he recently retired from the FDA, and yet the FDA has not been a leader in the fight against GHB. In fact, once DEA documents on GHB went to FDA (HHS) for review, it seemed to me that time stood still. In the late 80’s when GHB was being sold over the counter at “health food” stores (a strange name for a place that sells bizarre chemicals with little or no confirmation as to content or actual efficacy) and overdoses became an issue, the FDA merely banned GHB from OTC sales. It was not controlled. While the FDA criminal investigators could make arrests for manufacturing and interstate violations, DEA agents had no power and thus no interest in this drug. A few federal manufacturing cases were indeed handled, albeit a very long-term process. There are actually very few FDA criminal investigators per area, making it difficult to engage in the full-scale surveillance/investigation often needed on a criminal case. DEA agents could not help them. Unless it was state controlled, most state/local agencies might not help them either.

Overdoses continued to occur and in fact to start a significant uphill trend in 1993, especially after highly publicized death of a youth idol who MAY have ingested GHB, along with lethal doses of others drugs. Still no control. Meanwhile, DEA has had drug diversion professionals tracking GHB for years. One doctor was researching both GHB and flunitrazepam. Sometime after June of 1996, it became

impossible for one person to track both, and a second doctor was assigned to track GHB. Even with the all the material they amassed, DEA formally took no aggressive action. While in California the Los Angeles Police Department actively sought to initiate legislation, the first federal legislation came not from initiation by DEA, but from Congresswoman Sheila Jackson Lee, in response to the death of a 17 year old in Texas.

In my travels, I realized that there was no reporting system in place all this time for these drugs, especially GHB; therefore, there are not accurate records of overdoses. There is no actual reporting system for arrests or seizures or deaths. Statistics depend primarily on word of mouth, by polling of agencies or other hit/miss methods. In early 1997, DEA was saying there were six or seven GHB related deaths. I felt strongly that this was a bizarre understatement, and the DEA doctors agreed. Within a few months, the figure jumped to more than 20. Many of those "new" deaths had already taken place; they just weren't being "reported" to anyone. It became apparent that if someone simply called every coroner in the United States, the figure would simply continue to rise. That isn't even allowing for cases missed because the vast majority of coroners and toxicologists had never heard of GHB. Furthermore, that death list wasn't initially even acknowledged publicly by the DEA. It was like an in-house secret.

Neither the FDA nor DEA has taken a formal leadership role in developing testing skills and making them available to law enforcement, toxicologists and coroners. Some federal employees taking an interest in developing and sharing expertise seemed to be stifled by superiors.

Neither the DEA nor FDA speak openly to the news media, causing more confusion and misinformation. On December 31, 1996, Los Angeles experienced a night of horror, caused by 1,4 butanediol, an active analog of GHB. A RAVE concert turned into a mini-riot after more than 50 people suffered medical problems after ingesting "FX." Eight LAPD vehicles suffered damage and a 17 year old had a heart attack. We were baffled that FX contained no controlled substance and was negative for GHB. We had no ability to test further; and the case was turned over to the FDA. The news media wanted to help up with this, as they had been doing with flunitrazepam the year before. The FDA simply refused to release the test results. A private lab had also tested the product and identified the GHB analog, 1,4 butanediol. But, the FDA continued to refuse to assist the media. One local radio newsmen, who had the private lab's results, told me he was livid that FDA press relations personnel (both in California and Washington) refused to even provide him with basic information on 1,4 butanediol. He said he wasn't even asking for them to confirm that this matched their test results. Federal prosecution of the FX maker was very slow, resulting in minimal publicity of the finale.

FDA agents in California who developed expertise in GHB seemed to be discouraged from spending time on such cases. Keeping tabs on one GHB trafficker who supplied GHB from Hollywood to the RAVE parties in the California high desert where a 15-year-old died (January 1996) from ingesting GHB, FDA agents were aware of ongoing purchases of jug after jug of the precursor, gamma butyl lactone (GBL). It would be 1½ years before the blood of the dead 15 year old was tested for GHB and a criminal investigation actually launched. Once the case actually got underway, it has been handled aggressively and I understand is now pending. It would be October of 1997 before other members of that organization were arrested by the LAPD Clandestine Lab Squad in a separate incident. By then, GHB was illegal in California, and the Squad worked with the FDA agents to achieve a state-level case. Approximately three gallons of GHB was seized. There have also been nine and ten gallon seizures in California. Bear in mind, a 16 ounce water bottle holds approximately 80 capfuls, each capful being a "dose."

It is imperative to note that placing GHB Schedule I will not impact the orphan drug research underway for narcolepsy. If—and it is a very big if—GHB is ever approved for any use, it can easily be dropped to Schedule II at that time. I have interviewed narcolepsy researchers and read the literature. It is my personal opinion that GHB will never be approved for medical use. At best, it may be some distant cousin, safer and longer acting, and it is probably years away. One leading GHB/narcolepsy researcher apologized to me for a story aired on national news in late 1996, calling GHB the wonder drug. He said he had been interviewed for three hours and stressed repeatedly how dangerous this drug is. He said he keeps only one day's supply in his clinic for fear of diversion. He said that GHB was at least six to eight years away from qualifying for Schedule II consideration. Then Orphan Medical began lobbying to keep GHB from being controlled, and this doctor suddenly changed his tune. I was contacted by a man who said he was the president of Orphan Medical, trying to change my stance. I was amazed that he could not an-

swer some very basic questions about this oh-so-safe drug he was pushing so hard to protect.

The FDA has been more outgoing in recent months in response to problems arising from over the counter marketing of GHB's precursor and dangerous analog, sold as Blue Nitro, Remforce, Renewtrient, Revivariant, Re-energize and Firewater. But there is so much more to be done on the GHB topic in terms of legislation, education of law enforcement and public awareness.

1) Accurate and immediate federal legislation to control GHB as a Schedule I drug needs to be finalized. This will also provide guidelines to assist the more than 30 states still needing to complete legislation and will hopefully result in more continuity. Currently it is listed in Schedules from I to IV in the states who have made an effort.

2) Accurate and prompt training information on this drug and improved drug testing protocols need to be provided nationwide to assure enforcement intervention in the trafficking and abuse of GHB. This drug has numerous active analogs, making testing and standardized knowledge throughout law enforcement critical. In California a young man made it through the criminal justice system 2½ times as an "alcohol only" drunk driver, when in fact, he was an alcohol and GHB drunk driver. Each time his bizarre behavior didn't match his low blood alcohol (BA). Standard drug testing showed no other drugs. Fortunately his first case resulted in a conviction, despite the low BA, setting him up for more serious punishment later. His second case was treated as a "reckless" because of a very low BA, though with bizarre behavior. The third time, just a few weeks later, an innocent 27 year old died instantly, his car exploding on impact by the suspect's vehicle. He has since pled guilty and is spending 14 years in prison. The victim's mother, who described him as "a good kid who loved basketball and was never a problem," would love to have been here today to express her pain to you.

3) Education/publicity is crucial in counteracting the widespread misinformation about GHB and its analogs. Approximately 95 percent of the information on the Internet about GHB is inaccurate and misleading. About six months ago, I would have said 99.9 percent of it was inaccurate. The change has been made mostly by citizens and doctors trying to make a difference, and especially by one website in particular (www.ashesonthesea.com/ghb/), maintained by the parents of a 25-year-old casualty of GHB. GHB websites overwhelming claim that GHB is safe, non-addictive and can cure all things, besides being a lot of "fun." GHB is truly the Child of the Internet. The truth is, GHB is dangerous, addictive and harder than heroin to shake. I have learned this not from the FDA, but from the streets and from the referenced website. The site is currently being overwhelmed by comments from those who can't shake it and those who have had or seen horrid experiences from it. The input is coming in from all over the United States and Canada. For those of you with any doubts about how dangerous and widespread this drug is, the commentary pages of that site will forever erase your doubts.

GHB is the easiest drug on earth to make and the hardest drug to recognize.

What parent would suspect that seeing their son or daughter sip repeatedly from a common sports water bottle might foretell a deadly addiction?

Mr. UPTON. Thank you. We have a little bad news from the House floor in that when this vote is over, we have 10 minutes of debate, and then we will have five votes bang, bang, bang.

I think it would be best at this point to recess until probably about 11:30 a.m. So we will give you a little hour to visit your Member of Congress, watch what is going on on the floor, but we will come back at as close to 11:30 a.m. as we can.

[Whereupon, the subcommittee recessed, to reconvene at 11:30 a.m., the same day.]

Mr. UPTON. Thank you all for being back here promptly. Our votes are over now for a little while, so we will resume with testimony by Ms. Dyer.

TESTIMONY OF JO ELLEN DYER

Ms. DYER. Thank you. Mr. Chairman and members of the House committee, I am appearing before you to discuss my concerns about the potent new drug of abuse, gamma hydroxy butyrate, known as GHB.

The California Poison Control System has been assisting in identification and management of poisonings due to gamma hydroxy butyrate since we first identified the syndrome and reported cases to the State Department of Health and the FDA in 1990.

We reported the severe effects from its misuse. It is used as a nutritional supplement for body building, a drug of abuse for euphoria, a purported sexual enhancing drug and as an incapacitator for assault.

In 1998, we consulted on 232 cases of poisoning in California from GHB and its related products. I will tell you about some of our patients' experiences.

A 26-year-old female poured GHB into a glass to drink as an appetite suppressant for dieting. Almost immediately, she felt nauseated and went in the bathroom to vomit. She lost consciousness, fell on the floor, cut her head. Her sister witnessed seizure like jerking. She was vomiting. She was incontinent.

When the ambulance arrived, she was comatose, agitated, vomiting. Her heart rate had slowed. Airway support was necessary because she was vomiting while she was unconscious. She required admission overnight to the critical care unit. The life threatening clinical effects of GHB can cause an abrupt loss of consciousness, profound coma, and they can compromise breathing.

A 23-year-old female college student and body builder was taking three to five capfuls of liquid GHB for 1 year for the alleged anabolic effects. Over a 6-week time period, she increased her dose and frequency to every 3 hours around the clock to prevent the anxiety, tremors and insomnia she experienced without it.

She was admitted to a medical detoxification center, and GHB was discontinued. She became increasingly paranoid, experienced vivid hallucinations, disorientation and delirium. Her rate increased.

As this delirium syndrome progressed, she was transferred to an intensive care unit under heavy sedation and physical restraint to prevent injury, muscle breakdown and uncontrolled fever. She experienced a withdrawal course over 9 days. Frequent ingestion of GHB can lead to addiction and a severe, life threatening withdrawal syndrome.

A 29-year-old woman went to a party with her date. Her last memory was dancing with him. She awakened to find a man assaulting her. He claimed that her date had passed out and that she had consented to have sex with him. The response, when she called 911, was that without a description of events and no physical evidence of force, there was nothing that could be done.

A second report from that same location established a pattern. The victim identified the drug that was used. A search at that location revealed greater than 2,000 photos, videos, recipes to make GHB and margarita salt containers of GHB. Some of the victims that were identified from those photos did not even realize they had been raped.

This serial predator, a 38-year-old male, was convicted on 43 counts, receiving 77 years for sexual assaults and poisoning. He had placed GHB from an eyedropper carried in his shirt pocket into the drinks of his unsuspecting victims. GHB is easily used to incapacitate a victim, allowing physical or sexual assault.

A 71-year-old man, taking one teaspoon of gamma butyrolactone nightly for sleep, mistook the bottle at his bedside for water, and he drank some. Within 30 minutes, his wife found him slumped in a chair unconscious. She called 911. Paramedics found him not breathing.

In the emergency department, his depressed breathing was supported with mechanical ventilation. His heart rate was slow at 40 beats per minute, and he was profoundly unconscious. He was admitted to intensive care overnight.

The label on that product instructed, "Insure that those around you are aware that you may be unarousable and that this is normal. Unless drugs or alcohol have been ingested, the only treatment necessary is to sleep it off." Following these instructions could have been fatal.

GHB and its precursors, gamma butyrolactone and 1,4-butanediol, are promoted for many unsubstantiated health claims, while denying the dangers of their use. GHB and their precursors have demonstrated their abuse potential, their dependence liability, and they have been used to commit assault.

GHB and its precursors are a health hazard, and I want to emphasize the importance of placing GHB in a schedule that will stop the proliferation of these analogs also.

Thank you.

[The prepared statement of Jo Ellen Dyer follows:]

PREPARED STATEMENT OF JO ELLEN DYER, PHARM.D. CSPI, SR. TOXICOLOGY MANAGEMENT SPECIALIST, CALIFORNIA POISON CONTROL SYSTEM, SAN FRANCISCO DIVISION, ASSISTANT CLINICAL PROFESSOR OF PHARMACY, UNIVERSITY OF CALIFORNIA SAN FRANCISCO

Mr. Chairman and members of the House Subcommittee on Oversight and Investigation: I am appearing before you today to discuss my concerns about a potent new drug of abuse gamma hydroxybutyrate, GHB. Individual states have legislated GHB as a controlled substance due to the severe health effects from its misuse as a nutritional supplement for bodybuilding, a drug of abuse for euphoria, a purported sexual enhancer and an incapacitator for assault.

The California Poison Control System has been assisting in the identification and management of poisonings due to gamma hydroxybutyrate and its related products since we first identified the poisoning syndrome and reported the cases to the California State Department of Health and the FDA in 1990. Since that time we have continued to track, identify and report the new trends in abuse of this drug. See the attached reference list of our published medical literature on this subject.

The primary dangers of GHB

1. The life-threatening clinical effects of GHB can include an abrupt loss of consciousness, profound coma, and compromised breathing.
2. Frequent ingestion of GHB can lead to addiction and a severe life-threatening withdrawal syndrome.
3. GHB is easily used to incapacitate a victim allowing physical or sexual assault.
4. GHB and its precursors, gamma butyrolactone and 1,4-butanediol, are promoted for many unsubstantiated health claims while denying the dangers associated with their use.

The life-threatening clinical effects of GHB can include an abrupt loss of consciousness, profound coma, and compromised breathing. GHB is a powerful anesthetic drug, a depressant. It was developed in France in 1960 and evaluated as an anesthetic because it reliably induced rapid onset of coma. However, lack of pain relieving properties and unwanted side effects such as delirium decreased enthusiasm for its use. Although GHB was considered safe when used under direct supervision of a physician in surgical procedures, side effects still occurred. These side effects slowed heart rate; muscle jerking; agitation; and vomiting were controlled with the addition of other medications. GHB was not used as an anesthetic alone nor was it used without qualified medical supervision.

GHB now is abused in unsupervised situations where fatalities have occurred from the abrupt loss of consciousness resulting in injury, suffocation when the airway is blocked, and depressed breathing. Since 1995 GHB has been implicated in the deaths of at least six young people, ages 15-34, in California. Because blood tests for the presence of GHB have only recently become available, many fatalities have not been recognized as being caused by GHB, and this number may represent only the "tip of the iceberg".

The clinical effects of GHB are well known:

- Profound Coma—not just a deep sleep. Noise or pain cannot awaken you
- Myoclonus—involuntary muscle jerking
- Bradycardia—slow heart rate
- Respiratory depression—slowed or stopped breathing
- Loss of airway protective reflexes that keep breathing passages open and fluid and vomit out of the lungs
- Vomiting
- Incontinence—involuntary passage of urine or stool
- Chemical burns from incorrect manufacture using alkaline chemicals

GHB became a controlled substance in California in 1997. That year the California Poison Control System was consulted about 199 cases of poisoning from GHB and related products. Last year (1996) there were 232 reports to the California Poison Control System. The reporting of poisonings to the California Poison Control System is not mandatory and the number of reports undoubtedly underestimates the number of GHB poisonings in the state. Abuse was seen across all age groups in 1998. 23% of patients were under 21 years old, 46% were 21-29 years old, 23% were 30-39 years old and 6% greater than 40.

An evaluation of 88 cases treated in San Francisco General Hospital over three years revealed 50% of cases ingested GHB with another intoxicating substance. Importantly 50% of the patients ingested GHB alone. The severity of clinical effects with GHB does not rely solely on other drugs ingested. GHB taken alone is dangerous.

Frequent ingestion of GHB can lead to addiction and a severe life-threatening withdrawal syndrome. The misleading claims such as improved physique with no physical effort are persuasive enough that some patients take GHB frequently and as a result become addicted. These patients can experience a severe withdrawal syndrome that may last up to 2 weeks after GHB was discontinued. The withdrawal symptoms begin within just a few hours after the last dose of GHB. Early symptoms, insomnia, tremor, confusion, nausea and vomiting are mild and progress over 2-3 days. Then the more severe central nervous system symptoms of agitation, disorientation, and vivid hallucinations occur. The cardiovascular system reacts with a rapid heart rate. As this delirium syndrome progresses, heavy sedation and physical restraint are required to prevent injury, muscle breakdown, and uncontrolled fever. Intensive care is necessary over 1-2 weeks.

GHB is easily used to incapacitate a victim allowing physical or sexual assault. GHB produces a fast onset of profound coma that leaves a victim defenseless to assault. These cases are very difficult to prosecute due to amnesia for the events and the loss of consciousness that occurs minutes after ingestion of GHB. In addition, laboratory confirmation is difficult due to the short duration that GHB is detectable in the system. The profound central nervous system depression that occurs with GHB leaves victims incapable of resisting assault.

GHB and its precursors, gamma butyrolactone and 1,4-butanediol, are promoted for many unsubstantiated health claims while denying the dangers associated with their use. GHB and its precursors are easily available. They can be ordered over the Internet, purchased as kits for home manufacture or made according to detailed recipes for kitchen synthesis that are posted on the Internet starting with uncontrolled chemicals. The information promoting these products often makes outrageous claims such as: improved physique with no physical effort by increasing muscle mass and definition while decreasing fat, relief from depression or chronic fatigue syndrome, enhanced virility, smoother younger skin, and reversal of male pattern baldness. GHB products are claimed to be "non-toxic" and the label on one product instructs you: "to ensure that those around you are aware that you may be unarousable and that this is normal. Unless drugs or alcohol have been ingested the only treatment necessary is to sleep it off." Unfortunately, following these instructions may be fatal. Many of our patients wake up in a hospital intensive care unit shocked that this "natural", "non-toxic", substance caused their life-threatening condition.

The California Poison Control System continues to track and report trends in GHB abuse. We also provide education to the public, health care practitioners, and emergency medical response teams through phone consults, lectures, and publica-

tions. We have been active in training law enforcement, district attorneys, rape treatment counselors, FDA and DEA personnel in recognizing this new drug of abuse.

GHB and its precursors have demonstrated their abuse potential, their dependence liability, and they have been used to commit assault. GHB and its precursors are a health hazard. I am concerned about the ease of availability of GHB compounds.

Mr. UPTON. Thank you.
Lieutenant Bane?

TESTIMONY OF PAUL BANE

Mr. BANE. Mr. Chairman and members of the committee, good morning, and thank you for the invitation this morning.

During the week of February 7, 1999, five students were admitted to the emergency room at Salisbury Peninsula Hospital. We had an opportunity to speak with 3 of the 5 individuals, all of whom admitted to taking GHB and knew that they were doing so before they took it.

According to the emergency room staff after this incident, it would have been a fatal overdose for one of the individuals that had been admitted had she not gotten emergency room treatment.

In the exhibits that I gave you this morning, I have quoted a number of statistics involving death and abuse while under the influence of GHB. I am not going to regurgitate those statistics now. They are also the handiwork of DEA, and I am not going to steal their thunder.

We are just reaching the tip of the iceberg of GHB instances in the State of Maryland. After the incident occurred in Salisbury, I took a personal approach to contacting all the major universities in the State of Maryland to see if they could identify the number of abuses and incidents that they have had in the State. Much to my surprise, they indicated that there were no reported instances of GHB abuse.

Finding this somewhat to difficult to believe, I began questioning the police departments that were at those schools and began asking them pointed questions with regards to sexual assaults and things of that nature occurring at the schools where the victim either could not remember or had very little recollection of what had happened to them. Lo and behold, cases began to surface.

In remarks made earlier, I heard some comments with regard to education, and I think education is not only going to be important for the public, but I also think education is going to be necessary for the law enforcement community, as well as getting some reliable form of test kit available to the law enforcement community.

Maryland recognizes that these problems are very serious. The State police has proposed legislation to the State Senate with regards to scheduling Ketamine, and I also have in my possession a position paper from the Maryland State Police where we are recommending that it be made illegal to administer any drug in someone else's drink for the purposes of possible sexual advances.

Thank you.
Mr. UPTON. Thank you.
Dr. Adatsi?

TESTIMONY OF FELIX ADATSI

Mr. ADATSI. Thank you, Mr. Chairman, and members of the committee.

The discreet use of sedative drugs to overwhelm and/or—

Mr. UPTON. If you would just pull the mike a little closer? Thank you.

Mr. ADATSI. Thank you.

The discreet use of sedative drugs to overwhelm or incapacitate the victim for purposes of perpetrating a crime is an age-old forensic toxicology problem. When used to commit a crime of sexual assault, sedative drugs may be classified as date rape drugs.

Recently, attention has focused on the involvement of gamma hydroxy butyrate or GHB, gamma butyrolactone, GBL, Flunitrazepam, Rohypnol, and possibly Ketamine in drug-induced sexual assault cases.

In the majority of cases, the scenario is fairly similar, and it involves women who may be at parties in which alcoholic beverages are consumed. My presentation will examine the toxicological effects, the abuse potential, and the dangers posed by the indiscriminate exposure to these four drugs.

GHB is naturally occurring, and it is a metabolite of gamma aminobutyric acid in the human brain, and it occurs in other organs and tissues of the body. When administered in pharmacological doses, GHB is a potent central nervous system depressant.

The current availability of the drug is limited to investigational use only. GHB is manufactured in illicit labs, and simple, home-brewed recipes are available on the Internet and other underground publications. The starting material for GHB manufacture is GBL, which is fairly easy to obtain.

GHB is popular with a variety of abusers in the U.S., including high school and college students, bodybuilders and athletes. In this context, it has various names. It has been referred to as Georgia home boy, liquid ecstasy, liquid X, easy lay and scoop.

The popularity of GHB among abusers appears to be related to its promotion as a steroid alternative, as a sleep inducing agent and also as an agent that is capable of enhancing athletic and sexual performance.

GHB occurs as a clear, colorless, viscous liquid, which is heavier than water. It is tasteless and mixes very easily with water and other beverages. It can also occur as a powder and is found in gel caps. However, it is its property as a clear, colorless liquid with high solubility in water that facilitates its clandestine introduction into drinks and beverages of unsuspecting victims.

The onset of action of GHB is fairly rapid. In fact, in five to 30 minutes following ingestion, GHB can begin to take its effect. It has a relatively short half life; that is to say that 50 percent of the drug will be metabolized and broken in the body in a relatively short time. On the average, after 30 minutes of full exposure, 50 percent of the drug will be broken down.

The effects are varied and depend on the person who is consuming the drug, but include drowsiness, euphoria, dizziness, visual disturbance, nausea, unconsciousness, and this may persist up to about 3 hours.

Serious adverse reactions may include hallucinations, seizures, vomiting, severe respiratory depression and coma. Now, the adverse effects may also last up to 96 hours. If death occurs, it is normally due to a collapse of the cardiovascular system and respiratory depression.

The effects of GHB are further enhanced by the simultaneous administration of other CNS depressants. GHB has been implicated in deaths in your State, in about five cases in Michigan.

Like GHB, GBL has also been implicated in alleged sexual assault cases and death. GBL has commercial and industrial applications and is used as a solvent, a paint remover and as a dietary supplement. GBL is found in products marketed under names such as Renewtrient, Revivarant, Blue Nitro, GH Revitalizer and Gamma G.

Both GHB and GBL are chemically very similar. The toxicological effects of GBL include CNS depression, seizures, unconsciousness, vomiting and coma.

The next drug, Rohypnol, belongs to the class of compounds known as benzodiazepines. In this class of compounds there is Valium, except that Rohypnol is only about ten times more powerful than Valium. Rohypnol is manufactured by Hoffman LaRoche and is used in a number of European countries as a hypnotic and as an anesthetic inducing agent. It has also been implicated in several sexual assault cases around the country.

The final drug I want to discuss is Ketamine, which is also used to induce anesthesia in the U.S. and has been available since 1972. Ketamine is reportedly capable of producing the same hallucinogenic effect as PCP.

Our current findings suggest that GHB has a high abuse potential and has no current medical application. GHB is controlled as a Schedule I drug in the State of Michigan. It has serious toxicological and clinical side effects and has been implicated in a number of deaths across the country. It is elusive in detection, and controversy exists as to what constitutes an endogenous level, which will distinguish it from an exogenous level. Because of its close structural relationship to GHB and the fact that GBL can be converted to GHB, GBL also poses similar toxicological concerns for the entire population.

In light of the mounting evidence of abuse, toxicity and use as weapons of crime against these drugs, their use should be restricted or controlled.

Thank you.

[The prepared statement of Felix Adatsi follows:]

PREPARED STATEMENT OF FELIX ADATSI, PH.D TOXICOLOGIST, MICHIGAN STATE
POLICE, EAST LANSING, MI

SHOULD DATE-RAPE DRUGS BE CONTROLLED

The discreet use of sedative drugs to overwhelm or incapacitate a victim for purposes of perpetrating a crime is an age old forensic toxicology problem. When used to commit a crime of sexual assault, sedative drugs may be classified as date-rape drugs. Recently, attention has focused on the involvement of gamma hydroxy butyrate (GHB), gamma butyrolactone (GBL), flunitrazepam (rohypnol) and possibly ketamine in drug-induced sexual assaults cases. In the majority of cases, the scenario is fairly similar, involving women who may be at parties in which alcoholic beverages are consumed. This presentation examines the toxicological effects, abuse

potential and the dangers posed by the indiscriminate exposure to the four drugs listed above which may warrant their control.

GHB is a naturally occurring metabolite of gamma-aminobutyric acid in the human brain and in most other mammalian tissues in small amounts. When administered in pharmacological doses, GHB is a central nervous system depressant and has been used clinically as an anesthetic and hypnotic agent. The current availability of the drug is limited to investigational use only. GHB is manufactured in illicit laboratories and simple, home-brew recipes are available on the internet and in other publications. The starting active ingredient in these recipes is GBL. GHB is popular with a variety of abusers in the U.S., including high school and college students, body builders and athletes. In this context it has been referred to by several names to include Cherry meth, Georgia home boy, Liquid ecstasy, Liquid X, Easy lay, Natures quaalude and Scoop. The popularity of GHB among abusers appears to be related to its promotion as a steroid alternative, sleep inducing agent, and an agent capable of enhancing athletic and sexual performance.

GHB occurs commonly as a clear, colorless, viscous liquid, which is heavier than water. It is tasteless and mixes easily with water and other beverages. GHB also occurs as a powder and has been found in gel caps. However, it is its property as a clear, colorless and tasteless liquid with high solubility in water that facilitates its clandestine introduction into the drinks and beverages of unsuspecting victims. Once consumed in this fashion several effects and symptoms are possible and the victim is predisposed to a variety of criminal activities.

The onset of action of GHB following ingestion occurs within 5 to 30 minutes. GHB has a relatively short half-life (20-60 minutes). The effects are varied and depend upon the individual and the dose consumed. Effects include drowsiness, euphoria, dizziness, visual disturbance, nausea, and unconsciousness and may persist for about 3 hours. Serious adverse reactions include hypotension, hallucinations, seizures, vomiting, severe respiratory depression, and coma. These effects may persist for 2 to 96 hours or longer. Death may be due to severe respiratory arrest and collapse of the cardiovascular system.

The effects of GHB are further enhanced by the simultaneous administration of other central nervous system depressants such as alcohol and benzodiazepines. GHB has been implicated in about 5 deaths in Michigan. Like GHB, GBL has also been implicated in alleged sexual assault cases and death. GBL has commercial applications, being used as a solvent, paint remover and dietary supplement. GBL is found in products marketed under brand names such as Renewtrient, Revivarent, Blue nitro, GH Revitalizer and Gamma G. GHB and GBL are chemically very similar. Indeed it is reported that GBL is converted into GHB in the body. The toxicological effects of GBL include central nervous system depression, seizures, unconsciousness, vomiting and coma.

Rohypnol belongs to the class of compounds known as benzodiazepines. In this class of compounds is valium and the effects of Rohypnol are believed to be similar to valium but is about 10 times more powerful. Rohypnol is manufactured by Hoffman-La Roche and used in a number of European countries as a hypnotic and anesthetic inducing agent. Rohypnol abuse has been reported in middle schools and high schools, as well as by college students. It has been implicated in several alleged sexual assault cases around the country. The effects of Rohypnol occur within 20 to 30 minutes of ingestion and the symptoms include decreased blood pressure, muscle relaxation, dizziness, sleepiness, amnesia, mental confusion, and lethargy. When taken in combination with alcohol or other central nervous system depressant drugs, the side effects may progress to death.

Ketamine has been used as an anesthetic induction agent in the U.S. since 1972. Its structure and pharmacological properties are similar to phencyclidine (PCP). Ketamine is reportedly capable of producing the same hallucinogenic side effects as PCP. Ketamine is usually available by intravenous or intramuscular injection. Recently however, Ketamine has been implicated in alleged sexual assault cases. Indeed, in a recent GHB related case in Michigan, Ketamine reportedly was detected in a container which also contained GHB.

Current findings suggest that GHB has a high abuse potential and no current medically accepted application. GHB has serious toxicological and clinical side effects and has been implicated in a number of deaths across the country. It is elusive in detection and controversy exists as to what constitutes an endogenous level to distinguish it from a deliberate exposure for prosecution. Because of its close structural relationship to GHB, and the fact that it can be converted to GHB in the body, GBL also poses similar toxicological concerns for the entire populace. Rohypnol has been implicated in several sexual assault cases across the country and has very high abuse potential. In light of the mounting evidence of abuse, toxicity and use as

weapons of crime, against the above mentioned drugs, their use should be restricted and/or regulated as scheduled drugs.

Mr. UPTON. Thank you.
Ms. Snyder?

TESTIMONY OF DENISE SNYDER

Ms. SNYDER. Thank you, Mr. Chairman, and members of the committee.

I work at the D.C. Rape Crisis Center. We have seen upwards of two dozen women over the last 3 years who have been sexually assaulted in a drug-related situation, and I have started to do a lot of trainings around the country for both State and national training programs to talk about the issue of substance related rapes, and I have heard a lot of stories from other cities and States.

The primary thing that I want to get across today is that I am concerned that as we try to address this issue we do it in a way that is addressing the problem, which is drug related sexual assaults. We must deal with the act and not deal with the vehicle specifically that is being used because if we focus on specific drugs, I am afraid that what we are going to do is 2 years down the road find ourselves in the same place that we are in now.

I was a strong advocate of rescheduling Rohypnol, but I feel like we spent several years focusing on that. Rohypnol is now fading from the scene. Other drugs are taking its place. It is important that we not be sitting here 2 years from now talking about some other drug and trying to figure out how to deal with it. We need to deal with the act and not the specific vehicle.

Some of the specific concerns that come up with women who are sexually assaulted using some kind of a substance are a lot of mental health issues. Ms. Pruett mentioned some of them in her first discussion. Women who are sexually assaulted under a substance like this do not have any place to direct their anger. They have no idea who their assailant was, so there is no way to focus that and work through it in order to heal and move on.

The second issue comes from the anxiety of the unknowns; not knowing who was involved or what happened, so every time you see an individual who looks at you funny you might be thinking: Was he involved? Was he somebody who was there? Especially in situations where this happens in a small community such as a college campus, it can make it extremely difficult to just continue to be there.

The reactions that are fairly common have already been mentioned. I would just say that in general the dynamics of how this happens very much parallels any kind of date rape situation. We have had clients who were sexually assaulted in their home, in the assailant's home, at parties. The assailants have been platonic friends, dates, complete strangers or an acquaintance that was just met. It has happened in gay and lesbian relationships, as well as in straight relationships, and the age range is from early teens up through women in their forties.

It is also important to recognize that it is not only using alcohol. As several folks have mentioned, we have had cases where women were drinking tea, sodas, women who do not drink alcohol at all.

It makes it very difficult, I think, for a lot of women to try to defend themselves.

I also want to mention that in trying to deal with this problem, as a couple of other witnesses have already said, it is extremely important that education be a major component.

For Congress to pass legislation that tries to deal with it but the information about it does not get out to the general public, to law enforcement, and also to district attorneys and to the medical personnel who are dealing with these women, if that information is not gotten out there in a way that is accessible to them the value of the legislation is going to be greatly minimized.

In closing, again I would just ask that what we do is try to make sure we are focusing on dealing with the problem and the act of using substances to sexually assault women and not focus specifically on vehicles.

Thank you.

Mr. UPTON. Thank you all, witnesses. I want you to know that for many of us we serve on multiple subcommittees, and they all seem to meet at the same time in different buildings.

I know that Mr. Dingell, the ranking member of the full committee and a member of this subcommittee, would have liked to have been here to introduce a witness from his district. Knowing that he is back, I would like to recognize him first for the first order of questions. Mr. Dingell?

Mr. DINGELL. Mr. Chairman, thank you. I would like to welcome not only my constituents here, but the entire panel. Thank you for being here, and thank you for your very fine assistance.

Mr. Faistenhammer, I particularly want to welcome you. Now, I would address quickly, and I would note that you have been giving good information about the problems associated with these kinds of drugs nationwide. I am concerned a bit more about how we can assist you in your efforts with regard to GHB and Ketamine.

You are a law enforcement officer. Can you explain in detail the problems that Michigan has had with the two drugs just mentioned? GHB appears to be more of a problem in Michigan than does Ketamine; would you like to comment, sir?

Mr. FAISTENHAMMER. Yes. One of the key problems is we do not have a method for testing on the street. As you can see just here in front, it comes in various numbers of containers.

The uniformed officers that run into these types of containers on the street, even if they were smart enough to suspect GHB through training, they would not have a method of checking on the street as to what is in the container.

So, it is really a two-pronged assault I think from the State of Michigan for us in policing. One, we need to educate our officers. Two, we need some method to be able to show that there is some sort of field test available, sir.

Mr. DINGELL. Would it be helpful if we federally scheduled both GHB and Ketamine?

Mr. FAISTENHAMMER. Yes, it would be.

Mr. DINGELL. Is that the consensus at the table? Does anyone disagree with that?

[No response.]

Mr. DINGELL. Mr. Adatsi, do you wish to add anything to that?

Mr. ADATSI. Other than the fact that with the schedule at the Federal level I think and very stiff penalties, I think that will help, and also to improve education nationwide for this particular drug and how insidious the drug can be.

Mr. DINGELL. Thank you.

Mr. Faistenhammer, you, I am sure, are aware that both Mr. Stupak, one of my good friends and colleagues from Michigan, as a matter of fact a former member of the Michigan State Police, and also Ms. Jackson-Lee, a very fine Member, have for a long time recognized problems associated with both GHB and Ketamine.

For some 2 years now they have submitted legislation which scheduled both of these drugs. Am I fair in assuming that you would support the idea that these drugs should be federally scheduled?

Mr. FAISTENHAMMER. Yes, they should be.

Mr. DINGELL. Mr. Adatsi?

Mr. ADATSI. I believe so.

Mr. DINGELL. Mr. Faistenhammer, do you believe that scheduling would give additional tools for law enforcement? If so, could you tell us how those tools might be used?

Mr. FAISTENHAMMER. I do believe it would give us the tools that we need, as least as far as I can think of immediately right now as we would be getting Federal assistance. The Drug Enforcement Administration, the FBI, those agencies would come on board.

Mr. DINGELL. You also would have the benefit of the seizure laws, would you not?

Mr. FAISTENHAMMER. That is correct.

Mr. DINGELL. That would be a particularly significant benefit, would it not?

Mr. FAISTENHAMMER. If it would become scheduled, yes.

Mr. DINGELL. So if somebody set up a manufacturing operation in his basement, you could seize the house?

Mr. FAISTENHAMMER. That is correct.

Mr. DINGELL. That is something of a deterrent, I gather?

Mr. FAISTENHAMMER. Yes. Yes.

Mr. DINGELL. Mr. Adatsi, do you wish to add anything to that?

Mr. ADATSI. No. We have had precedents here in other cases, other drugs before, so by forming a particular type and process we would have been doing something that has precedent.

Mr. DINGELL. Now, Mr. Faistenhammer, you mentioned that the State police in Michigan are in need of a field test kit. Is there a test kit of that sort which does exist?

Mr. FAISTENHAMMER. No, there is not.

Mr. DINGELL. So you would have to have one developed? Is that right?

Mr. FAISTENHAMMER. That is correct.

Mr. DINGELL. As I understand the chemical processes and chemical engineering and so forth, the development of a test of that sort with a proper exercise of resources is not awfully hard, though. Is that not true?

Mr. FAISTENHAMMER. It seems to be in this particular case that it is in that many of the things that you would utilize to break down GBL, as an example, would turn it into GHB.

Mr. DINGELL. All right. Now, Mr. Adatsi, is there anything we can do to help you in your efforts on addressing this GHB problem in Michigan?

Mr. ADATSI. Well, my laboratory currently does not test for GHB. We do have a lot of support from the Department already.

Other than the fact that this should be scheduled at the Federal level and the education and training for law enforcement personnel, I think that would be my request at this point.

Mr. DINGELL. Mr. Chairman, I think my time has expired. I thank you for your courtesy, and I thank you for holding this hearing.

Ladies and gentlemen of the panel, we appreciate your assistance and courtesy. Thank you.

Mr. UPTON. Thank you, Mr. Dingell.

Ms. Pruet, I know that the night that you were raped you also I think had a friend with you that went along. What happened to him or her? Tell us a little bit about that.

Ms. PRUETT. Her trial was separate from mine.

Mr. UPTON. She was raped as well?

Ms. PRUETT. They could not prove her being raped, but—I do not know much about her trial.

Mr. UPTON. Did she also end up in a coma as you did?

Ms. PRUETT. I am not sure.

Mr. UPTON. Okay. The question Mr. Dingell asked about trying to put GHB as a little tighter schedule, I or II. I have a question, and one of the concerns I have is how easy it is to manufacture GHB and one of its analogs.

My own personal belief is that we ought to have it on a schedule high enough so that one of its analogs, whether it be GBL or some other derivative, would not be the next in line and would simply take its place, and we would all of a sudden get into this game of finding out what is next.

I would be interested to know what your comments, maybe with Ms. Porrata first, having some reference from the State of California and others that might want to comment.

Ms. PORRATA. Well, one of the problems is it does have several active analogs, and these are only two of them, GBL and 1,4-butanediol. Most States do have an analog law, as we do, and the Federal Government does, too, that covers Schedule I and Schedule II.

I think if you put it in Schedule III or IV, even if you put special wording next to it that adds the analogs again the system is already in place. Analogues are covered in the top two schedules.

It is really important. There is a slight problem with GBL. It is a precursor also, so people get confused by that. It might be important to go ahead and actually designate it as an analog to clear up that issue so that it is also covered because there is some chaos over that.

Mr. UPTON. California was one of the two States I think that was referenced. Ms. Sheila Jackson-Lee indicated there were two States that on their own had designated it as Schedule I, I believe, California and Pennsylvania.

Ms. PORRATA. Actually, there are 17 States that have.

Mr. UPTON. Seventeen States? Okay?

Ms. PORRATA. But some of them are Schedule I. Some are Schedule II. We are actually Schedule II. Again, it was because of this controversy that a doctor came in and said oh, I want to use it for narcolepsy. The legislators said well, we should make it available by making it Schedule II.

Making it Schedule II in California did not approve it, nor did it allow it to be prescribed. That was one of the problems. It ended up Schedule II, but we do have an analog law so technically it is covered.

Again, the precursor issue became very confusing. I think we are probably going to end up clarifying that with legislation to make it crystal clear that GBL is equal to GHB under California law.

Mr. UPTON. Dr. Adatsi, did you want to comment on that?

Mr. ADATSI. Well, that—

Mr. UPTON. Again, if you could put that mike particularly close?

Mr. ADATSI. Thank you.

Mr. UPTON. That would be helpful.

Mr. ADATSI. Yes. In my presentation, I did emphasize that because GBL is a precursor to GHB, the use or access to GBL should also be restricted.

As Ms. Snyder did indicate, it will not be a bad idea to have a statement that is quite encompassing for this CNS depressant so that a year or a couple years from now we do not revisit this same issue.

In the State of Michigan GHB is a Schedule I, and the language is isomers or a sort of an isomer. It does not specifically speak to GBL. I suppose an aggressive prosecutor could find somebody to interpret that to refer to GBL as well.

However, if the Federal schedule is such that GBL could be included, I think that will in the long run serve a very useful purpose.

Mr. UPTON. The case that really prompted me to begin the work to have this subcommittee hearing today was the case in Grosse Ile back in January. I guess my next question would be if Michigan has this already labeled as Schedule I, do we know what the drug was yet in terms of the woman that died in Grosse Ile, the 15-year-old?

Maybe Sergeant Faistenhammer and you both would like to just comment, and I will yield to Mr. Stupak. If we are at Schedule I already, how did that impact the death of the young woman in Michigan?

Mr. FAISTENHAMMER. There may have been some GBL involved in that case, as opposed to GHB.

Mr. UPTON. And that would have been a loophole because of the—

Mr. FAISTENHAMMER. Because there is some argument as to whether GBL is an analog or not.

The Wayne County Prosecutor's Office has not issued warrants on that case and will not until Monday, so they are sort of asking me to hold off on saying too much about it.

Mr. UPTON. Okay. Did you want to just quickly comment?

Mr. ADATSI. Yes, sir, and that is because I had the privilege of speaking with a prosecutor who was going to prosecute his case only last week.

He did indicate that they did find GHB in the decedent's system and also GBL. The alleged perpetrators are swearing that it was GBL they administered to this lady. However, upon analysis the levels of GHB found in the decedent are large enough to suggest that there must have been some exogenous administration to this lady.

I suppose that together with the law in Michigan, with the proper questioning this particular case should not fall through any cracks.

Mr. UPTON. Okay. Thank you.

Mr. Stupak?

Mr. STUPAK. Mr. Chairman, if you have more questions, go ahead.

Mr. UPTON. No. Go ahead, Bart. I do have another question or two, but I will—

Mr. STUPAK. I would prefer that you—

Mr. UPTON. Do you want me to go? All right. Without objection.

Mr. STUPAK. No objection.

Mr. UPTON. I am interested in how these drugs are coming into the hands of some of these folks. I know recently we had a demonstration here as I opened up my remarks in terms of its access on the Internet, but it really is pretty easy. We did that in our office a couple weeks ago, to show me just how easy it was.

It was very disturbing in fact when you saw that at the end of the scroll where you could plug in your Visa card or your American Express and literally have it delivered to whatever address you wanted the next day, including a how-to kit and eyedroppers and a whole number of different items of paraphernalia that I guess would make it easier for someone to get this material off the Internet.

In your relationships on the panel, have you seen the Internet being used to get this into the mainstream of our society? Maybe I would like to start with Ms. Snyder as one who is really on the front lines of these types of issues.

Ms. SNYDER. Yes. Accessibility is not at all an issue. I mean, it is very easy to get. One of the problems that comes with that, however, is the potency is always varied because you took this amount last time, and you got this desired result. You take the same amount next time. The potency could be completely different, and you could either end up in a coma or perhaps death.

Mr. UPTON. Our police officials, do you recognize that the Internet has been a great tool for some of these folks?

Mr. FAISTENHAMMER. Yes. We recently seized computers out of several defendants' homes. All are using the Internet. All are shipped via UPS and ordered over the Internet.

Mr. UPTON. Ms. Porrata?

Ms. PORRATA. This is truly the child of the Internet. I do not think any other drug has been delivered across the board in the way that GHB has through the Internet.

It is illegal to sell the kits to make GHB. The Department of Justice has already handled some cases on that. The hard part, of course, is finding these people. In one of the cases, they—

Mr. UPTON. It is pretty easy in our office.

Ms. PORRATA. Well, I mean it is easy to find them and order it. I am talking about physically find them to arrest them.

I think one of the cases they did he was arrested in Florida. There was property actually seized, warehousing seized in two or three other States. We took money out of his bank account in L.A. and New York and Florida, so it is not really easy to physically find them.

The problem is again the GBL issue. They believe that it is more legal to ship GBL around if you are not putting it in a kit. That is again where Federal leadership is so critical.

We need Federal laws and Federal scheduling for two things. One, so that that issue is clear cut at the interstate level, because that is what it involves here, and, two, you need to set a precedent to help these poor States.

States still have to pass the laws in order to make arrests, but they could use some guidelines and some guidance. Right now the States that have it, it is Schedule I, Schedule III, Schedule IV. We could use some leadership here.

Mr. UPTON. Ms. Dyer, do you have anything to add to that, or Lieutenant Bane?

Ms. DYER. These products, the Gamma G came in with a 42-year-old woman. She ordered it over the Internet.

This is a kit that a 30-year-old man had used and had become dependent on it, had repeatedly ordered this kit. This is the gamma butyrolactone. This is the sodium hydroxide pellets. You mix them together in a pan, and you get GHB.

Mr. UPTON. Lieutenant Bane?

Mr. BANE. No, sir. As I have indicated, we are kind of just getting into this now. We have not had that many cases reported before this time, and as such the law enforcement community right now is pretty ignorant of this drug right now.

Mr. UPTON. Thank you.

Mr. Stupak?

Mr. STUPAK. Thank you, Mr. Chairman. Mr. Chairman, let me thank you again for holding this hearing.

I think the scope of this hearing here today with our first two panels, and I know we are going to have more, but certainly has shown us the scope of the problem we have here, the frustrations that law enforcement has and others.

Thank you again for your leadership and for scheduling this hearing. Again, I look forward to working with you to move this along.

Let me ask a few questions. On the street drug kits there, Sergeant, any indication of any kind of a common droplets, whatever, we are going to use out there? Nothing on GHB?

Mr. FAISTENHAMMER. No. Really it is so varied. That is the problem with it is recognizing it. It is a clear liquid that comes in so many different containers.

Mr. STUPAK. In order to have GHB, you have to have GBL. Nothing to do to try to detect GBL?

Mr. FAISTENHAMMER. No. There is nothing out there.

Mr. STUPAK. Okay. Any suggestions?

Mr. FAISTENHAMMER. No. I have a problem with it. I have called around trying to get some method—

Mr. STUPAK. Right.

Mr. FAISTENHAMMER. [continuing] to street test it so we would have probable cause for arrest on contact with these people, even just for the driving offense. They are just not available.

Mr. STUPAK. Mr. Adatsi, or Doctor, did I hear you say that in Michigan the lab does not test for GHB?

Mr. ADATSI. No. Unfortunately—

Mr. UPTON. Could you use the mike?

Mr. ADATSI. Unfortunately, we are currently not able to test for the GHB. We facilitate, however, the sample transportation to other labs that are capable of doing so.

Mr. STUPAK. What labs around the country are capable then of doing the testing?

Mr. ADATSI. There is a lab down south in Mississippi. The name of that lab is Elsol Lab. The FDA lab, I understand, is capable of doing that. There is also a lab in California, the coroner's office in California. They are capable of doing that.

Mr. STUPAK. Is the reason why, and I am not trying to put words in your mouth, but why? Is it a complex test? The cost of the test? Why is it that we do not have more labs doing this type of testing if it is a law enforcement problem?

Mr. ADATSI. My opinion is because it is a new drug that is out there, and it takes a little bit of time for the research and development to be worked out.

Combine that with the fact that other labs probably already have their own backlogs and cases to deal with and have not been able to rise to this occasion as quickly as they would have.

Mr. STUPAK. Is there any talk within Michigan to put this test within your laboratory system?

Mr. ADATSI. Yes. Actually, I am the head of that lab, and I have directed research and development to be initiated to try and address the point.

Mr. STUPAK. Okay. Thanks.

Does anyone on the panel think that we should not schedule GHB or Ketamine? Does anyone think we should not?

[No response.]

Mr. STUPAK. Okay. Since GBL is a precursor for making GHB, and GBL is already a readily available solvent in many industrial applications, how do we control GBL? Any suggestions? Ms. Porrata?

Ms. PORRATA. Frankly, it only has a few industrial considerations. It is not really like some huge thing that is very common. It is easily accessed, but it is not like widely used. Many of the labs only carried one bottle of it until it became an abuse factor, and now they carry more.

I think it can be heavily restricted to where, much more like Ephedrine, it can be put on to where it is tracked much better. That is a start right there. Again, the issue here becomes human consumption—

Mr. STUPAK. Right.

Ms. PORRATA. [continuing] as opposed to industrial use.

Mr. STUPAK. On the Ephedrine, and you are right. That is what we did on my legislation to do Ephedrine to get rid of the Cat problem. I am sure we do not have it totally wiped out yet.

Again, in my legislation we do have the tracking for GBL, but any other suggestions you would have along that line? I mean, you have to have GBL to get GHB, right? That is the key ingredient is GBL?

Ms. PORRATA. That is the key ingredient. Again, I think a big issue is education with so many of these kids. There is a lot of confusion. The whole issue of health food supplements and this over the counter type stuff, and these kids believe that if you walk in a store and buy something in a bottle that that makes it safe.

I think a lot of education on that aspect even, especially if you are drinking something out of a bottle that is not labeled and somebody gave you. That is a real clue. There might be something in it that is not safe. I think education is really critical.

Mr. STUPAK. Is there any other precursor or common ingredient in Ketamine that would make that easier to control or track?

Ms. PORRATA. No. Ketamine is all legally manufactured.

Mr. STUPAK. Right.

Ms. PORRATA. There is no illicit Ketamine. I think again part of the problem with Ketamine misuse is an education thing. It is mostly among the young kids, and it is used much like crystal meth and stuff.

It is not a huge factor. It is not used a lot of times in raves. I think it needs to be scheduled. It has legitimate uses. It could be Schedule II, or Schedule III. Schedule II means that the doctors have to track it a little more carefully, and I think that is probably adequate for it.

Mr. STUPAK. Ms. Porrata, you seem adamant that GHB should be scheduled as a Schedule I drug. Why is that, and what effect do you think such scheduling would have on companies like I think it is Orphan Medical that currently has an investigational new drug application pending with FDA?

Ms. PORRATA. Well, first and foremost, it is a question of the integrity of the drug scheduling concept. We have a system by which drugs are supposed to be scheduled. It seems like we are starting to piecemeal and we should avoid that. That is part of the issue.

Second, there are no approved medical uses. I do not care what Orphan Medical says. It has not been approved yet, has not been substantially shown that it is safe. They are trying to get the cart before the horse here by doing that.

I understand they are also opposed to Schedule II. Well, even the legitimate Schedule II drugs that do have approved medical uses, they have to struggle with the security issues. They have to struggle with all the safety precautions. I do not think there is any reason to say that one drug company and one drug should be excluded from that type of security, but at this point this is an extremely deadly drug.

I want to stress the issue is not the bathtub brew. The issue is GHB. I do not care if it comes from a research lab. GHB is what is dangerous and GBL by themselves, not the potency. The potency adds an extra problem, and the addition of the sodium hydroxide and the pH factor adds additional hazard, but it is GHB that is dangerous. It is GHB that puts people in comas and kills them. The other things are instrumental to that.

We need to schedule it where it belongs. We need to then let the proper process for research continue, and if and when it is approved—I have talked to narcolepsy researchers who admit that it will probably be several years before, in their opinion, it is really a Schedule II drug. I just cannot personally worry about drug companies, you know, and their profits.

Mr. STUPAK. In the GHB, some would say if we made it Schedule I and II it is not the profits. It is the research efforts because it is an orphan drug, which is a small amount that is available for the research.

The application, as you indicated, may be limited, but do you believe that research should continue as to see if there is some legitimate uses of GHB?

Ms. PORRATA. Oh, absolutely. I think the research should continue, and I think it will. History has shown there are other drugs that were in Schedule I. They were researched and eventually changed. There is nothing that precludes that. Obviously it makes it easier if it is not.

I think there has also been a lot of talk about well, if we can get our foot in the door with this, you know, then it will be easier. People can use it for more reasons if we can get it approved. It is now opening the door.

We are trying to open Pandora's box here. Again, put it where it belongs. Let us try to deal with it to the absolute, most serious degree we can because this is a huge epidemic. Then we will worry about that.

I think the research will continue. I think it is always easy to say well, we are not going to touch it if it is Schedule I. I do not think that is true.

Mr. STUPAK. You indicate in your testimony, and let me quote, that you were contacted by a man who said he was the president of Orphan Medical and that you were amazed he could not answer some very basic questions about this oh so safe drug he was pushing so hard to protect.

What were the questions that you wanted him to answer that he could not?

Ms. PORRATA. I asked him some specific questions about some of the effects that it has and some of the dangers, and one of the questions was did he know what it does to brain waves, especially on the research animals, but there is some question whether it is in humans also. He did not even know what I was talking about, so he did not seem to be terribly familiar with the history of the research on this drug.

Dr. Winters, who researched this drug 30 years ago, predicted this would be the most dangerous drug of abuse in the world. Nobody really took him seriously at the time. It is not really totally a central nervous system depressant. It actually is considered also by some of the researchers as central nervous system excitant. It puts the brain waves into epileptic seizure mode in the research history.

Dr. McKay from UCLA also feels this way, that it is actually a stimulant to the brain and that everything else shuts down so we see it as a depressant, but it has some other unique features to it that are pretty dangerous.

There is also a lot of talk about its research and use in alcoholism. You know, all I can tell you is sure, an alcoholic loves this because it does not have the hangover. You get drunk without the hangover.

I think we are talking some very dangerous territory there because it is a terribly impairing drug. These people can go into a coma at 60 miles an hour. You can be driving down the street at 60 and hit coma level. That is terribly, terribly dangerous.

Mr. STUPAK. In your testimony you were also concerned about DEA's passivity, if I can say that, or being very passive when you felt they should be on the cutting edge.

Having been in law enforcement and those of us in law enforcement, we see these drugs come out. Unfortunately, we are always reactive instead of proactive. Maybe Cat was the only one we got a little ahead of the curve.

Can you tell me a little bit more about what you meant or elaborate on DEA being passive and not quite active enough on this?

Ms. PORRATA. Well, there are a lot of agents and the doctors who are involved in the research on this, some of the chemists, who have been on top of it and known about this for a long time, but we seem to get lost in the bureaucracy when it goes to higher levels.

I think, and I have seen this at State level and some of the medical boards and pharmacy boards where sometimes the legislatures do not really use those people as resources to be on the cutting edge. They do not ask them to be on the cutting edge. In fact, their top officials sit around worrying about well, we do not want to say too much because this guy might not like it, and that might cause trouble.

Everyone is so worried about politics that people do not speak out about what is right. As an agency even sometimes they do not speak and say what needs to be said and let you then handle that information. You need to task your agencies to be on the cutting edge of this kind of stuff so that they can provide leadership.

I do disagree a little bit on one issue. Yes, we need to deal with the issues of rape and assault, but we must deal with the specific drugs. What we need to do is find a way to expedite these issues so that when a new drug does surface we can control it. You cannot avoid controlling these and having law enforcement handle it. We need to be able to expedite this process. It should not take 5 or 6 years.

Today, because of the Internet and because of the sophistication of these kids, kids meaning everyone up to 40 at this point, we have to be far faster at dealing with this stuff. They are out there systematically searching. If you go to the Internet and go to these chat rooms, okay, if they take GHB and GBL from us, what are we going to do next?

Mr. STUPAK. Right.

Ms. PORRATA. You know, we need to speed up this process to where DEA is on top of it, they are allowed to be on top of it, they are asked to be on top of it, and then you have a little faster system to where we can address these things in a much more rapid manner.

Mr. STUPAK. Well, there is no doubt that we need to be more rapid in it, in the synthetic drugs, taking legal substances to make them illegal for an illegal use. Certainly as the Internet and everything else expands, it is going to become more and more of a problem.

I go back to Ephedrine being a legal substance which was being used illegally to make the Cat, the Methcathadone that we had. We were able to get in front of that curve.

Besides, DEA does have some emergency policies, and I am going to ask them why they were not used, but the quickest way that I know of to get a handle on this stuff is doing it this way, is doing a legislative process.

That is why maybe at times I may have been a little frustrated with it has been 2 years to get the hearing, so I want to again close my questions by once again thanking my friend from Michigan for providing the leadership to at least get to the hearing stage.

I am sure after all your testimony we can move a little faster and get this bill or combination of bills moved to the floor.

With that, Mr. Chairman, thank you again. I will yield back my time.

Mr. UPTON. Thank you.

Witnesses, we appreciate your testimony and your indulgence with us as we go through our normal day of votes. Your comments are well taken. We look forward to working with the entire community and moving something positive.

Thank you for telling your story. You are excused for lunch.

Mr. UPTON. We will have the next panel, Mr. Nicholas Reuter, Associate Director of the Domestic and International Drug Control of the Food and Drug Administration; Dr. Stephen Zuckin from the National Institute on Drug Abuse, National Institutes of Health; Mr. Terrance Woodworth, Deputy Director of the Office of Diversion Control for the Drug Enforcement Agency; and Ms. Patricia Maher, Civil Division of the Department of Justice.

Again, I appreciate you staying with us today obviously. As you heard me explain to the earlier two panels, we do have a long history of asking folks to have their testimony sworn in. Do you have any objection to that?

[No response.]

Mr. UPTON. We also allow, if you prefer, to have a counsel with you. Do any of you prefer to have a counsel with you?

[No response.]

Mr. UPTON. If not, if you would stand and raise your right hand?

[Witnesses sworn.]

Mr. UPTON. Thank you very much. You are now under oath. We will begin with Ms. Maher. Again, if you can keep your comments to 5 minutes, knowing that we will put your full statement into the record, it would be appreciated.

TESTIMONY OF PATRICIA L. MAHER, CIVIL DIVISION, DEPARTMENT OF JUSTICE; TERRANCE W. WOODWORTH, DEPUTY DIRECTOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION; NICHOLAS REUTER, ASSOCIATE DIRECTOR, DOMESTIC AND INTERNATIONAL DRUG CONTROL OFFICE OF HEALTH AFFAIRS, FOOD AND DRUG ADMINISTRATION; AND STEPHEN ZUKIN, DIRECTOR, CLINICAL AND SERVICES RESEARCH, NATIONAL INSTITUTE ON DRUG ABUSE, NATIONAL INSTITUTES OF HEALTH

Ms. MAHER. Mr. Chairman and members of the subcommittee, good morning. My name is Patricia Maher. I am a Deputy Assistant Attorney General in the Civil Division of the Department of Justice.

In that capacity I oversee the Office of Consumer Litigation, the Civil Division's office that handles civil and criminal cases brought under a number of Federal consumer protection statutes, including the Federal Food, Drug and Cosmetic Act.

At your invitation, I will speak to you about our experience prosecuting traffickers of illegal drugs that are used to get high and that over the last few years have been used by perpetrators of sexual assault to incapacitate their victims.

The substance with which the office of Consumer Litigation has been most actively involved is gamma hydroxy butyrate or GHB. GHB is not approved in this country for general consumer use. Twenty-one States have made it a controlled substance, but it is not a controlled substance under Federal law. It is regulated as a drug under the Federal Food, Drug and Cosmetic Act, and Federal prosecutions against distributors are brought under that statute.

The emergence of GHB as a black market street drug can be traced to convicted anabolic steroid dealer and amateur chemist Mark Thierman in Tucson, Arizona. In 1989, Thierman devised a formula for GHB, hired people to make it and began to sell GHB throughout the country by mail order. Thierman sold hundreds of thousands of dollars of GHB in powder form.

Although GHB was originally intended by Thierman and others as a muscle building product, users found that the drug caused euphoria, and it quickly developed a reputation as a widely available way to get high.

GHB is made by combining two relatively common chemical compounds, gamma butyrolactone or GBL, which is an industrial solvent, and sodium hydroxide, commonly known as lye.

Shortly after GHB's discovery as a party drug, health officials throughout the country began to receive reports of serious adverse health effects associated with it, including extreme vomiting, sudden and uncontrollable onset of sleep, seizure like conditions and coma. On receipt of these reports, in November, 1990, the FDA issued a warning to consumers against use of the drug.

Subsequently, our Office of Consumer Litigation, in conjunction with the U.S. Attorney's Office in Arizona, investigated and indicted Thierman and his distributors for felony violations of the Federal Food, Drug and Cosmetic Act.

Eleven defendants were ultimately convicted of charges, including conspiracy, manufacturing and distributing misbranded and adulterated drugs with the intent to defraud and mislead, and op-

erating an unregistered drug manufacturing facility with the intent to defraud or mislead.

Starting in late 1992, however, GHB began to be used across the country. Since 1992, GHB has been responsible for numerous deaths and numerous instances of drug facilitated sexual assault.

A number of factors have contributed to the current popularity of GHB. First, in 1992, Daniel Duchaine, a self proclaimed steroid guru, published a book entitled *The Underground Steroid Handbook for Men and Woman, Update, 1992*. In it, Duchaine tells readers how to make a home brew for liquid GHB.

Second, and even more insidiously, money hungry individuals began to market GHB kits over the Internet. The kits provide the purchaser with the ingredients and directions for making the product in the home. The kits are sold to anyone, including children, without any warnings about the extreme dangers associated with both the manufacture and the use of the drug. Not surprisingly, the number of deaths attributed to GHB has increased since the recipe for this dangerous drug was made widely available over the Internet.

Beginning in 1995, GHB was identified with perpetrators of sexual assault. Typically the predator surreptitiously places liquid GHB into the victim's drink. Within 20 minutes, the drug can cause the victim to lose consciousness or to lose the ability to control muscle function. The predator then sexually assaults the victim.

In a few hours, the drug wears off, sometimes leaving the victim with no memory of the event and with no trace of the drug in his or her body, with no physical signs of forcible assault. It is this pernicious aspect of GHB, the fleeting nature of the evidence, that has made the identification and prosecution of the predators who assault with GHB difficult.

The Civil Division's Office of Consumer Litigation has been prosecuting traffickers of GHB for some time. We brought our first GHB prosecution against Mark Thierman in 1992 and obtained a sentence of 49 months' incarceration. We have successfully prosecuted more than 30 individuals in 12 districts and have numerous pending cases.

In one particularly egregious case, an adult has been charged with manufacturing and distributing GHB to underage individuals and with the sexual assault of several young women.

We spearheaded a multi-district, multi-agency criminal investigation of Internet GHB kit traffickers. Working with Federal, State and local law enforcement agents, OCL coordinated the execution of search warrants directed at the largest kit distributors in four States. Those investigations are ongoing. OCL attorneys have also provided substantial assistance to local prosecutors and other law enforcement authorities in a number of GHB related cases.

Recently we have encountered a GHB precursor product, gamma butyrolactone or GBL, which becomes GHB in the body when it is ingested. Although some GBL distributors have labeled their product a dietary supplement, on January 21, 1999, the FDA issued a public notice clarifying that GBL that was marketed for human consumption is an illegally marketed, unapproved new drug. A

number of manufacturers have recently recalled GBL from the market.

Attorneys from the Office of Consumer Litigation have been active in the investigation and prosecution of distributors of these and other dangerous drugs.

The Office of Consumer Litigation, along with the Criminal Division's Narcotics and Dangerous Drugs Section, have served as a clearinghouse for prosecutorial information, which includes helping local prosecutors prepare cases, distributing information to State and Federal prosecutors and presenting seminars on date rape drugs in forums such as the National Association of Attorneys General, the National District Attorneys Association and the National Association of Prosecutor Coordinators.

Despite the steps taken by Federal and State law enforcement and prosecuting offices, the availability of GHB, GBL and other drugs involving them continues to grow. We remain committed to finding and prosecuting the traffickers of these drugs.

Thank you.

[The prepared statement of Patricia L. Maher follows:]

PREPARED STATEMENT OF PATRICIA L. MAHER, DEPUTY ASSISTANT ATTORNEY
GENERAL, CIVIL DIVISION, DEPARTMENT OF JUSTICE

Mr. Chairman and Members of the Subcommittee: Good morning. My name is Patricia L. Maher. I am a Deputy Assistant Attorney General in the Civil Division of the Department of Justice. In that capacity, I oversee the Office of Consumer Litigation (OCL)—the Civil Division's office that handles civil and criminal cases brought under a number of federal consumer protection statutes including the Federal Food, Drug, and Cosmetic Act (FFDCA). This morning at your invitation, I will speak to you about our experience prosecuting traffickers of illegal drugs that are used to get high and that, over the last few years, have been used by perpetrators of sexual assaults to incapacitate their victims. At this time, I do not advocate any particular legislative action be taken with respect to these drugs, but rather hope to inform you about the Office of Consumer Litigation's efforts to combat this serious problem.

The substance with which the Office of Consumer Litigation has been most actively involved is gamma hydroxy butyrate or "GHB," known on the street as "easy lay," "liquid ecstasy," "Georgia Home Boy," and "scoop." GHB is not approved in this country for general consumer use. Twenty States have made it a controlled substance, but it is not a controlled substance under federal law. It is regulated as a "drug" under the FFDCA, and federal prosecutions against distributors are brought under that statute. GHB was developed in the 1950's as a human anaesthetic in Europe.

The emergence of GHB as a black-market street drug can be traced to convicted anabolic steroid dealer and amateur chemist Mark Thierman in Tucson, Arizona. In 1989, Thierman devised a formula for GHB, hired people to make it, and began to sell GHB throughout the country by mail order. Thierman sold hundreds of thousands of dollars of GHB in powder form. Although GHB was originally intended by Thierman and others as a muscle-building product, users found that the drug caused euphoria and it quickly developed a reputation as a widely available way to get high. GHB is made by combining two relatively common chemical compounds: gamma butyrolactone (GBL), an industrial solvent, and sodium hydroxide, commonly known as lye.

Shortly after GHB's discovery as a "party" drug, health officials throughout the country began to receive reports of serious adverse health effects associated with it, including extreme vomiting, sudden and uncontrollable onset of sleep, seizure-like conditions, and coma. On receipt of these reports, in November 1990, the FDA issued a warning to consumers against use of the drug.

Subsequently, our Office of Consumer Litigation, in conjunction with the U.S. Attorney's Office in Arizona, investigated and indicted Thierman and his distributors for felony violations of the FFDCA. Eleven defendants were ultimately convicted of charges including conspiracy, manufacturing and distributing misbranded and adulterated drugs with the intent to defraud and mislead, and operating an unregistered drug manufacturing facility with the intent to defraud and mislead.

Starting in late 1992, however, GHB began to be used across the country. Since 1992 GHB has been responsible for numerous deaths and numerous instances of drug-facilitated sexual assault. A number of factors have contributed to the current popularity of GHB.

First, in 1992, Daniel Duchaine, a self proclaimed “steroid guru,” published a book entitled the “Underground Steroid Handbook For Men And Women—Update: 1992.” In it, Duchaine tells readers how to make a “home brew” for liquid GHB. Second, and even more insidiously, money hungry individuals began to market “GHB kits” over the Internet. The kits provide the purchaser with the ingredients and directions for making the product in the home. The kits are sold to anyone, including children, without any warnings about the extreme dangers associated with both the manufacture and use of the drug. One illustrative case involved a GHB kit user who was admitted to an emergency room in New York with burned lung tissue that was attributed to aspiration of gastric contents containing GHB that had been made with too much lye. Not surprisingly, the number of deaths attributed to GHB has increased since the recipe for this dangerous drug was made widely available over the Internet.

Beginning in 1995, GHB was identified with perpetrators of sexual assault. Typically, the predator surreptitiously places liquid GHB into the victim’s drink. Within about 20 minutes, the drug can cause the victim to lose consciousness or to lose the ability to control muscle functions. The predator then sexually assaults the victim. In a few hours, the drug wears off, sometimes leaving the victim with no memory of the event, or with no trace of the drug in his or her body, or with no physical signs of forcible assault. It is this pernicious aspect of GHB—the fleeting nature of the evidence—that has made the identification and prosecution of the predators who assault with GHB difficult.

The Civil Division’s Office of Consumer Litigation has been prosecuting traffickers of GHB for some time. As noted above, we brought our first GHB prosecution against Thierman in 1992 and obtained a sentence of 49 months’ incarceration. We have successfully prosecuted more than thirty individuals in twelve districts and have numerous pending cases. In one particularly egregious case, an adult has been charged with manufacturing and distributing GHB to underage individuals and with the sexual assault of several young women. We spearheaded a multi-district, multi-agency criminal investigation of Internet GHB kit traffickers. Working with federal, state and local law enforcement agents, OCL coordinated the execution of search warrants directed at the largest kit distributors in four states. Those investigations are ongoing. OCL attorneys have also provided substantial assistance to local prosecutors and other law enforcement authorities in a number of GHB-related cases, including cases involving rape, homicide and kidnaping.

Recently, we have encountered a GHB precursor product, gamma butyrolactone (GBL), which becomes GHB in the body when it is ingested. Although some GBL distributors have labeled their product a “dietary supplement,” on January 21, 1999, the FDA issued a public notice clarifying that GBL that was marketed for human consumption is an “illegally marketed unapproved new drug.” A number of manufacturers have recently recalled GBL from the market.

In addition to GHB and GBL, I would also like to mention another drug that has been used by perpetrators of sexual assault to facilitate their crimes. It is an animal and human anaesthetic called ketamine hydrochloride, known on the street as “Special K,” which has also been used to get high and has been associated with drug-facilitated rape. Traffickers of ketamine, a non-scheduled drug at the federal level, could be prosecuted under the FFDCA. Ketamine has been made a controlled substance in eighteen states.

Unlike GHB (which can be made at home), ketamine is only available as a legitimate injectable product which is then diverted for street use. Ketamine users typically snort the drug rather than inject it. The recipe for converting the injectable liquid to powder is widely available on the Internet and requires cooking and drying the liquid to a solid and grinding the solid into a powder. Users claim that a mere 0.2 gram dose may induce a “mellow, colorful wonder-world” with a feeling of being transformed into a robot, sometimes referred to as “K-land.” A 0.5 gram dose can produce “out-of-body, near-death experience,” called a “K-hole.” Ketamine is extremely popular at large music parties called “raves” where drug use can be abundant.

Attorneys from the Office of Consumer Litigation have been active in the investigation and prosecution of distributors of these and other dangerous drugs. For example, OCL recently worked with the U.S. Attorney in Minnesota in obtaining an indictment charging a man with raping two women after giving them zolpidem (trade name “Ambien”), a schedule IV controlled substance. Significantly, one of the

victims was 15 at the time of the offense. This indictment was the first case in the nation under the federal Drug Induced Rape Prevention and Punishment Act.

The Office of Consumer Litigation along with the Criminal Division's Narcotics and Dangerous Drugs Section have served as a clearinghouse for prosecutorial information, which includes helping local prosecutors prepare cases, distributing information to state and federal prosecutors, and presenting seminars on date rape drugs in forums such as the National Association of Attorneys General, the National District Attorneys Association, and the National Association of Prosecutor Coordinators.

Despite the steps taken by federal and state law enforcement and prosecuting offices, the availability of GHB, GBL, and ketamine, and the number of cases involving them continues to grow. We remain committed to finding and prosecuting the traffickers in these drugs.

Thank you. I look forward to answering your questions.

Mr. UPTON. Thank you very much.

Mr. Woodworth?

TESTIMONY OF TERRANCE W. WOODWORTH

Mr. WOODWORTH. Thank you, Mr. Chairman, for the opportunity to appear before the subcommittee today on the subject of drugs of abuse and their use in sexual assault cases. I will very briefly provide you with DEA information on the three substances that are the subject of today's hearing.

GHB is not currently a controlled substance and has no accepted medical use in the United States. However, there is extensive data demonstrating that it is being abused for its psychoactive effects, and DEA believes it should be controlled under the Controlled Substances Act.

As required by law, DEA is currently waiting for a scientific and medical evaluation and a scheduling recommendation from the Department of Health and Human Services on GHB.

Among other reasons, GHB is abused for its ability to produce euphoria, and its adverse side effects include convulsions, severe respiratory depression and coma. GHB is even more dangerous when used with alcohol. Medical examiners have reported 32 fatalities since 1995 in which GHB was detected, and in many of those deaths GHB was used in combination with alcohol.

Drug Abuse Warning Network data indicates that estimated emergency room episodes involving GHB increased from 54 in 1994 to 764 in 1997. On a national level, GHB related cases have been documented by Federal, State and local law enforcement officials in 41 States and the District of Columbia. In regard to sexual assault cases, DEA is aware of at least 13 sexual assault cases involving 22 victims under the influence of GHB.

The GHB encountered by law enforcement has all been clandestinely manufactured. As you have heard, the manufacture of GHB is a simple process requiring no special chemical expertise. The primary precursor for GHB is gamma butyrolactone, GBL, a readily available industrial chemical. GBL plays a role in the GHB problem, and it will likely be necessary to place some type of control on it after GHB is controlled.

Flunitrazepam, commonly known as Rohypnol, belongs to the benzodiazepine class of drugs and is abused by high school students, college students, gang members, rave party attendees and heroin and cocaine abusers. The drug produces profound intoxication, boosts the high of heroin, modulates the effect of cocaine. It

is also commonly used in combination with alcohol, which potentiates its toxic effects.

The DEA has documented approximately 4,500 Federal, State and local law enforcement investigations involving the illegal distribution and possession of Flunitrazepam in 38 different States. The majority of these cases have been in Florida and Texas.

The data from the Drug Abuse Warning Network includes 167 emergency room episodes involving Flunitrazepam from 1994 through 1997. Flunitrazepam has also been used to facilitate sexual assault. Since 1994, DEA is aware of nine people who have been convicted of sexual assault in which there was evidence that Flunitrazepam was used to incapacitate the victim.

Flunitrazepam was placed into Schedule IV of the Controlled Substances Act back in 1984 due to international treaty obligations. At that time, there was little abuse of Flunitrazepam in the United States. More recently, with the increase in trafficking and abuse, DEA began to consider the merits of transferring Flunitrazepam into another schedule.

As the subcommittee is aware, HHS has recommended that Flunitrazepam remain in Schedule IV. After considering the relevant data and the HHS recommendation, DEA concluded that we did not have sufficient grounds to justify administratively rescheduling Flunitrazepam.

Ketamine. Ketamine is the only drug of these three discussed that has been approved for marketing in the United States. It is primarily used in veterinary medicine as a fast acting, general anesthetic. The pharmacological profile is essentially the same as Phencyclidine, PCP, which leaves the individual anesthetized, detached or disconnected from their pain and the environment. It has both analgesic and amnesic effects.

As a drug of abuse, Ketamine has become common at rave parties and is largely abused by teenagers and young adults. 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 manufacture of Ketamine to date, and it has been diverted primarily from distributors and veterinarians. From 1993 to 1997, there were 145 emergency room episodes in DAWN. The DEA is aware of one incident of rape.

The HHS has recommended on two occasions that Ketamine be placed in Schedule III of the Controlled Substances Act based largely on the pharmacological profile of the drug. On both occasions, DEA determined that the incidence of actual abuse was not sufficient to sustain the proposed scheduling action.

However, Ketamine's recent emergence as a drug of abuse prompted DEA to request another evaluation by HHS in April 1998. They have already responded and again recommended that Ketamine be placed in Schedule III. DEA will be publishing a notice in the Federal Register very shortly.

In conclusion, Mr. Chairman, the DEA is on record and continues to support rescheduling of Flunitrazepam and the control of both GHB and Ketamine. These drugs are being abused for their

psychoactive effects and also used by rapists to incapacitate their victims.

At least in the case of GHB, it may well be that legislative action is the quickest way to achieve control status. However, DEA is not opposed to congressional action in regard to any of these substances.

I would like to thank the subcommittee for the opportunity to offer DEA's comment.

[The prepared statement of Terence W. Woodworth follows:]

PREPARED STATEMENT OF TERRANCE W. WOODWORTH, DEPUTY DIRECTOR, OFFICE OF DIVERSION CONTROL, DRUG ENFORCEMENT ADMINISTRATION

Mr. Chairman, distinguished members of the Committee, I want to thank you for the opportunity to address you today on behalf of the Drug Enforcement Administration (DEA) Administrator, Thomas A. Constantine. I will provide you with some specific data on three drugs, gamma-hydroxybutyrate (GHB), flunitrazepam and ketamine. Additionally, I will discuss the GHB precursor, gamma-butyrolactone (GBL). While each of these drugs has a unique chemical structure and specific pharmacological properties, as drugs of abuse, they share a number of similarities. Before I talk about each of these drugs individually, I would like to take a few moments and comment about some of the things they have in common.

Collectively, these three substances are referred to as "party" drugs because of their availability and distribution at bars, night clubs and all-night dance parties called raves or techno parties. Gamma-hydroxybutyrate (GHB, Goop), flunitrazepam (Roofies) and ketamine (Special K) are new additions to a long list of substances that have often been encountered in these settings. In the 1980s we saw the abuse and trafficking of psychedelics like MDMA (Ecstasy) and its analogues and the depressant, methaqualone (Ludes). Other drugs that are also encountered in these settings include LSD (Acid), PCP (Angel Dust), amphetamine, cocaine and marijuana. As their street names imply, these drugs are touted to be fun. They have a wide range of pharmacological effects and are often taken in combination with each other or with alcohol. A disturbing factor is that these three substances are primarily being abused by teens and young adults.

While the illicit trafficking and abuse of these substances are DEA's primary considerations with regard to Federal control measures, we are aware and concerned about the use of these substances to facilitate the commission of sexual assault. As such, these three substances are referred to as "date rape" drugs implying this more sinister aspect of their illicit use. Individuals intent on sexual assault are aware of the availability of these substances, especially at bars and night clubs, and of their pharmacological profiles, both of which provide some insight into why they might find these drugs so appealing.

Each of these substances has gained popularity among drug abusers in recent years. Since their emergence as drugs of abuse, the DEA has been collecting data on their illicit manufacturing, distribution, trafficking and abuse. I will provide you with a summary of that data. Based on that data, the DEA now views these substances as having significant abuse potential. There is evidence that individuals are taking these substances in a manner and amounts sufficient to create a hazard to their health or to the health and/or safety of others. There is significant clandestine production of GHB and significant diversion of the pharmaceutical products containing flunitrazepam and ketamine. Large quantities of flunitrazepam have been illicitly smuggled into the U.S. and ketamine has been diverted from legitimate veterinary supplies within the U.S. Individuals are taking these substances on their own initiative rather than on the advice of a medical practitioner. Actually, only ketamine is approved for medical use in the U.S.—neither GHB nor flunitrazepam has been approved for marketing as a medicine by the Food and Drug Administration (FDA). In addition, these substances share many of the same pharmacological properties of drugs that have been identified as having serious abuse potential and are already controlled in the Controlled Substances Act (CSA). This data indicates that each of these drugs should be placed under control in the CSA. At this time, however, only flunitrazepam is controlled at the Federal level.

Although Congress has passed legislation that expedites the scheduling of drugs and other substances under the CSA, the temporary or emergency scheduling provision of the CSA could not be used for any one of these three substances. Emergency scheduling action is not possible when a substance is (1) being evaluated as part of a DHHS approved research program as is the case with GHB; (2) already a con-

trolled substance as is the case with flunitrazepam; or (3) already marketed in the United States as is the case with ketamine. As a consequence, all three of these drugs have proven to be a challenge with regard to more effectively controlling their abuse. Action to curb the trafficking and diversion of these drugs has been difficult and time consuming. Prior to changing the control status or placing any new substance under control using administrative or traditional scheduling process of the CSA, the DEA must gather the necessary data, forward that information to the Department of Health and Human Services (DHHS) and request, receive and consider a scientific and medical evaluation from the DHHS. In addition, the CSA requires specific findings for each of the five schedules that must be based on scientifically valid and legally defensible data (See Attachment). Scheduling actions must be substantiated by the available evidence. From the time the DEA identifies a new drug of abuse to the time that substance is finally placed under control in the CSA, if warranted, a significant amount of time may elapse when the administrative scheduling process is utilized.

Gamma-hydroxybutyrate (GHB)

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 1980s, 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. Doctors do not prescribe it, pharmacists do not sell it and patients do not use it. However, 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 in the U.S., 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 in overdose, unconsciousness can occur in as little as 15 minutes and profound coma can occur within 30 to 40 minutes. 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. Most individuals regain consciousness within two to four hours. However, since 1995, Medical Examiners have reported 32 fatalities in which GHB was detected in the decedent. Many of these deaths involved the use of GHB in combination with alcohol which potentiates the depressant effect of GHB. Of these 32 cases, GHB was found to be the sole cause of death in eight cases.

Since 1993, more than 3,500 GHB-related cases of abuse, overdose, possession, illegal manufacturing, illicit diversion and trafficking have been documented by Federal, state and local officials. This data has been obtained from DEA case files, state and local law enforcement case files, state and Federal forensic laboratory reports, the Drug Abuse Warning Network (DAWN) data, the FDA Office of Criminal Investigations and poison control center data bases. This data shows that GHB is frequently taken in combination with other drugs that often heighten its effects, and it is frequently found at bars, night clubs, rave parties and gyms. The primary users are teenagers and young adults. 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.

The number of cases in which GHB has been used facilitate sexual assault is impossible to determine; many such cases may go unreported or unsubstantiated due to the difficulty of detecting its use. GHB is quickly eliminated from the body making detection in the body fluids unlikely. In addition, GHB's fast onset of depressant effects and its amnesiac effect render victims unable to recall the details of the attack. Nonetheless, DEA is aware of 13 sexual assault cases involving 22 victims under the influence of GHB since 1996. These assaults occurred in California, Florida, Louisiana, Maryland, Massachusetts, Michigan, Texas, and Wisconsin.

GHB is illicitly produced in clandestine laboratories. Since 1997, the DEA is aware of at least 100 cases involving GHB illicit laboratories and over 200 submissions to DEA and state and local forensic laboratories. GHB has been encountered in every region of the United States 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.

The clandestine synthesis involves the use of two common, non-regulated chemicals: gamma-butyrolactone (GBL), the primary precursor chemical, and sodium hydroxide (lye). The synthesis is a simple one-pot method requiring no special chemical expertise. GBL is a solvent with a wide range of industrial uses. Tens of thousands of metric tons are produced annually and it is readily available from chemical supply companies. In addition, kits for making GHB containing GBL and sodium hydroxide are being sold on the Internet. GBL, once absorbed from the gastrointestinal tract after oral administration, is readily converted to GHB in the body and produces the same profile of physiological and behavioral effects as GHB.

The DEA is reviewing various control measures for GBL. If GHB is placed under Schedule I or II of the CSA, GBL could be treated as an analogue for the purposes of criminal prosecution if it is being distributed for human use outside of an FDA approved Investigational New Drug (IND). As there are no regulatory controls imposed on handlers of analogues, the licit industrial or pharmaceutical use of GBL would be unencumbered by this method of control. Alternatively, if GHB is controlled in any schedule of the CSA, GBL can be controlled as an immediate precursor in the same or lower schedule as GHB. The full range of CSA drug control measures would then apply to GBL. Another method of controlling GBL distribution and use by clandestine manufacturers would be to make GBL a listed chemical with a level of control commensurate with its current industrial use. Both of these last two measures (immediate precursor and listed chemical) could be taken by the DEA following a notice and comment rulemaking process. In October 1998, the DEA published a Federal Register notice seeking information about the industrial uses and handling of GBL. The DEA is currently evaluating this information.

The abuse of GHB is associated with significant adverse effects to the abuser and health risk to the general public. The DAWN estimated that there were 54 GHB emergency room mentions in 1994 compared to 764 in 1997. In 62 percent of these episodes, recreational use was cited as the reason for taking this drug. Alcohol, which intensifies the depressant and psychoactive effects of GHB, was reported in 86 percent of the mentions. Poison control centers reported over 600 GHB incidents in 1996 and over 900 GHB incidents in 1997. GHB is repeatedly detected in driving under the influence (DUI) cases indicating the public health and safety hazards associated with its abuse. As previously mentioned, there have been 32 GHB-related deaths since 1995 and 22 GHB-related sexual assaults reported to DEA since 1996.

Despite data indicating that the continued, uncontrolled clandestine manufacture, distribution and abuse of GHB is an imminent hazard to the public health and safety, the DEA cannot place GHB under temporary control because it has an active IND exemption. As a consequence, the DEA is pursuing measures to administratively schedule GHB. In September 1997, the DEA forwarded its scheduling review to the Department of Health and Human Services (DHHS) and requested their scientific and medical evaluation and a scheduling recommendation. The DEA continues to document law enforcement encounters and GHB-related abuse cases and, as required by law, awaits a response from the DHHS before proceeding with any proposed scheduling action. The DEA has also conducted an informal field survey on GHB. Forty-one states and the District of Columbia reported incidents involving GHB. Most of the incidents reported in the survey occurred between January 1996 and March 1998. Reports were received from hospitals, poison control centers, coroners, police and sheriffs departments, public health department laboratories, security departments of colleges and universities and drug rehabilitation centers. Georgia, California and Texas reported the highest number of incidents with 312, 237 and 223 reports, respectively.

Twenty states have already controlled GHB. Alabama, Delaware, Georgia, Hawaii, Idaho, Illinois, Michigan, Nebraska, Nevada, Oklahoma, Rhode Island, and Wisconsin have placed GHB in Schedule I. California, Florida, Indiana, Louisiana and New Hampshire have placed it in Schedule II and Alaska, North Carolina, and Tennessee have controlled GHB in Schedule IV. In addition, New Jersey and Texas have criminalized the sale and possession of GHB and placed it in the same penalty group as LSD and marijuana.

Flunitrazepam

Flunitrazepam, commonly known as Rohypnol, 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 oral administration, and last approximately 4 to 6 hours. Some residual effects can be found 12 hours or more after administration. Although it is in Schedule IV of the CSA along with other benzodiazepines (due to compliance with the Psychotropic Convention), flunitrazepam has never been approved for medical use in the United States. 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 is abused by a wide variety of individuals including 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 and frequently in combination with alcohol. To a much lesser extent, it is also abused by crushing the tablets and snorting the powder.

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 nine individuals have been convicted of sexual assault in five state court cases in which there was evidence that they used flunitrazepam to incapacitate the victim. The DEA is aware of 17 other sexual assault cases from 1994 to 1998 in which there is evidence to suggest that flunitrazepam was used to facilitate the assault.

For a variety of reasons, it is difficult to estimate just how large a problem flunitrazepam-facilitated sexual assault is 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 tests available in the United States. If flunitrazepam exposure is to be detected at all, urine samples must be collected within 72 hours of ingestion and subjected to sensitive analytical tests. The problem is compounded by the onset of amnesia after ingestion, a factor on which the assailant relies to conceal the facts surrounding the rape. This amnesiac effect may lead to critical delays in reporting the assault, making it difficult or impossible to obtain appropriate biological samples for toxicology testing.

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 a withdrawal syndrome when the drug is discontinued. Flunitrazepam impairs cognitive and psychomotor function which affect 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. There were 167 flunitrazepam emergency room episodes reported in DAWN from January 1994 through December 1997. Nearly half of the episodes involved males under the age of 20. In nearly 50 percent of the episodes drug dependence was reported as the motive for taking the drug. Eighty percent of the episodes involved other drugs, including alcohol (59%), marijuana (44%) and cocaine (35%).

The increased popularity of flunitrazepam has led to 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.

Since 1985, the DEA has documented approximately 4,500 Federal, state and local law enforcement cases involving the illegal distribution and/or possession of flunitrazepam in 38 states. The largest number of cases in the past has been concentrated in Texas (1,600) 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 212 cases involving over 544,000 flunitrazepam tablets for the period of January 1, 1985 to February 28, 1999. Most of these investigations were conducted in Texas and Florida. There were 34,000 tablets of

flunitrazepam seized in 1994, 227,199 tables seized in 1995, 155,000 tablets in 1996; and 35,000 seized in 1997. However, during 1998, the number of tablets seized increased over the previous year with 56,000 tablets being seized. The vast majority of these tablets were either the one milligram (mg) pharmaceutical (Rohypnol) tablet or counterfeit two mg tablets which contain flunitrazepam and are designed to look like the pharmaceutical Rohypnol tablet.

The two mg pharmaceutical tablet, until recently, has 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 was a significant reduction in law enforcement encounters with the pharmaceutical two mg tablets. This was followed quickly by increases in encounters with the one mg pharmaceutical tablets and with counterfeit tablets containing two mgs of flunitrazepam. Counterfeit tablets demonstrate that there is an established illicit market in the U.S.

Flunitrazepam was placed into Schedule IV of the Controlled Substances Act (CSA) in 1984 due to international treaty obligations. At that time there was no known abuse of flunitrazepam in the United States. However, over the last several years, DEA has been concerned with the problem of flunitrazepam abuse and approximately four years ago, began to consider the merits of transferring flunitrazepam to a different schedule. While the abuse and trafficking of flunitrazepam are considered to be an imminent hazard to the public safety, the DEA could not take immediate steps to curb this abuse by using the temporary scheduling provision of the CSA because this drug was already a controlled substance. As a consequence, the DEA proceeded with the administrative scheduling process and, as required under the CSA, the DEA submitted its data on the abuse and trafficking of flunitrazepam to the DHHS in April, 1996. Along with DEA's document was a request to the DHHS for a scientific and medical evaluation and a scheduling recommendation. In January, 1997, after the appropriate scientific and medical review, the DHHS provided its scheduling recommendation to the 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 DHHS recommended that flunitrazepam remain in Schedule IV. After careful analysis of the relevant data and in consideration of the DHHS recommendation, the DEA concluded that sufficient grounds did not exist to administratively reschedule flunitrazepam. Several states, however, have determined that the existing controls were inadequate to address the abuse and trafficking of flunitrazepam within their jurisdictions and have rescheduled flunitrazepam through their state administrative process or by state legislation. 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.

Even though the control status of flunitrazepam has not changed, other actions have been taken. 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 personal use amounts of flunitrazepam encountered at border points of entry. This action was taken in response to the growing abuse and trafficking problem and the fact that it is not approved for use in this country.

Ketamine

The final drug I would like to discuss is ketamine. It is the only one of the three which has been approved for marketing in the United States although its primary use is 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 (pain relief) and amnesic (memory loss) properties. The use of ketamine as a general anesthetic for humans has been quite limited due to its adverse effects including the delirium and hallucinations which some experience after 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 similar to that of LSD or PCP but lasts only 30 to 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 a similar effect.

"Special K" is prepared by evaporating the liquid from the legitimate pharmaceutical injectable product and grinding the residue into a powder. Ketamine is difficult to synthesize and there have been no reports of its clandestine manufacture. 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 on 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.

Prior to 1993, there were few documented law enforcement encounters, emergency room mentions, or reported thefts of ketamine. However, since 1993, the frequency of law enforcement encounters as well as emergency room and medical examiner's reports has increased, indicating the increased abuse of ketamine. Abuse of ketamine is indicated in the 145 emergency room episodes reported to DAWN during the period 1993 to 1997. 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, the DEA is 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 could lead to the under-reporting of the use of flunitrazepam and GHB in sexual assault apply to ketamine as well.

The DHHS 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, along with its status as a prescription drug with limited distribution, did not provide sufficient cause to place ketamine under CSA control. Ketamine's recent emergence as a drug of abuse has prompted the DEA to reevaluate its placement in the CSA. The DEA requested a new scientific and medical evaluation and scheduling recommendation from DHHS in April 1998. The DHHS conducted an expeditious review and responded to our request in December 1998. The DHHS again recommended Schedule III placement. The Federal control of ketamine is proceeding and a notice of proposed scheduling should be published within 60 days.

Eighteen states have already controlled ketamine: California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, and Wisconsin have placed it in Schedule III; Missouri and Tennessee have placed it in Schedule IV; and Massachusetts has placed ketamine under the same penalty category as LSD and PCP.

Conclusion

GHB, flunitrazepam and ketamine are three recent drugs of abuse. Their continued illegal distribution and abuse pose serious risks to the American public health and safety. In reviewing the data presented here today, it is clear that GHB and ketamine should be placed under control in the CSA and that the actions taken to deter flunitrazepam smuggling and illegal distribution and abuse must be continued. The DEA applauds the actions taken by various states authorities to quickly address the abuse, diversion and trafficking of these substances in their areas. Such actions are also part of the evaluation process for Federal control of these drugs when warranted. Emergency scheduling action to increase the regulatory controls and curb the illicit availability and abuse of certain substances is not possible when those substances are: (1) already controlled [flunitrazepam]; (2) already marketed in the U.S. [ketamine]; or (3) are being evaluated as part of a DHHS approved research program [GHB]. We are working within the Executive Branch with DHHS to examine alternatives to current procedures.

The continued abuse and trafficking of GHB are of grave concern to the DEA. Congress may legislatively place any of these substances under the CSA and the DEA would not be apposed to Congress taking this action especially in regard to GHB. Congress has taken similar action in the past. It directed that methaqualone be moved from Schedule II to Schedule I in 1984 and it added anabolic steroids to Schedule III in 1990.

Mr. Chairman, in closing, I would like to thank you and the Committee for providing me with the opportunity to offer the DEA's position and comments on the very serious problem of abuse of GHB, flunitrazepam and ketamine. I will be happy to answer any questions you may have.

FINDINGS REQUIRED TO PLACE A SUBSTANCE IN SCHEDULES I-V AS SET OUT IN 21 U.S.C. 812(B)

Schedule I:

- (A) The drug or other substance has a high potential for abuse.
- (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
- (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Schedule II:

- (A) The drug or other substance has a high potential for abuse.
- (B) The drug or other substance has a currently accepted use in treatment in the United States or a currently accepted medical use with severe restrictions.
- (C) Abuse of the drug or other substance may lead to severe psychological or physical dependence.

Schedule III:

- (A) The drug or other substance has a potential for abuse less than the drugs or other substances on schedules I and II.
- (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
- (C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

Schedule IV:

- (A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.
- (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
- (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Schedule V:

- (A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.
- (B) The drug or other substance has a currently accepted medical use in treatment in the United States
- (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

Mr. UPTON. We thank you for being here as well.

Mr. is it Reuter or Reuter?

Mr. REUTER. It is Reuter—

Mr. UPTON. Reuter.

Mr. REUTER. [continuing] from the news agency.

Mr. UPTON. So I had it right.

Mr. REUTER. I answer to Reuter as well.

Mr. UPTON. All right. Thank you. Thank you for coming.

TESTIMONY OF NICHOLAS REUTER

Mr. REUTER. Thank you. My name is Nick Reuter, and, Mr. Chairman, members of the committee, thank you for the oppor-

tunity to testify on the role of the Food and Drug Administration in the scheduling of drugs under the Controlled Substances Act. We recognize and share your interest and concern in this matter.

Before we begin, we wish to express our sympathy with all those affected, especially the families of the young women involved in the tragic incidents in Michigan and Texas. These types of incidents certainly highlight the problems with the use of illicit substances.

You have asked us today to focus on FDA's role in the scheduling process and to specifically discuss three drug substances of interest to the committee. As requested, I will restrict my oral comments to 5 minutes and ask that my full written statement be included in the record.

The primary role of FDA under the CSA is to provide the Secretary of Health and Human Services with our scientific and medical evaluation of drugs. FDA's consultative role stems from the provisions of the CSA. This role is consistent with FDA's mission of public health protection.

Under this act, the Secretary is charged with evaluating certain medical and scientific factors and making recommendations to the Attorney General as to whether the substance under review should be managed as a controlled substance or removed from control and the appropriate level of control.

The CSA establishes the factors and findings determinative for control. The eight factors set forth in this law allow the Attorney General, and by delegation the Drug Enforcement Administration, to schedule a drug if she finds that the drug has a potential for abuse that warrants control.

The Attorney General must also take into account whether the drug has a currently accepted medical use within the U.S. and the extent to which the use of the drug may lead to physical or psychological dependence. The Attorney General also must request from the Secretary of DHHS a scientific and medical evaluation of the drug and make a recommendation as to whether the drug should be controlled and, if so, under what schedule.

After evaluating the eight factors, the Secretary must make a scheduling recommendation. The Secretary of HHS has delegated the responsibility for this recommendation to the Assistant Secretary for Health, who relies on FDA and NIDA to develop the medical and scientific evaluation and consider the appropriate factors and scheduling criteria, which are all set forth in the law.

These evaluations and recommendations are unique to the drug in question and are based on the substance's relative abuse potential, its medical usefulness and its capacity to produce dependence. Upon completion, the medical and scientific evaluation and scheduling recommendation of FDA and NIDA are forwarded to the ASH, who makes the final determination on behalf of the Secretary.

The medical and scientific evaluation and the recommendation as to the appropriate schedule for the drug are then forwarded to the Drug Enforcement Administration. I would refer you to my written statement for details on the importance of the Department's mandated scientific and medical review under the Controlled Substances Act.

A detailed discussion of the three drugs, GHB, Ketamine and Rohypnol, you asked FDA to address are contained in my written statement as well. Given the time, I will not discuss those in great detail.

I would like to discuss the effort of FDA, and particularly FDA's Office of Criminal Investigations, to address the abuse of GHB. It is important to stress this because FDA is not only reviewing drugs for control under the Controlled Substances Act, but we are also enforcing provisions of the Food, Drug and Cosmetic Act.

Indeed, the Office of Criminal Investigations has initiated aggressive enforcement actions against the manufacture and interstate distribution of GHB. These initiatives are directed at large scale interstate manufacturers and distributors, including Internet website vendors as we saw this morning.

Working with the Office of Chief Counsel and FDA's Center for Drug Evaluation and Research, OCI has developed investigation and prosecution strategies that have been highly effective in identifying and convicting violators.

Also, OCI and the Center for Drugs within FDA and the Department of Justice have developed and maintained a list of scientific experts available to testify in court proceedings. OCI also uses its expertise and resources to assist State and local police departments in conducting numerous investigations.

As part of our systematic efforts to combat the abuse of GHB, FDA's Office of Criminal Investigations has initiated and supported a number of Federal and State prosecutions throughout the U.S. related to the illegal manufacture and distribution of the drug.

To date, the Government has obtained over 33 GHB related convictions nationwide, and it really does not stop there. Our technical and investigative assistance is invaluable to the approximately 20 States that have enacted legislation to make GHB a controlled substance. We have held a number of training seminars for Federal, State and local enforcement administration agencies.

Let me conclude by saying that drug control evaluations and recommendations under this CSA can be complex. They definitely require the balancing of more than one public health interest.

FDA would agree that there is a critical need to protect the public health from the dangers posed by drugs and substances of abuse. At the same time, we have to recognize that many drugs that have the potential for abuse may also be medically beneficial, and a large segment of the population might benefit from the optimization of drug development. These interests sometimes create tension in this scheduling process.

In FDA's dual role as the evaluator of products that promote public health and the evaluator of substances that present a danger to the public, we will use the best available scientific data to make the speediest and best decisions.

We are committed to optimizing our interactions with our critical partners, Federal, State and local officials, scientific, the clinical and industrial community. There is no question that FDA needs to move quickly to assist in the evaluation of these drugs and substances so that scheduling under the CSA can move forward.

I want to thank the committee and the chairman for the opportunity to testify, and I will be glad to answer questions.

[The prepared statement of Nicholas Reuter follows:]

PREPARED STATEMENT OF NICHOLAS REUTER, MPH, ASSOCIATE DIRECTOR FOR DOMESTIC AND INTERNATIONAL DRUG CONTROL, OFFICE OF HEALTH AFFAIRS, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Chairman, thank you for the opportunity to testify on the role of the Food and Drug Administration (FDA or Agency) in the scheduling of drugs under the Controlled Substances Act (CSA), 21 U.S.C. § 811. We recognize and share your interest and concern in this matter and before we begin, we wish to express our sympathy with all those affected, especially the families of the two young women involved in the tragic incident in Michigan. These types of incidents certainly highlight the problems with the use of illicit substances. You have asked us today to focus on FDA's role in the scheduling process and to specifically discuss three drug substances of interest to the Committee.

FDA ROLE

The primary role for FDA under the CSA is to provide the Secretary of the Department of Health and Human Service (DHHS) with our scientific and medical evaluation of drugs. FDA's consultative role stems from the provisions of the Comprehensive Drug Abuse Prevention and Control Act (Act) of 1970. Pub. L. 91-512 (October 27, 1970). Such a role is consistent with FDA's mission of public health protection. Under the Act, the Secretary of DHHS is charged with evaluating certain medical and scientific factors and making recommendations to the Attorney General as to whether the substance under review should be managed as a controlled substance, or removed from control, and the appropriate level of control. Title II of the Act, now fully incorporated into the CSA, establishes the factors and findings determinative for control. The factors set forth under 21 U.S.C. § 811 allow the Attorney General and, by delegation, the Drug Enforcement Administration (DEA), to schedule a drug if she finds that the drug has a potential for abuse. The Attorney General also must take into account whether the drug has a currently accepted medical use within the United States and the extent to which the use of the drug may lead to physical or psychological dependence.

When evaluating a particular drug, the Attorney General must, under 21 U.S.C. § 811 (c), consider the following factors:

- (1) Its actual or relative potential for abuse.
- (2) Scientific evidence of its pharmacological effect, if known.
- (3) The state of current scientific knowledge regarding the drug or other substance.
- (4) Its history or current pattern of abuse.
- (5) The scope, duration, and significance of abuse.
- (6) What, if any, risk there is to the public health.
- (7) Its psychic or physiological dependence liability.
- (8) Whether the substance is an immediate precursor of a substance already controlled under this title.

Before proceeding to control a drug under this process, the Attorney General also must request from the Secretary of DHHS a scientific and medical evaluation of the drug and make a recommendation as to whether the drug should be controlled and, if so, under what schedule. In making such a recommendation, the Secretary of DHHS must take into consideration factors (2), (3), (6), (7) and (8) and any scientific and medical considerations involved in factors (1), (4) and (5) as described above.

After evaluating the eight factors, the Secretary must make a scheduling recommendation based on the substance's relative potential for abuse, its accepted medical use and its capacity for producing physical and psychological dependence. Under the CSA, substances in Schedule I have a high potential for abuse and no accepted medical use. Substances in Schedule II have a high potential for abuse but do have an accepted medical use. Substances in Schedules III-V have an accepted medical use and a relatively lower potential for abuse.

The legislative history of the CSA is replete with hearings, discussion and statements that the scientific and medical evaluation of DHHS is important and critical to the process. The operative provisions of the CSA reflect that history. In particular, 21 U.S.C. § 811(b) states:

The recommendation of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance.

The Secretary of DHHS has delegated responsibility for DHHS's recommendation to the Assistant Secretary of Health (ASH). The ASH, in turn, relies on FDA and the National Institute on Drug Abuse (NIDA) to develop the medical and scientific evaluation and consider the appropriate factors and scheduling criteria. Under an

interagency Memorandum of Understanding (MOU), FDA and NIDA cooperate in completing the medical review, evaluation, and recommendation that DHHS conducts as part of the domestic drug scheduling process.¹

Proceedings to add, delete or change the schedule of a drug or other substance may be initiated by DHHS, DEA or by petition from any interested person such as a drug manufacturer, medical society, pharmacy association, public interest group or state and local government. Typically, FDA will not begin its medical and scientific evaluation until it receives, through the ASH, a formal request for such an evaluation from DEA. FDA may also initiate such an evaluation. FDA typically will do so during the investigational stages of drug development or at such time that an application to market a new drug is received by FDA and the Agency believes that the substance may be a candidate for scheduling under the CSA as provided for in 21 U.S.C. § 811(f) which states:

If, at the time a new drug application is submitted to the Secretary for any drug having a stimulant, depressant, or hallucinogenic effect on the central nervous system, it appears that such drug has an abuse potential, such information shall be forwarded by the Secretary to the Attorney General.

PROCESS WITHIN FDA

The scientific and medical evaluation process is a complex one which is a part of the balancing of the interests of various agencies. There is a critical need to protect the public from the dangers posed by drugs and substances of abuse. At the same time, we recognize that many drugs that have the potential for abuse also may be medically beneficial and a large segment of the population might benefit from the optimization of drug development. These interests can create a tension in the scheduling process.

The FDA Office of Health Affairs (OHA) is responsible for the coordination of the DHHS activities in preparation of the report and recommendation on scheduling. Internally, once a scheduling request is referred to FDA, there is a review period during which FDA's Center for Drug Evaluation and Research (CDER), with assistance from others within the Agency, conducts a review of the drug. The data review includes review of the chemical properties, pharmacology studies and clinical studies and reports related to the drug.

This evaluation involves the careful analysis of many kinds of data: data on chemical synthesis and solubility; data on absorption and metabolism; information gathered from studies designed to investigate whether animals develop physical dependence and will work to self-administer the drug; and, whether an animal can distinguish a given drug from other controlled substances. Interaction studies with other agents, including alcohol, also may be evaluated. Human adverse events (relating to the drug's ability to cause physical dependence, alter moods, cause hallucinations, etc.) are collected and reviewed from clinical trial reports and from postmarketing experience if applicable.

In the case of a new drug under investigation, the data specific to the issue of abuse potential may not already be developed by the sponsor unless there has been some reason to suspect that it may indeed have abuse potential. These kinds of specialized studies are not a routine aspect of the drug development process. The development of this information, therefore, may take many years as studies are initiated and completed and as more clinical trial experience becomes available.

FDA has an Advisory Committee, composed of non-FDA employees, available if necessary, to review the data and provide recommendations to FDA concerning the medical and scientific evaluation, abuse potential and the need for scheduling controls. The CDER Division will then forward a recommendation for review by CDER's Center Director. Once the recommendation is signed by the Center Director, it is reviewed by the Office of Commissioner, including OHA. The recommendation is then forwarded for formal interagency review, a process coordinated by OHA.

During this period, there are informal consultations with NIDA. Under the MOU, FDA transmits the scheduling request from DEA upon receipt from DHHS to NIDA for concurrent review. An interagency group, the Interagency Drug Scheduling Working Group (IDSWG), which includes representatives from FDA, NIDA and the Substance Abuse and Mental Health Services Administration (SAMHSA), convenes periodically to assess the status of the scheduling review. Occasionally, the IDSWG will identify the need for additional abuse liability testing, or, on rare occasions, a public hearing under Part 15 of FDA regulations.

¹*Memorandum of Understanding With the National Institute on Drug Abuse and the FDA*, March 3, 1985 (50 FR 9518)

The MOU, noted above, describes procedures for sharing information between the agencies, and outlines FDA's role in preparing the initial recommendation and eight factor "basis" document. Upon completion, the medical and scientific evaluation and scheduling recommendation of FDA and NIDA are forwarded to the ASH who makes the final determination on behalf of the Secretary. The medical and scientific evaluation and the recommendation as to the appropriate schedule for the drug are then forwarded to the DEA.

Since the inception of the scheduling process in 1970, there have been dozens of substances reviewed for control under the CSA. On average, DHHS completes its response to a scheduling request within 8-10 months. In addition, FDA, DEA and NIDA meet monthly to discuss issues of mutual concern in the drug abuse control area. The Interagency Committee on Drug Control, formed in the early 1970s, provides a forum to discuss emerging drug issues and monitor the status of ongoing activities within the agencies.

It should be noted that there are other scheduling mechanisms that I will not discuss in detail but I do want to mention. Many substances were controlled under the CSA at the time the law was enacted in 1970. Scheduling also can be accomplished by legislation. The scheduling of Methaqualone (Qualuudes) and anabolic steroids are examples of legislative control. In addition, there is scheduling to fulfill treaty obligations. Finally, DEA can "emergency" schedule certain substances not subject to an investigational new drug application, under certain conditions on a temporary basis if there is an imminent hazard to the public health. 21 U.S.C. § 811(h)(1).

Ketamine, Rohypnol (Flunitrazepam) and GHB (Gamma-Hydroxybutyrate)

There are three drugs you requested that we specifically discuss in our testimony, Ketamine, Rohypnol and GHB. These drugs have been the subject of abuse in varying degrees for a number of years.

Ketamine—Ketamine is an anesthetic and has been approved both for human and animal use as an anesthetic. It was approved both as a human and veterinary drug in 1970. Ketamine has powerful analgesic and amnesic actions in humans and is typically used in humans in pediatric and obstetric procedures and is prominently used in veterinary procedures. Approximately 90% of the Ketamine legally sold today is for veterinary use. In the 1980s, Ketamine emerged as a recreational street drug because consumption of large doses cause reactions similar to those associated with use of PCP. Symptoms associated with recreational use of ketamine include dream-like states and hallucinations. The Drug Abuse Warning Network (DAWN) documented at least two Ketamine related deaths between 1993 and 1997 in which no other drugs, including alcohol, were used.

DHHS has evaluated Ketamine three times pursuant to requests from DEA for a medical and scientific evaluation and has forwarded a scheduling recommendation each time. The first time was in 1981; the second in 1986 and recently in 1998. Each time a recommendation was made to DEA from DHHS that Ketamine be placed in Schedule III of the CSA. Each time a request for a recommendation was made, FDA had to review current medical and scientific data to ensure that the Schedule III recommendation was appropriate. To date these recommendations have not been finalized.

Rohypnol—Rohypnol (flunitrazepam) is an unapproved drug in the United States, although it is approved in Europe and is used in over 60 countries. The drug belongs to the class of drugs known as benzodiazepines (such as Valium, Halcion, Xanax, and Versed) and is used outside the United States as a treatment for relief of insomnia, to induce sedation and as a pre-anesthetic. The drug can cause anterograde amnesia, thus, individuals may not remember certain events they experienced while under the effects of the drug. This effect is presumably what has led to the drug's use in sexual assaults. Without the ability to recall the sexual assault or rape, the victim is hindered in assisting law enforcement officials in providing information leading to the prosecution of the perpetrator. For these reasons, one of the street names for Rohypnol is "the forget me pill." The drug is tasteless, odorless and dissolves easily in carbonated beverages.² The sedative and toxic effects of Rohypnol also are aggravated by the concurrent use of alcohol. Even without alcohol, doses as small as 1 milligram can incapacitate a victim for 8-12 hours.

Rohypnol is not approved or available for medical use in the United States, but it is temporarily controlled in Schedule IV pursuant to a treaty obligation under the 1971 Convention on Psychotropic Substances. At the time flunitrazepam was placed

² It should be noted that the drug manufacturer, located in Ireland, has indicated that efforts are underway to change the solubility of the drugs and to introduce a coloring to the drug that will appear when dissolved.

temporarily in Schedule IV (November 5, 1984), there was no evidence of abuse or trafficking of the drug in the United States.

In March 1996, DEA requested that DHHS conduct a scientific and medical evaluation and provide a permanent scheduling recommendation for Rohypnol. DHHS provided a recommendation to DEA in January 1997 that it remain in Schedule IV. This action has not been finalized.

FDA continues to work with the United States Customs Service (Customs) and DEA to control the illegal importation of Rohypnol into the United States through smuggling from other countries. FDA issued an import bulletin in December 1995 and the Agency continues to work to help control the illegal entry of the drug.

GHB—GHB is an unapproved drug in the United States and currently is not scheduled under the CSA. It is approved in other countries for use as an anesthetic in humans. The drug is a central nervous system depressant that can induce deep sleep. GHB is presently the subject of several investigational new drug applications (IND) and is being studied for commercial development in the United States. FDA designated GHB as an orphan drug in 1987 for the treatment of patients with narcolepsy and the constellation of symptoms of cataplexy, sleep paralysis, hypnagogic hallucinations and automatic behavior. FDA also has issued orphan product grants for the study of GHB in the treatment of narcolepsy. Orphan Medical, Inc., has submitted an IND to FDA to review the use of GHB in the diagnosis and /or treatment of narcolepsy.

At the same time, GHB also is being abused as an intoxicant, depressant, euphoriant, growth hormone releasing agent and as an agent in sexual assaults. Unlike the two drugs discussed above, GHB poses a particularly acute law enforcement problem in that it can be easily synthesized by individuals with a limited knowledge of chemistry. Gamma Butyrolactone (GBL) and Sodium Hydroxide are the chemicals necessary to make GHB. Both of these chemicals are readily purchased from numerous chemical supply houses. Also, the recipe to manufacture the drug can be obtained easily over the Internet.

FDA has been involved in evaluating the reports of abuse of GHB and investigating the adverse events suffered as a result of the abuses. Since it was established in 1992, FDA's Office of Criminal Investigations (OCI) has tried to take aggressive enforcement actions against the manufacture and interstate distribution of GHB. OCI's investigative initiatives are directed at large scale interstate manufacturers and distributors including Internet web site vendors. Working with the Office of Chief Counsel and CDER, OCI has developed investigative and prosecution strategies that have been highly effective in identifying and convicting violators. From 1993 until the present, OCI has worked closely with CDER and FDA's National Forensic Chemistry Center to develop an expertise in the safe handling and processing of GHB when collected as evidence. Also, OCI, CDER and the Department of Justice have developed and maintained a list of scientific experts available to testify in court proceedings. OCI also utilizes its expertise and resources to assist state and local police departments in conducting numerous investigations. As a part of our systemic efforts to combat abuse of GHB, FDA/OCI has initiated and supported a number of federal and state prosecutions throughout the United States related to the illegal manufacture and distribution of the drug. To date the government has obtained over 33 GHB-related convictions nationwide.

Our technical and investigative assistance is invaluable to the approximately 20 states that have enacted legislation to make GHB a controlled substance. In March 1997, the OCI San Diego Field Office conducted a training seminar for federal, state and local law enforcement agencies who were responsible for controlling the rapid growth in the use and abuse of GHB in Southern California. In July 1997, OCI continued to assist state and local law enforcement efforts when its San Francisco Resident Office conducted a GHB training seminar for law enforcement personnel in Northern California.

OCI also has responded to a request from DEA's Office of Drug Diversion, Drug and Chemical Evaluation for all available information related to the synthesis, tracking, usage and other illicit commerce involving GHB. The recent surge in the popularity of GHB and its precursors (GBL or 1, 4 butanediol) has made combating its illegal use increasingly difficult. Investigations are resource intensive and the laws used to prosecute distribution under the Federal Food Drug and Cosmetic Act are relatively complex.

FDA has issued several alerts and warnings concerning GHB. FDA also has worked with Customs to stop the importation of GHB and in May 1992, FDA issued an Import Alert providing for automatic detention of the product.

Most recently, FDA moved to alert consumers not to purchase or consume products, some of which are labeled as dietary supplements, that contain GBL. When taken orally, GBL is converted in the body to GHB. FDA pressed the companies that

manufacture these products to cease the manufacture and distribution of these products and to voluntarily recall them. As of this date, all of the manufacturers that were contacted agreed to cease the manufacture and distribution of their GBL-containing products. All but one has agreed to recall the products. The Agency had received reports of serious health problems—some that are potentially life-threatening—associated with the use of these products. Although some of these products were labeled as dietary supplements, the products were, and are, illegally marketed unapproved new drugs. They are promoted with fantastic and unsubstantiated claims to build muscles, improve physical performance, enhance sex, reduce stress and induce sleep.

GBL related products have been associated with reports to FDA of at least 55 adverse health events, including one death. In 19 cases, the individuals became unconscious or comatose and several required intubation for assisted breathing. Other reported effects included seizures, vomiting, slow breathing and slow heart rate. There have been reports of at least five children under 18 years of age who have been injured or who have suffered these kinds of effects.

As a result of the increased abuse of GHB, DEA requested in September 1997 that DHHS conduct a scientific and medical evaluation of GHB and submit a scheduling recommendation for GHB. In response to DEA's request, the Department has continued to gather and evaluate scientific data on GHB's potential for abuse. These activities have proceeded in conjunction with the OCI enforcement actions and the ongoing clinical investigation of GHB for the treatment of narcolepsy.

In December 1998, FDA determined that the sponsor could provide GHB under a treatment IND. Once under a treatment IND, the product may then be legally prescribed to appropriate patients before general marketing is allowed. Treatment INDs are a means of facilitating, even before general marketing of the product, the availability of promising new drugs to desperately ill patients for whom no other therapy is available. FDA approves treatment INDs if there is preliminary or presumptive evidence of drug efficacy and the drug is intended to treat a serious or life-threatening disease, or if there is no comparable alternative drug or therapy available to treat that stage of the disease in the intended patient population. The drug also must be considered safe for its intended use under a physician's care. Patients who receive the drug under the treatment IND are not eligible to be in the definitive clinical trials, which must be well underway, if not almost finished. These ongoing investigations may allow FDA to learn more about GHB's relative potential for abuse, to aid in the scheduling review and to develop additional information for the product labeling.

FDA is completing its evaluation and recommendation on GHB to DHHS. As part of the review, the Agency is determining if GHB's abuse potential is "high" relative to substances controlled currently in Schedules I and II (such as heroin, PCP, LSD, marijuana, etc.) or if its abuse potential is closer to anabolic steroids or benzodiazepines, currently controlled in Schedule III and IV.

CONCLUSION

Increasingly, our citizens have had to face the increasing availability and abuse of drugs and other substances. In FDA's dual role as the evaluator of products that promote public health and evaluator of substances that present a danger to the public, we will use the best available scientific data to make the speediest and best decisions. We are committed to optimizing our interactions with our critical partners—federal, state and local officials, scientific, clinical and industrial. There is no question that FDA needs to move quickly to assist in the evaluation of these drugs and substances so that scheduling under the CSA can move forward.

Thank you for the opportunity to testify.

Mr. UPTON. Thank you very much.
Dr. Zukin?

TESTIMONY OF STEPHEN ZUKIN

Mr. ZUKIN. Mr. Chairman and members of the subcommittee, I am grateful for this opportunity to testify.

I am the Director of the Division of Clinical and Services Research at the National Institute on Drug Abuse, which is the research institute at the National Institutes of Health responsible for supporting research in the health aspect of drug abuse and addiction.

I will provide you with a brief overview of what science has shown concerning gamma hydroxy butyrate. Although GHB will be the main focus of my attention today, I will be happy to answer questions about Ketamine or Rohypnol or other drugs.

As you heard from earlier panels, GHB is one of a number of drugs reportedly being used to sedate women to facilitate sexual assault. Many of the drugs discussed today, including GHB, are predominantly central nervous system depressants which relax or sedate the body.

GHB is a naturally occurring compound which is found in the brain. Research suggests that GHB itself may act as a neurotransmitter. However, more research needs to be conducted to determine the true psychological function of GHB.

The predominant effects of GHB are sedative, though GHB can produce a wide range of pharmacological effects, depending upon the dose. At lower doses, GHB can relieve anxiety and produce relaxation. However, as the dose increases, the sedative effects result in sleep, then seizures and eventually coma or death.

Research also shows that GHB increases dopamine levels in the brain. This is relevant because we have come to believe that the ability to increase brain dopamine levels is a common characteristic of most drugs of abuse.

GHB has also been found to stimulate the release of growth hormone. Plasma levels of growth hormone rise quickly and steadily after administration of GHB, which probably accounts for the popularity of GHB among body builders.

The existing scientific data makes it difficult to determine with precision the abuse liability of GHB. Abuse liability is a composite term used to assess the likelihood of a drug's abuse potential through evaluation of its pharmacological and behavioral effects and review of its actual abuse and consequences.

Animal studies suggest that GHB may be reinforcing. For example, when rats are given a choice between water and a solution containing GHB, they tend to prefer the GHB and appear to regulate their intake to maintain a constant GHB concentration in the body. Primate studies, however, are more ambiguous. Some primates will self administer GHB, but not all, and not to the same extent as other drugs such as heroin or cocaine.

There have been very few clinical studies conducted on GHB abuse in humans. However, there have been reports that GHB causes both tolerance and dependence in human subjects. Research has shown that GHB's effects are usually seen ten to 20 minutes from the time the drug is taken. The effects typically last up to 4 hours, depending on the dosage. Low doses can sedate an individual, whereas high doses can be lethal. The drug's relatively short half-life makes it difficult to detect in emergency rooms and other such facilities.

GHB is relatively easy to make from common ingredients with recipes available on the Internet and in underground literature. The chief ingredient used to make GHB is gamma butyrolactone or GBL, which is converted by the body into GHB. GBL is used in a number of dietary supplements found in health food stores and health clubs.

The fact that GHB is relatively easy to make may be one of the reasons why a number of monitoring mechanisms are suggesting that GHB use is increasing. For example, NIDA's own Community Epidemiology Work Group is seeing increases, particularly among young adults who attend raves or private clubs. Poison control centers have documented numerous cases of acute poisonings associated with GHB.

According to the Drug Abuse Warning Network or DAWN, there has been a significant increase in the number of emergency room mentions associated with GHB. The number has grown from one in 1991 to 629 in 1996. The DAWN medical examiner's report shows that there has been one GHB related death in combination with alcohol reported between 1992 and 1995. However, the Drug Enforcement Administration has documented 32 deaths associated with GHB, some of which were attributed to GHB alone.

In conclusion, NIDA and the Department remain concerned about the harmful effects of GHB. Therefore, NIDA will continue to support research that examines the behavioral and pharmacological mechanisms of action and the relative abuse liability of drugs such as GHB.

We will share this information, as well as information gleaned through our surveillance systems, with the general public and policymakers to insure that everyone has the most current and accurate information that science has to offer.

Thank you again for the opportunity to testify.

[The prepared statement of Stephen Zukin follows:]

PREPARED STATEMENT OF STEPHEN ZUKIN, DIRECTOR, DIVISION OF CLINICAL AND SERVICES RESEARCH, NATIONAL INSTITUTE ON DRUG ABUSE, NATIONAL INSTITUTES OF HEALTH

Mr. Chairman and Members of the Subcommittee, I am Dr. Stephen Zukin, Director of the Division of Clinical and Services Research at the National Institute on Drug Abuse (NIDA), one of the research institutes at the National Institutes of Health. I am here today with my colleagues to present what the science has come to show about drugs such as ketamine, rohypnol and gamma hydroxybutyrate (GHB), drugs that are reportedly being used in sexual assault incidents.

Gamma hydroxybutyrate (GHB) is the drug that I will focus much of my discussion on today, though I will be pleased to answer questions about the other drugs as well. GHB is one of a number of drugs that have been reported to be used as a "date rape" drug. These drugs are predominantly central nervous system (CNS) depressants. Because these drugs are often colorless, tasteless and odorless, they can be easily added to beverages by individuals who want to intoxicate or sedate their victims.

There is some evidence that GHB is a naturally occurring compound found in the brain. Research suggests that GHB itself may be a neurotransmitter. Brain receptor sites have been reported, as well as brain mechanisms for synthesis, release and uptake of GHB. GHB has been found to be related to the brain's major inhibitory neurotransmitter, GABA. There is also some evidence that the brain has the ability to convert GHB into GABA. However, more research needs to be conducted to determine the true physiological function of GHB.

The predominant effects of GHB are sedative, though GHB can produce a wide range of pharmacological effects depending on the dose. At lower doses GHB can relieve anxiety and produce relaxation. However, as the dose increases, the sedative effects result in sleep and eventual coma or death.

Research also shows that GHB increases dopamine levels in the striatum of the brain. Dopamine is a neurotransmitter that is intimately involved in reward and pleasure. We have come to believe that the ability to increase brain dopamine levels is a common characteristic of most drugs of abuse.

GHB also stimulates the release of growth hormone from the anterior pituitary gland. Plasma levels of growth hormones rise quickly and steadily after administra-

tion of GHB, which probably accounts for the popularity of GHB among some bodybuilders.

From the existing preclinical and clinical scientific data it is difficult to determine with precision the "abuse liability" of GHB. Abuse liability determinations, simply put, assess pharmacological and behavioral effects of drugs relative to known drugs of abuse, as well as their consequences. It is a way for scientists to assess the likelihood that a drug will be abused. Factors such as the reinforcing appetitive effects that the drug has on the individual, the possible physical dependence that may develop from using the drug, and the potential consequences associated with use of the drugs, are considered in the abuse liability determination.

Animal research has confirmed that GHB is anxiety-reducing and sedating. Other animal studies suggest that GHB may be reinforcing in self-administration studies. For example, rats given a choice between water and a solution containing GHB prefer the GHB and appear to regulate their intake to maintain a constant GHB concentration in the body. Self-administration studies of GHB in primates are more equivocal, primarily because high dose evaluations are limited due to solubility difficulties and sedation of the animals. However, some primates will also self-administer GHB but not to the same extent as other drugs such as heroin or cocaine.

There have been relatively few human or clinical studies conducted on GHB. Investigators report that some individuals experience pleasure after taking the drug. GHB's intoxicating effects are usually seen 10-20 minutes from the time the drug is taken. The effects typically last up to four hours, depending on the dosage. The behavioral and physiological effects of GHB are dose dependent. Low doses can relax an individual, whereas high doses can be lethal. The drug has a relatively short half-life, making it difficult to detect in emergency rooms and other such facilities.

Tolerance, and as I mentioned earlier physical dependence, are also factors used to determine a drug's abuse liability. Both tolerance to GHB's euphoric and sedative effects and physical dependence have been reported. These properties may contribute to continued abuse. Case studies describe the illicit purchase of GHB for abuse of its sedative, euphorogenic, and anabolic effects and also that some users tend to escalate doses. Physical dependence is evidenced by a withdrawal syndrome characterized by insomnia, muscle cramps, tremor and anxiety when GHB is discontinued. Various sources describe instances of dose escalation, compulsive use, unsuccessful efforts by individuals to decrease or discontinue use, drug-seeking, and continued use despite adverse consequences.

The available data on the actual abuse of GHB and its associated consequences is largely anecdotal. GHB is usually abused either (1) for its intoxicating/sedative/euphoriant properties or (2) for its growth hormone releasing effects.

GHB was widely available over the counter in health food stores during the 1980s, purchased largely by body builders for its ability to stimulate release of human growth hormone, which aids in fat reduction and muscle building. GHB has not been sold over-the-counter in the United States since 1992. However, products containing gamma butyrolactone (GBL), a chemical that is converted by the body into GHB, are used in a number of dietary supplements in health food stores and gymnasiums. GHB is still being marketed in Europe as a general anesthetic, a treatment for insomnia and narcolepsy, an aid to childbirth, and as a treatment for alcoholism.

GHB is relatively easy to make from common ingredients with recipes available on the Internet and in underground literature. GHB is now a popular drug with the young adults who attend "raves" or private clubs. An advance report from NIDA's Community Epidemiology Work Group (CEWG), a network of epidemiologists and researchers from 21 major U.S. metropolitan areas who meet semiannually to monitor community-level trends in drug use and abuse, found that GHB was used at "raves" in Miami, Minneapolis/St. Paul and Seattle. Overall, of the 21 areas included in the CEWG Report, 10 areas reported increased incidences of GHB use.

Poison Control Centers have documented numerous cases of acute poisonings associated with GHB. Initial symptoms of acute GHB toxicity include vomiting, drowsiness, dream-like state, decreased muscle tone, and vertigo. Loss of consciousness, irregular and depressed respiration, tremors, or myoclonus sometimes followed. Seizures, bradycardia, hypertension, and/or respiratory arrest have also been reported. Symptom severity and durations of action are dose dependent and also relate to the absence or presence of other CNS depressants.

The only systematic reporting of harm associated with GHB abuse is the data from the Drug Abuse Warning Network (DAWN), which is a surveillance system run by our colleagues at the Substance Abuse and Mental Health Services Administration. The number of emergency room (ER) mentions associated with GHB has grown from one in 1991 to 629 in 1996 for a total of 892 GHB-related ER mentions. Most of the reports involve white males. 95% of the patients are between the ages

of 18-34. Most were using GHB to receive its pleasurable effects. GHB was abused most often in combination with other drugs, usually with alcohol, but also with stimulants, hallucinogens, marijuana, and sedatives. Most DAWN ER reports were from San Francisco, Dallas, Los Angeles, San Diego, and Atlanta.

The DAWN Medical Examiners have reported one GHB-related death in combination with alcohol between 1992-1995, occurring in 1995 in the Midwest. However, the Drug Enforcement Agency (DEA) has documented 32 deaths associated with GHB (4-attributed to GHB alone).

Another drug that the Subcommittee asked us to address is ketamine. Ketamine is also reportedly being used as a "date rape" drug. Ketamine is a rapid-acting general anaesthetic. It has sedative-hypnotic, analgesic, and hallucinogenic properties and is marketed in the United States and a number of foreign countries for use as a general anesthetic in both human and veterinary medical practice. Ketamine is similar to phencyclidine (PCP), although ketamine is more rapid in onset and less potent. We have quite a bit of information on this particular drug, which we would be happy to provide if that would be helpful to the members.

Given that the Food and Drug Administration has included information on Rohypnol in their testimony, I will not address this drug in my formal statement. I will be happy to provide additional information if it would be useful.

The Role of the Department of Health and Human Services

As the government's principal agency for protecting the health of all Americans, the Department of Health and Human Services is involved in making recommendations on domestic scheduling of drugs of abuse. Once the Attorney General initiates a scheduling proceeding, a request is made to the Secretary of HHS to provide a scientific and medical evaluation of the drug and a recommendation as to whether the drug should be controlled domestically. The Food and Drug Administration takes the lead role in gathering data from relevant HHS agencies.

As the world's leading research institute on drug abuse and addiction, NIDA has a memorandum of understanding with FDA (*Memorandum of Understanding With the National Institute on Drug Abuse and the FDA*, March 3, 1985 (50 FR 9518)) to provide expertise to the FDA in investigating and evaluating the abuse liability of drugs.

NIDA advises the FDA on the Department's "Eight Factor Analysis." The factors taken into consideration in evaluations and recommendations for each substance under consideration include: Its actual or relative potential for abuse; Scientific evidence of its pharmacological effects; The state of current science regarding the substance; Its history and current pattern of abuse; The scope, duration and significance of abuse; What, if any risk there is to the public health; Its psychic or physiological dependence liability; Whether the substance is an immediate precursor of a substance already controlled.

Conclusion

In conclusion, as a protector of the public's health, the Department realizes the harmful effects that drugs like GHB can have. That is why NIDA continues to support research on all drugs of abuse. In particular, NIDA will continue to support research that examines the behavioral and pharmacological mechanisms of action and relative abuse liability of drugs like GHB and Ketamine. We will share this information with our federal colleagues to ensure the best available science informs important decisions, such as scheduling, which impact the overall health of our Nation. We will also disseminate this information to the general public and policy makers to ensure that they also have the most current and accurate information about the effects of these drugs. Information that we retrieve through NIDA's drug monitoring mechanisms, particularly NIDA's Community Epidemiological Work Group (CEWG) will also be useful in alerting us to emerging drug problems. This information will also be shared as expeditiously as possible.

Thank you for the opportunity to testify before this Subcommittee.

Mr. UPTON. We thank all of you for testifying.

As you heard those buzzers, that means we are called again. We have a series of votes, two votes, and I think what we will do is reconvene at 1:30 p.m. Sorry about that. We will come back at 1:30 p.m.

[Brief recess.]

Mr. UPTON. I do not think we will be interrupted again unless we go a long time. We have a couple hours before the next vote.

We thank you for your testimony, and we will proceed with the 5 minute rule for the members that come back. Again, I apologize for the members that are not here as there are a number of sub-committee marks and hearings all over the place, so we will be having members come in and out.

I guess, from my perspective when I first heard about the case in Michigan and asked myself and my staff what are we doing to prevent drugs like these from getting out particularly to young girls like we heard testify here. Ms. Pruett, was age 15 when she was raped, as was another 15-year-old in Michigan.

I noticed in some press clips from Michigan, I guess this was from the Detroit News, an Ecorse High School date rape fight goes to the schools. I talked to some of my superintendents in my district when I was back last week about it as well.

The bottom line for me, and I am not a lawyer. I am not a scientist. I am not an engineer. I am not a lot of things, but I am interested in the bottom line. Whether it is a piece of legislation or whether it is an agency rule or regulation to try to restrict something. It seems to me to make sense that we ought to take it.

As I heard the testimony from the first two panels, including Ms. Sheila Jackson-Lee, who, like me, was impacted by a death of a young woman in her district and as I talked to other members who have had the same type of experience in their States and as we assembled this panel, I just want to know what else is there that we need to know about this, to know that this is a bad drug, that it ought to be banned somehow, some way?

As I listen to the testimony of you four, and I have read it at length as well, I end up with that same question. I just wonder. Is there any more evidence that we need to submit? I guess I am going to make a little bit of a rambling statement, but then I would like you all to comment.

As I read, Dr. Reuter, your testimony where it says on page 6 that on average DHHS completes its response to a scheduling request within eight to 10 months, and I read the testimony from the DEA and others, Dr. Zukin's folks as well, that the request had been I think originally to schedule this, you know, somewhere along the line I, II, even III or IV, even as early as September 1997. If you add it up, that is what, 18 or 20 months. I mean, we are twice as long as what the average timeframe is.

Is there something else that we need? Do we need to proceed with legislation to get the job done? Can we do this administratively so we do not need that, though certainly I am prepared to speak and encourage my colleagues to co-sponsor such legislation and begin to move it through the process and see where we are in the Senate, as well as where we are in the House? What else do we need to do?

Maybe, Mr. Woodworth, if you want to comment on that and Dr. Zukin? I do not know if there is any more evidence. Then, Mr. Reuter, maybe you can respond. Has all your evidence been submitted? Have you been asked for anything else to provide?

Mr. WOODWORTH. The normal process is that once we have done our piece, we forward it to the Secretary of Health. Once it is returned, then we will complete some further analysis because we

continue to collect data during the interim, so we are continuing to collect data with regard to GHB.

Mr. UPTON. Okay. So the ball is not in your court is what you are saying at the moment?

Mr. WOODWORTH. At this time.

Mr. UPTON. Okay. Dr. Zukin?

Mr. ZUKIN. Well, I think—

Mr. UPTON. If you could use the mike?

Mr. ZUKIN. Yes.

Mr. UPTON. I can hear okay, but I am not sure everybody else can. It is for the stenographer here, too.

Mr. ZUKIN. Under our memorandum of understanding with FDA, FDA does take the lead, as indicated in their testimony. Perhaps Mr. Reuter could also respond.

In other words, when FDA forwards a copy of their final recommendation to us, at that point we officially become involved in the process in terms of whether we concur with the FDA recommendation or not and so forth.

Of course, there has been extensive staff discussion between NIDA and FDA through this process, but we have not yet seen their final recommendation.

Mr. UPTON. Mr. Reuter?

Mr. REUTER. Yes. You talked a little bit about the language in the written testimony about the length of time, eight to 10 months, ten to 12 months. It might be good to understand a little bit about why sometimes—

Mr. UPTON. Sorry. You are not saved by the bell this time. You have to finish.

Mr. REUTER. [continuing] in carrying out these scientific and medical evaluations under the CSA, which is the law that controls us here, how sometimes it is difficult to find the appropriate level of control for a substance.

What is it about GHB? First of all, it is a drug that is under development for medical use and, you know, that balancing act they talked about a little bit this morning, the medical need versus the need to protect the public from these substances that pose a danger.

It is easily manufactured clandestinely with ingredients that have extensive industrial uses, which presents a bit of a complication. There is a specific subculture that appears to abuse these drugs more than one other group, and there is a sense that scheduling itself might not solve the problem.

I mean, with Rohypnol we had an interagency effort with Customs, with DEA, with FDA. There were States involved. All these things taken together call out for an expansive, coordinated Federal role.

I would say that we take this problem very seriously. We are moving to expedite the review within HHS for the scheduling recommendation on this substance.

Mr. UPTON. Just a last quick question, and then I will yield to Mr. Stupak.

As we were over on the floor today on these last votes, one of our first questions any member asks is what time are we going to be done today. Are we going to be done by 7 p.m.? Are we going to

be done by 10 p.m.? Are we going to be in tomorrow with votes? When do we get to go back?

Do you have a sense as to when a final recommendation is going to be made? Is it going to be made in the spring? Is it going to be made, you know, at Easter? Is there some sense in terms of when the timing is in terms of a final decision being made in terms of Schedule I, II, III or IV? Next year?

I am a Cubs fan. You know, we all say next year, although I hope it will be this year.

Mr. REUTER. I am an Oriole fan, and we are looking at the year after.

We are actively working on the recommendation, and I can tell you that it will be soon. It will be forwarded very soon.

Mr. UPTON. But you cannot be better? You know, if we ask when are we going to out of session, soon, that is not good enough. Do we know? Spring? Fall? Do you have any better sense of—

Mr. REUTER. I wish I could. It is still under very active deliberation, and it really would be premature and inappropriate to pick a specific date or even a general date.

I guess it would surprise me if it went past next year. I mean, at the outset that would be well beyond the pale. It is under active investigation. We are taking it very, very seriously.

Mr. UPTON. So you would not mind then if the Congress moved ahead with a piece of legislation then? You would not object to us moving ahead with legislation along the lines of Ms. Sheila Jackson-Lee or Bart Stupak, my colleague, or other folks?

Mr. REUTER. I think along with all the other panelists here, we are looking for ways to optimize the process. DEA had some language in their testimony about what might be an appropriate way to expedite control.

We participated in a technical assistance endeavor last fall. You know we are committed. We are willing. We are ready to work with the committee to move this along.

Mr. UPTON. Mr. Stupak?

Mr. STUPAK. Thank you, Mr. Chairman.

Have you looked at any of the legislation, either my legislation or the Jackson-Lee legislation, from a technical point of view, Mr. Reuter, to suggest if it could be approved or it should be approved?

Mr. REUTER. We have not carefully studied it. It has not been submitted for formal review. You know, just in glancing at it in the package this morning, you can see differences.

Mr. STUPAK. Sure.

Mr. REUTER. We have recommended Ketamine for Schedule III, but legislation appears to place it in a different schedule. No, we do not have formal views to offer on it at this time.

Mr. STUPAK. My concern is it has been a long time. If I am reading your testimony correct, it says since it was established in 1992, FDA's Office of Criminal Investigations has tried to take aggressive enforcement actions against the manufacture and interstate distribution of GHB. That is found on page 10 of your statement.

It is now 1999. This is just going on and on and on, and I can understand some frustration with FDA and others. Why is it taking so long to do this?

You know, this first came to my attention in 1996, early 1997. We put some bills in to try to address it. When we did the Families First Juvenile Justice bill we tacked it in there. Then we did a free-standing bill because it is a very pressing problem. I am just concerned that we continue to push back that time line. Nothing is being done.

When can we expect some action? Fred was being polite. Soon is not a good enough answer.

Mr. REUTER. Unfortunately, that is the best answer I can give, Mr. Stupak.

I tried to explain a little bit about the balancing we need to do and the weighing of factors and how GHB presents these kind of unique situations on a case by case basis that we have to take into consideration.

Mr. STUPAK. But it seems we have been balancing since 1992. Can we get some commitment to get technical assistance on any type of legislation then that we would propose?

Mr. REUTER. Yes. I think I mentioned earlier that we are ready to work with Congress to move this along as best we can. We provided technical assistance on legislative matters in the past, and we are willing to work with you to move it along.

Mr. STUPAK. Okay. Let me go to some other questions.

In the 20 or 21 States that have GHB, how do they have it scheduled, Schedule I, Schedule II, Schedule III or Schedule IV or V? Do you know?

Mr. REUTER. Well—

Mr. STUPAK. Does anyone know, any one of you? Mr. Woodworth?

Mr. WOODWORTH. There are 20 States, I believe, as far as DEA information, that control GHB.

Mr. STUPAK. Right.

Mr. WOODWORTH. Twelve States control it in Schedule I, including Michigan.

Mr. STUPAK. Right.

Mr. WOODWORTH. If you would like the names of those, I can give them to you.

Five States control GHB in Schedule II, no one schedules it in III, and three States, Alaska, North Carolina and Tennessee, have put it in Schedule IV. Three other States, Texas, New Jersey and Massachusetts, have criminalized activity.

Mr. STUPAK. Thank you. So only three States have criminalized it?

Mr. WOODWORTH. Yes, sir.

Mr. STUPAK. Okay. Go ahead.

Mr. WOODWORTH. Three States have criminalized without putting it under schedule.

Mr. STUPAK. Right.

Mr. Reuter, I want to go back to where we were a little bit more about the time line that has been taken. Let me ask you this question.

If these States have already scheduled Ketamine and GHB into various schedules, do you know how the States have been able to move so quickly on this? Why have the States been able to move quicker, and we have not been able to make any solid recommendations here?

Mr. REUTER. Well, in referring to my written testimony in this case and a little bit of the oral testimony as well, I think we explained that our Office of Criminal Investigations has been active in assisting the States, usually through their legislative process, in adding Ketamine to the various schedules of control available within their State offices.

There is a sense, I do not know precisely how many, but I think there is a sense that many of the States have gone through a legislative procedure to effect control.

Mr. STUPAK. So if the feds did it legislatively, that is fine too then? I mean, if the States can do it, we should be able to take a lead and put it underneath one schedule so we all know what schedule we are dealing with at least.

Mr. REUTER. Yes. I think in some of the testimony we even cite some cases where legislative scheduling has been accomplished with anabolic steroids and I also believe—

Mr. STUPAK. Right.

Mr. REUTER. [continuing] with Methaqualone.

Mr. STUPAK. My 5 minutes are up. Thanks.

Mr. WHITFIELD [presiding]. Thank you.

Mr. Bryant?

Mr. BRYANT. Thank you, Mr. Chairman.

Ms. Maher, let me ask you a question. You may not have the answer to this. Someone else may, but I want to ask this, and I have several other questions I would like to follow with, so if you could keep your answer as concise as possible that would be great.

I ask you this because you are from the Department of Justice. Again, you may know this, and you may not. Do hospitals and law enforcement personnel have the resources to adequately test for the presence of these date rape drugs in the blood system?

Ms. MAHER. I am not sure I am the person to ask on that. My understanding is that they do not have, you know, all the tests that might be helpful in testing for these, but I would defer to others in answering that question.

Mr. BRYANT. Okay. I have been in and out of the committee in other committees, so I have missed some of I guess the middle panel, which would probably have been the better one to ask this to, but I understood there was a concern about the inability in the testing to pick this up after the fact. Okay. Maybe I can submit that to the other panel.

I also am very concerned about the length of time, the delay involved at least on the administrative side of reclassifying this drug. Mr. Reuter, going back to Mr. Upton's question about the average time, the FDA's role in this is typically eight to 10 months and this is going on I think longer, and not just the FDA, but perhaps DEA to some extent and Human Services to some extent.

This just does not seem to be a priority in terms of the issues that we have heard from the first two panels, the concerns that are out there. Tell me I am wrong.

Mr. REUTER. This is a very high priority. This is a very serious matter to the Food and Drug Administration, and we have been actively reviewing this. We have been actively gathering more information to aid in our assessment on GHB. While we have been

doing that, we have been pursuing enforcement actions under the Federal Food, Drug and Cosmetic Act.

I talked a little bit about our Office of Criminal Investigation activities. It is one of the highest priorities within our Office of Criminal Investigation, so indeed we do place a very high priority on this.

Mr. BRYANT. This decision by the FDA, is the paperwork not in the Office of the Commissioner right now to make a decision? My understanding is it has been there since early January of this year, and I am wondering why are we still here in March waiting for a decision?

Mr. REUTER. Well, I will go back and say we are very actively reviewing this. It is an interagency review and recommendation process. The ultimate decision on this is by the Assistant Secretary for Health, as delegated under the CSA.

Mr. BRYANT. Well, again my understanding is that the DEA had made a request of the FDA in September 1998 for a scientific determination on scheduling GHB, and the Division had made a recommendation for Schedule III, which now resides in the Commissioner's office. This is as of January 14, 1999. Is it still in the Commissioner's office?

Mr. REUTER. It is still in the review process within the Department of Health and Human Services.

A recommendation is not a recommendation until it really leaves the Department of Health and Human Services. It is probably not beneficial to split it out where it is in the process because sometimes it could be in the Commissioner's office, and my experience is it can go back for more thorough review and rewriting. So, when it leaves the Department of Health and Human Services, my experience is that is when the recommendation is complete.

Mr. BRYANT. Mr. Woodworth?

Mr. WOODWORTH. You asked also with DEA if it was a priority, and I just wanted to tell you that it was an extremely important priority.

Of the three drugs that we are discussing today, the other two are made by legitimate manufacturers. Even though Flunitrazepam is not available for use in the United States, it is made by a pharmaceutical company.

GHB is not. It is of clandestine manufacture. That is what is found here in the United States. It is made by criminals. They make it mixing an industrial solvent with a drain cleaner.

Mr. BRYANT. Is that against the law now?

Mr. WOODWORTH. Not federally.

Mr. BRYANT. Okay. Just real quick, Mr. Reuter, if you would give us a report, an answer? Could you tell me at least and perhaps the committee precisely if the Commissioner has this recommendation, exactly where it is in the FDA?

I understand that, you know, it can mean a lot of different things, but really what we are looking for is just where it is in the FDA in the process. You can do that after the hearing. You can just submit a letter or something.

Mr. REUTER. Thanks. I prefer to do that.

Mr. BRYANT. Thank you.

Mr. WHITFIELD. Thank you, Mr. Bryant.

Since I have not asked any questions, I think I will take the prerogative as the chairman and ask some questions myself, giving me 5 minutes. Thank you.

Ms. MAHER, I notice you are with the Civil Division at the Department of Justice. Maybe you are not the appropriate person to ask these questions to, but when Representative Lee was testifying she talked about the importance of an education program to make young people more aware of the dangers out there related to these types of drugs.

We were talking to her about funds available for educational purposes as it relates to drug education, and she mentioned that in the community relations department of the Department of Justice that there was money available. Do you know if that is the case?

Ms. MAHER. I do not know specifically what she was referring to.

Mr. WHITFIELD. Are you aware of any pool of money at the Department of Justice that can be used for educational purposes?

Ms. MAHER. I am just not aware of that.

Mr. WHITFIELD. Okay. Is there any money over at FDA for something like that or any of the other agencies represented here today?

[No response.]

Mr. WHITFIELD. We will talk about that later.

Mr. REUTER. I would just say that I would be glad to check and respond to that in writing.

Mr. WHITFIELD. You all are not really aware of any then. Okay.

I also asked Representative Lee about what States already have laws on the books relating to possession of GHB, and she said two States, California and Pennsylvania. Someone mentioned today that there are 18 States that already have this drug classified as a Schedule I, II or III. Is that correct?

Mr. WOODWORTH. Twenty. Correct.

Mr. WHITFIELD. Twenty. Okay. When we say classified as Schedule I, II or IV, does that mean that it is a felony? Schedule I, II and IV, are those felonies or misdemeanors or a combination thereof?

Mr. WOODWORTH. I would imagine it is a combination. Each State is different, and I am unable to answer that other than to speculate that possession would be covered by the States that have it under control.

Mr. WHITFIELD. Okay. So there are more States than just two that are dealing with this presently then, this issue?

Mr. WOODWORTH. Yes, sir.

Mr. WHITFIELD. Okay. The States of Texas, New Jersey and Massachusetts were specifically mentioned. Who mentioned those States?

Mr. WOODWORTH. I did.

Mr. WHITFIELD. What did you say about this?

Mr. WOODWORTH. They had criminalized the activity involving GHB without placing it under a specific schedule.

Mr. WHITFIELD. Okay. So it is not under a schedule, but it is criminalized.

Does the Department of Justice have an official position on whether or not GHB should be placed on schedule?

Ms. MAHER. When we were asked to testify, we had understood that the committee was seeking our testimony on the experience of

the Office of Consumer Litigation in prosecuting cases under the Federal Food, Drug and Cosmetic Act.

Since we learned earlier this week that the committee would like a position from the Department as a whole, we have commenced the process to seek input from other components other than our office that would have views on that, and we can provide that to the committee.

Mr. WHITFIELD. Okay. Okay. We would look forward to receiving that then.

I think that is all the questions that I have. Are there any other questions for this panel?

Mr. STUPAK. Yes, Mr. Chairman.

What are the views then? What have you learned?

Ms. MAHER. We have only begun this 2 days ago. We have begun the process of seeking input from other components that are interested, and we will provide that to the committee, but I am not prepared to do that today.

Mr. STUPAK. Would it help or hurt to?

Ms. MAHER. Well, from a law enforcement perspective, scheduling a drug will always provide additional tools to prosecutors, but we understand that there are other considerations in scheduling a drug other than simply the law enforcement considerations so—

Mr. STUPAK. Sure.

Ms. MAHER. [continuing] from a law enforcement perspective it would certainly help.

Mr. STUPAK. Before you schedule a drug, you have to be concerned about what schedule or what class you put it in, I, II, III, IV, V, or liability reasons if there is a drug manufacturer out there or someone else who wants to use the drug for legitimate purposes because if it is not properly classified you are subject to civil litigation. Is that correct?

Ms. MAHER. I do not—

Mr. STUPAK. Maybe FDA can answer that.

Mr. REUTER. Yes.

Mr. STUPAK. I mean, you just cannot willy nilly put one of these drugs in Schedule I, II, III, IV, V. There are consequences if it is illegally classified. I do not want to say illegally. Improperly classified, correct? It has to stand up in Court subject to judicial review, subject to lawsuits, correct?

Mr. REUTER. Yes.

Mr. WOODWORTH. I would just—

Mr. STUPAK. Yes. Go ahead.

Mr. WOODWORTH. [continuing] respond to that. For a controlled substance, the Drug Enforcement Administration has the final responsibility for defending the Federal decision on a scheduling action.

Regardless of the schedule, it is possible to conduct an activity to develop a drug. For example, if a drug is in Schedule I, we do have a registration category for a researcher, so research and development of the drug can continue while it is placed under control.

Mr. STUPAK. If the Congress passes a piece of legislation that made GHB Schedule III, that would be Congress' statement and, therefore, you would be not subject to these liability or legal challenges? Is that correct?

Mr. WOODWORTH. I have maybe a three part response to that—

Mr. STUPAK. Sure.

Mr. WOODWORTH. [continuing] if I might. Absolutely. Congress can do that without regard to the criteria under 21 USC 812.

If Congress did so, I would suggest perhaps that a couple of other things would apply. Schedule III would not include GBL as an analog.

Mr. STUPAK. Correct.

Mr. WOODWORTH. It would have to be in Schedule I or II. Schedule III, of course, has a connotation of legitimate medical use, and GHB does not have legitimate medical use.

Schedule III has a connotation of a lower level of abuse than I and II, which DEA does not feel applies to GHB. We feel that abuse is very high, if not severe, so there are some other considerations that we would make.

Mr. STUPAK. Sure. Go ahead.

Mr. WHITFIELD. I thought of a couple more questions.

Ms. Maher, do you have any idea when the Justice Department might complete its study?

Ms. MAHER. I guess I should not say soon, right? We can get a view to the committee promptly, within I would imagine the next several weeks.

Mr. WHITFIELD. The next several weeks. Okay. Good.

One other question for Mr. Woodworth. Does DEA have a position on whether GBL meets the definition of an analog to GHB?

Mr. WOODWORTH. We do, and it is in several pieces.

Mr. WHITFIELD. Okay.

Mr. WOODWORTH. First of all, GBL could not be considered as an analog unless GHB is controlled—

Mr. WHITFIELD. Okay.

Mr. WOODWORTH. [continuing] in Schedule I or II only. If it is scheduled in III, IV, V, it cannot be considered as an analog.

Mr. WHITFIELD. Okay.

Mr. WOODWORTH. If GHB is scheduled in I or II, GBL would be considered an analog if it met the definition of an analog, which is to have a similar chemical structure to drugs in Schedule I and II, has a stimulant, depressant or hallucinogenic effect similar to drugs in Schedule I or II, or has been represented to do so and is intended for human consumption. That is a very important piece there.

What the analog provision does is it criminalizes the illegal activity outside of the investigational new drug process where development can continue. The only activity that is criminalized is that illegal activity, but it must be intended for human consumption.

This has to be proven in Court. There is not a list of analogs. You would testify at Court that this met the definition for an analog and was intended for human use.

I would point out one small possible difficulty with that is that that would address GBL as a drug, not as a chemical, so if GBL is—

Mr. WHITFIELD. Correct.

Mr. WOODWORTH. [continuing] given and represented to be for human consumption, then it is covered. If GBL is just sold to some-

one, there is not a further representation, then it would not be considered as an analog.

Therefore, DEA would recommend that it be considered as a listed chemical also covered under the Controlled Substances Act as a List I chemical, and certain measures could be taken to accommodate the industry, which has been very cooperative.

You may be aware that we have published a notice in the Federal Register in October soliciting comments about GBL, and the industry has been very cooperative and told us what their concerns and needs are. That would be a possibility.

Mr. WHITFIELD. Okay.

Mr. WOODWORTH. I hope that answers your question.

Mr. STUPAK. Mr. Chairman, may I?

As a listed chemical, that means tracking then, right, who sold that chemical? We have some track as to the means and where it went—

Mr. WOODWORTH. Absolutely.

Mr. STUPAK. [continuing] and the amount, basically what our legislation addresses?

Mr. WOODWORTH. Yes, sir.

Mr. WHITFIELD. You all are a popular panel.

Mr. Bryant?

Mr. BRYANT. We just do not want you to go. Mr. Woodworth, do I understand you to say that it would be DEA's position that GHB ought to be scheduled as a Schedule I or II, as opposed to III or IV, were Congress to act?

Mr. WOODWORTH. Yes, sir.

Mr. BRYANT. And that GBL, the DEA's position would be that preferably that it be scheduled itself on the CSA as a Schedule I?

Mr. WOODWORTH. No, sir.

Mr. BRYANT. No. As a chemical?

Mr. WOODWORTH. As a chemical. As a List I chemical, not as a drug. That would cover the chemical aspects, and then the analog provision would apply and address its use as a drug if it is represented for human consumption.

Mr. WHITFIELD. Okay. We are going to have one more question from Mr. Stupak, and then that is it.

Mr. STUPAK. Thanks, Mr. Chairman.

I would just like to ask each on this panel has industry been cooperative in your efforts and research and trying to track and things like this, GBL especially?

Mr. WOODWORTH. With regard to GBL, the industry has been extremely cooperative, yes.

Mr. STUPAK. We have mentioned about four different drugs here or byproducts. Has industry not been cooperative on any of them, Ketamine or GHB or any of the others? Well, GHB is an illegal drug, but Ketamine or the—

Mr. WOODWORTH. No. Not from DEA's point of view, no.

Mr. STUPAK. Okay. Ms. Maher?

Ms. MAHER. We would not really have occasion to seek cooperation from industry.

Mr. STUPAK. Mr. Reuter or Mr. Zukin?

Mr. REUTER. They have been cooperative, as far as I know.

Mr. STUPAK. Okay.

Mr. ZUKIN. NIDA has not dealt directly with industry on this matter.

Mr. WHITFIELD. Okay. I want to thank—

Mr. STUPAK. Just one follow up.

Mr. Woodworth, if you listed GBL, would it put any burden on industry? Can they live with it?

Mr. WOODWORTH. We would design it with their comments in mind—

Mr. STUPAK. Sure.

Mr. WOODWORTH. [continuing] where there would be specific exemptions to prevent sale to consumers, for example.

Most of the activity is very large quantities of GBL. There are tens of thousands of tons produced in the United States. What people need for GHB production is a very small quantity. That is what we would focus on. We would craft our regulation to do exactly that.

Mr. STUPAK. Sure. You just would not allow it to show up at Post Office Box 143 up in Menominee, Michigan.

Mr. WOODWORTH. Right. Yes, sir.

Mr. WHITFIELD. I want to thank this panel for your patience. We really appreciate your testimony. We look forward to hearing from you and working with you on this important issue. Thank you.

Now at this time we will call Ms. Patti Engel, who has also been very patient. We apologize that she has had to wait so long.

Mr. UPTON. Ms. Engel, welcome to the subcommittee.

Ms. ENGEL. Thank you.

Mr. UPTON. As you have heard undoubtedly the other panelists, do you have any objection to swearing under oath, and do you have a counsel that you need to have?

Ms. ENGEL. No.

Mr. UPTON. Terrific.

[Witness sworn.]

Mr. UPTON. Thank you very much. I recognize you for 5 minutes. Your whole statement will be made as part of the record.

Ms. ENGEL. Thank you.

Mr. UPTON. We appreciate you having the indulgence to stay with us most of the day.

TESTIMONY OF PATTI ENGEL, ORPHAN MEDICAL, INC.

Ms. ENGEL. Mr. Chairman and members of the committee, my name is Patti Engel, and I work for Orphan Medical, a very small company in Minnesota that specializes in developing medications for people who suffer from rare diseases, life threatening rare diseases that most people have never even heard of.

Mr. Chairman, before I begin my comments, I want to respond to two comments that were previously made. First, I want to state unequivocally that Orphan Medical does not believe that scheduling GHB as a Schedule III will magically somehow produce an FDA approval. We know that the data in our NDA will be the basis for approval; nothing less.

Second, I want to assure you that Orphan Medical does indeed understand how this drug affects the human brain in patients with narcolepsy.

I would like to say at the outset that Orphan Medical agrees with this subcommittee and others that the use of GHB or any other chemical to commit a crime, especially a rape, is unconscionable, and they must be severely punished. We know, too, that home-brewed GHB is dangerous.

We agree that the illicit use of GHB must be stopped, but we also believe that dealing with complex issues that can at one time save lives and other times hurt them is complex and should be looked at from various perspectives. We appreciate the opportunity to share this perspective with you.

Orphan Medical first learned about GHB in 1994. At that time, the FDA did something that it does not often do. The FDA Office of Orphan Products asked us to develop this drug to treat the disabling symptoms of narcolepsy called cataplexy. The FDA believed GHB was a promising medication, but had been unable for 20 years to generate any commercial interest in this agent. Because orphan drugs are our business, we accepted this challenge.

While the daytime sleepiness component of narcolepsy is treated with a number of medications, including a newly approved medication called Modafanil, there is virtually nothing that works for cataplexy, the condition that GHB treats. For many years, doctors have treated cataplexy with anti-depressants. Unfortunately, these medications do not really treat the disease itself and thus are not truly effective.

About 10 years ago, FDA learned that GHB could treat cataplexy in a very different way. The drug appears to induce a restful sleep that people with narcolepsy do not typically experience. It promotes REM or rapid eye movement sleep, thereby reducing cataplexy attacks.

About 5 years ago, after Orphan Medical was contacted by FDA about developing this medication, I myself had the chance to visit sleep centers and talk to patients who had used this experimental agent in clinical trials. I spoke firsthand to patients who told me that GHB had changed their lives. The use of GHB had reduced cataplexy attacks in some patients from 50 a day to two a month. It enabled patients to work, to go to school, to live normal lives.

Frankly, these testimonials sounded too good to be true, and we were skeptical and knew that we had to put this drug to scientifically rigorous tests to validate or to disprove the claims of the patients and the researchers with whom we talked.

In 1998, under FDA's guidance, we initiated rigorous, well-controlled clinical trials at sleep centers in 14 States to study the use of GHB. The FDA considered our findings of GHB safety and efficacy for controlling the symptoms of narcolepsy to be significant and asked us to conduct a treatment IND to increase patient access to this promising new medication.

The data collected under the treatment IND will be added to the years of evidence we have already collected and will be used in our NDA. We expect to submit our NDA later this year or early next.

During the time that we have been developing GHB as a treatment for cataplexy, concern about its illicit use has grown, but it is very important to note that no medical grade GHB has ever been diverted for illicit use despite its use in clinical trials in 14 States.

We share the concern for public safety that has been eloquently described today, and over the past 3 years we have worked with FDA, DEA and Members of Congress to find an appropriate way to control this illegal use.

Our goal and message have been consistent. Severely punish those who illegally manufacture, distribute or possess GHB and its analogs. Severely punish sexual predators who would use this and any chemical to commit assaults, but do so without denying narcolepsy patients access to the only medication that will treat their cataplexy.

We suggested to various Members of Congress that one solution to this extremely serious problem is to amend the CSA to list GHB as a Schedule IV controlled substance, but to punish anyone who manufactures, distributes or possesses GHB or its analogs with Schedule I penalties.

It is important to recognize that the chemical precursor, GBL, needs to be considered. Today, GBL, as you have heard, is used legally by manufacturers of paints, beer and electronics, but there is absolutely no reason for any individual to possess GBL.

You have heard this morning about the problems associated with GBL, which is called scoop. GBL will not be stopped by making GHB a Schedule I. Some have suggested that the solution to this problem is to take action at a national level, and we agree wholeheartedly.

We believe that the proposal to solve this terrible problem by listing GHB as a Schedule I or controlled substance would in fact have dire consequences for patients with narcolepsy, whether the scheduling is done during research or after the drug is approved by FDA, and let me explain.

The fact that Schedule I drugs can be used in research, while technically accurate, does not respond to the real world difficulties of working with such a product. Research studies can only be done if a company can manufacture the drug or find a manufacturer willing to make it and if doctors are willing to participate in the clinical trials.

If GHB were put as a Schedule I, the company which currently manufactures the pharmaceutical grade GHB for the clinical trials will cease production. We have also been told that sleep centers now participating in the clinical trials would not participate if GHB were a Schedule I substance.

While theoretically we could find another manufacturer, we have been unable to locate someone willing to do so to date because of the very limited commercial potential of this agent.

Even if GHB were listed as a Schedule II agent, a 20,000-square-foot vault made of 8-inch thick concrete walls would be required. At an estimated \$20 million, that would more than double the cost of developing this agent, which is an agent used for a very rare disease. We would be forced to tell FDA to find another company willing to develop this drug, and the patients who need this for narcolepsy would be forced to wait many more years.

We hope that you will agree that the medical grade GHB should be listed as a Schedule III or IV and that criminals who use this and other chemicals to perpetrate crime should be penalized.

Mr. Stupak's bill and, as we have heard this morning, Ms. Jackson-Lee's proposed amendments to her bills are approaches that strike the right balance between punishing wrongdoers and preserving patient access to crucial medicines.

I also want to mention that statements are attached to my testimony from the American Sleep Disorder Association, from the National Association for Rare Diseases and the National Sleep Foundation, and I respectfully request that these statements be included in the hearing record along with my full written statement.

Thank you for the opportunity to testify.

[The prepared statement of Patti Engel follows:]

PREPARED STATEMENT OF PATTI ENGEL, VICE PRESIDENT, ORPHAN MEDICAL, INC.

Mr. Chairman and Members of the Committee, my name is Patti Engel. I work for Orphan Medical, a very small company in Minnesota that specializes in developing medicines for people who suffer from rare diseases—life-threatening rare diseases that most people have never heard of.

One such disease is Congenital Sucrase-Isomaltase Deficiency. This is a genetic disorder that leaves children unable to digest common table sugar and some starches, leading to malnutrition and developmental delays. Another orphan disease for which we have developed a drug is Homocystinuria, which affects children by making them unable to metabolize homocystine. This condition leads to mental retardation, blindness, and death.

Both of these conditions affect fewer than 1,000 children in the US. The medicines we've developed help people with these orphan conditions and others live more normal lives.

Currently, Orphan Medical is working to complete the studies needed for approval of a New Drug Application (NDA) for the drug gammahydroxybutyrate (GHB) to treat the most severe form of narcolepsy.

I'd like to say at the outset that Orphan Medical agrees with this Subcommittee and others that use of GHB or any other chemical or drug to commit a crime—especially a rape—is unconscionable and must be severely punished. We know too that “home-brewed” GHB is dangerous. We agree that illicit use of GHB must be stopped. But we also believe that dealing with a substance that can at once save lives and hurt them is complex and should be looked at from various perspectives. We appreciate the opportunity to share our perspective with you.

Orphan Medical first learned about GHB in 1994. The FDA Office of Orphan Products asked us to develop this drug to treat the disabling effects of narcolepsy. The FDA believed GHB was a promising therapy, but had been unable for 20 years to generate any commercial interest in the drug. Because orphan drugs are our business, we accepted this challenge.

Narcolepsy is a rare, disabling sleep disorder that affects about 180,000 Americans. Many think of narcolepsy as a disease that causes people to fall asleep at inappropriate times, but actually it is much more serious than that. About 65% of narcolepsy patients experience a symptom of the disease called cataplexy—sudden and total loss of muscle control. A total cataplectic attack results in immediate, complete body collapse. This can happen anywhere or at any time, no matter what a person is doing—walking, driving, swimming, or holding a baby. During these attacks the patient appears unconscious; in reality, however, the person is quite alert and awake, but unable to talk, move, or even remove himself or herself from a potentially dangerous situation. Cataplexy is often triggered by stress, fatigue, or emotional reactions such as laughter, fear, surprise, or sadness.

Because of the unpredictability and frequency of attacks, people with cataplexy are unable to live normal lives. They often can't work outside the home or drive a car. They can't go to a movie, mow the lawn, or hold a baby.

While the daytime sleepiness component of narcolepsy is treated with a number of medications, including a newly approved medication called Modafanil, there is virtually nothing that works for cataplexy. For many years, doctors have treated cataplexy with antidepressants in an effort to “flatten” the emotional outbursts which can lead to an attack. Unfortunately, these medicines do not really treat the disease itself and thus are not truly effective. Furthermore, antidepressants often have undesirable side effects, not to mention that patients are unable to experience fully the emotions that you and I associate with normal life.

About 10 years ago, the FDA learned that GHB could treat cataplexy in a different way. This drug appears to induce a restful sleep that people with narcolepsy don't ordinarily experience. It promotes REM, or rapid eye movement sleep, thereby reducing cataplexy attacks.

Early on, FDA approached some drug companies about developing GHB as an orphan drug, and several actually started development. However, as they ran into challenges, each of these companies abandoned the project, in part because the very limited commercial market potential made this an unfavorable investment of research funds.

About 5 years ago, after Orphan Medical was contacted by FDA about developing GHB, I had the chance to visit some sleep centers where the drug was being used as an experimental treatment for narcolepsy patients. I spoke first-hand to patients, who told me that GHB had changed their lives. Use of GHB reduced cataplexy attacks in some patients from 50 a day to 2 a month. It enabled patients to work, go to school, live a normal life.

Frankly, these testimonials sounded too good to be true. We were skeptical and knew we had to put this drug to a scientifically rigorous test to validate or disprove the claims of the patients and the researchers with whom we had talked.

In 1998, with FDA's guidance, we initiated rigorous, well controlled clinical trials at sleep centers in 14 states to study the use of GHB as a treatment for narcolepsy. In August 1998 we presented the clinical findings from this study to FDA.

The FDA considered our findings of GHB safety and efficacy for controlling the symptoms of narcolepsy to be so significant that they asked us to conduct a "treatment IND," to increase patient access to this promising new drug. It is important to note that a treatment IND is a mechanism to make available to patients, outside of clinical trials, promising therapies for serious and life-threatening diseases for which there are no satisfactory alternative treatments. In the past, drugs for cancer, AIDS, severe Parkinson's Disease, multiple sclerosis, respiratory distress syndrome in infants, and diabetes have been made available under treatment INDs. Now, narcolepsy patients also will benefit from this.

The data collected under the treatment IND will be added to the years of evidence we've already collected, and will be used in our NDA. We expect to submit our NDA later this year or early next year.

During the time that we've been developing GHB for the treatment of narcolepsy, concern about its illicit use has grown. As you already have heard, information about how to make and use GHB is readily available on the Internet. Its chemical precursor, gammabutyrolactone (GBL), is readily available and can be obtained easily. Anyone with a computer, credit card, and the inclination to surf the Net can find the recipe, buy the ingredients, and make a batch of "home-brewed" GHB. Because the material is home-brewed, the levels of toxicity vary dramatically, a capful of one batch may be as toxic as a cup of another.

It is very important to note that *no* medical grade GHB has *ever* been diverted for illicit use, despite its use in clinical trials in 14 states.

The "reputation" of GHB and its easy manufacture have caused tremendous problems for law enforcement. We share the concern for public safety that has been so eloquently described this morning. Over the past three years, we have worked with FDA, DEA, and members of Congress to find an appropriate way to control the illegal use of GHB.

Our goal and message have been consistent: Severely punish those who illegally manufacture, distribute, or possess GHB or its analogs. Severely punish sexual predators who would use this chemical to commit an assault. But do so without denying narcolepsy patients access to the only medication which will treat their cataplexy.

We have suggested to various members of Congress that one solution to this extremely serious problem is to amend the Controlled Substances Act to list GHB as a Schedule IV controlled substance, but to punish anyone who manufactures, distributes, or possesses GHB or its analogs with Schedule I penalties. That is, on conviction of these illegal acts, a person would be subject to imprisonment of up to 15 years and a fine of up to \$250,000.

Mr. Chairman, we maintain that such Schedule I level penalties are at the heart of the issue. As the recent tragedy in Michigan has shown, simply having a substance on Schedule I is not a deterrent. But knowing that you are going to get 15 years in prison and a quarter-million-dollar fine is.

A similar approach was taken in the 1996 Date Rape Act, supported by both Republicans and Democrats. This Act effectively adds 10 years to the rape conviction of anyone who used any substance to facilitate a sexual assault.

Mr. Chairman and members of the committee, it is also important to recognize that the chemical precursor of GHB, GBL, and chemical analogs of GHB also need

to be considered. Today, GBL is used legally and appropriately by manufacturers of paints, beer, and electronics. One key to stemming the illicit manufacture of GHB is to criminalize the illegal use and possession of GBL. There is absolutely no reason for any individual to possess GBL. If an individual, as opposed to a legitimate manufacturer, has GBL, it is for one reason, and that is to make GHB, or to use it as if it were GHB.

GBL is the necessary ingredient in making GHB. As I mentioned earlier, GBL is easy to find and purchase. Nearly 100% pure GBL can be purchased off the Internet for as little as \$35. Or, if a person is looking to run a major GBL trafficking operation, the chemical can be obtained in bulk with little if any screening of the purchaser. As a test, last summer we contacted four reputable chemical suppliers. We used a false company name, a false phone number, and a credit card. Two of these suppliers quickly offered to set up an account for us to obtain GBL in huge quantities.

Florida authorities tell us that last year illicit manufacturers of GHB learned they did not have to bother going to the trouble of brewing GHB. They discovered that GBL is naturally converted in the body to GHB. Now, they are just selling caps full of diluted GBL. They call it "Scoop." A small bottle of GBL can be diluted to make 50 doses of "Scoop." At about \$20 per dose, that's a lot of money for the dealer. A sexual predator could use the GBL in a small bottle to help him commit as many as 15 sexual assaults.

In Florida, GHB abuse is dropping as GBL abuse is increasing. Florida law enforcement officials tell us that the demographics of abusers have changed, and that while GHB abuse was occurring among 20-30 year olds, GBL abuse is occurring among 15-20 year olds. This is an outrage. Making GHB a Schedule I agent will do nothing to prevent this. Florida has responded to this problem by modifying its statutes and including GBL as a controlled substance.

Some have suggested that the solution to this problem is to take action at the national level. We agree wholeheartedly. However, we believe the proposal to solve this terrible problem by listing GHB as a Schedule I or II controlled substance would have dire consequences for patients with rare diseases, whether that scheduling is done during the research or after the drug is approved by FDA. Let me explain what I mean.

The fact that Schedule I drugs can be used in research, while technically accurate, does not respond to the real-world difficulties of working with such a product. Research studies can only be done if a company can manufacture the drug or find a manufacturer willing to make it, and doctors are willing to participate in trials which use a Schedule I drug. If GHB were listed as a Schedule I substance, the company which currently manufactures pharmaceutical grade GHB for our clinical trials would cease production. We also have been told that sleep centers now participating in our clinical studies in at least some cases would not participate if GHB were a Schedule I substance.

While theoretically we could find another manufacturer, we have been unable to date to locate one willing to manufacture a product of such low volume and potential profitability, even if the drug is not a controlled substance. This difficulty would be exacerbated if we were seeking a manufacturer to make a Schedule I substance. The reason for this is the enormous investment a manufacturer would have to make, for the small financial return of an orphan drug.

Even if GHB were listed as a Schedule II agent, a 20,000 square foot vault (the size of a small airplane hangar) with 8-inch concrete walls would be required to store the pharmaceutical-grade GHB. The cost of construction, estimated at \$20 million, would more than double the costs of developing this drug. The economic disincentive alone would result in a discontinuation of the clinical trials, the NDA process, and the hopes of narcoleptic patients with cataplexy. We would be forced to tell FDA to find another company willing to develop this medication for this rare disease. The history of GHB tells us that narcolepsy patients would have to wait many more years for GHB to be available to them.

We hope you will agree that medical grade GHB should be listed as a Schedule III or IV drug and that criminals who use this or other chemicals to perpetrate crimes should be severely penalized.

I want to thank you for the opportunity to testify and would be happy to answer any questions.

AMERICAN SLEEP DISORDERS ASSOCIATION

THE USE OF GHB IN TREATING NARCOLEPSY

POSITION STATEMENT & RECOMMENDATIONS OF THE ASDA

Rationale

The following position statement was commissioned by the American Sleep Disorders Association (ASDA) Board of Directors and provides a review of the evidence on gamma-hydroxybutyrate (GHB) as well as recommendations for its classification schedule. The report focuses on proven scientific and therapeutic uses of GHB; potential for abuse; and how GHB might best be classified if it becomes a controlled substance. The best, published evidence from peer-reviewed, scientific journals about GHB was considered and primary observations other than reviews, editorials, letters, or reports in newspapers and magazines were concentrated on.

Proven Therapeutic Use Of GHB In Narcolepsy

Several independent investigators have reported beneficial effects in narcolepsy with GHB but only 2 double-blind studies have been published (Scrima et al, 1989 and 1990; Lammers et al., 1993). The first was performed by Scrima (1989 and 1990) in 20 patients using 50 mg/kg/night. A significant decrease in cataplexy was observed but no significant effects on daytime sleep attacks were reported when compared to placebo. The second study was performed by Lammers (1993). Twenty-four patients received GHB, 60 mg/kg/night. Hypnagogic hallucinations and daytime sleep attacks decreased significantly. Cataplexy was also reduced by 50 percent, but the effect was not significantly different from placebo due to large inter-individual variation. In both studies, sleepiness as measured using MSLT sleep latencies was only slightly affected (maximum difference in mean sleep latency: 1 minute).

Based on these two reports, there is little doubt that the drug is helpful to narcoleptic patients. Several other independent investigators have confirmed the findings in open labeled studies (Broughton and Mamelak, 1979; Mamelak et al., 1986). The most consistent and least controversial effects are improved cataplexy and improved nocturnal sleep disruption with GHB treatment (Scrima et al., 1990; Broughton and Mamelak, 1980; Bedard et al., 1990). Further investigations would be needed to confirm a possible beneficial effect for daytime sleepiness.

Importantly, GHB anti-cataplectic effects are clearly mediated by a different mode of action when compared to those produced by antidepressant compounds. As such, patients who do not tolerate classical antidepressant treatment because of side effects, tolerance or contraindications would not have any other choice if GHB were not available to them.

Therapeutic Use Of GHB In Other Medical Disorders

Besides its demonstrated efficacy in narcolepsy, GHB has proved useful when evaluated in controlled trials for anesthesia (Kleinschmidt et al., 1997; Kleinschmidt et al., 1998) and for treatment of withdrawal syndromes (Gallimberti et al., 1989; Gallimberti et al., 1992; Gallimberti et al., 1993).

Use Of GHB In Basic Neuroscience Research

GHB is a unique tool in neuroscience research. Maitre (1997) just reviewed the neurobiology of GHB. The compound is a natural metabolite of GABA; it is synthesized and accumulated in neurons in the brain. Investigators have shown that GHB behaves as a genuine CNS neurotransmitter distinct from GABA. GHB receptors have been identified and a pharmacological antagonist of the compound (NCS-382) has been synthesized. The most established pharmacological effect of the compound is to dramatically decrease the firing rate of mesocorticolimbic dopaminergic neurons in the brain while activating dopamine synthesis. This effect produces an acute increase in dopamine stores. Higher doses are also believed to activate GABA-B receptors.

One of the most interesting properties of the compound is its ability to increase both REM and Slow Wave Sleep (SWS). Almost all other hypnotic compounds available to us suppress REM and SWS, thus GHB produces a more "natural" sleep architecture. This difference in profile has been established in several animal species including humans. It is also clear that not only the hypnotic profile of GHB but also its mode of action is distinct from all other commonly prescribed hypnotic compounds. No other known compound has the paradoxical effect on dopaminergic transmission described above. As such, it is not only an interesting compound but research in the area may lead to the discovery of novel hypnotics that may have clinical application far beyond narcolepsy.

Prevalence And Severity Of GHB Abuse

GHB, also known as sodium oxybate, is a naturally-occurring fatty acid derivative that is neuroactive and has abuse potential. GHB has powerful depressant effects on the central nervous system and has been used as an anaesthetic, however in lower doses it can produce a state of euphoria which has led to popular recreational use (Li et al, 1998). Also, GHB has been used by bodybuilders because of its anabolic effects. Physical dependence can occur. In addition, prolonged abuse may result in seizures and withdrawal symptoms. The withdrawal syndrome includes insomnia, anxiety and tremor that usually resolves in 3-12 days.

GHB has been referred to as a "date rape" drug when combined with flunitrazepam, because of the tendency to induce initial euphoria and subsequent CNS depression. Excessive intake of GHB has led to serious sequelae including respiratory arrest and death.

Typically, profound unconsciousness occurs in severe GHB toxicity, and despite full (and often rapid) recovery, most patients require medical intervention, including intubation and mechanical ventilation. Interestingly, GHB has hypoxia-sparing effects that may aid the total recovery seen in the majority of cases of severe toxicity. The adverse effects are more serious when GHB is used with other illicit drugs and alcohol (Ryan et al., 1997). Of the 10 deaths reported with GHB all have been associated with the use of mixed drugs (Li J, personal communication). However, in lower doses, the drug has been used to aid withdrawal from opiate and alcohol addiction. GHB has led to abstinence of alcohol in 78% of 179 alcohol dependent subjects (Addorato et al., 1996).

Although available since 1990, the current prevalence of GHB use is not known, however it is believed that it is relatively low compared with cocaine and marijuana. In 1995-1996, poison control centers in New York and Texas reported 69 acute poisonings and one death attributed to GHB (JAMA, 1997).

Since the recent widespread publicity about GHB there have been numerous sources of information available on how to make GHB, particularly on the internet. GHB can be easily synthesized from Lactone (gamma-hydroxybutyral lactone), also a potent euphoric drug that is inexpensive and occasionally sold as GHB. Lactone is widely used and available in industry with little prospects of regulation of its availability. Two states have made GHB a schedule I drug, and 20 states have made it a misdemeanor or felony to distribute GHB (Li J, personal communication). Most states have legislation pending.

Recommendations Of The ASDA

GHB has demonstrated therapeutic usefulness in narcolepsy, cardiac anesthesia, and withdrawal syndromes. GHB abuse is a problem, but there is no documented evidence that supplies of GHB from the medical and scientific community have been diverted for illegal uses. Classification of GHB as a Schedule I drug is likely to impede further research into clinical and scientific applications of GHB. The ASDA opposes a Schedule I classification of GHB.

References:

- Addorato G, Castalli E, Stefani GF, Casella G. An open multicentric study evaluating 4-hydroxybutyric acid sodium salt in the medium term treatment of 179 alcohol dependent subjects. *Alcohol* 1996;31(4):341.
- Bedard MA, Montplaisir J, Godbout R., Lapierre O. Nocturnal Gamma Hydroxybutyrate. *Clin. Neuropharmacology* 1989;12(1):29-36.
- Benet LZ. *Principles of prescription order writing and patient compliance instructions*. In: Hardman JG, Limbird LE (Eds). *Goodman and Gilman's The Pharmacological Basis of Therapeutics* (9th Edition), McGraw Hill, New York, 1996:1703.
- Broughton R, Mamelak M. The treatment of narcolepsy-cataplexy with nocturnal Gamma-Hydroxybutyrate. *J Cann Neurol Sci* 1979;6:1-6.
- Broughton R, Mamelak M. Effects of nocturnal Gamma-Hydroxybutyrate on Sleep/waking patterns in narcolepsy/cataplexy. *J Cann Neurol Sci* 1980;7:23-31.
- From the Centers for Disease Control and prevention. Gamma Hydroxybutyrate use—New York and Texas. *JAMA* 1997;277(19):1511.
- Gallimberti et al. Gamma-hydroxybutyric acid for treatment of alcohol withdrawal syndrome. *Lancet* 1989;2(8666):787-9.
- Gallimberti et al. gamma-Hydroxybutyric acid in the treatment of alcohol dependence: a double-blind study. *Alcohol Clin Exp Res* 1992;16(4):673-6.
- Gallimberti et al. Gamma-hydroxybutyric acid for treatment of opiate withdrawal syndrome. *Neuropsychopharmacology* 1993;9(1):77-81.
- Kleinschmidt S, et al. Total intravenous anaesthesia using propofol, gamma-hydroxybutyrate or midazolam in combination with sufentanil for patients undergoing coronary artery bypass surgery. *Eur J Anaesthesiol* 1997;14(6):590-9.
- Kleinschmidt S, et al. Total intravenous anaesthesia with gamma-hydroxybutyrate (GHB) and sufentanil in combination with sufentanil for patients undergoing coronary artery bypass graft surgery: a comparison in patients with unimpaired and impaired left ventricular function. *Eur J Anaesthesiol* 1998;15(5):559-64.

Li J, Stokes SA, Woeckener A. A tale of novel intoxication: a review of the effects of gammahydroxybutyric acid with recommendations for management. *Ann Emerg Med* 1998;31(6):729

Maitre M. The Gamma-Hydroxybutyrate signalling system in brain: Organization and functional implications. *Prog Neurobiol* 1997;51:337-361.

Mamelak M, Scharf M, Woods M. treatment of narcolepsy with gammahydroxybutyrate: a review of clinical and sleep lab findings. *Sleep* 1986;9:285-289.

Ryan JM, Stell I. Gamma hydroxybutyrate—a coma inducing recreational drug. *J Accid Emerg Med* 1997;14(6):411.

Scrima L, Hartman PG, Johnson FG, Thomas EE, Hiller FC. Efficacy of Gamma hydroxybutyrate versus placebo in treating narcolepsy-cataplexy: double blind subjective measures. *Biol Psychiatry* 1989;26:331-343.

Scrima L, Hartman PG, Johnson FG, Thomas EE, Hiller FC. The affects of Gamma-hydroxybutyrate on the sleep of narcoleptic patients: a Double blind study. *Sleep* 1990;13:479-490.

Sharf MB, Brown D, Woods M, Brown L, Hirschokitz J. The effects and effectiveness of gammahydroxybutyrate in patients with narcolepsy. *J. Clin Psychiatry* 1985;46:222-225.

Mr. UPTON. Without objection. We again appreciate you waiting this long during the day to come before us.

I do not really have a question. I have a comment, and that is I sense that we are all on the same page. I do not know the best way to do it, but from Fred Upton speaking I want to see this stuff stopped from getting into our kids' systems. I want to do it in a way that it is not going to trigger or see it trigger some precursor or some analog which is going to come about, whether it be GBL or some further hybrid later on.

As I begin to scratch the surface on this, I do not know whether it is better to have a Schedule I, II, III or IV with appropriate penalties, but I think based on what I heard you just say as part of your testimony is that from industry's perspective, at least yours, you would like to see it at least Schedule IV, if not Schedule III—I understand your concerns with Schedule II—with some type of penalty along the lines that we have seen in either Ms. Sheila Jackson-Lee's bill or my colleague Bart Stupak's bill with the penalties so that you cannot move to that second or third or fourth step where we heard so much testimony particularly from the States.

Actually, one of the questions I wanted to ask Panel 2, and I think it stemmed from Mr. Dingell's question. We do not really have a kit to even decipher where we can find it, and it is because it is odorless. It is tasteless. It is easily passed off as water.

If we get the appropriate stop gates to prevent it, it seems to me that at least your industry, and probably other industry folks, would be happy. Is that correct?

Ms. ENGEL. That is correct, Mr. Chairman.

I would like to add that Orphan Medical has in fact a validated assay for GHB and is very willing and has shared its willingness with law enforcement and whatnot as to working together to be able to help come to solutions to these challenging problems.

While we are a small company and, unlike what you heard earlier, we are, frankly, not profitable—

Mr. UPTON. I know Minnetonka. I do not think there is anything big in Minnetonka.

Ms. ENGEL. We are not able to do that ourselves, but we would welcome the opportunity to work with law enforcement to assist them with the already in hand knowledge that we have about this compound and about its assay methodology.

Mr. UPTON. Thank you.

Mr. Stupak?

Mr. STUPAK. Thank you.

Ms. Engel, I take it then you could support our bill, which would place this GHB as a Schedule III with Schedule I penalties?

Ms. ENGEL. Yes, we would support that bill, especially given the penalties as Level I for the possession, distribution and manufacture of not only GHB, but all of its precursor chemicals and analogs.

Mr. STUPAK. So the tracking of—

Ms. ENGEL. Exactly.

Mr. STUPAK. There is no problem then with the chemical with—

Ms. ENGEL. No.

Mr. STUPAK. [continuing] your use?

Ms. ENGEL. No. As I mentioned earlier, the GBL is widely used in much commercial manufacture.

Mr. STUPAK. Right.

Ms. ENGEL. Paints, beers, plastics components. These manufacturers are quite accustomed to dealing with regulated chemicals.

Mr. STUPAK. Tell me a little bit more about your testing that you think may be of some help to law enforcement to do a test kit, an on the road test kit.

Ms. ENGEL. Currently in our clinical trials, we assay the patient's blood for the presence of GHB. I am not a scientist by training so I do not want to mis-speak, but I believe the test is a GC mass methodology.

Mr. STUPAK. So you would have to draw blood?

Ms. ENGEL. Yes.

Mr. STUPAK. So then we are back to the idea of search warrants.

Ms. ENGEL. What we learned from Dr. Ward Donovan just a few days ago, who runs the Poison Control Center at Penn State-Geisinger in Pennsylvania, is that it is not impossible by any means to do GHB levels.

It is very common, however, that the typical emergency room screening that is used when a patient is admitted—

Mr. STUPAK. Sure.

Ms. ENGEL. [continuing] does not include that, so unless a physician is aware of GHB and GBL and knows to ask for a GHB screening, it does not happen, but those tests are available.

Mr. STUPAK. But that would be more emergency room setting, right?

Ms. ENGEL. That is exactly right. As—

Mr. STUPAK. Does it become—I am sorry.

Ms. ENGEL. I am sorry. I was going to mention as I mentioned, we would be willing to work with whatever agencies would be willing to assist us in the development of forensic testing, would that be possible.

Mr. STUPAK. Having been in law enforcement, you try to do it in the field. We usually have a kit, and we put a drop of this or a drop of that and see what kind of color it turns, which would indicate, not conclusively conclude, that a drug may be present in this substance.

With the vials and little containers that Ms. Porrata had earlier, that is what law enforcement is running into, and they need some

kind of field test to see if GHB or whatever is present in those substances.

Ms. ENGEL. Yes.

Mr. STUPAK. I have no further questions, Mr. Chairman.

Mr. UPTON. Mr. Whitfield?

Mr. WHITFIELD. I just have one question, Mr. Chairman.

If you placed GBL into a Schedule III, which Mr. Stupak's bill does, I believe—

Mr. UPTON. GHB or GBL?

Mr. WHITFIELD. I think it is GHB. GHB into Schedule III, which you recommend, it is my understanding that there are like 17 or 18 different analogs out there and that in doing that you are not able to take care of the other analogs or cover those. How would you respond to that?

Ms. ENGEL. Well, what I can tell you is that in the State of Florida they have utilized legislative language that deals with gamma hydroxy butyric acid. It is esters, it is ethers, it is salts and any isomers of esters, ethers or isomers.

They believe there that no matter how you do this language, you are going to have some very bright bathtub chemist within a few years find a loophole, so in Florida what they have attempted to do is make the legislative language so very broad that any creative chemist would not find a loophole around it. We would support that same approach.

By utilizing the scheduling process and to put GHB in a gross schedule of a I suggesting no appropriate medical use or a Schedule II or the easy fix, if you will, of being able to deal with its analogs, we appreciate that that may be easy for law enforcement, but, unfortunately, this is not an easy problem.

There are patients out there with a condition called cataplexy who have no other options, and we believe that a complex situation like this will and does require some complex thought and thus have supported very strongly Mr. Stupak's bill and these more encompassing languages.

Mr. WHITFIELD. I yield to Mr. Stupak.

Mr. STUPAK. My legislation does that with the ethers, the salts and all that, but how is it working in Florida? Is it working?

Ms. ENGEL. The language there was only recently passed. From what we hear from law enforcement there is that they are now able to go after the GBL issue, so, you know, that is what I know today.

Mr. STUPAK. Has any derivative drug developed from it?

Ms. ENGEL. Not that we know of.

Mr. STUPAK. Thanks.

Mr. WHITFIELD. I yield back the balance of my time. Thank you.

Ms. ENGEL. Thank you.

Mr. UPTON. Again, I appreciate your testimony and all those folks that came and were with us for the day.

I think we have outlined a very serious trouble that really does need some action. I certainly am prepared to work with my colleagues to address this situation so that it no longer could remain as a nightmare for parents across the country.

Thank you very much. This hearing is adjourned.

[Whereupon, at 2:25 p.m. the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF ABBEY S. MEYERS, PRESIDENT, NATIONAL ORGANIZATION
FOR RARE DISORDER

Mr. Chairman and Members of the Subcommittee: as many on this Committee already know, the National Organization for Rare Disorders (NORD) represents patients and families of patients with rare, or orphan, diseases and disorders. For most of these people, there is no therapy or treatment; for many, treatments are offered that are costly and ineffective. Orphan conditions are often life-threatening, frequently disabling, and always physically and psychologically debilitating.

NORD's interest in the controlled substance scheduling of the drug product gamma-hydroxybutyrate (GHB) relates to our concerns about the impacts on current research, on the future availability of this drug for patients with cataplexy, the most severe and debilitating form of narcolepsy, and on the future of orphan drug research in general.

If GHB is placed on Schedule I or II, current research almost certainly will stop because of the prohibitive cost of meeting security and control requirements for the manufacture and distribution of the drug for research use.

If the clinical research is not completed, no New Drug Application will be filed with FDA and no safe and effective drug will be available to patients. We are thus depriving very ill people of their best chance to live normal lives despite the presence in their lives of an incurable illness.

Finally, a decision to place GHB on Schedule I has the very real potential to disrupt the system that has led to progress in the development of orphan drugs. The reason GHB is under development today is that a small company, Orphan Medical, responded to FDA's request to develop the product for the treatment of cataplexy. If we are to hope for similar success in the future, we must not send a message that if you agree to take a financial risk and begin development of an orphan product, the government might later throw you a curve that will prevent you from ever completing your work.

NORD's roots are with patients and families who worked together for the enactment of the Orphan Drug Act of 1983, which provides modest financial incentives to encourage companies to invest in the research and development of drugs for small patient populations—drugs for which there are small markets and small potential profitability. In the years before the Orphan Drug Act was signed into law, fewer than ten orphan drugs were developed. Now, there are more than 850 designated orphan drugs; 170 have been approved by FDA. For many patients NORD represents, this is miraculous progress. But we are not at the end of the road. Our objective is a solution for every patient and every family. This is a long course which only can be finished step by step. We can reach the finish line if the hurdles along the way are manageable—but not if they are insurmountable.

We are convinced that scheduling GHB as a Schedule I or II controlled substance would be such an insurmountable obstacle.

It is important to keep in mind that the patient population for GHB is extremely small. This drug is not the same as one FDA recently approved, and it is not intended for the same narcolepsy patients. GHB currently is being studied in a subset of narcolepsy patients, and it is for this subset that the drug will be indicated. These are narcolepsy patients who suffer from cataplexy, the most severe form of narcolepsy. Patients with cataplexy literally can become unconscious and fall to the floor as a result of an emotional reaction such as laughter or anger, or when they become excited; during sleep, they become paralyzed as though in a coma. This means the market for the drug is very limited, and the ability of a company to make a return on its research investment is extraordinarily limited. If the cost of that research were more than doubled, as it would be if the company had to meet the requirements for making a Schedule I controlled substance, the possibility of a profit virtually could disappear—as would the possibility that the drug, once marketed, could be priced so that cataplexy patients could afford it.

In carrying out its responsibilities under the Orphan Drug Act, FDA's Office of Orphan Product Development works hard to identify promising drugs and companies willing to develop them. With GHB, FDA not only recognized the promise of the drug but also provided funding, through an Orphan Drug Research Grant, for the first U.S. clinical trial of the drug. Then, the office took steps to find someone willing to do the work necessary to get this drug approved. They found one and only one company.

Early on, FDA recognized the abuse potential of this chemical, and took steps to try to prevent its being sold through various nontraditional channels. In doing this, FDA also knew that the only option for patients was to get an approved prescription drug on the market as soon as possible. Orphan Medical, a small company in Minnesota dedicated to the development of orphan drugs, has brought the research on

GHB close to completion, and there is a strong likelihood that an approved product will be available to patients in the fairly near future. To take an action now that would impede this process would be a tragic mistake not only for patients whose lives depend on this drug, but for the signal such an action would send to other companies. If other drug companies see that FDA can encourage them to develop an orphan drug but the government can come along at any later point and place the substantial research investment of the company in jeopardy, this would spell disaster for future orphan drug development.

It has been suggested that the pharmaceutical industry is big business and if one company won't develop a drug, another company will, or if one drug can't be developed, another can that will serve the same purpose. For orphan drugs, this is simply not the reality. For patients with orphan diseases, it is a virtual wonder when a single therapy is developed. For these patients, choice among drugs is never an option; for them, it is only a choice of one thing or nothing. For this very small market, and for these often extremely complicated conditions, it simply is not the case that drug companies are competing to put multiple products on the market. For patients with cataplexy, GHB is their only hope. For the development of GHB, Orphan Medical is our only hope. Making GHB a Schedule I or II controlled substance destroys that hope.

We agree with those who say this drug should be controlled. We know it has been abused, and that abuse cannot go unchecked or unpunished. We are aware that GHB has been implicated in the heinous crime of rape. Those who have committed that crime, possibly using GHB or its precursor chemical Gamma-butyrolactone (GBL) as an agent, must receive the strongest possible punishment. Severe penalties should also be imposed on individuals who possess GHB for no reason other than to use it improperly and illegally. This can be done without placing the drug under Schedule I and thus jeopardizing cataplexy patients. Controlling GHB under Schedule III or IV, but providing the authority to the Department of Justice to levy the maximum penalty for abusing the drug—the same penalty as for a Schedule I drug provides a deterrent against criminal use and gives law enforcement officers the ability both to punish wrongdoers severely.

But probably the most significant action that could be taken right now would be to get control of the Internet and get the formula for GHB off of the World Wide Web! In none of the crimes involving GHB or GBL has the medical version of GHB been used. In every case, either GBL has been purchased and used in a crime or amateurs have purchased the raw ingredient and made GHB themselves. This is NOT diversion of the drug GHB. It is diversion of the raw ingredient and illegal "manufacture" of GHB.

As we have done so often in the past, we are ready and willing to work with this Subcommittee, the Health and Environment Subcommittee, and the full Commerce Committee to try to solve this problem. We will happily provide you with any additional information you may need regarding orphan diseases, the Orphan Drug Act, or the importance of GHB for patients with cataplexy. We urge you to remember that some well-intentioned actions, which may seem to be helping some people, have unintended consequences of harming others. Placing GHB on Schedule I or II would be such an action. Thank you for the opportunity to present our views.

DEPARTMENT OF HEALTH & HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
April 27, 1999

The Honorable FRED UPTON
Chairman
Subcommittee on Oversight and Investigations
Committee on Commerce
House of Representatives
Washington, D.C. 20515

DEAR MR. CHAIRMAN: This letter is to provide responses of the Food and Drug Administration (FDA or Agency) to two questions posed at the March 11, 1999 hearing on "date rape" drugs. FDA's witness at the hearing, Mr. Nicholas Reuter, Associate Director for Domestic and International Drug Control, Office of Health Affairs, had agreed to provide responses to these questions for the record.

The first question, posed by Representative Ed Bryant, was to ascertain the status of Agency review of the recommendation for scheduling gamma hydroxybutyrate (GHB) under the Controlled Substances Act.

Jane E. Henney, M.D., Commissioner of Food and Drugs decided in late March what FDA's proposal for a scheduling recommendation by the Department of Health

and Human Services (DHHS) will be. At this time, the Agency is finalizing the documentation in support of the Commissioner's decision. This proposal has been shared with the National Institute of Drug Abuse for review and comment. We expect the proposed recommendation to be forwarded to the Assistant Secretary for Health, DHHS, early next month.

The second question, posed by Representative Ed Whitfield, was whether a pool of money is available at FDA to fund efforts to educate young people about the dangers of drugs used in sexual assaults.

FDA does not have such a fund. Nothing in our Congressional appropriation is specified for education on drugs of abuse. FDA, however, does undertake educational efforts on using prescription drugs in a safe manner and we do pursue public education efforts to alert consumers to dangerous drugs or substances that are being promoted either as health aids or for recreational use. As an example of these efforts, enclosed are two *FDA Talk Papers*, alerting the public to the dangers of GHB and of gamma butyrolactone (GBL), a GHB analogue.

We hope this information is helpful to the Subcommittee. If we can be of further assistance, please let us know.

Sincerely,

MELINDA K. PLAISIER

Interim Associate Commissioner for Legislative Affairs

2 Enclosures

cc: The Honorable Thomas J. Bliley, Jr.
Chairman, Committee on Commerce
The Honorable John D. Dingell
Ranking Minority Member
Committee on Commerce
The Honorable Ron Klink
Ranking Minority Member
Subcommittee on Oversight and Investigations
Committee on Commerce

FDA TALK PAPER

FDA WARNS ABOUT PRODUCTS CONTAINING GAMMA BUTYROLACTONE OR GBL AND ASKS COMPANIES TO ISSUE A RECALL

The Food and Drug Administration is alerting consumers not to purchase or consume products, some of which are labeled as dietary supplements, that contain gamma butyrolactone (abbreviated as GBL). FDA has also asked the companies that manufacture these products to voluntarily recall them. The agency has received reports of serious health problems—some that are potentially life-threatening—associated with the use of these products.

Although labeled as dietary supplements, these products are illegally marketed unapproved new drugs. Products containing GBL are marketed under various brand names including Renewtrient, Revivarant or Revivarant G, Blue Nitro or Blue Nitro Vitality, GH Revitalizer, Gamma G, and Reinforce. They are promoted with claims to build muscles, improve physical performance, enhance sex, reduce stress and induce sleeds.

GBL is also known by the chemical names 2(3H)-furanone dihydro; butyrolactone; gamma-butyrolactone; 4-butyrolactone; dihydro-2(3H)-furanone; 4-butanolide-2(3H)-furanone, dihydro; tetrahydro-2-furanone; and butyrolactone gamma.

GBL related products have been associated with reports of at least 55 adverse health effects, including one death. In 19 of those cases, the consumers became unconscious or comatose and several required intubation for assisted breathing. Other reported effects included seizures, vomiting, slow breathing, and slow heart rate. There are reports of at least 5 children under 18 years of age who have been injured or who have suffered these kinds of effects.

When taken orally, GBL is converted in the body to gamma hydroxybutyrate or GHB. GHB is a very potent unapproved drug. It is currently being investigated under the supervision of doctors for the treatment of narcolepsy. Because of its serious side effects, GHB should not be taken unless in the context of these FDA approved investigations. FDA and the Justice Department have ongoing criminal enforcement actions against GHB. GBL should not be taken.

Products containing GBL are sold in liquid and powder form. They are sold via the Internet, in some health food stores, and in some gymnasiums and fitness centers.

Consumers are advised to dispose of any products of this type in their possession. If they have experienced adverse health problems from use of these products, they should promptly contact a physician. FDA requests consumers and physicians to report adverse events to FDA's MEDWATCH 1-800-332-1088.

The Trimfast Group, Inc. has agreed to recall the product Revivarant, 32 ounces of liquid in a plastic bottle, and Revivarant G, 200 grams of powder in a pill bottle. Other companies manufacturing products containing GBL are being asked by the FDA to voluntarily recall them.

FDA is considering all potential regulatory actions at its disposal if products containing GBL are not recalled. The agency will act expeditiously to protect the public health.

FDA TALK PAPER

FDA RE-ISSUES WARNING ON GHB

In recent months there has been a resurgence of media and public interest in the use of gamma hydroxybutyric acid (GHB) for body building and "recreational" uses. Despite renewed claims that it is legal, GHB continues to be an unapproved and potentially dangerous drug and cannot be legally marketed in the U.S. Therefore, FDA is renewing its warning against the use of this product. The following can be used to answer questions:

GHB is a chemical that has been promoted as a steroid alternative for body building and other uses for several years. Recently it has gained favor as a recreational drug because of its intoxicating effects. Although in the past GHB has undergone clinical testing for several indications, it has never been approved for sale as a medical product in this country.

Starting in 1990, FDA began an intense investigation of GHB distribution after numerous cases of GHB-related illness were reported. Reported symptoms have included vomiting, dizziness, tremors and seizures. Many of those injured required hospitalization, and some deaths have been linked to the consumption of GHB products.

By the end of 1991, FDA and the Department of Justice had taken enforcement action against several firms and individuals involved in manufacturing, distributing and promoting GHB. The agency also instituted an automatic detention policy to prevent products containing GHB from being imported. These actions—along with embargoes, public education campaigns and other measures taken by state and federal authorities—appeared to temporarily diminish the distribution and abuse of GHB.

Recently, however, there appears to be a resurgence in the abuse of GHB: virtually all of the products now encountered have been produced in clandestine laboratories. This increase in use has been accompanied by an increase in reports of GHB-related injuries, including deaths.

Although some promotion schemes occasionally make unlawful claims that GHB is a legal drug, it is illegal for any person to produce or sell GHB in the U.S. FDA's Office of Criminal Investigations is working with United States Attorneys offices around the country to arrest, indict and convict individuals responsible for these illegal operations. FDA, the Centers for Disease Control and Prevention and the Drug Enforcement Administration are continuing to monitor GHB abuse and to develop the most effective measures to protect the public health.