COMMONWEALTH OF PENNSYLVANIA
HOUSE OF REPRESENTATIVES

HOUSE HUMAN SERVICES COMMITTEE HEARING

STATE CAPITOL
B-31 MAIN CAPITOL BUILDING
HARRISBURG, PENNSYLVANIA

WEDNESDAY, JUNE 19, 2019

IN RE: INFORMATION ON THE UTILIZATION OF SUBOXONE/BUPRENORPHINE IN THE TREATMENT OF OPIOID PROBLEMS

BEFORE:

HONORABLE EUGENE DiGIROLAMO, MAJORITY CHAIRMAN
HONORABLE BARBARA GLEIM
HONORABLE JAMES GREGORY
HONORABLE DOYLE HEFFLEY
HONORABLE JONATHAN HERSHEY
HONORABLE MIKE JONES
HONORABLE NATALIE MIHALEK
HONORABLE TOM MURT
HONORABLE MARCI MUSTELLO
HONORABLE ERIC NELSON
HONORABLE TODD POLINCHOCK
HONORABLE JAMES STRUZZI

JEAN DAVIS REPORTING
POST OFFICE BOX 125 • HERSHEY, PA 17033
Phone (717)503-6568

APPEARANCES (cont'd.):

HONORABLE DANILO BURGOS
HONORABLE ISABELLA FITZGERALD
HONORABLE JOE HOHENSTEIN
HONORABLE KRISTINE HOWARD
HONORABLE STEPHEN KINSEY
HONORABLE MAUREEN MADDEN
HONORABLE DAN MILLER
HONORABLE MIKE SCHLOSSBERG
HONORABLE BRIAN SIMS

JEAN M. DAVIS, REPORTER
NOTARY PUBLIC

I N D E X
TESTIFIERS

P R O C E E D I N G S

*** * ***

MAJORITY CHAIRMAN DiGIROLAMO: Good morning.

Good to see everybody. I'd like to call this hearing of the Human Services Committee to order.

Welcome, everybody.

I'd like to first ask everybody to stand for the Pledge of Allegiance to the flag.

(Pledge of Allegiance)

MAJORITY CHAIRMAN DiGIROLAMO: We're not going to take roll call, but what I'd like to do is just give the members that are here -- and it is a very, very busy morning here in the Capitol -- an opportunity to say hello and let you know where they come from.

Tom, I will start with you.

REPRESENTATIVE MURT: Good morning, everybody.

My name is Tom Murt. I represent part of Philadelphia and part of Montgomery County.

REPRESENTATIVE FITZGERALD: Good morning.

I'm Isabella Fitzgerald. I represent the 203rd Legislative District in Northwest Philly.

REPRESENTATIVE BURGOS: Good morning.

Danilo Burgos, representing the 197th Legislative District, North Philadelphia.

REPRESENTATIVE STRUZZI: Good morning.

Jim Struzzi, 62nd District, Indiana County.

REPRESENTATIVE GREGORY: Good morning.

Jim Gregory, representing the 80th District. And of the committee meetings I attend, I'm always, as a freshman, just amazed at how there are more people that show up for this meeting than any other committee meetings that I attend. So this is pretty cool.

Thank you.

REPRESENTATIVE HERSHEY: I'm Jon Hershey from the 82nd District in Juniata, Mifflin, and Franklin Counties.

MAJORITY CHAIRMAN DiGIROLAMO: Gene DiGirolamo.

I'm the Republican Chairman of the Committee from Bucks County, the 18th District.

REPRESENTATIVE SCHLOSSBERG: Good morning, everyone.

Mike Schlossberg, State Rep from the 132nd District in Lehigh County. I suppose I'm Acting Chair today for the Democrats.

REPRESENTATIVE POLINCHOCK: Todd Polinchock from the 144th, Central Bucks County.

REPRESENTATIVE KINSEY: Good morning. Stephen Kinsey, Philadelphia County.

MAJORITY CHAIRMAN DiGIROLAMO: Okay.

Welcome to our two guests. I'm going to introduce you in a minute.

I just have kind of like an opening statement to make of why we're here today.

First, the hearing is about Suboxone, which is also called Buprenorphine, but I'm going to stick with Suboxone through the hearing. Suboxone is a MAT.

This is for the members that are here. And I know we have a lot of new members on the committee. And that's a Medication-Assisted Treatment. It's an opiate. The two main MATs are Suboxone and Methadone.

The difference between the two -- they're both opiates -- is that for the most part if someone is on methadone for the treatment of opiate or heroin abuse, they report to a clinic every day, every morning, and they get their dose of Methadone. It's a supervised visit where someone is watching you actually take that dose of Methadone and it's in a liquid form.

And then you leave there and you go about your day, whether it's go to work or whatever you do.

The Suboxone is prescribed by a doctor who has taken a course. And that Suboxone -- the person who goes to the doctor goes once a month and is given a prescription of Suboxone, a 30-day supply. And they take that prescription and they take it home and they take one. Whether it's a pill or now it's mostly I think prescribed as a strip and they take it once a day and go home and come back and see

the doctor in a month. So they walk out of a pharmacy with a 30-day prescription.

Now, the idea behind both of these is that you're addicted to heroin or the opiates and you stay on the Methadone or the Suboxone for a period of time. And at some point in time and, of course, directed by a physician or medically, you're weaned off of the Suboxone and hopefully get into recovery where you're not on the opiate anymore.

Well, I just want -- from my perspective, I spent a lot of time studying both of these. I'm just going to talk about the Suboxone and the good and the bad as I see it. There's certainly a place for Suboxone when it comes to treatment.

Suboxone is used in detox to help people who are in that stage of detox, whether it be three or four days, to help them as they try to get off of the heroin. And it's used beautifully, as far as I can see, for that. And it is also again, as I just mentioned, used for treatment.

And I think we need Suboxone. And I think there are a lot of doctors who are doing it the right way. And when I mean the right way, I mean they are -- and also psychiatrists -- they are taking Suboxone and they are not trying to take in 200 or more patients a month, but taking in 25 or 50 or 75 patients a month. They're doing counseling along with the Suboxone. And I think in that

situation it works out pretty well.

But I'm telling you what else I'm hearing from around the State, the abuse of Suboxone. And I'm just going to say this as best I can. It's all over the street. Whether you're in Southeastern Pennsylvania or in Western Pennsylvania, it's all over the street being sold.

And the only way it's getting there is because it is being diverted from the addicts going to get their prescription. And addicts -- and I say this all the time -- are the most entrepreneurial people that there are. And they know -- they know -- they figured out that they can go get the prescription. It's cash with the doctors. A lot of these docs are charging cash. And I'm going to get that out in a minute. They get the prescription. They pay for the prescription with their Medicaid or their insurance. And then they go out on the street and sell this 30-day supply of Suboxone. They can make money. And they can use that extra money that they're making to go buy their other drugs.

We're not allowed to put Suboxone in the database so there is no way for doctors to determine whether the person that they're seeing has gone to two, three, four, five doctors and obtained a prescription of Suboxone.

The docs, a lot of these docs, and I'm hearing it, are charging cash only for the Suboxone. I'm hearing 150, 200. Last week I heard $250 a visit. And according to

Federal regulations, depending how long they've been seeing patients, I mean, I think it's up to over 200 patients a month that they're allowed to be seeing.

Now, just figure that out, 200 patients a month on average, 200 bucks a pop. That's $40,000 in cash a month that they're making. And I've also heard from some of the addicts that a couple of them, that they're also -- besides taking the cash, they're also charging Medicaid for the visit as well.

There's just something wrong with that as far as I'm concerned. Something is wrong with that. I'll bet the Department of Revenue would love to do a little bit of an investigation to see if all this cash is being turned in on their taxes. I'll bet it's not.

(Applause)

MAJORITY CHAIRMAN DiGIROLAMO: I'm just going to close before I introduce our two guests. Michele Brooks got a bill passed in the Senate I think yesterday or Monday. It's over in our Committee. I would really like to take that bill up next week if we have the ability to do that.

Senator Brooks's bill would give DDAP a process of licensure for the docs that are prescribing Suboxone. It also would mandate that counseling be done by doctors who prescribe Suboxone. And it would be addiction counseling and addiction treatment. And I think both of those ideas

are really, really good.

I also have a bill that I would like to move as well. And I put the cosponsorship memo in front of everybody. And it would create a Suboxone death review team into the Department of Drug and Alcohol Programs. And the way that would work is that if the coroner certified that Suboxone is a primary or secondary cause of death, that it must be reported to DDAP. And they would have a death review team. They would review the cause of death and come back with recommendations to the General Assembly on what they might be able to do. So I'd really like to try to move those two bills.

And I'm just going to close with this. This to me is just appalling. It's in your packet. And it's from the Department of Justice and it's a news release. And I'm just going to read it.

Indivior, who was one of the main drug companies that produces Suboxone, indicted -- and this is April of this year -- for fraudulently marketing prescription opiates. The company allegedly -- and again, this is allegedly -- lied to doctors and public health care benefits program about the safety and diversion risks of Suboxone.

Indivior is accused of engaging in an illicit nationwide scheme to increase prescriptions of Suboxone, an opiate drug used in the treatment of opiate addiction the

Department of Justice announced.

We've got problems with this. I mean, it's helping people. I realize that. But, boy, we really have problems with this in Pennsylvania. That's why I'm real happy to have these two people here to testify.

Before we get started and I introduce you, I know some other members have come in. I want to give them the opportunity to say hello.

Brian, do you want to just say hello and let everybody know where you're from?

REPRESENTATIVE SIMS: Hi.

Representative Brian Sims from Center City Philadelphia.

Mr. Chairman, my apologies for being late.

REPRESENTATIVE MADDEN: Good morning.

Representative Madden from the 115th District in Monroe County.

REPRESENTATIVE HOWARD: Hi.

I'm Kristin Howard from the 167th in Chester County.

REPRESENTATIVE HOHENSTEIN: Joe Hohenstein from the 177th in Philadelphia.

And thank you, Chairman, for continuing to address these issues.

REPRESENTATIVE MUSTELLO: Marci Mustello from

Butler County.

And I apologize for my tardiness.

MAJORITY CHAIRMAN DiGIROLAMO: No need to apologize. I would like to welcome Marci. This is actually her first hearing. She's a new member of the Human Services Committee. And as I always say to new members, you must have really made leadership mad for them to put you on Human Services.

But welcome.

We're going to get started. I'm going to introduce my two guests. I'd like to welcome them. First we have Judith Grisel, who is a Professor of Psychology in the Department of Psychology in Bucknell University, and also Quinn Chipley, who is a Counseling Coordinator for Health Sciences Center at the University of Louisville.

I want to thank the both of you for being here.

I'm not sure who is going to go first.

Judith, are you going to go first?

MS. JUDITH GRISEL: That's me. Yes.

MAJORITY CHAIRMAN DiGIROLAMO: You may begin whenever you're ready.

MS. JUDITH GRISEL: Good morning, members.

Thank you for having me. I'm here to share with you what I've learned in the past 43 years as a drug researcher. The first ten or so were spent on the streets

where I pursued a voracious desire to get and stay high almost to the grave.

As a result, by the time I was 23, I had been kicked out of three schools, was homeless. I contracted Hepatitis C from sharing dirty needles. And I lost the respect of virtually everyone I knew, including myself.

When I ended up in treatment and learned that I had a fatal disease that required me to stay clean and sober if I wanted to live, I thought, no way. I was face-to-face with the reality of my addiction. I couldn't live with drugs and I didn't want to live without them.

With the wiliness though and the tenacity characteristic of an average addict, in addition to being entrepreneurial, I came up with a scheme. I would study the disease and find a cure. Frankly, this seemed easier than spending the rest of my life straight.

I'm now 56. I eventually got a Bachelor's, Master's, and Ph.D. I did three years on Genetics of Addiction. I haven't found a cure and neither has anyone else. In fact, the chance of dying of a substance use disorder is the same today or higher as it was 50 years ago.

Despite this, we do know quite a lot about how addiction develops and what facilitates recovery. I'm going to spend the remainder of my time giving a short course in my field of research, which is psychopharmacology.

So psychopharmacology is the study of how drugs affect the brain. And in your packet you have that kind of distilled into three principles, so I'm going to quickly go through those. You can read it later if you want. I am a teacher, but I'm not going to quiz you later.

So these are kind of the axioms. This is the core of a whole semester course in med school.

All drugs work by changing the rate of what's already happening in the brain. They don't do anything new.

All drugs have side effects.

And the most interesting one and important for us, I think, today is that if a drug produces its effect by altering brain activity, as addictive drugs do, the brain will counteract the drug by opposing that neural activity and producing the opposite behavioral effects. And that's what leads to addiction.

So narcotics work because they mimic natural endorphin-like neurotransmitters. There are dozens of these chemicals that our brain produces that mediate all kinds of behaviors and experiences, including pain, stress, mood, feeding, sex, arousal, parenting, and other social interactions, play and bonding, learning and memory. So they are all over the brain in small amounts doing all these important things.

And that's how opiate drugs work. They co-op

those existing substrates, which is the first axiom.

Because those existing substrates mediate so many different kinds of things, narcotics have side effects. And they affect all the things I just spoke about. Recreational users are looking for euphoria, so a change in their mood state, but it affects everything else that we just talked about and more.

Unlike these natural neurotransmitters, which are released in small quantities in discrete locations kind of as needed, opiates flood the whole brain and so they have side effects.

The third axiom, though, as I said, is the most important. And that is that chronic drug use imposes a persistent change on the brain activity. And that persistent change is contrary to the main business of the brain. So the brain is unable to see if anything is really going on in our environment if it's perpetually elevated or perpetually depressed. And that's why we have a stable mood state.

If you all got elected President or one of you did, you would be happy for a short time and then go right back to your general mood state. And if you lost an election, I guess, you would be sad for a short time and then go back to your basic state. That basic state is critical to knowing what's happening. And the brain is

terrific at making sure that basic state is maintained.

So the brain adopts to the drugs presence, the chronic drugs presence, by compensating for it. And the effect of that adaptation is tolerance, dependence, and craving. Those are the hallmarks of addiction. As the brain counteracts the drugs' effects, more drug is required to produce the same feeling. And that's tolerance.

The adapted or tolerance state isn't so bad, as you can just take more drug, as long as you can take more drug. But if you run out of money or drug, then you're in withdrawal. And that's a sign of dependence. So you're dependent when the drug is gone and you don't feel okay.

And withdrawal is always the opposite, not just for opiates; but for every drug, withdrawal is always the opposite of the acute effects of the drug because it reflects this adaptation.

So opiates, as we know, produce euphoria, sedation, analgesia, and constipation, among other things. And withdrawal is characterized by dysphoria, agitation, pain, and diarrhea, among other things. So it's always the opposite.

Because of this, the user craves the drug and is willing to sacrifice time, relationships, money, employment, and even life to keep their brain bathed in the substance. They are really imprisoned.

Recovery occurs as the brain readapts to the absence of the drug by returning the neural structures and the activity toward the nascent state so that the user is no longer tolerant or dependent. That takes time. Just like it takes time to develop an addiction, it takes time to recover.

In general, the longer the person has been using, the longer it takes them to recover. And the more they've been using, the longer it takes them to recover. Also the earlier -- you know, there's a lot of factors that influence that but time is the key one.

Three things in general cause relapse in someone who is trying to recover. The first is a taste of the drug or any addictive drug because all addictive drugs are addictive because they stimulate the same reinforcing pathway in the brain, a small set of neurons that release Dopamine in the nucleus. And every addictive drug shares that capacity.

A taste of any addictive drug that reminds that pathway of how it feels to be, you know, elevated again is a cause for relapse. So that's the primary cause.

I can remember -- you know, I would say, well, I'm not going to -- I don't know -- drink today after having a bad day. And then I would smoke a little weed and I'd think, well, it's noon. It's the time for a drink. So it

doesn't take long for one drug to lead to another.

The second one is stress. I think that we all agree that's too big for us to do anything about today.

And the third one are environmental queues that predict the use of the drug. So some people, including me, who get clean and sober are really challenged when we see the dealers or a wad of cash or a spoon or the music or whatever it is that reminds us of our method of escape.

At any rate, Suboxone is an addictive drug, as we know. And it's less effective at activating those opiate pathways than street drugs in general but it still does so.

And I think virtually all addicts are like I was, which is that we would take anything. So it still will activate those systems and therefore it is still counteracted by the brain. In other words, regular use of Suboxone in a way still causes the adaptation that leads to tolerance, dependence, and craving, which is addiction.

When it's used as a short-term bridge to mitigate withdrawal during the initial phases of recovery while the brain is beginning to readapt, it can be really helpful. But long-term use perpetuates the very state of opiate addiction that it was designed to treat. I just want to say that again. Taking Suboxone for a long time, like taking Methadone for a long time, perpetuates and deepens the addiction that we're trying to treat.

The goal of treatment should be to assist someone in achieving and maintaining abstinence. Early on this is almost impossible. People cannot sleep. And not being able to sleep for days and weeks is torture. And so it's really hard to resist the urge of relapse.

Buprenorphine, which is the active ingredient in Suboxone, mutes withdrawal by substituting for the opiate. Ideally, in the context of inpatient treatment, the dose of Suboxone would be titrated down a little bit at a time. And this is true with any drug you're trying to get off for a long time. Take it away a little bit at a time so that the brain didn't quite get as high and it readapts slowly.

During that time, addicts and patients can develop other ways of coping with things like frustration and disappointment and pain and annoyance. And believe me, it's not easy when you've been escaping all those things for so long. It takes time.

So this should go maybe in most cases for a few days or weeks or months, depending on how long the addiction has been around. In younger people, less would be better. Maintaining a patient on Suboxone for longer than this time reflects a scientific and an ethical failing that sells the addicts as well as the families and communities short.

Full recovery is possible with adequate support as the brain will readapt. Even in an old person like me,

but in anybody, the brain is able to adapt to the changes that the opiate use caused. So we should focus our efforts on facilitating abstinence.

I hear from many people after writing this book and trying to explain the way the brain causes addiction and responds to addiction who are on Suboxone and who regret having ever started taking it. I think that's easy to say because they're not withdrawing. Withdrawal is awful and it is always awful.

I kind of think it's like having a bank account. And if you've taken all the money out, you know, to feel good, feel good, feel good, feel good, you have to put that back in. You're not going to get the bank full without sort of climbing out slowly.

So I hear from these people though who are dependent on Suboxone who realize that it's compromising their life and their freedoms and their capacities but who don't have the resources or the know-how to get off of it.

So I was in the rotunda this morning and I saw this beautiful room. I mean it's gorgeous. And it said on the ceiling, let us do the thing that is wise and just. And I think in this case, what is wise and just is the same. And that is to work to benefit the addicts and their families and their communities and not the industries that are making so much from this drug.

Thank you.

(Applause)

MR. QUINN CHIPLEY: My name is Quinn Chipley.

I appreciate being here. I've always been taught to be careful whom I follow. I must try to follow that but please bear with me.

So respected members and guests, I'm really grateful to be asked to be here today. It's really rare in these current, very fractious times of contentious partisan alignments that I, as a rather left-leaning Democrat, find comfort and welcome with cooperation with what I think is a very wonderful bipartisan approach to really be dealing with a very serious issue within our states, within our nation.

I'm from Kentucky, but I can empathize with all the issues that you've outlined here.

I hope to keep really close to the matters that I know best and to avoid unwarranted generalizations. And I certainly want to avoid the demonization of any one medication or even the beatification of any one method. I also would hope that those who differ strongly would avoid the demonization of any one method and also avoid the beatification of any one medication along the way.

I fall back on one of the first rules that was taught us in pharmacology and when I was in medical school and I will clarify that even though I did receive my M.D.

and I trained for a short period of time in psychiatry, there were issues that arose for me healthwise that shifted me back into psychology as a practice, which I'm really happy to be doing.

But I learned an awful lot. I value what I learned in medical school. And the first thing was that all substances, any substance, is toxic in sufficient quantity. That's true for oxygen and it's true for water. There's actually psychological disorders in which people can kill themselves by drinking too much water. I always keep that in mind. It doesn't matter how good a substance might be in certain circumstances. In other circumstances it might be very bad.

I also revisit another foundational notion within brain science. And that is although it is true that we are all more alike than we are different, it does not mean that we also do not clump together in groups of individual differences. And that means that not all brains are going to respond in the same way to the same substance.

All bodies, for instance, will not respond to the same medication in the same way along the way. And that means that those different ways of responding can be roughly classified three different categories of what I call good, bad, and indifferent. We have to pay a lot of attention to that. And a lot of that is learned by history.

Another basic rule that we learned in clinical medicine was when we see someone with a problem and when we get the history about the problem, the first question we ask is, did we, in medicine, cause a problem?

The first rule of thumb in generating your list of hypotheses, did one of the medications or one of the treatments that we actually placed upon someone actually create a problem that we're now seeing?

We do that because, first of all, it happens fairly frequently and, secondly, it's the most easy thing to correct. So we always keep that first and foremost, is this a problem that we ourselves caused along the way?

And another thing which I learned in life -- I think Samuel Johnson, the fellow who wrote the dictionary several centuries ago, had the famous phrase, the road to hell is paved with good intentions. We know that there are a lot of different approaches and treatments out there which were well-intended. It does not necessarily mean that they always had great outcomes along the way.

I won't bore you with all the details of different things which have been tried along the way in medicine. But we have to be very cognizant of the fact that good intentions do not guarantee good outcomes along the way.

My joke is for you guys who are in Legislatures

who get lobbied by the people who actually do road maintenance, you know good and well what it's like when you get the concrete guys in one day and the asphalt guys in the next day and they're all trying to make sure that you support them.

I fall back on a fundamental understanding of human nature and I'm going to use two different words. Profit spelled with an F and prophet spelled with a PH. The profits with an F will corrupt prophets with a PH every time all the way. So it doesn't matter how good the intentions are along the way. When there's a lot of money on the table, a lot of change is going to occur very rapidly and not necessarily in a good way.

From my understanding, I'm going to really distinguish strongly between harms reduction, which can be a good and noble goal particularly within public health, versus treatment and recovery. Those are two different things. There's an intersection when you draw the diagram with the little circles. There might be an intersection but those are very distinct entities along the way.

My observations from knowing something of the history of the development of this medication of Buprenorphine, which later there was an addition of another medication to try to prevent people from injecting it and being successful with injection -- Naloxone which is what

gave us the name Suboxone as the tradename.

The original purpose of this was, in fact, to provide a short-term method of helping people step down off of opiates or opioids -- and I won't go into the distinction between those two today but opioids are all things, including opiates. It was to help them step down in a fairly quick manner and by quick I mean we're talking, you know, weeks to maybe a couple of months, to the point of not being on any of those substances. It was to help them detoxify along the way with the final goal being that these people could, in fact, lead lives, as was mentioned earlier, which were free from all external substances which cause dramatic internal changes. We sometimes call those substances of reward. That was the final goal.

This changed very dramatically. If you go back and review the literature which was developed, particularly the research that was done in the 1980s and 1990s and the early 2000s, the whole goal was, in fact, to use Buprenorphine products in order to help people step down and to become free of using all products of any kind.

This changed with the notion of harms reduction. And the harms that they were targeting were not the harms actually of the addiction itself. They were the harms secondary, such as the acquisition of the HIV virus or the Hepatitis C virus, certain other kinds of things, injection

sites, infections with staph aureus and things of that nature which affect the heart along the way.

So the whole notion was that they were trying just to keep those particular side effects from proliferating. And they really were not targeting in their harms reduction their whole notion of treating the addiction itself.

So the other thing that's interesting about those early studies is that they were all very carefully selected populations of subjects who only had one substance of abuse. If someone came in and they had a strong history of also using alcohol or stimulants, they were not included in the study. So it was only people with opioid addiction. Later on it was only people -- early on it was only the prescription opioids.

Then they did some with people who were only heroin users. And the problem is you can't generalize from that to a population which are pretty much what I call equal opportunity employers. It's kind of like, yeah, I had my preferences but on any one given day, if I can't get my preference, then I'm -- you know, it's not a real strong walk for me to go over to use something else that's a little different along the way, a different category entirely.

So the generalization does not work. And it was already alluded to. The reason for that is that all brains

are not the same. People who are prone to the disease of addiction -- or these days we might call that substance use disorder severe. Those people's brains -- we have three different things that happen in our brains naturally.

One is a punisher. That's to say, don't do that again. That wasn't good. Okay. It tends to be run by a neurotransmitter called norepinephrine. We have another whole system that says, I must do something. And this is run by a neurotransmitter called dopamine. And then we have another one that says, awe, that was fantastic. And it's run by our endogenous endorphins which react with our receptors and interaction with another thing called gamma.

And those three different things have to work in very careful synchronicity to help us negotiate daily life in the real world in a good way. And it comes disordered very easily for people who have a predisposition for many different reasons towards becoming disorders.

So this brings me to what I do know. And I came into this sideways. This was never a strong area of primary interest. It is a strong area of my own social interest and my own I think civic participation. Those of us who have benefited from recovery along the way who have helped other people with recovery along the way started listening to what they were telling us.

And particularly Dr. Burns Brady, who is the

former Chairperson of the Kentucky Physician Health Foundation, after retirement began working with populations within the prisons within Kentucky with the substance abuse program there.

And he started listening to the guys. He didn't know much about Buprenorphine. He started hearing them tell these stories about this thing called Buprenorphine, Suboxone, whatever. And he says, well, you're not supposed to be able to get high on this and they said, oh, let us tell you. We know how to get high on this. And they said, well, it's not supposed to be addictive. And they say, oh, this was the worst stuff in the world that I ever had to get off of.

And so all of these stories of the people who are in the trenches are telling us were contradicting all the things that were being told to us at the level of publications and pharmaceutical representatives.

So a group of us got together and said, okay, how can we go about changing mere anecdotes because there's a joke in science that the plural of anecdotes is not data. We said, how can we take these anecdotes and process them in a way which approximates what we would love to have as data?

And so we simply went into the populations that we knew within Kentucky. The Recovery Kentucky Organization, which are explained somewhat in the handout I

had given to you, along the way just asked people in a very systematic way, with trained interviewers, what have your experiences been? And they told us what their previous experiences had been with Buprenorphine.

And the amazing thing and the outcomes of this were, you know -- this is what was most important to me was the fact that only a quarter of them said at any point along the way in their journey had it been helpful. 31 percent or so said it really did nothing for them, either pro or con. And then a huge population, 43 percent, said it made everything worse. And so we listened to that carefully.

Then we also asked them, what were you doing with the medications? How did you get them? Only 4 percent of them had actually only received their Buprenorphine only by legal prescription methods. We had more than 60 percent who had received their Buprenorphine along the way illegally, that is, off the streets, borrowed, stolen, bought. And then we had an overlap somewhere, 30, 37 percent of people who sometimes would get it by prescriptions, sometimes they would get it off the streets.

So we began seeing that this was a problem. And I went back and looked at the history on this, too. And we were told early on that this would not be a divertable substance because there was supposed to be a ceiling effect on euphoria that they weren't going to get high and that

they wouldn't really want to trade it around.

Actually it didn't make any sense when we looked at our very first study on it -- it was in 1978 -- because one of the three subjects that they had, which to me was appalling they only had three subjects, said this was the best high I ever had in my life.

But these people were telling us, you know, that they were, in fact, able to get high off of everything. And this was contradicting what was being told to us by all of the reports that were coming to us from the pharmaceutical companies.

In the early 2000s when the Food and Drug Administration was trying to figure out how to classify this opioid, which it is -- it's what we call a semi-synthetic -- they started asking different groups of interest to weigh in. Not surprisingly the people who were producing it wanted it to be what we call a Schedule 4, which is the same thing as Imodium, which you buy over the counter which, interestingly enough, is actually synthetic opioid, by the way. So they wanted it to be over the counter.

At the time, the Drug Enforcement Administration, the DEA, immediately said, no, this should be the same thing as a Schedule 2, which is like Morphine, Oxycodone, etc. They settled on something in between Schedule 3, which is why it's in this category to where with the exemption that

the doctors can't achieve -- that they can't prescribe it in an outpatient setting. So it's a really unique drug in that regard.

So to summarize my particular position at this point is that it has a place. The place that it was originally studied for is a really actually very small segment of the population of people who suffer from substance use disorder. I would not ever want to prevent those people from having access to it used in the way that it was originally designed and originally studied.

I think that we have probably erred grossly by overgeneralization and application to people with polysubstance issues. It is not benign. The person who has no previous exposure to any opioids who is what we call opioid naive can, in fact, overdose and die directly from Buprenorphine. That's why you'll find in your handout that there are black box warnings along the way from the FDA.

When Buprenorphine is sold as an analgesic, which it is marketed as a pain reliever, it gets these warnings stating that this can, in fact, be fatal. But when it's sold as a Medication-Assisted Treatment in which it's prescribed at 8 to 12 times the average dosing, those black box warnings are not included because that was with the presumption that these were being marketed towards people who were not opioid naive.

The problem is that once it gets out on the streets, there are no more boxes. The person who gets it on the street may be opioid naive. They may be opioid experienced. They may not know what it is that they're doing at all and it's kind of dangerous.

I'm not here to promote any other medications along the way. I would offer there was a statement that was accurate earlier that currently the two most prevalently used of the MAT medications are Buprenorphine with Naloxone, which we call Suboxone sometimes as a trade name, and then Methadone, which is primarily prescribed -- well, it is through clinics and usually not with take-home doses. There can be cases where they get take-home doses. But they have to earn that along the way. They have to earn that right.

There is another medication which blocks the effects entirely of all opioids as long as it can stay on those receptor sites. It's called Naltrexone. And closely related to that compound is something called Naloxone. And that's what's used these days for rescue with the tradename Narcan by the way. But the Naltrexone is also one of the MATs which is out there.

We do not find that it is sold on the streets in its oral form. No one wants to go buy something that harshes their high. And having used the word high, let me just emphasize I am not out to harsh people's highs. That's

not my issue. It's not I'm going around being the high police. Stop feeling that way now, you know. The whole issue is this: We know that for people who are prone to addiction who have the disease, once we tickle the high receptors, they are not going to be satisfied with the tickle, that they will go back and find whatever it was that used to really get them where they thought they needed to be.

They usually end up being disappointed along the way to find out that they can't get back to that same space. But it does not keep the brain from remembering what it used to be like when it was triggered. So I just wanted to emphasize that. I'm not particularly puritanical but I, you know, do literally want to emphasize that. It's like an antibiotic but there's certain people that you don't give penicillin to because they will become anaphylactic or if you have to give it to them for certain diseases, you put them in the hospital and you titrate them in over three weeks' time before you actually give them their full dose.

So the point being is patient selection is everything in all good treatments. It doesn't matter what treatments are there. And right now there has been an umbrella attempt to avoid patient selection and to do patient lumping. And that is going to end up creating problems both for the patients who are receiving the

medications and for the public at large as the medications leak out into the streets.

So I think I will quit with that at this point. I hope I've been clear enough.

Thanks.

MAJORITY CHAIRMAN DiGIROLAMO: Okay. I want to thank you both.

(Applause)

MAJORITY CHAIRMAN DiGIROLAMO: I want to thank you both. I was really riveted listening to your testimony.

We only have the room until 10 o'clock. We have to hold to that because there's another committee coming in. So we have about ten minutes for questions and answers. I have just one quick question for Judith.

I want you to emphasize your statement about the long-term use of Suboxone and Methadone included both in there and the problems with that.

Could you just say that again? Just real quickly.

MS. JUDITH GRISEL: Yes. I'm not real sure exactly how I said it then. But I guess when I faced long-term recovery from all drugs -- and opiates were not my main drug of choice because of the time and place I was in -- I thought that life would not be worth living without it.

And I've been really surprised. I have a very full, rich life that I attribute to a great treatment center, a halfway house, a lot of support and time. And I think that we are selling people short by keeping them medicated.

Is that the set of conversations?

MAJORITY CHAIRMAN DiGIROLAMO: Yes.

MS. JUDITH GRISEL: I think that there's a lot of potential that we're losing, individual potential, and potential for all of us in just medicating these people and kind of keeping them in this quasi day state of living.

MAJORITY CHAIRMAN DiGIROLAMO: I'll tell you, I hear that all the time from families about the length of time that they are on the Suboxone. It just seems like there's no plan at all to get them off, to just keep them on.

After listening to you two, I mean -- and I hear this all the time, that Suboxone is the gold standard of treatment. I just don't think that's true.

MS. JUDITH GRISEL: For who?

MAJORITY CHAIRMAN DiGIROLAMO: I don't know. The gold standard of treatment I hear it over and over again here in our State, the gold standard of treatment. And I talk to parents and families and that's not what I'm hearing. I'm going to leave it.

I'm going to ask Representative Schlossberg if you have questions.

REPRESENTATIVE SCHLOSSBERG: Thank you, Chairman.

And thanks to the both of you. This has been a fascinating hearing.

I will say from my overview of the research, from my familiarity with this issue, this hearing has left me more than a little bit concerned based on the evidence that I've seen in front of me.

I'm going to take a moment to quote from the National Institute on Drug Abuse, which is a Federal Government drug abuse website.

Abundant evidence -- and it goes on to cite a variety of studies -- shows that Methadone, Buprenorphine, and Naltrexone all reduce opioid use and opioid use disorder related symptoms as well as reduce the risk of infectious disease transmission. So it's criminal behavior associated with drug use.

These medications also increase the likelihood that a person will remain in treatment, which itself is associated with a lower risk of overdose mortality.

We received communication earlier today from the Pennsylvania Society of Addiction doctors who expressed concerns with efforts, broad-based efforts, to limit access to Medication-Assisted Treatment.

Personally I have zero -- and it's clear from indictments from the Federal Government and at the State level, that there are issues with Medication-Assisted Treatment.

But this hearing has left me concerned because while I appreciate the perspective, it also conflicts with a lot of available information that is out there which shows that there is a place for Medication-Assisted Treatment and counseling.

I will again confess I don't know where exactly that line has to be drown. But I am deeply worried with efforts that would limit access to certain people for Medication-Assisted Treatment, which the research shows can and has been very effective for some.

So I'm looking forward to continuing this conversation. But I wanted to put that alternative perspective out there for my colleagues that there's a role for Medication-Assisted Treatment. And I would argue based on what I've seen that it's a stronger role than maybe some in this room would believe.

And I'm certainly happy to hear any response you folks have.

MR. QUINN CHIPLEY: I hope that I had actually made that clear that there is a role and it has to be by patient selection and not by broad strokes. And that

therefore -- now to put that into perspective, what it amounts to right now, when you have someone who has probably substance use disorder or sort of going into right now into being first interviewed in any particular setting or clinic, even the emergency department sees today, without patient selection, without reviewing their prior history, without reviewing family history of propensities for addictions, etc., they are immediately encouraged to go on to and quite frankly they're immediately encouraged to go on to the Buprenorphine products.

The reason for that is that Buprenorphine products can be started approximately 48 hours earlier than the Naltrexone products because of requirements for going into a certain level of detoxification before you can start it. And that is not always a good option for all those people.

My point is this -- and this is a little beyond the scope of this hearing -- we are not treating this epidemic or this disease in the way that we've always treated other epidemics. We are not actually saying what you deserve to have is the ability to be immediately and without stigma hospitalized, to be placed in controlled settings to actually receive the treatment that you truly deserve to allow you to be humanely detoxified so that you have other options along the way.

The joke is this. If someone walks into a hospital and if they even utter sideways the statement of suicide or I might kill myself or I can't stand this any more, we slap a 72-hour hold on them and they don't leave. When someone comes in with an overdose of opioids that just about killed them and they're only breathing three to four times per minute and you Narcan them up and they jumped off of the table and say, I'm leaving, they go.

Now, quite frankly, I don't understand how this has ever been allowed to happen. They are both life-threatening illnesses. So my advocate goes to the fact that we need to be putting more into what is available for people at the front end rather than saying, you know, we treat in street and good luck to you.

REPRESENTATIVE SCHLOSSBERG: That's a very good argument.

MS. JUDITH GRISEL: Can I just add that it's a great crutch but the idea is not to keep people on a crutch. It's to enable them to learn how to walk on their own.

(Applause)

MAJORITY CHAIRMAN DiGIROLAMO: Thank you.

Representative Gregory. And we have five minutes and four people that want to ask questions.

Representative Gregory.

REPRESENTATIVE GREGORY: Thank you very much for

being here.

As you described, the use of this drug to treat, I was struck by the notion that maybe addicts should be the people that are creating the drugs rather than the people that don't understand addiction.

But can you address anything that we are aware of when it comes to shortages of Suboxone for being able to prescribe it? In my area, we recently were made aware of Indivior mislabeling a supply of Suboxone leaving my pharmacist in a crisis situation because they were not allowed to prescribe the generic version.

However, my task force director informs me today that they are making more arrests for illegal Suboxone than even meth today, including in our prisons. A prisoner was just found to have it as contraband in the prison.

So we may have a shortage of it legally. But we certainly don't have a shortage of it illegally. How does that happen? That's my question. What are we doing? How does that happen? Can you address that?

MR. QUINN CHIPLEY: I actually cannot because of all the things I do in life, two of them are I don't do law and I am absolutely horrible at business.

Quite frankly, this is a business-model issue at this point. And I really can't -- I just don't know.

MS. JUDITH GRISEL: And I think Representative

DiGirolamo's comment about entrepreneurialism is really what you can say here. If there is a will, there is a way. And that is the most clear fact about addicts. I mean, they have such a will. So it is desperate to not be able to get the drug, you know, any opiate. Any opiate will substitute for any other in the right dose. And they're going to find it.

REPRESENTATIVE GREGORY: And you were given the gift of desperation to do what you did. It's a gift for people like you.

Thank you.

MAJORITY CHAIRMAN DiGIROLAMO: Representative Struzzi.

REPRESENTATIVE STRUZZI: Thank you, Mr. Chairman.

Thank you, both, for being here. Your presentation is very insightful.

Truly, as we try to look for a solution to this addiction crisis, I think that you highlighted some very key points. But my question is -- and I'm going to keep this very brief -- we understand that these treatments work and they're effective. But we tend to create our own problems.

And the question that I have is, how do we know when enough is enough? You mentioned that full recovery is possible and you're evidence of that. But for many people, they don't even believe that's the truth.

How do we know when we've prescribed enough of Suboxone that they need to stop because, you know, people go on and on with Methadone and Suboxone. We hear those stories more prevalently. But how do we know when enough is enough, when someone has reached that point of full recovery and then we stop this?

I found it very alarming that Representative DiGirolamo mentioned that we don't really regulate how much Suboxone is given. I think that's something that needs to be addressed.

The question is, how do we know when enough is enough? And then what recommendation would you have for us to make some changes to effectively get us to that end solution?

Thank you.

MS. JUDITH GRISEL: I think in this case it's hard to ask the addict because I didn't want to be clean and sober at all. And if someone had offered me some substitutes that would sort of keep me a little high, I would have been grateful. So I don't think we can ask the addict.

But I also think that it's a collaboration that takes time and support, therapy, alternative coping mechanisms, resources, jobs. You know, where opiate addiction recovery is very successful in doctors and pilots

and lawyers where they are going to have a lot of oversight, where they're checked all the time, where they're given the resources they need, that's the antithesis of giving them a script for Suboxone and sending them out on the street.

So I think it has to be one part of a treatment. And honestly, the titration down could be fairly quick. It could be two to three weeks with no problem. And it's not pleasant to get off of. But it's definitely doable and it should be our goal.

REPRESENTATIVE GREGORY: Thank you.

MAJORITY CHAIRMAN DiGIROLAMO: I've got one more minute. Representative Hohenstein, you've got it.

REPRESENTATIVE HOHENSTEIN: Thank you, Mr. Chairman.

I have a question on the financial interest because you talked about profits. I would like to know if there's any connection between the financial interest of the companies that produce and market Buprenorphine and the companies that produced and marketed other opioids like Oxycodone, Percocet, Vicodin. What are those connections?

How do you think those things might be affecting what we're seeing as far as the push and the marketing that happens with MAT and in particular Buprenorphine as the drug within an MAT regimen?

MR. QUINN CHIPLEY: Very quickly. A very unique

arrangement developed between the Federal Government and the company Reckitt Benckiser that originally developed Buprenorphine. And it became a cooperative agreement. They were granted a seven-year patent on the basis of financial hardship. At the time the patent came to expire, the company decided that they would reformulate the drug into strips rather than tablets supposedly because of danger.

And that has simply been disproven within the courts recently, that that was not their motivation. They were trying to reformulate in order to extend their patent. There was a strong financial incentive to maintain that as a market.

Now, when it comes to -- I can't really speak to Purdue Pharma because they were Oxycodone, although they are one of the major producers now of Narcan, or the rescue drug.

MAJORITY CHAIRMAN DiGIROLAMO: Quinn, I'm going to have to cut you off.

MR. QUINN CHIPLEY: Okay.

MAJORITY CHAIRMAN DiGIROLAMO: We have my good friend here, the Chairman of the Education Committee, ready to move in.

But I want to thank everybody for being here and thank the both of you for testifying.

(Applause)

MAJORITY CHAIRMAN DiGIROLAMO: Thank you.

(Whereupon, the hearing concluded.)

I hereby certify that the proceedings and evidence are contained fully and accurately in the notes taken by me on the within proceedings and that this is a correct transcript of the same.

Jean M. Davis
Notary Public