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HOUSE OF REPRESENTATIVES

HOUSE HEALTH COMMITTEE HEARING

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HARRISBURG, PENNSYLVANIA

TUESDAY, MAY 23, 2017

IN RE: COVERAGE OF ANTI-OBESITY DRUGS AS A COMPENSABLE SERVICE IN THE MEDICAL ASSISTANCE PROGRAM

BEFORE:

HONORABLE MATTHEW BAKER, MAJORITY CHAIRMAN
HONORABLE AARON BERNSTINE
HONORABLE ALEXANDER CHARLTON
HONORABLE BECKY CORBIN
HONORABLE JIM COX
HONORABLE KRISTIN HILL
HONORABLE DAWN KEEFER
HONORABLE HARRY LEWIS
HONORABLE PAUL SCHEMEL
HONORABLE JESSE TOPPER
HONORABLE JUDITH WARD
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I N D E X

TESTIFIERS

P R O C E E D I N G S

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MAJORITY CHAIRMAN BAKER: This is the House Health Committee. We have a hearing on anti-obesity medications. I welcome all the members and guests and speakers.

First up we have the prime sponsor of the legislation, Representative Donna Oberlander. I'm not going to make any opening remarks. Michael is not either. So we'll start with Donna.

I've heard from at least six members that they have other committee engagements, bills moving, and voting meetings, so we'll be seeing a lot of movement during the course of the hearing.

Welcome, Donna.

REPRESENTATIVE OBERLANDER: Thank you, Chairman.

Thank you, members.

I just want to say that I really appreciate the opportunity to share information on this important bill. It did pass the Committee last year and then was held up for various reasons, so shedding light on it is very important.

As the Chair of the Diabetes Caucus, this legislation has particular importance to me given that during my tenure as the Chair of that Committee, we have found that the link between diabetes, obesity, heart

disease, and other very serious conditions is very costly.

So when the opportunity presented itself to be part of this legislation, I jumped at the chance because if we can help people reduce their weight and then reduce the other extenuating circumstances and health issues that it creates, what better way to save not only their lives but costs to our State.

The legislation seeks to allow the Department to cover drug therapy. It is not a mandate. It would rather be a choice. And currently they are precluded from even allowing that as an option. So I do look forward to the testimony.

And again, thank you very much for your consideration.

MAJORITY CHAIRMAN BAKER: And, Donna, just to clarify, when you say Department, the Department of Human Services?

REPRESENTATIVE OBERLANDER: Department of Human Services.

MAJORITY CHAIRMAN BAKER: The Medicaid program?

REPRESENTATIVE OBERLANDER: Correct.

MAJORITY CHAIRMAN BAKER: Okay.

REPRESENTATIVE OBERLANDER: Thank you.

MAJORITY CHAIRMAN BAKER: Great. Thank you.

Not seeing any questions or comments at this

point, we'll get started. Thank you, Donna. We appreciate it.

We have speaking first Terri Cathers, Doctorate of Pharmacology, Director of Pharmacy Programs, Office of Medical Assistance programs within the Department of Human Services.

Welcome. You may begin.

MS. TERRI CATHERS: Thank you.

Good morning, Chairman Baker, Chairman Fabrizio -- I don't see him -- members of the Committee and staff.

I am pleased to be here today to provide testimony on the topic of coverage of anti-obesity drugs and the Medical Assistance, or MA, program.

I am Terri Cathers. I hold a Doctorate of Pharmacy Degree and I'm a registered pharmacist in Pennsylvania. I serve as the Director of Pharmacy Programs for the Department of Human Services and the Office of Medical Assistance programs.

Today I will share with you some information about the Department's rationale for not covering anti-obesity drugs as a compensable service in the MA program. I will also describe the scope of compensable services in the Department that we cover for beneficiaries who meet the Centers for Disease Control and Prevention or CDC definition of overweight or obese, including those with

other medical conditions.

The Department recognizes the prevalence of obesity and the accompanying serious morbidity and mortality risks associated with obesity and provides coverage of outpatient services and specific surgical procedures related to the treatment for this disease.

In Pennsylvania, the MA program provides coverage of a very broad array of drugs, including brand-name drugs, generic drugs, and over-the-counter drugs. However, the scope of covered drugs does not include drugs to treat obesity or weight gain.

These drugs fall within a unique class of drugs that the Federal law and regulation permit a state Medicaid program to restrict from coverage. The Department historically chose to exclude weight loss drugs from coverage because they raise serious concerns about patient health and safety, place and treatment, efficacy in terms of long-term outcomes and to some degree cost effectiveness, as supported by current peer-reviewed medical literature.

The Department's concerns related to patient health and safety focus on the side effects of weight loss drugs prescribed to control obesity. The potential side effects range from nausea, diarrhea, fecal urgency, dizziness, fatigue, metallic taste, agitation, skin numbness, tingling or itching, and insomnia, to impaired

cognition and low blood sugar, all of which pose significant challenges to a patient's willingness to comply with treatment on an ongoing basis. Some even carry a warning to avoid use in patients with heart disease, gallbladder disease, uncontrolled hypertension, and seizure disorders.

The Department recognizes that some healthcare professionals may prescribe drug therapy for patients who meet the CDC definition of overweight or obese, after a careful evaluation of risks and benefits to the patients.

However, those healthcare professionals typically prescribe drug therapy as an adjunct to the treatment regimen for obesity and not as the first line of therapy.

Current medical literature consistently supports lifestyle changes as the first line of therapy and calls into question the efficacy of drug therapy in terms of long-term outcomes. According to a literature review that is current through April 2017, by UpToDate, which is an evidence-based clinical decision support resource that healthcare professionals rely on to make decisions at the point of care.

I quote, "The initial management of individuals who would benefit from weight loss is a comprehensive lifestyle intervention, a combination of diet, exercise, and behavioral modification. UpToDate also states that along with diet, exercise, and behavioral modification, drug

therapy may be a helpful component of treatment for patients who are overweight or obese.

The role of drug therapy has been questioned, however, because of concerns about efficacy, safety, and the observation that body weight slows and then plateaus with continued treatment, and most patients regain the weight when their weight loss drugs are stopped.

Consistent with current, peer-reviewed medical literature that identifies behavior modification or behavioral therapy as the gold standard in the treatment for obesity, the Department provides coverage of outpatient services designed to support beneficiaries who are committed to controlling obesity and weight-related conditions.

Coverage services include nutritional counseling and a comprehensive scope of behavioral health services that include counseling and therapy, essentially getting to the root of why the person overeats. Bariatric surgery is also covered for persons with extreme or severe obesity when medically necessary and the benefits outweigh the risks and side effects of the procedure.

Finally, looking at the weight loss of patients in clinical trials of these medications and the lack of proof that weight loss medications improve long-term outcomes, combined with cost, raises questions about the cost effectiveness of coverage of these medications.

For example, the weight loss for a participant in a clinical trial of one of these medications versus the placebo was 8 pounds in one year at a cost of $200 per month. The Department questions whether spending $2,400 a year for a patient to lose 8 pounds, which the patient may likely regain after stopping the medication, is a prudent and cost-efficient use of public funds.

The Department maintains that providing services like nutritional counseling and behavioral counseling and therapy is both clinically effective and cost efficient. These covered services are consistent with the medically accepted first line of therapy as documented in peer reviewed medical literature. They provide the education and support for lifestyle modifications that can enhance the potential for success in achieving and maintaining weight loss goals, reduce the long-term risks for morbidity and mortality associated with being overweight or obese, and reduce the long-term cost associated with those risks.

The Department is not alone in its rationale for not providing coverage of drugs to manage obesity. The Massachusetts Medicaid Pharmacy Director recently shared the results of an informal e-mail survey of all state Medicaid programs nationwide, asking the question, does your fee-for-service Medicaid program provide coverage for obesity management drugs?

Of the 35 states that responded, four states indicated that they provide coverage with prior authorization; 31 states, including Pennsylvania, do not provide coverage of obesity management drugs. Medicare Part D also has a provision for restriction of certain drugs similar to Medicaid. Medicare drug plans aren't required to cover weight loss drugs, but a plan may choose to do so.

The Department recognizes that achieving and maintaining weight loss goals is difficult. While some claim that drug therapy with anti-obesity drugs may be a helpful component of treatment for patients who fail to achieve weight loss goals through diet and exercise alone, the fact remains that these drugs do not cure obesity and they pose concerns about efficacy, safety, and long-term outcomes. Lifestyle interventions, including diet, exercise, and behavioral modification, remain the clinically accepted first line of treatment.

The Department chose to exclude weight loss drugs from coverage and instead provide nutritional counseling and behavioral health services that are consistent with what is considered the gold standard of care. These services are medically accepted treatment and provide support that enhances the potential for positive long-term outcomes without the risk to the health and safety of our beneficiaries.

Thank you for the opportunity to provide the testimony on behalf of the Department.

MAJORITY CHAIRMAN BAKER: Thank you, Dr. Cathers.

Dr. Cathers, I noted in your remarks that bariatric surgery is covered for persons with extreme or severe obesity when medically necessary, and the benefits outweigh the risks and side effects of the procedure.

I know bariatric surgery can be expensive. Some of the side effects or risks that are connected with bariatric surgery, you can say that about obesity medications. In fact, if one carefully listens to commercials on TV and you get all those disclaimers about the side effects, it's no wonder anybody takes medicine. But yet, it's recommended. It's approved by the FDA.

These anti-obesity medications are approved by the FDA. And so obviously they've gone through rigorous clinical trials and approval process. Why not anti-obesity medications, whether it be a first-line or a second-line recommendation? If it's deemed medically necessary from a doctor, why not give that a try for folks?

This is a significant problem, obesity, morbid obesity. The morbidity risks and problems associated with obesity is significant, particularly in the diabetes space. And if other states -- I think you said four -- can give this, I would be interested in knowing -- I don't know if

you have that information -- what the experience and what the result has been in those four states. I'd be very interested in knowing if there was effectiveness and what the results were in those states.

And quite frankly, I happen to know -- I have a friend who had gastric bypass bariatric surgery. And yet while we approve that here in Pennsylvania, I also know that's not always effective. In fact, without naming names, the gentleman has just put weight back on, even with bariatric surgery. So why not give this a try?

Are the risks so high that it's contraindicated? Or if the risks are comparable to bariatric surgery, it seems to me that maybe even a limited regimen approval of these medications might be indicated as an option to bariatric surgery and may even be less expensive.

What is the cost of bariatric surgery -- 5,000, 6,000, or more?

MS. TERRI CATHERS: I'm not sure what the Department's fee schedule is for bariatric surgery. That's not my area of expertise.

MAJORITY CHAIRMAN BAKER: Okay.

MS. TERRI CATHERS: I can find that out for you, though.

MAJORITY CHAIRMAN BAKER: Okay.

MS. TERRI CATHERS: I can get back to you.

MAJORITY CHAIRMAN BAKER: Okay. Thank you.

MS. TERRI CATHERS: Absolutely.

MAJORITY CHAIRMAN BAKER: Thank you so much.

Obviously, you're taking some of my questions in a rhetorical manner, since I didn't get any answer from you. But we'll move along to the other members' questions.

Pam, Pam DeLissio.

REPRESENTATIVE DeLISSIO: Thank you, Mr. Chairman.

Good morning.

MS. TERRI CATHERS: Good morning.

REPRESENTATIVE DeLISSIO: In your testimony -- and I apologize if I missed that -- I understood the parameters you're outlining for when the Department makes decisions under the Federal guidelines that you're allowed to make decisions under. With what frequency are those guidelines reviewed at a State level?

MS. TERRI CATHERS: In terms of whether we exercise the option to cover the drugs deemed optional under Federal law and regulation?

REPRESENTATIVE DeLISSIO: Correct.

MS. TERRI CATHERS: I don't know how often they are revisited to determine if they should be, if that option should be exercised. I know that obviously it would have a budget impact.

REPRESENTATIVE DeLISSIO: Correct. So that would be one question.

And the other was, is there a mechanism whereby there's a process for exceptions? I think sometimes -- sometimes private insurers, there's a process, an articulated one at least, for exceptions to be considered. It's a little arduous. It's time-consuming.

Is there a like process in the Medicaid program for instance, a drug like this, that, you know, the states allowed the restriction. We certainly heard a lot about healthcare and what the states may or may not be allowed to do in the coming months or years. So is there an exception process that you're aware of?

MS. TERRI CATHERS: Well, it would be an exception to the State regulation, which deems these products not covered. So while the Department would entertain program exceptions outside the scope of coverage, in the nearly 13 years that I've been here, I have never received one for an anti-obesity drug.

REPRESENTATIVE DeLISSIO: On an individual basis?

MS. TERRI CATHERS: Yes.

REPRESENTATIVE DeLISSIO: All right. Thank you. Thank you, Mr. Chairman.

MAJORITY CHAIRMAN BAKER: You're welcome.

Representative Daley.

REPRESENTATIVE DALEY: Thank you, Mr. Chairman.

So it's pretty clear that we don't know where we're going to be in the coming years with healthcare and with Medicaid. But I saw in the paper today that there was -- that a reduced amount is going to be given out to the states.

So my question is, how does the State -- does the State get a fixed amount or if the State were to include anti-obesity drugs and coverage for them as part of its compensable coverage, is that something that then the Department has to weigh with other things that it's being asked to do or does the Federal Government put in additional funds to cover that or is it something that has to be managed within the Pennsylvania Department?

MS. TERRI CATHERS: I think that will depend upon how that Federal money is allotted to the states for the programs. If it's done through like a per capita basis or a fixed amount, then the State Medicaid Agency would have to live within the confines of that budget or risk using State funds, finding other measures, or cutting benefits.

That's my understanding. I am definitely not a fiscal expert.

REPRESENTATIVE DALEY: I appreciate that.

I don't really know exactly how the compensation works.

MS. TERRI CATHERS: We can absolutely follow up.

REPRESENTATIVE DALEY: I think that would be helpful for a lot of us to know. But I also say that just recognizing that we don't really know exactly what's ahead of us.

MS. TERRI CATHERS: Absolutely.

REPRESENTATIVE DALEY: And the rules may all change as soon as you send us something. But it would be interesting to know how they work right now because you do know that.

MS. TERRI CATHERS: Okay.

REPRESENTATIVE DALEY: And then we would have something to compare it to as we move forward.

MS. TERRI CATHERS: Sure.

REPRESENTATIVE DALEY: Thank you.

Thank you, Mr. Chairman.

MAJORITY CHAIRMAN BAKER: Representative Corbin.

REPRESENTATIVE CORBIN: Thank you, Mr. Chairman.

I suppose this is more of a comment or a commentary on the comment in your testimony about instead providing nutritional counseling. I question the benefits of just relying on that.

Several years ago I was part of a Policy Committee Poverty Initiative Study that we did and I was head of the food group. And what we found was that in the

case of many Medicaid recipients, they are living in areas that are so-called food deserts. And there's no access to grocery stores, a variety of foods. And we were finding people who were also receiving SNAP benefits, using their SNAP benefits to go to the only store around, which could have been a Sheetz, a Wawa, and purchasing high-fat, high-calorie snack food to feed their families or themselves.

And, you know, they can have all the counseling in the world. But that's not going to help them be able to purchase nutritious food. In addition, the local farmers markets, which provide fresh produce, vegetables, fruits, are not taking the SNAP benefit card. So that's a huge problem.

So I think we really have to take another look at also providing pharmaceutical treatment, if necessary, to help these obese patients because nutritional counseling in the case of many people isn't going to help because they don't have access to nutritious food.

MS. TERRI CATHERS: I think that you're going to find that these drugs will not be efficacious in those patients either. They must be used, if they're going to be effective, in conjunction with nutritional counseling and behavioral changes. Otherwise you're paying essentially for no benefit. And the side effects, if the person continues

to eat high-fat foods, taking drugs like Orlistat probably they wouldn't be able to leave the house. Fecal urgency is not something that anyone wants. And literally the fat runs out of you.

REPRESENTATIVE CORBIN: Thank you.

Thank you, Mr. Chairman.

MAJORITY CHAIRMAN BAKER: Representative Ward, Nurse Ward.

REPRESENTATIVE WARD: Thank you, Chairman.

Before I came to the Legislature, I did wellness for a company that was self-insured so it behooved everyone to get healthy. You know, that is the goal, to get everybody healthy. But I came to realize for some people -- everybody is different; everybody is an individual -- what works for one person may not work for another person.

And you mentioned diet and exercise, which is the gold standard. But there's some folks who have, because of their obesity, other issues, orthopedic issues that would prevent them from exercise, so one leg of the stool is knocked out. I would just hope that we have options for all people. I guess that's my point here.

You know, what works for one person doesn't work for another. So I would just hope that we have -- the physician has some flexibility and some personal input into the treatment plan for folks.

Thank you.

MS. TERRI CATHERS: Sure.

REPRESENTATIVE WARD: Thank you, Mr. Chairman.

MAJORITY CHAIRMAN BAKER: Representative Schemel.

REPRESENTATIVE SCHEMEL: Thank you, Chairman.

Doctor, I guess the Department has limited resources. So with every treatment you probably evaluate cost versus the benefits; is that accurate? I would think that would be, whether it's cancer treatment or anything else.

MS. TERRI CATHERS: Yes. We absolutely try to do that very diligently.

REPRESENTATIVE SCHEMEL: Sure.

The Department can't afford, with its limited resources, to cover everything for everything. And I would assume, based upon your testimony, that's what the Department did in this case, is you evaluated the treatments that were existing, the outcomes, and made a determination that the use of these drugs did not -- you know, does not financially make sense for the Department based upon the outcomes.

Through quick math, that's about $300 per pound lost. But is that correct? Did the Department in this case evaluate it with the professionals that you have within the Department and determine that based upon the outcomes and

the limited resources you have, that this was not cost effective for the Department?

MS. TERRI CATHERS: Yes, that's accurate.

REPRESENTATIVE SCHEMEL: Okay. That's how I heard it. Thank you, Doctor.

MS. TERRI CATHERS: You're welcome.

REPRESENTATIVE SCHEMEL: Thank you, Chairman.

MAJORITY CHAIRMAN BAKER: Thank you, Representative Schemel.

I just want to make a comment. Represent Ward's comment earlier about some individuals are just not able to do the exercise and they have a lot of other kinds of issues.

I used to work in a law firm. I represented the disabled before Federal Judges. And there's an automatic entitlement on disability if an individual is of such a height, such a weight, and has major weight-bearing impairments. And there are other obvious qualifiers there, people that are morbidly obese or obese.

Obviously there are a number of folks that have a lot of physical limitations that would seriously impair their ability to exercise.

MS. TERRI CATHERS: Absolutely.

MAJORITY CHAIRMAN BAKER: And so it's not just a matter of behavioral or mental or emotional issues, but it

could be a combination of that obviously. But it's really based on the physical limitations of an individual as well as their age, education, past relevant work experience.

MS. TERRI CATHERS: Yes.

MAJORITY CHAIRMAN BAKER: It just seems to me that if a doctor, the physician/patient relationship, if a doctor believes this is the best way to go in terms of treatment, it would seem to me that we should listen to the doctors as well.

We appreciate your testimony. I don't see anyone else. Thank you very much, Doctor.

MS. TERRI CATHERS: Thank you.

MAJORITY CHAIRMAN BAKER: Next up we will have Ted Kyle, MBA, RPh, Obesity Action Coalition.

My apology. We're going to do a whole panel at once. Okay. Also, Tim Clark, Senior Director, Governmental Affairs, Policy and Corporate Advocacy; Elena Nikonova, MD, Medical Director, U.S. Medical Affairs Neurology Business Group; and another medical doctor, Dr. Mehta, Director of Bariatric Medicine, St. Luke's Weight Management Center, Allentown, Pennsylvania .

Welcome.

Who would like to go first? Yes, sir.

MR. TIM CLARK: I drew the short straw today.

Thank you, Chairman Baker. And thank you to the

Committee for spending the time to talk about this incredibly important healthcare issue that's facing not only Pennsylvania but the entire country. And I want to especially thank you, Representative Oberlander, for her leadership in this area. It's been quite, quite important.

Again, my name is Tim Clark. I'm the Senior Director of Government Affairs, Policy and Advocacy for Eisai, Incorporated. Eisai is a global pharmaceutical manufacturer. We discover and develop medicines in the metabolic, neurology, and oncology space, including a product called BELVIQ, one of the newer anti-obesity medicines.

I have Dr. Elena Nikonova who will speak to the medical side of our product.

As Dr. Cathers informed you all, the states are provided the flexibility to determine what products they are going to cover under their State Medicaid program. And many states across the country determined many years ago to not cover anti-obesity agents.

I think it's important to note that many of these determinations were made 10 years ago, 15 years ago, when what we were looking at was Fen Phen. And that certainly was a significant and important point in the obesity continuum as we developed drugs.

But what we're here to talk about is the newer

generations of drugs. These are drugs that have only been approved by the FDA since 2012. And there's an entire development program that the FDA put in place to ensure patient safety that referenced, you know, sort of the discussion around what the impact of weight loss at a 5 to 10 percent weight loss number was for individuals.

Look, I think the numbers are stark. You know, we look at Pennsylvania. For example, the Pennsylvania obesity rate now is 30 percent. Those are people who are medically determined to be obese. For obese and overweight, that's a BMI of 25 or above. It's 66 percent in Pennsylvania.

The Latino and African-American community are disproportionally affected by that with the Latino community at almost 40 percent obesity rate and the African-American community at 35 percent.

We're not winning this fight. And the health outcomes are astounding. I mean, we look at in 2010 in Pennsylvania, 1.135 million diabetes patients; 2.75 million cases of hypertension; 892,000 heart disease patients; 228,000 obesity-related cancer cases. We have more and more cancers that are directly attributable to obesity and the diagnosis of obesity.

And the economics are just as astounding. You know, obesity-related medical treatments cost upwards of

$210 billion a year nationally. I'll speak to some national numbers.

Cumulative obesity-related costs among full-time employees are estimated as $73.1 billion per year. And so as we look at what we are doing for obesity, what we're looking at for this disease, we're fortunate. This trend is reversible, much like we saw with smoking.

There are options available to help individuals in their struggle with obesity. But we are not doing enough both at the Federal level -- and I can speak to the Federal prohibition, as well as the state prohibition, because, as Dr. Cathers referenced, there is a continuum of care that's available to those patients who are suffering from obesity for which one is absolutely prohibitive.

You have diet and exercise, you can have medicines, and then you have surgery. But in Pennsylvania, as there are other states, we have -- there are 12 states.

We have a report that I'll share with you, Chairman, that shows there are 12 states that provide some level of coverage for drugs.

So in effect what you're saying is, if you do not succeed in diet and exercise, you're going to wait until you qualify for surgery and then we're going to do surgery. That to us doesn't make a lot of sense.

If you're looking at the root cause of spending

inside of every healthcare system, we know that obesity drives 90 different comorbidities. Obesity is the No. 1 preventable disease in our country.

And so I think it's important to note -- and I'll wrap on this -- a couple things. Absolutely the Medicare Part D Program prohibits coverage for medicines for anti-obesity agents.

And as Dr. Cathers referenced, Medicare Advantage Plans, those plans that you can purchase, do provide some level of coverage. So there was 15,000 prescriptions in the last calendar year in the Medicare program. We are working on the Medicare policy as well.

And again, this references products back in 1990 that were unsafe. So we have a newer, safer class of products. And I think it's important to note that I, as a representative of Eisai, am not here advocating just for BELVIQ. We're advocating for the entirety of the class.

As you referenced, Chairman Baker, there are people that metabolize drugs differently. Side effects may hit someone and may not hit someone else. But what we want is to have the patient that you spoke to -- and the physicians will touch on that -- that they have an option, that they have another option. Because there are some for which a conversation with their physician or the physician assistant about their diet and their exercise, they will be

successful and that's great. We support that.

There are others that are going to need a little bit of extra help. And then there are still others who may need a surgical intervention in order to be successful. But the underlying problem here is the obesity rates in Pennsylvania continue to climb while our policy remains stagnant.

And if we're looking at Medicaid as a program, if we're looking at flexibility and we can talk about sort of the budget that the President released yesterday and what that's going to look like, there's clearly going to be more flexibility provided to states to determine how they cover their Medicaid population.

And I would suggest that one of the ways that you do that is you go at the root cause of what's driving spending. And clearly the root cause is obesity.

I thank you for your time. I'm happy to turn it over to Dr. Nikonova who can speak to BELVIQ in particular and then we'll go down the line.

So thank you.

DR. ELENA NIKONOVA: Hi, Chairman. Hi to the members. Thank you so much.

I'm Elena Nikonova. I'm a Medical Director for BELVIQ, U.S. Medical Affairs of Eisai. Thank you so much for having us today, you know, and being able to talk about

our product a little bit.

So according to the 2016 American Association of Clinical Endocrinologists guidelines, which has just been published in 2016, obesity is a chronic disease. This is a disease. This is not a lifestyle. This is not, you know, poor choices. It's a disease with a chronic duration. And it does require management targets that address both weight-related complications and (inaudible) on its own, overall, you know, aiming to improve the health and quality of life.

The goal would be -- the goal of the treatment will be to facilitate the high-quality care of patients with obesity and provide a rational and scientific approach to management and optimize health outcomes.

As Tim mentioned, you know, there are 90 diseases that pretty much grew out of obesity. And the last time I checked the website, I counted 16 different cancers that are directly related to obesity. I think, you know, this is something that, you know, is quite powerful.

And as Tim highlighted, you know, just being able to tackle the root problem, it may prevent in the future not only the development of certain comorbidities but definitely related costs, etc.

As I describe in the letter, addressing your questions, thank you so much for actually giving us an

opportunity to address your questions as well. I gave you a little bit of the overview of the algorithm in terms of, you know, there's a staging for the combination of BMI and the presence or absence of complications. And depending on the staging done, you know, a healthcare professional and patient that could come up with individual goals and, you know, find a very specific treatment plan for that particular patient.

For example, if patients are overweight, which is a BMI above 27 kilograms per square meter or a BMI above or equal through kilogram per square meter but there is no complications, essentially, you know, it's up to, again, the discussion that should take place between HCP and the patient whether this patient would require pharmaceutical therapy at this point. So this is so-called Stage 0, no complication, per se.

And once the patient starts gaining those different comorbidities, you know, at least with one morbid comorbidity, only moderate weight loss is required according to this algorithm. So there is no need to aim for 30 percent weight loss for those particular patients. This is so-called Stage 1.

And Stage 2, this is when patients gain either severe complications -- and one of those severe comorbidities could actually be tied to diabetes. So this

is when the more significant weight loss should be considered during the treatment therapy planned development.

So the treatment, as I mentioned, is based on the clinical judgment for each individual's goals. I think it's very important that there is this conversation and educational component between the HCP and patient in terms of, okay, what are the goals for you to lose the weight?

If somebody has a wedding in two weeks and they want to lose, you know, 12 pounds, something short term, this is one thing. But what we see that's going on and how (inaudible) is that, you know, people are taking obesity as something that needs to be taken into consideration for long term because it is highly preventable for multiple comorbidities.

So if patients start thinking that, you know, if I do have obesity now, I can take control of some of the blood pressure, some of the problems from the blood pressure, or my sugar, or, you know, some other factors. If that mentality can be set up, you know, between the patient and HCP, I think the approach would also be a little bit different. So there is no cosmetic component, per se, anymore.

Obesity is a disease. And actually according to the physician's statement from the American Association of Clinical Endocrinologists as of December 2016, they are

working on so-called A, B, C, D. This is positive-based chronic disease management. So they are viewing a patient who is obese as someone who already may have a range of comorbidities. And those patients they would require not only symptomatic management of, say, blood pressure but, you know, tackling the root cause of the problem.

I am a Medical Director for BELVIQ. But we do need multiple tools. Because all those multiple medications for weight loss management, first of all, some of them are for long-term management, such as BELVIQ. So we do have clinical evidence that BELVIQ works for as long as two years.

But some of them, such as Phentermine, it's only for three months. They can't use it for longer than three months according to the FDA regulations. So that's why we need the multitude and, you know, the whole variety of different drugs that would help patients to reach their goals.

And each and every drug has its own benefit risk profile. So that's why there should be a perform match between that and the patient, per se.

So we were talking about the diet and exercise. And I think this is a very good and absolutely important component of the weight reduction overall management. However, we did some research, some internal research within

the patient's journey. What we found was quite staggering. It took an average six attempts without pharmacal therapy for weight reduction before the patient was getting to age 49. Six attempts without pharmacal therapy. So that means that, you know, people try and fail. And what we're trying to say is that, you know, diet and exercise alone is fine. And it does work for many, many, many people.

However, there are even more people maybe who would benefit from adding pharmacal therapy to this particular regimen. And as I mentioned, the algorithm defines very nicely stage by stage, very specific (inaudible) with very specific comorbidity indications with and when pharmacal therapy would be most beneficial for a particular patient. So six attempts without pharmacal therapy on average.

So regarding BELVIQ. Very, very quickly. This is a medication that is indicated for long-term weight management, specifically as adjunct to diet and exercise for adults. Adult patients with a BMI greater or equal to 27 with at least one comorbidity or patients with BMI greater or equal to 30, which is obesity within the obesity category.

BELVIQ and BELVIQ XR is believed to decrease food consumption and promote satiety by selectively activating serotonin receptors in the hypothalamus. So on the

background of increased exercise and a lower calorie diet it pretty much helps them very well to achieve their weight reduction goals.

There are only two limitations of use. One is pregnancy and the other hypersensitivity. These are the contraindications. There are a bunch of warnings and precautions for use as well. They are all listed within the information.

So the things I would like to highlight is that the clinical program which is comprised of three trials, so-called BLOOM and BLOSSOM and BLOOM-DM. And those trials involve patients without Type 2 Diabetes, obese and overweight or patients with Type 2 diabetes. And for patients with Type 2 Diabetes, those were on oral medications.

(Inaudible testimony. The following are submitted written remarks:)

Introduction:

BELVIQ (lorcaserin HCI) was approved for use by the FDA in 2013 on the basis of three pivotal clinical trials which used lorcaserin 10 mg immediate release tablets administered twice daily.

BELVIQ XR (lorcaserin HCI) CIV was approved in 2016 on the basis of bioequivalence data comparing the 20 mg XR formation once daily versus lorcaserin 10 mg twice daily.

Mechanism of Action:

BELVIQ and BELVIQ XR is believed to decrease food consumption and promote satiety by selectively activating serotonin 2C (5-HT2c) receptors in the hypothalamus. The exact mechanism of action is not known.

Indication:

BELVIQ and BELVIQ XR is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

30 kg/m2 or greater, or 27 kg/m2 or greater with at least one weight-related comorbid condition.

Limitations of use:

The safety and efficacy of co-administration of BELVIQ and BELVIQ XR with other products intended for weight loss including prescription drugs (e.g., phentermine), over-the-counter drugs, and herbal preparations have not been established.

The effect of BELVIQ and BELVIQ XR on cardiovascular morbidity and mortality has not been established.

Key points:

Efficacy: From pivotal studies using lorcaserin 10 mg immediate release twice daily, it has been shown that patients reach weight loss (WL) of either greater than or

equal to 5 or greater than or equal to 10 percent twice as effectively as diet and exercise alone (placebo). Long-term two-year data show that more patients (67.9 percent or 258/380) who continued taking BELVIQ for two years maintained a weight loss of greater than or equal to 5 percent versus those started on BELVIQ and switched to placebo (50.3 percent or 88/175).

A. BELVIQ was evaluated in three randomized, double-blind, placebo-controlled trials with nearly 8,000 patients with overweight (OW) and comorbidities or obesity.

B. In the pooled BLOOM and BLOSSOM trials, patients with overweight/obesity without diabetes taking BELVIQ immediate release twice daily:

i. Lost more weight than patients taking placebo (5.8 kg vs 2.5 kg, respectively),

ii. More BELVIQ vs placebo patients lost greater than or equal to 5 percent of their body weight (47.1 percent vs 22.6 percent, p less than 0.0001; OR 3.1. p less than 0.0001) and greater than or equal to 10 percent of their body weight (22.4 percent vs 8.7 percent, p less than 0.0001; OR 3.1, p less than 0.0001) at one year.

iii. Patients taking BELVIQ also demonstrated improvements in cardiometabolic risk factors, including decreases in blood pressure (systolic: -1.8 vs -1.0 mmHg, p=0.007; diastolic: -1.6 vs -1.0 mmHg, p=0.003) and total

cholesterol (-0.9 percent vs o.4 percent) versus placebo.

C. BLOOM-DM (N=604) evaluated the safety and efficacy of BELVIQ immediate release twice daily as adjunctive therapy for weight loss in OW (BMI greater than or equal to 27) adult patients with T2D who were treated with metformin and/or a sulfonylurea (SFU). At one year:

i. More BELVIQ vs placebo patients lost greater than or equal to 5 percent (37.5 percent vs 16.1 percent; p less than 0.001; OR 3.1, p less than 0.0001) and greater than or equal to 10 percent of their body weight (16.3 percent vs 4.4 percent; p less than 0.0001; OR 4.1 p less than 0.0001) at one year.

ii. BELVIQ patients also had significantly greater mean weight loss than placebo patients (4.7 kg vs 1.6 kg; p less than 0.001).

iii. Glycemic improvements were significantly greater with BELVIQ vs placebo in HbA1C (0.9 percent vs 0.4 percent) and fasting glucose (27.4 mg/dl vs 11.9 mg/dl) (p less than 0.001).

iv. There were changes from baseline in heart rate (-2.0 vs -0.4 bpm) treated with BELVIQ and placebo.

Safety:

a. Contraindication:

i. BELVIQ and BELVIQ XR is contraindicated during pregnancy, because weight loss offers no potential

benefit to a pregnant woman and may result in fetal harm.

ii. BELVIQ and BELVIQ XR is contraindicated in patients with prior reactions to lorcaserin or to any of the product components. Hypersensitivity reactions have been reported.

b. Warnings and Precautions:

i. Serotonin Syndrome or Neuroleptic Malignant Syndrome (NMS)- like reactions.

ii. Valvular heart disease.

iii. Cognitive impairment.

iv. Psychiatric disorders.

v. Potential risk of hypoglycemia in T2D patients.

vi. Priapism, hematological changes, prolactin elevation, pulmonary hypertension.

vii. Heart rate decreases.

c. Most Common Adverse Reactions:

i. In the BLOOM and BLOSSOM studies, upper respiratory infections, headache, nasopharyngitis, dizziness, nausea, and fatigue were the most common adverse events that occurred more frequently in patients taking BELVIQ 10 mg twice daily than placebo.

ii. In the BLOOM-DM study, headache, back pain, nasopharyngitis, and nausea were the most common adverse events that occurred with greater incidence in patients

taking BELVIQ 10 mg twice daily than placebo, particularly if on a concomitant sulfonylurea.

iii. Common side effects in patients on BELVIQ XR were similar to those seen in patients on BELVIQ.

d. BELVIQ and BELVIQ XR is not a stimulant or narcotic. It is a federally controlled substance (CIV) because it may be abused or lead to dependence.

For more information about BELVIQ and BELVIQ XR, including important information, please refer to the provided full prescribing information.

BELVIQ XR Bioequivalence:

BELVIQ XR 20 mg administered once daily was compared with immediate-release lorcaserin hydrochloride 10 mg tablet administered twice daily under fasted conditions in 34 healthy subjects in an open label, randomized, crossover clinical trial.

At steady state, the time to reach peak plasma concentrations of lorcaserin (tmax) following BELVIQ XR 20 mg once daily was approximately 10 hours compared with 1.5 hours for immediate-release lorcaserin hydrochloride 10 mg tablet twice daily.

A single dose administration of BELVIQ XR 20 mg resulted in comparable total plasma exposure (AUCo) but approximately 25 percent lower peak exposure (Cmax) relative to two doses of immediate-release tablets administered 12

hours apart.

At steady state, however, both Cmax, ss and area under the plasma concentration versus time curve (AUCo-24) of BELVIQ XR 20 mg administered once daily were bioequivalent to immediate-release lorcaserin hydrochloride 10 mg tablets administered twice daily under fasted conditions.

Intake of high fat, high calorie breakfast before a single 20 mg oral dose of BELVIQ XR resulted in approximately 46 percent increase in Cmax and 17 percent increase in AUCO but no change in tmax. At steady state, however, there was no significant food effect on the rate or extent of absorption of BELVIQ XR.

Dosing:

The recommended dose of BELVIQ is 10 mg twice daily.

BELVIQ XR is 20 mg administered orally once daily. BELVIQ XR tablet must be swallowed whole and must not be chewed, crushed, or divided.

BELVIQ and BELVIQ XR can be taken with or without food.

3. Focus on long-term rather than short-term benefits of weight management had been emphasized and appreciated by many professional organizations. As there is no one-size-fits-all treatment and diet and exercise

continue to underperform for some patients with overweight (plus greater than or equal to comorbidity) and obesity, healthcare professionals need additional tools to meet those patients' needs. Pharmacotherapy recommended in AACE guidelines as an adjunct therapy to diet and exercise can be such a powerful tool. As multidisciplinary clinicians use patient-centered approach, the question will be which drug provides the most appropriate benefit-risk profile for their patients.

Conclusion:

BELVIQ and BELVIQ XR is believed to decrease food consumption and promote satiety by selectively activating serotonin 2C (5-HT2c) receptors in the hypothalamus. The exact mechanism of action is not known. In clinical trials, lorcaserin immediate-release tablets was proven more than twice as effective at helping patients lose greater than or equal to 5 and greater than or equal to 10 percent of body weight over diet and exercise alone.

In addition, in patients without Type 2 diabetes, there was a decrease in blood pressure and cholesterol vs placebo. In patients with diabetes, there were changes from baseline in heart rate treated with BELVIQ and placebo.

For more information about BELVIQ and BELVIQ XR, including important safety information, please refer to the provided full prescribing information. Eisai recommends

that PA state add BELVIQ and BELVIQ XR as covered medications for appropriate patients.

Thank you very much for your time and consideration. I would be happy to address your questions, if any.

(End of written submitted remarks.)

MAJORITY CHAIRMAN BAKER: Thank you very much.

I'm not sure which one goes next.

Mr. Kyle.

MR. TED KYLE: Thank you.

MAJORITY CHAIRMAN BAKER: Sure.

MR. TED KYLE: My name is Ted Kyle. And I'm here as a citizen of the Commonwealth of Pennsylvania and a member of the Obesity Action Coalition Board of Directors. I am here at my own expense. I am a volunteer for the Obesity Action Coalition.

And I'm here to say that I vigorously support Committee approval and ultimately final passage of this bill, which would make drugs treating obesity allowable for coverage under the State's Medicaid program if determined to be medically necessary by managed care organizations.

Obesity is a complex, chronic disease that requires serious interventions for both prevention and treatment. Untreated obesity leads to a whole range of other chronic diseases that include Type 2 diabetes,

hypertension, heart disease, lipid disorders, liver disease, cancer, sleep apnea, arthritis, and mental illness.

Evidence-based obesity care is absolutely essential for improving the overall health and quality of life for people with obesity. Good care for obesity prevents chronic diseases that become costly and lead to premature deaths.

All of those chronic diseases, just like obesity, if you stop the treatment of those diseases, those diseases return. I'm taking a lipid-lowering agent. If I stop taking my lipid-lowering agent, my lipids will go back up. If people stop taking their hypertension medicines, their blood pressure will go back up.

Five years ago my father died from the complications of obesity. He was never offered any treatment other than dietary counseling. My mother is living with the complications of obesity, most notably heart disease and joint disease. These complications have led her to needing intensive medical care and accepting severe limitations that prevent her from living a full and active life.

I myself have been taking an anti-obesity medication for now 12 years. That medication has allowed me to resolve the diagnosis of obesity, live at a lower BMI and prevent the progression of other chronic diseases that exist

within my family history.

But discriminatory coverage practices combined with growing scientific evidence surrounding obesity led the AMA to declare obesity as a chronic disease in 2013. Subsequently, the AMA adopted formal policy supporting patient access to the full continuum of care and evidence-based obesity treatment such as behavioral, pharmaceutical, psychosocial, nutritional, and surgical interventions.

Numerous other healthcare professional and patient organizations support the AMA policy. They recognize that obesity leads to more than 30 other chronic diseases including, as I've mentioned, cardiovascular disease, diabetes, and cancer.

The last ten years have brought significant medical advances in obesity care. We're still not where we need to be. No doubt about that. You're more likely to be cured of cancer than you are to be cured of obesity.

Health plans continue to exclude coverage for FDA-approved obesity drugs. And those practices are out of date and out of touch with the current scientific evidence for obesity treatment.

In recent years, the FDA has approved four new obesity drugs, BELVIQ, Contrave, Qsymia and Saxenda, as well as several other promising drugs that are progressing

through the Agency's approval process.

Pennsylvania currently has the 24th highest level obesity rate in the country. We're not doing as badly as some and we're not doing as well as others. With more than 30 percent of our citizens affected by obesity, it is imperative that our citizens, particularly those, as the Committee has noted, have multiple impacts on their health, have access to the full range of evidence-based obesity care in order to avoid the progression of this difficult, complex, and chronic disease.

Thank you so much for the opportunity to testify. I'm happy to answer questions as they arise.

MAJORITY CHAIRMAN BAKER: Thank you, Mr. Kyle.

Doctor.

DR. SAGAR MEHTA: Last but not least.

Good morning. I'm Dr. Sagar Mehta and I'm the Director of Bariatric Medicine at St. Luke's Weight Management Center in Allentown.

Today I'm speaking on behalf of the Obesity Society, the leading professional society dedicated to better understanding, preventing, and treating obesity. Through research, education and advocacy, TOS is committed to improving the lives of those affected by the disease.

I appreciate the opportunity to speak before the House Committee today regarding anti-obesity medications and

obesity treatment in general. Obesity is a multi-factorial chronic disease requiring a comprehensive approach to both prevent and treat. As mentioned by other members of the panel, obesity is associated with a large number of comorbid conditions. Therefore, care should not be seen as simply having the goal of reducing body weight but should additionally be focused on improving overall health and quality of life.

The media loves to sensationalize weight loss efforts through such shows as the Biggest Loser or My 600 Pound Life. There are advertisements in almost every magazine and commercial break that promotes something related to weight loss.

Fad diets, fad exercise regimens, and over-the-counter weight loss supplements come and go so frequently that I don't even bother to keep up with them anymore.

As an expert, it's easy for me to separate fact from fiction. But someone who so desperately wants to or needs to lose weight is more than willing to try something at least once. As one of a few fellowship-trained obesity medicine physicians in the U.S. with Board certifications from the American Board of Obesity Medicine, the National Board of Physician Nutrition Specialists, and the American Board of Internal Medicine, it is my role, rather than my

duty, to help my patients navigate this confusing realm of weight loss using all available evidence-based treatment options.

My perspective today comes as an obesity medicine specialist who founded, developed, and helped integrate our medical or non-surgical weight loss services to a hospital-based comprehensive weight management center offering surgical and non-surgical interventions through a multi-disciplinary team approach.

Treatment for obesity is quite complex mainly due to the multi-factorial etiology of this disease process. And successful outcomes require a multi-modal treatment plan utilizing a multi-disciplinary approach.

If it was as simple as putting down the fork and exercising more, then why would more than two out of three Americans deal with excess weight issues? Granted the cornerstone of obesity treatment will rely on consistent lifestyle changes of nutrition, behavioral, and physical activity modification. However, sometimes that's just not enough.

Weight loss is generally not the challenging part. I'm sure almost everyone in this room has had successful attempts at weight loss at some point in their life. How difficult has it been to maintain it? The human body loves homeostasis or keeping things normal. And there

are several physiologic theories that suggest weight loss maintenance is such a challenge due to alterations in metabolism and in appetite regulating hormones that occur after weight loss. So it's not just about willpower but about having effective strategies to overcome this.

When I see a patient for consultation, one of the first questions I ask is, what brings you in today? As obvious as the question is, it allows me to gain a little insight as to how the patient views their weight issue.

At times I will get the response, because I'm fat. And I'll gently remind the patient that we don't use the F word here. I try to refer to the condition with less stigmatizing words such as excess weight or unhealthy weight.

Most of the time, however, the response to that question is, it's because of my health. I now have joint pains that make physical activity or activities of daily living more difficult or now I have diabetes, sleep apnea, high blood pressure, or some other weight-related condition. I have kids or grandkids that I want to be around for. I want to enjoy my time with them, be active with them and go on roller coasters with them.

I also try to listen to some modifying factors with regard to the weight history. Many female patients will attribute their weight issues to pregnancy or

menopause. Some patients gain significant weight after quitting smoking or due to medications for treatment of other medical conditions. Weight gain due to medical conditions themselves is possible as well as from conditions such as Polycystic Ovarian Syndrome, low thyroid disorders, or cortisol excess just to name a few.

For some patients food has become a coping mechanism for stress, anxiety, or depression. I distinctly recall two female patients that purposely kept an unhealthy weight as a protection mechanism, one due to being in an abusive relationship, another to appear less desirable due to sexual child abuse as a child.

It is well known that behavioral health issues are not uncommon among patients with obesity. For most of my patients this is not their first time at the rodeo as they've tried many different diets and exercise regimens, over-the-counter supplements with varying success. Some of them even had bariatric surgery.

Next I go on to do a thorough medical history, a physical exam, and finally discuss all available treatment options in an objective manner, which can potentially include bariatric surgery, a structured physician-supervised weight loss program with options of utilizing meal replacements and dieticians in a class or individual setting and the possibility of FDA-approved weight loss medications.

I allow the patients to make the best treatment choice for them. And I also emphasize that there's no magic bullet. Lifestyle changes are going to be paramount to long-term success and that there's no right option. It just has to be right for them.

Over the past two and a half years I've seen close to 2,000 new patients. And with all my patients, I emphasize the benefits of a modest 5 to 10 percent weight loss that can have a decreasing cardiometabolic risk and the importance of a multi-disciplinary approach to weight loss, including dietary, behavioral, and physical activity modification.

And in patients who have demonstrated some consistency in their lifestyle change attempts, only then will I bring up the possibility of using anti-obesity medications. Appetite regulation primarily occurs in the brain, particularly in the hypothalamus where the action in most of these medications occur.

I've successfully and unsuccessfully utilized all the medications available on the market to help patients struggling with appetite or even cravings. As a medical provider trying to treat such a complex disease process, it is of the utmost importance that I have every available tool to my patients to achieve improved health through weight loss.

Here are a few examples of patients that I have treated with success: JC is a 43-year-old male who had been as heavy as 700 pounds. He underwent bariatric surgery at an outside institution and successfully lost close to 400 pounds but life circumstances occurred. He became less consistent with important lifestyle changes. And over time he gradually regained about 200 pounds.

When I first saw him in February of 2016, he was tipping the scale at 507 pounds. Initially we discussed the possibility of a provisional bariatric surgery. But since he was on disability and had Medicare coverage, this was not a covered benefit.

I worked with him for a few months. He was making positive changes such as food logging, making better food options or food choices, and was even doing pool exercises three to four times per week. Because of his joint issues, he was unable to do land exercises.

He was slowly losing weight but appetite continued to be an issue. We explored anti-obesity medications, but given that he had Medicare, the new anti-obesity medications would not be covered. We elected to piecemeal together a generic alternative for Qsymia.

The weight loss continued and it was more manageable for him to stick with dietary guidelines and he was able to graduate to land exercises. He continues to

stay consistent with lifestyle changes. And as of his last visit in March of this year, he weighed 420 pounds, a weight loss of 87 pounds.

CT is a 37-year-old female who I first saw in April of 2015 with an initial weight of 194 pounds. She has struggled with weight gain after her first pregnancy and had high cholesterol with increased weight.

Like my first patient, we started with lifestyle changes but she was always feeling hungry. I adjusted her calories, protein, fiber, and fluid needs to see if we could overcome this issue through dietary changes, but to no avail.

We discussed the different medication options. At first she was hesitant, so we gave it a few months. And then she expressed the desire to try it. She elected to try Saxenda. At her last visit in March 2017, she weighed 140 pounds, with a total loss of 54 pounds. She's now in a normal BMI range and her LDL cholesterol went from 186 to 123.

Lastly is DB, a 47-year-old female whose presenting weight in May of 2015 was 195 pounds. She had completed our 12-week intensive lifestyle intervention program and successfully met the 5 to 10 percent target. But she had more she wanted to achieve.

Due to cost concerns, we elected to go to the

generic (inaudible). She continued to make positive lifestyle changes. And at her last visit in March of 2017, she weighed 145 pounds, a weight loss of 50 pounds. And her sleep apnea -- she no longer needs to wear her CPAP machine.

These are the patients that come to memory, patients who continue to follow up with me. But unfortunately there are many patients who do not follow up because they hit a dead end due to lack of insurance coverage for services that have been shown to be effective in the fight against obesity.

Patients have been denied physician and dietician visits, bariatric surgery, multi-disciplinary intensive lifestyle intervention programs, such as the ones that we offer, which are similar to the ones used in the diabetes prevention program that show that these lifestyle changes were the most effective in preventing the onset of diabetes on prediabetic patients, and also due to the lack of coverage for weight loss medications.

It is these patients that are nameless and fade our memory, the ones we were unable to help. I urge the House of Representatives to support House Bill 899 so that the forgotten ones have a chance to succeed at health.

Thank you.

MAJORITY CHAIRMAN BAKER: Thank you very much, Doctor and panelists.

Of the four anti-obesity drugs that the FDA has approved that you have listed, are any of those biologics?

DR. SAGAR MEHTA: No.

MAJORITY CHAIRMAN BAKER: No, they're not. Okay.

And in terms of -- because a lot of these discussions eventually get reduced to costs, obviously, some of the objections. That's a legitimate concern, the costs of these medications.

In terms of mitigating and reducing the costs and the impact on the budget, because it could be a significant amount, of those four, which one would be the most cost effective and are we eventually looking at generics and reduction of costs through generics as well?

MR. TIM CLARK: I don't think we're in a position to have a cost effect in this conversation. We can certainly direct you towards -- there's an organization called the Institute for Clinical Effectiveness Research out of California that has done some work in this area that we can direct you to. I don't want to speak to my competitors.

Certainly always in the pharmaceutical industry generics will come at some point.

MAJORITY CHAIRMAN BAKER: Okay.

MR. TIM CLARK: I think one point -- so Saxenda, the product from Nova Nordisk, is an insulin-based product. So I'm not sure how it was approved, through what avenue it

was approved by the FDA. It could be a biologic. But we can certainly follow back up with you.

DR. ELENA NIKONOVA: It's actually (inaudible). But just to your point, this is the only injectable in the group so probably the cost would be more.

MAJORITY CHAIRMAN BAKER: And that is which one again?

MR. TIM CLARK: Saxenda. So it's the one from Novo Nordisk. It's the one most recently approved.

DR. ELENA NIKONOVA: It's 3.0 milligrams.

MAJORITY CHAIRMAN BAKER: And apparently there's several other promising drugs that are being worked on.

MR. TIM CLARK: In the pipeline.

MAJORITY CHAIRMAN BAKER: Okay.

DR. ELENA NIKONOVA: Yes, the pipeline.

MR. TIM CLARK: So in answer to your question about which is the most cost effective. I think it might be helpful to think about these -- you know, unlike a lipid-lowering agent where you have half a dozen that you can prescribe and you get similar effects in different patients, they operate by similar mechanisms of action, the response to anti-obesity medications is extremely individualized. So the real answer, given what we have today, is the most effective anti-obesity medication is one that a patient responds to. And generally speaking, you can

tell if someone is going to respond within about the first 12 weeks. And if they are responding, then they are thrilled and you want to continue the therapy. And if they aren't responding, you want to quit wasting your money and your time on that therapy.

MAJORITY CHAIRMAN BAKER: In addition to these FDA-approved drugs, I understand there is a fair amount of over-the-counter type, anti-obesity type. What do you think of those?

DR. ELENA NIKONOVA: We can't testify for those.

But I think with the checkpoints, specific checkpoints, they do vary. It's between three and four months depending on the medication.

And for the weight loss assessment for that particular point, also depending on medication, it could be as low as 3 percent and all the way greater or equal to 5 percent. So there is a chance, you know, for both HCP and patients to kind of assess whether this drug, this particular drug, is working and to discontinue if not.

If I may quickly say something. I think this is true what Ted brought up in terms of the variety of the drugs, but also the benefit risk for each drug is really, really important. For example, if a patient is, you know, older than 50 with hypertension and we do know that the medication does increase either heart rate or blood

pressure, maybe, you know, the choice would be toward something that does not increase blood pressure and heart rate.

So, you know, this is again to the point that we do need the whole range of different tools so people and patients could, you know, make their decision on the best choice.

MAJORITY CHAIRMAN BAKER: Thank you.

And, Doctor -- and then I'm going to go to Representative Daley. She has to leave.

Your colleagues in the Pennsylvania Medical Society, family physicians, specialty, subspecialty groups, do they support your position of having the option to prescribe?

DR. SAGAR MEHTA: I don't know officially what their position is. I can tell that you the majority of patients that I see are referred to me by other physicians in our network. Two-thirds of my patient population is from that source. So clearly they are in line on the need for obesity treatment and things like that.

These are the things that are not really taught in med school, not taught in residency training. You know, there's a lot of awareness now being devoted to these issues. But I can tell you when I went through med school, my nutrition class was about a week long. And residency,

you know, it was mainly an inpatient type of setting so I didn't have that much outpatient.

I was fortunate to go through a clinical fellowship of obesity medicine nutrition to allow me this experience and education to better understand this disease process. As a result, it allowed me to treat it appropriately.

So I think we all know in healthcare that this is a huge health burden and that we need to utilize the most effective evidence-based treatment modalities that we have.

MAJORITY CHAIRMAN BAKER: But it is accurate to say that the American Medical Association supports it?

MR. TED KYLE: Yes.

DR. ELENA NIKONOVA: And actually there is an American Board of Obesity Medicine certification exam, which more and more multi-specialty physicians are taking lately.

MAJORITY CHAIRMAN BAKER: Thank you.

Representative Daley.

REPRESENTATIVE DALEY: Thank you, Mr. Chairman.

I do have to run off to Appropriations in a couple of minutes.

You know, I'm kind of really torn sitting and listening to this. Because I keep reminding myself and listening to you talk about the prevalence of obesity and what a major health issue it is. I think that we can all

recognize that.

I'm also looking at obesity that there are reasons that obesity happens. And I spent a little bit of time while listening to you, inactivity, poor food choices, genetics, age, socioeconomic environment. And they all have subsets of what you can, you know, think about in those.

But then I -- you know, I'm running off to an Appropriations Committee hearing so the cost is something that also concerns me. Because as a representative, we have to balance and figure out how do you make decisions based on the choices that are in front of you?

And it seems -- I guess I should state I'm not a huge fan of drugs for treating things. I think that, you know, we've learned that some of the use of opioids was treated because physicians were -- the model was to relieve pain for patients. And they did that. And then we have a whole group of opioid drugs that that's exactly what they do, but they've become so addictive and we have another emergency.

And so I'm looking at also what can we do related to prevention? And when I look at -- I went back and I found the article that I read earlier today that the President is projecting cuts, his budget is projecting cuts to Medicaid and CHIP, which would affect more families, shifting the cost to the states with annual limits, cutting

welfare programs such as SNAP and TANF, which are actual programs that help people in poverty to be able to hopefully afford to get better food, which clearly would then address some of these issues.

And I look at what we're doing here in Pennsylvania. House Bill 218, there were home nursing programs which were cut. And the reason that gets to me is because those are programs that help pregnant women through their pregnancy until their children are three years old.

You know, if moms can't deal and have obesity, they're more likely to be raising children with obesity. So I think that we are stuck with making decisions. And this is -- I realize a bill is a single subject and we need to stick to that. But you can't live in a vacuum and not consider all of these other things.

So those are the other things that I'm considering as I listen to you because I realize that there are people today who are living with obesity. Believe me. My daughter just lost 47 pounds because she went to Weight Watchers and started exercising. She did it over a six-month period. I am thrilled. I never thought of her as obese. But when she told me 47 pounds -- and she's on top of the world right now. And she's still working to lose more. You know, that's a behavioral program I think, the Weight Watchers. And the exercise is clearly something

that's important.

So when I listen to the Doctor from the Department of Human Services, I have to listen to that, that nutritional counseling isn't something that we want to start when we're obese. You have to start it -- we have to start these programs and find ways to prevent this.

This may not be addressing what you're talking about. But they're certainly things that I need to think about when making decisions like this. So I really appreciate that. I feel like I learned a lot sitting here listening. I just also feel like the pieces that I brought up are things that we're going to have to contend with as the House of Representatives because life is about choices. I'm having trouble just focusing on those.

But I have a meeting in about two minutes and I have to run over to that.

MR. TIM CLARK: So can I just get 30 seconds? I promise you.

REPRESENTATIVE DALEY: Sure. You can have 30 seconds.

MR. TIM CLARK: I certainly appreciate the enormity of the challenges that you face from a State budget perspective. I think it makes it even more important for us to make determinations and decisions on those things that are actually driving costs through the system.

And I think, you know, while the President has proposed a budget, it is a proposal. I don't suspect that that 610 billion is going to be taken out of Medicaid. Congress is going to have something to say about that.

But certainly there is going to be more flexibility, which will provide with you the opportunity to make those changes.

REPRESENTATIVE DALEY: And, Mr. Chairman, that's part of the reason that I raise those things, because I think they're important for all of us hear. And I'm going to keep stressing them because, yes, I recognize it's a proposal; and, yes, I recognize House Bill 218 is not the final word. But I think that it's important to state these are impacts that, you know, have consequences.

Thanks.

MAJORITY CHAIRMAN BAKER: You're welcome. Thank you.

Representative Topper.

REPRESENTATIVE TOPPER: Thank you, Mr. Chairman.

I thought I'd come up here in case anybody wanted to use it. I wasn't stealing one of the mikes from one of you guys.

Let's talk about -- I heard long-term care. So what are we talking about? I think it was Mr. Kyle said he's been on this medication for 12 years. I mean, are some

of these meds that folks are going to be on the rest of their life?

MR. TED KYLE: I think the best way to think about it is just like anti-hypertensive, any anti-diabetic medications, if it's working, then presumably you would want to continue it. And if you stop an anti-hypertensive medication, your blood pressure will likely go up. If you stop a lipid-lowering medication, your lipid disorder will come back.

And the placebo-controlled crossover studies have been done with these medications to say that they are effective at maintaining a lower weight that you achieve. Usually the weight loss occurs in the first six -- most of it occurs in the first six months. But if you stop taking it, you will go back to close to the baseline.

And the same thing happens with bariatric surgery. The magnitude of weight loss with bariatric surgery is great. There is typically some regain. And if the bariatric surgery is reversed or, you know, there are gastric balloons now, when they are removed, most of that weight comes back.

And so this is a chronic disease that we manage. It's not something, as was correctly said earlier, that we cure, anymore than we cure diabetes or cancer or heart disease. We manage it to maximize health.

REPRESENTATIVE TOPPER: And I guess the concerning part to me is also what Representative Daley just said, which is we have currently been traveling all over the State for the past year and a half talking about managing care, you know, chronic pain, for instance, that is not something that can be cured.

Even yet that has led us now to -- I respect what Chairman Baker said about trusting the doctors in terms of prescribing medication. And yet we have passed bills as part of an opioid package that tells doctors you can only prescribe so much medication. You know, if you're an emergency room doc, you can only do so much.

So I feel like we're moving in a different direction based on what issue we are talking about when it comes to medication. I want to try, as somebody who's not in the pharmaceutical field or in the medicine field but in the public policy field, to establish good, sound, public policy.

Yes, there are stories from both sides. But we have to look at a big picture. So the long term versus the short term, just to clean up that thought, short term is for the short-term medications that are three months, for instance, what are they doing? Are we saying that we feel that those medications are for folks that once they do the three months, they can be on track on their own? Why are

there short-term medications if long-term medications are preferable in your opinion?

MR. TED KYLE: All of the medications that have been prescribed, that have been approved recently, are approved for chronic use because this is a chronic disease. By and large, the guidelines for treatment do not specify short-term treatment for this chronic disease any more than you describe short-term treatment to clear up your diabetes and then you're off free.

These are chronic diseases that we don't yet have the capacity to cure. It would be great to have the capacity to cure it, to correct the weight regulation thermostat essentially that exists and becomes disrupted in the hypothalamus but we are definitely not there.

REPRESENTATIVE TOPPER: Okay.

Thank you, Mr. Chairman.

MAJORITY CHAIRMAN BAKER: You're welcome.

And, Doctor, did you have a response?

DR. SAGAR MEHTA: With regards to the three-month one, yes. That medication is Phentermine. That was developed in the '50s. And so back then, they did not do long-term trials on it. Three months was it. That was all.

But I can tell you that one of the newer medications out there is Qsymia. Qsymia does have a Phentermine component in it. And they have done long-term

clinical trials on that. And it has been shown to be effective in weight loss and weight loss maintenance beyond one year.

MAJORITY CHAIRMAN BAKER: And I'm going to go to Representative Schemel next. But in terms of the 12 states that allow this, it would be helpful and informative if we could determine what is long term, what is short term. Are they first line? Do they require preauthorization? Those kinds of things might be helpful in the development.

MR. TIM CLARK: I can speak to this quickly.

So they're an adjunct to diet and exercise. So the first is diet and exercise and then you add. They are all subject to preauthorization across the country. And that is perfectly understandable and justifiable. The preauthorization is perfectly fine.

DR. SAGAR MEHTA: Just one more quick comment about that medication class. It's a stimulant class. So with that --

DR. ELENA NIKONOVA: Not all of them. BELVIQ is not a stimulant.

DR. SAGAR MEHTA: The three month, the short term?

DR. ELENA NIKONOVA: Yes.

DR. SAGAR MEHTA: Phentermine is a stimulant. And so, you know, with that comes the increased risk of

higher heart rate, higher blood pressure.

DR. ELENA NIKONOVA: Right.

DR. SAGAR MEHTA: Anxiety issues. You know, someone who has got hypertension, heart disease, someone who already has got a high level of anxiety, this is not a good medication to go to. So that's really the only medication class that we have that's in a generic form.

MAJORITY CHAIRMAN BAKER: Becca.

MS. BECCA SAMMON: With Qsymia, that's formed from a combination of Phentermine and another drug called Topamax. Are they ever used separate of each other?

DR. SAGAR MEHTA: In one of my patient examples, I do use them. Before Qsymia was available, that's what we had.

MS. BECCA SAMMON: Right.

DR. SAGAR MEHTA: The difference is that Topiramate that's in the Qsymia is extended release. And that is the difference between some of these medications. Because Contrave is also a combination of two medications that have been on the market for a long time, Bupropion, which is a well-known antidepressant, and Natrexone, which is an anti-opioid for alcohol abuse medication.

But again, the formulation of this is different. And sometimes the tolerability of these medications can be better in that formulation.

MS. BECCA SAMMON: Both of those drugs are -- have been on the market for quite some time. And their safety isn't something that we're questioning at this point.

MAJORITY CHAIRMAN BAKER: Topamax, is that the migraine drug?

MS. BECCA SAMMON: It is. I actually take Topamax for migraines.

MAJORITY CHAIRMAN BAKER: It's a very helpful drug.

MS. BECCA SAMMON: It is. It was developed as a seizure medication. And then they found that it had (inaudible) for migraines. I lost a lot of weight when I went on it for migraines. I didn't know I was going to lose weight, but just the Topamax created that.

DR. ELENA NIKONOVA: I guess they all came after 2012. BELVIQ was approved by the FDA in 2013 in IR formulation, 10 milligrams, twice daily.

And lately in 2016, just one daily tablet of 20 milligrams. And again, this is the only drug that works directly on the hypothalamus. So that's why maybe there are not that many side effects.

As we keep saying, this really depends on the patient's need and what drug would be the best choice for them.

MAJORITY CHAIRMAN BAKER: Our last question --

because we do have to be up on the Floor to vote in about five minutes or so -- will be from Representative Schemel.

REPRESENTATIVE SCHEMEL: Thank you, Mr. Chairman.

Reflecting on Dr. Cathers's testimony, her agency has a finite amount of money. In order to cover your drug, they would have to elect not to cover some other treatment or drug. That's the choice they have to make.

They said in their analysis, that at 8 pounds per year, at an average cost of $2,400, that it just was not cost effective. And maybe there were other things that went into that analysis.

So I would ask all of you that are experts in this area, are any of you familiar with the methodology or the analysis that the Department of Health did? And do any of you with that familiarity say that they are wrong or made any wrong judgments in that analysis?

DR. ELENA NIKONOVA: Well, I can testify for the efficacy of the BELVIQ. And I can tell you that after one year in patients without non-diabetes, they lose more than eight pounds. So it's 5.8 kilograms, which is close to 12 pounds, 11.8 pounds, if I'm not mistaken, versus placebo 2.5 kilograms. And for patients with Type 2 diabetes, 5 kilograms, which is close to 11 points.

REPRESENTATIVE SCHEMEL: So, Doctor, you said earlier that that particular drug is one that's used as a

supplement to other things, diet and exercise.

DR. ELENA NIKONOVA: Um-hmm.

REPRESENTATIVE SCHEMEL: You say an average of 12 pounds per year. And that is together with diet and exercise. Can you identify that the drug is really -- would diet and exercise itself not cause weight loss?

DR. ELENA NIKONOVA: That's why in randomized controlled trials, you do have the comparison, versus placebo. You know, placebo values are much, much less. So it's 12 pounds versus 6 pounds.

REPRESENTATIVE SCHEMEL: On someone who is obese -- and I know it depends on height and other things like that -- how many pounds would they generally need to lose? I mean, when you're obese, how many pounds over the average are you generally?

DR. ELENA NIKONOVA: As I mentioned earlier, according to the 2016 algorithm, if it's mild to moderate complication, that patient would just require the (inaudible) weight loss between 5 and 10 percent.

And if it's severe comorbidity, such as full-blown Type 2 diabetes, maybe, you know, that they would require something more.

So, you know, there are very well-written predefined parameters to justify use of certain pharmacal therapies versus bariatric surgery versus other

interventions written by the American Association of Clinical Endocrinologists.

MR. TIM CLARK: And we can follow up with you, Representative. There's new additional data that shows an even higher level of weight loss from our responders. So the average is about 33 pounds and the split is between 15 and 82 pounds. We can follow up with you on that.

REPRESENTATIVE SCHEMEL: Sure.

And you can see why I struggle with when we have an Agency that is there to analyze these things and make these determinations and we say, well, we're not physicians or experts but we're going to decide differently.

DR. ELENA NIKONOVA: Right. And also it's, you know, the numbers I talked to you about is an overall (inaudible) population. And Tim mentioned so-called responders. So, you know, if you analyze people who responded to therapy, you would expect high numbers because they are responders.

But as with any anti-obesity medications, it's pretty easy to see whether the drug works on not. And, you know, patients need to make choices between the drugs.

MR. TED KYLE: The one thing that I would add is that I would be cautious about looking at an analysis that applies an average response rate in this category where responses are extremely variable across an entire

population. In an individual who is responding well, it's extremely cost effective. In an individual who is not responding well, it's pretty much useless.

DR. ELENA NIKONOVA: And it's close to 50 percent responders on BELVIQ in particular.

MAJORITY CHAIRMAN BAKER: And, Representative Schemel, just to clarify for the record, it's not the Department of Health. It's a Medical Assistance Advisory Committee within the Department of Human Services.

REPRESENTATIVE SCHEMEL: No problem.

MAJORITY CHAIRMAN BAKER: Thank you very much.

We appreciate the panelists, all the speakers, and all the great questions.

The Health Committee is adjourned.

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