

Ted Kyle, RPh, MBA

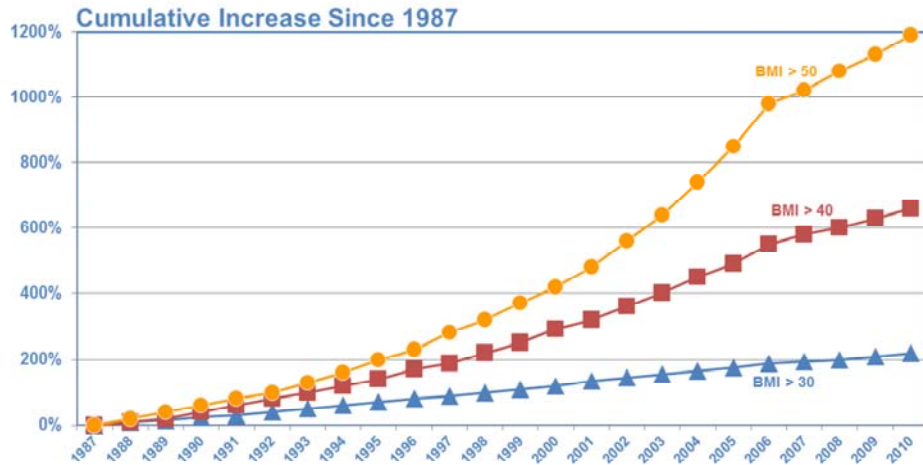
Pittsburgh, PA

My name is Ted Kyle and I am here as a person affected by obesity and a healthcare professional. I am a pharmacist, an active member of the Obesity Society and Chairman of the Obesity Action Coalition. Two years ago, my father died from complications of obesity. He was never offered any treatment other than dietary counseling.

I have no financial interest in the sponsor, but I do offer my advice to anyone who will listen, and have provided advice to the sponsor. I am attending today's meeting at my own expense and the opinions I offer are mine alone.

Thank you for the opportunity to address the committee today.

Severe Obesity Is Growing in Adults



Source: Sturm and Hattori, 2012.09, LJO

Like me, you have probably heard news stories suggesting that obesity rates might be leveling off. But already, more than two-thirds of Americans are affected.

AND the growth of severe obesity, the subject of this hearing, shows no sign of slowing down.

Untreated Obesity Harms Virtually Every Organ System

- Pulmonary
- Nonalcoholic fatty liver
- Gall bladder disease
- Gynecologic
- Osteoarthritis
- Dermatologic
- Gout



- Intracranial hypertension
- Stroke
- Cataracts
- Cardiovascular
- Diabetes
- Pancreatitis
- Cancer
- Phlebitis

With relentless growth in severe obesity comes devastating results for people affected and for American healthcare.

Severe obesity affects every organ system.

NASH Will Soon Become the #1 Reason for Liver Transplantation

The New York Times

Threat Grows From Liver Illness Tied to Obesity

By ANAHAD O'CONNOR JUNE 13, 2014 10:07 PM 345 Comments



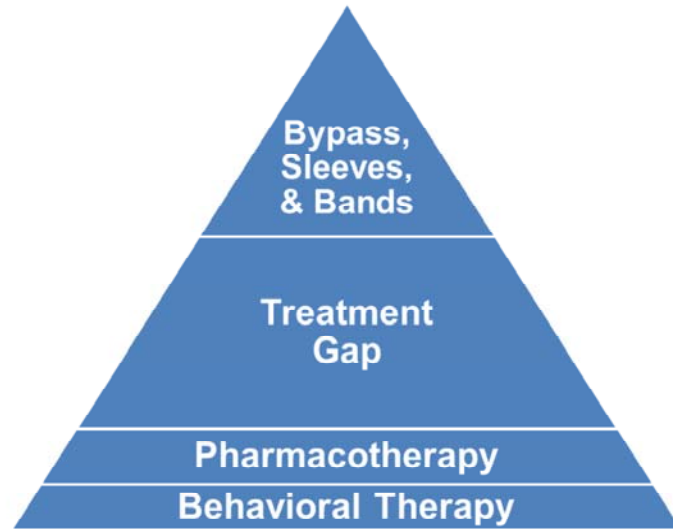
Yubelkis Matias, 19, a student at Bronx Community College, lives with fatty liver disease.

Nancy Dorowick/The New York Times

Charlton et al, 2011.10. Gastroenterology

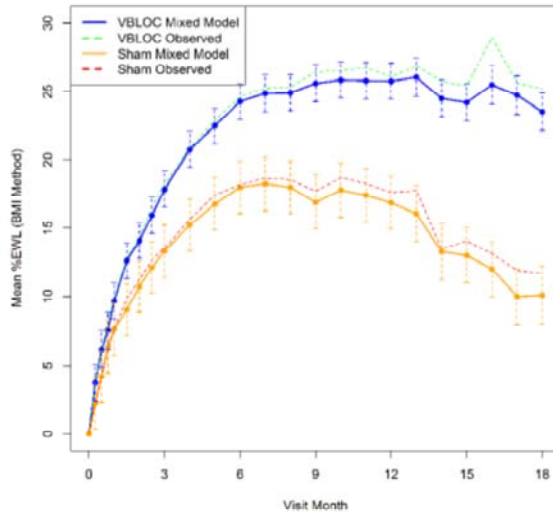
One example of the impact is recent news that non-alcoholic fatty liver disease is growing out of control because of severe obesity. It will soon become the number one reason for liver transplantation.

Innovation Needed to Fill the Gap in Treatment Options



Yet treatment options are limited for people with severe obesity. Behavioral and drug treatment can be helpful for some, but for the vast majority, they are inadequate. The surgical treatment options currently available are very effective, but most patients are put off by the risks they believe these procedures entail. The dietary restrictions are daunting, as well.

VBLOC Therapy Works Safely



- 24% EWL
- 3.7% SAE Rate

Source: FDA Executive Summary
Prepared for the June 17, 2014 meeting of the
Gastroenterology and Urology Devices Panel

The briefing documents that FDA published on Friday make it clear that VBLOC therapy provides weight loss greater than usual care, superior to a sham control. And it appears to have exceeded FDA's pre-specified standard for safety.

The question is whether you will reject this therapy because it did not exceed a hurdle of more than 10% superiority over the sham control group.

This is a standard for which no precedent exists.

Regulatory Actions Have a Tremendous Impact on Innovation

- **Requiring super-superiority**
- **Would erect an unprecedented barrier**
- **When severe obesity
requires more innovation, not less**

Your action today will have a tremendous impact on innovation

VBLOC therapy clearly helps patients with severe obesity lose about a quarter of their excess weight. And it does so with a good safety profile compared to other bariatric procedures.

So I am here to ask that you not erect a new barrier to innovation in the treatment of severe obesity with an unprecedented hurdle of super superiority over sham surgery.

I am here to urge you to approve this treatment, which meets a need for another option to help people with severe obesity.

Thank you.