To the Staff and our Clients at Southampton Health Services regarding two "new" appetite suppressants;

The U.S. Food and Drug Administration (FDA) recently approved two "new" weight-loss drugs*, Belviq* and *Qsymia*. It was done, not because these medications are particularly unique or more effective, but because the FDA has not approved anything in the past 13 years to help decrease our national obesity epidemic. At this time, SHS will not be prescribing either of these medicines.

As background, SHS has provided a safe weight reduction program for over 30 years. We have 5 internal medicine specialists with expertise in Bariatrics who review continually the medical literature and adjust our weight reduction protocols accordingly. For example, when *Meridia* (subutramine) was introduced in 1997, we were concerned that the increased blood pressure it caused could create problems. Therefore, we never prescribed it. In 2010, after it had been on the market for 13 years, the FDA determined *Meridia* increased the risk of heart attacks and strokes and it was taken off the market.

How effective are these new medicines?

In one year treatment trials, patients taking *Belviq* lost about 5% of their body weight while those on *Qsymia* lost about 10%. To put it into perspective, patients at SHS must lose 12 pounds over the first three months of the program, which is usually about 5% of their body weight. Within one year, our patients commonly lose 20 to 30% of their weight.

How do these medicines work and are they safe?

Belviq (lorcaserin) is structurally similar to and acts on the same brain serotonin "craving receptors" as dexfenfluramine, the "*Fen*" of *Fen-Phen*. Unfortunately "*Fen*" also acted on heart valve tissue, causing them to thicken, leak, and eventually become irreversibly damaged. Because of this, in 1997, *Fen-Phen* was taken off the market.

The FDA's approval of *Belviq* came with a significant warning that its safety and effectiveness when used alongside other diet medications was not established. Its effect on the long-term risk of having, or dying from, a heart attack or stroke has not been determined. To appease the FDA's concern about it causing heart valve disease, the maker of *Belviq* conducted regular and multiple echocardiograms to examine the heart valves of trial participants. At 12-months, they found no significant increase in valve problems. Participants received 18- and 24-month follow-up echocardiograms, but these results were not reviewed. The FDA was urged to reject *Belviq* by consumer watchdog, Public Citizen.

Qsymia is a combination of 15 mg phentermine (half the dose we usually prescribe at SHS) and 92 mg topiramate (*Topamax*), an anti-seizure medication at the dose usually prescribed to prevent migraine headaches. *Qsymia* can cause fetal harm. It was previously disapproved by the FDA due to the fact that topiramate causes a two fold increase of birth defects, including cleft palates and to concerns regarding its increased cardiovascular risk (heart attacks and strokes). Well recognized side-effects from topiramate include memory loss, "fogginess", problems with word-finding, parasthesias (tingling and numbness), suicidal thoughts, hair loss, and kidney stones. Women of reproductive age must not become pregnant when taking *Qsymia*. They must have a negative pregnancy test before treatment and

get monthly tests thereafter while using effective contraception when taking it. If one becomes pregnant while taking *Qsymia*, treatment must be discontinued immediately, and the patient informed of the potential hazard to the fetus.

BOTTOM LINE

What we do at SHS works. Our medications are "tried and true", safe, and effective. With our regimen and team approach, our patients routinely lose 20-30% of their weight.

We feel *Belviq* and *Qsymia* are less effective than the medications we currently prescribe and could be dangerous. Their risks, including possible heart valve disease and fetal malformations as well as significant undesirable side-effects, far supersede their benefit.

We will continue to monitor outcomes regarding efficacy and adverse effects of these medicines. If, and when we feel them to be safe, we will prescribe them.

Until then, we strongly discourage you participate in any program that advocates them as the new "silver bullet", because they are not. Your health is more important than your weight!

David Connito MD

Medical Director