

# Battle of the Bulge: A Review of Weight Loss Medications and Supplements

Andrea Chase, Pharm.D.  
PGY-1 Pharmacy Resident  
Iowa City Veterans Affairs Health Care System  
December 12, 2017

## Disclosure

- Andrea Chase does not have any actual or potential conflicts of interest to disclose
- No discussion of off-label use of prescription medications, but will discuss a variety of non-prescription agents for weight loss

2

## Presentation Overview

- Introduction
- Discontinued Medications
- Current FDA Approved Medications
- Dietary Supplements
- Herbal Medicine
- Counseling Patients
- Summary

3

## Learning Objectives for Pharmacists

- Understand the varying definitions and metrics of obesity
- Evaluate the most common side effects of weight loss medications
- Summarize contraindications and precautions of each FDA approved medication
- Given a patient case, select the most appropriate initial weight loss medication
- Formulate 3 counseling points for patients interested in herbal supplements for weight loss

4

## Learning Objectives for Pharmacy Technicians

- Recall the 6 FDA approved medications used for weight loss
- Identify which FDA medication is also approved for OTC use
- Learn about the regulatory differences between dietary supplements and medications
- List 2 supplements commonly used for weight loss

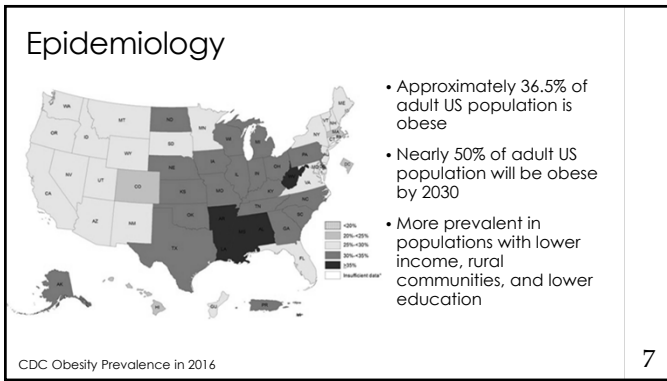
5

## What Is Obesity?

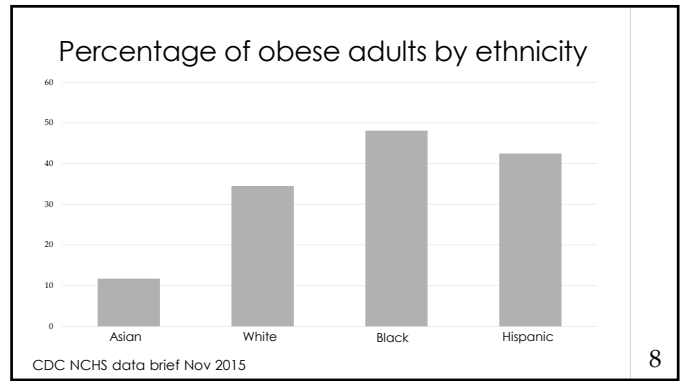
- Excess adipose tissue increases health risks
- Range of biological responses
  - Reduction in energy expenditure
  - Changes in hunger and satiety favoring increased food intake
  - Decreased insulin sensitivity

Am J Clin Nutr. 2006;83:461S-5S.

6



7



8

### Defining Obesity

- Body Mass Index (BMI)
  - Devised in the 1830s by a Belgian astronomer, statistician and sociologist
  - Divide weight (kg) by height squared (m<sup>2</sup>)
- Coined in 1972 in the *Journal of Chronic Diseases*
  - Explicitly cited as appropriate for **population** studies
  - Inappropriate for individual evaluation

*Arch Dis Child.* 2006;91(4):283-286.

9

### BMI

Weight Classification	BMI (kg/m <sup>2</sup> )
Underweight	< 18.5
Normal	18.5 to 25
Overweight	25 to < 30
Obesity (Class 1)	30 to < 35
Obesity (Class 2)	35 to < 40
Obesity (Class 3)	40 or higher

CDC: Defining Adult Overweight and Obesity

10

### Oversimplification of BMI

- In 2013 the American Medical Association classified obesity as a disease with the definition of BMI ≥ 30
- Healthcare work force, insurance companies, and general public started using BMI cut-offs as diagnostic
- Individuals can have weight-associated health problems at BMI < 25, others can have no identifiable health problems at BMI ≥ 30

*Circulation.* 2014;129(3):102-38.

11

### BMI Limitations

- BMI cannot assess **body fat** percentage or regional fat distribution
- Generally accepted cut-offs may not be appropriate for different ethnic populations

*Endocr Pract.* 2016;22(3):1-203.

12

### Other Methods of Measurement

- Waist circumference
- Percentage above ideal body weight
- Body fat percentage
  - Calipers
  - Tape Measurements
  - Bioimpedence
  - Bod Pods
  - DEXA Scan



<http://www.ccsu.edu/bdfac/images/BodPod.png>  
[http://www.bodyandbone.com/wp-content/uploads/2015/11/88\\_dexa-scan.jpg](http://www.bodyandbone.com/wp-content/uploads/2015/11/88_dexa-scan.jpg)

### Contributing Factors to Obesity

- Nutrition
- Physical activity
- Sleep
- Workplace
- Commuting
- Leisure activities
- Community planning
- Genetics
- Secondary causes
- Medication side effects

*Endocr Pract. 2016;22(3):1-203.  
 J Clin Endocrinol Metab. 2015;100(2):342-62.*

### Medications with Weight Gain Side Effects

Class	More Weight Gain Potential	Less Weight Gain Potential
Anti-depressants	mirtazapine, paroxetine, amitriptyline	bupropion, fluoxetine
Anti-hypertensives	beta-blockers	ACEIs, ARBs, CCBs
Anti-psychotics	Second generation	First generation
Contraceptives	Depo Provera	oral contraceptives
Corticosteroids	Long-term use, higher doses, systemic, inhaled	Short-term, lower doses, topical
Hypoglycemics	insulin, sulfonylureas	metformin, GLP-1 analogs, SGLT-2 inhibitors

*Endocr Pract. 2016;22(3):1-203.*

### Health Risks Associated with Obesity

- Cardiovascular disease
- Gallstones
- Gout
- Hyperlipidemia
- Hypertension
- Non-alcoholic fatty liver disease
- Osteoarthritis
- Sleep apnea
- Some forms of cancer
- Type 2 diabetes

*Endocr Pract. 2016;22(3):1-203.  
 J Clin Endocrinol Metab. 2015;100(2):342-62.*

### The Cost of Obesity

- Estimated at \$149.4 - \$215 billion dollars annually
- Health care costs are approximately 42% higher for obese patients compared to normal-weight patients
- CDC estimates 112,000 excess deaths per year associated with obesity
- Individuals with obesity are often excluded from clinical trials, creating paucity of data guiding treatment

WHO Obesity and overweight fact sheet no 311, 2017.  
 TFAH & RWJF, 2016.

### Patient Case

JG is a 32-year-old Hispanic female. She is 62" tall and currently weighs 236 lb, her BMI is 43. She also has pre-diabetes and takes metformin. Latest A1c 6.2%. She works 2 jobs and only gets 5-6 hours of sleep most nights.



She decided a year ago ago to change her eating habits and joined a local gym. After losing 10 lb her weight loss has stalled and hasn't budged for the last 6 months.

She feels "doomed to be fat" because her whole family is overweight. You ask if she has considered pharmacotherapy to assist with her weight loss efforts, and she replies, "Aren't those drugs dangerous?"

### Patient Case Continued

1. Which of the following obesity risk factors apply to JG?

- A. Ethnicity (Hispanic/Latina)
- B. Family history of obesity
- C. Reduced sleep
- D. All of the above

2. What weight classification is JG?  
(Weight 236 lb, BMI 43)

- A. Overweight
- B. Obesity (Class 1)
- C. Obesity (Class 2)
- D. Obesity (Class 3)

19

### Discontinued Weight Loss Agents

Agent	Introduced	Withdrawn	Concerns
Thyroid Extract	Late 1800s	1960s	Increased BP, chest pain, arrhythmia
Dinitrophenol	1930s	1938	Organ failure
Amphetamines	1950	1973	Addictive properties
Phenmetrazine	1956	1965	Addictive properties
Aminorex furarate	1965	1968	Pulmonary hypertension
Fenfluramine	1973	1997	Pulmonary hypertension Valvular heart disease
Phen-Fen	1992		
Dexfenfluramine	1996		
Sibutramine	1997	2010	Increased HR, BP Cardiovascular complications
Phenylpropanolamine	1982	2005	Increased risk of stroke

Dis Model Mech. 2012; 5(5):621-626.  
20

## Current FDA Approved Medications for Obesity

21

### FDA Approved Medications


- Phentermine (Adipex, Lomaira)
- Orlistat (Xenical, Alli)
- Lorcaserin (Belviq)
- Phentermine/topiramate ER (Qsymia)
- Naltrexone/bupropion (Contrave)
- Liraglutide (Saxenda)

Orlistat [package insert] 2016, Lorcaserin/Lorcaserin XR [package insert] 2017, Phentermine/Topiramate ER [package insert] 2014, Naltrexone/Bupropion [package insert] 2014, Liraglutide [package insert] 2017.  
22

### Class Characteristics

- Indication for all anti-obesity medications
  - BMI  $\geq 30$  kg/m<sup>2</sup>
  - BMI  $\geq 27$  kg/m<sup>2</sup> in the presence of other risk factors
- Pharmacotherapy is recommended only as an adjunct to lifestyle modifications
- Contraindication for entire class: pregnancy or lactation

Orlistat [package insert] 2016, Lorcaserin/Lorcaserin XR [package insert] 2017, Phentermine/Topiramate ER [package insert] 2014, Naltrexone/Bupropion [package insert] 2014, Liraglutide [package insert] 2017.  
23



### Phentermine (Adipex, Lomaira)

- Approved in 1959 for short-term use only (12 weeks)
- MOA: indirect sympathomimetic, anorectic
- Dosing: 15 to 37.5 mg once daily
  - Lomaira approved in 2016
  - 8 mg tablet three times daily
- Schedule IV Drug


Phentermine [package insert] 2012.  
24

### Phentermine (Adipex, Lomaira)

Precautions/Warnings	Hypertension, heart failure, abuse potential
Contraindications	History of CV disease, hyperthyroidism, MAOI use (within 14 days), glaucoma
Adverse Effects	Increased HR and BP, restlessness, insomnia, dry mouth, arrhythmic, pulmonary hypertension (extended use)
Drug Interactions	Anti-hypertensives, CNS stimulants

Phentermine [package insert] 2012. 25

### Orlistat (Xenical, Alli)



- Approved in 1999, and as OTC in 2007
- MOA: gastric and pancreatic lipase inhibitor, reduces absorption of ingested fat
- Dosing: 120 mg three times daily with meals
- Available in OTC formulation (Alli)
  - Alli is half the prescription dose (60 mg)

Orlistat [package insert] 2016. 26


### Orlistat (Xenical, Alli)

Precautions/Warnings	Risk of cholelithiasis, severe liver injury with hepatocellular necrosis (rare)
Contraindications	Cholestasis, chronic malabsorption syndrome
Adverse Effects	Abdominal pain, diarrhea, flatulence, loose stools, oily spotting
Drug Interactions	Warfarin, anti-retrovirals, immunosuppressants, anticonvulsants, levothyroxine, fat soluble vitamins

Patients on orlistat should also take a daily multi-vitamin with Vitamins A, D, E, K, and beta-carotene

Orlistat [package insert] 2016. 27

### Lorcaserin (Belviq)



- Approved in 2012
- MOA: selective serotonin 5HT-2C receptor agonist
- Dosing: 10 mg twice daily
- ER formulation (20 mg daily) approved in 2016

Lorcaserin/Lorcaserin XR [package insert] 2017. 28


### Lorcaserin (Belviq)

Precautions/Warnings	CNS depression, diabetes, psychiatric disorders, priapism
Contraindications	Severe hepatic impairment ESRD
Adverse Effects	Headache, hypoglycemia, constipation, bradycardia, serotonin syndrome
Drug Interactions	Serotonergic agents

Lorcaserin/Lorcaserin XR [package insert] 2017. 29

### Phentermine/Topiramate ER (Qsymia)

- Approved in 2012
- MOA: sympathomimetic and anticonvulsant
- Initial Dosing: 3.75 mg / 23 mg once daily for 14 days, then titrate upward
- Guideline recommended dose: 7.5 mg / 46 mg
- Maximum dose: 15 mg / 92 mg
- Schedule IV Drug



Phentermine/Topiramate ER [package insert] 2014. 30

### Phentermine/Topiramate ER (Qsymia)

Precautions/Warnings	Fetal toxicity (REMS program), cognitive impairment
Contraindications	Glaucoma, hyperthyroidism, MAOI use (within 14 days), ESRD
Adverse Effects	Constipation, headache, paresthesia, dizziness, dry mouth, hypokalemia
Drug Interactions	CNS depressants, anti-hypertensives

Phentermine/Topiramate ER [package insert] 2014.

31

### Naltrexone/Bupropion SR (Contrave)

- Approved in 2014
- MOA bupropion: dopamine and norepinephrine reuptake inhibitor
- MOA naltrexone: opioid receptor antagonist
- Dosing: requires titration (8 mg / 90 mg)
  - Week 1: one tab once daily
  - Week 2: one tab twice daily
  - Week 3: two tab AM, one tab PM
  - Week 4: two tabs twice daily



Naltrexone/Bupropion [package insert] 2014.

32

### Naltrexone/Bupropion SR (Contrave)

Precautions/Warnings	US Boxed Warning: Suicidality and Antidepressant Drugs
Contraindications	Opioid use, history of seizures, MAOI use (within 14 days), ESRD, severe hepatic impairment
Adverse Effects	Increased HR and BP, headache, insomnia, nausea, hepatotoxicity
Drug Interactions	Psychotropic medications

Naltrexone/Bupropion [package insert] 2014.

33

### Liraglutide (Saxenda)

- Approved in 2014, updated label 2017
- MOA: glucagon-like peptide 1 (GLP-1) receptor agonist
- Dosing: daily subcutaneous injection, requires titration
  - Initial dosing 0.6 mg daily
  - Increase by 0.6 mg weekly
  - Target dose 3 mg daily



Liraglutide [package insert] 2017.

34

### Liraglutide (Saxenda)

Precautions/Warnings	US Boxed Warning: Risk of thyroid C-cell tumors
Contraindications	Medullary thyroid carcinoma
Adverse Effects	Nausea, constipation, diarrhea, hypoglycemia, cholecystitis, pancreatitis
Drug Interactions	Oral contraceptives Hypoglycemic agents

Liraglutide [package insert] 2017.

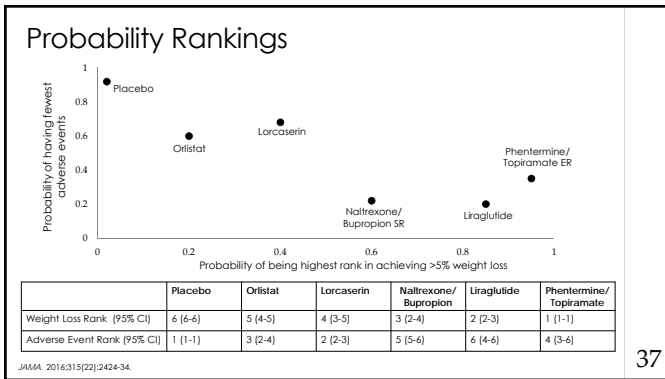
35

### Systematic Review and Meta-Analysis

Drug	Mean weight loss in kg (95% CI)	OR > 5% weight loss (95% CI)	OR of d/c due to Adverse Event (95% CI)
Orlistat (Xenical)	-2.63 (-2.94, -2.32)	2.69 (2.36, 3.07)	1.84 (1.55, 2.18)
Lorcaserin	-3.35 (-3.55, -2.95)	3.09 (2.49, 3.83)	1.40 (0.96, 2.03)
Phentermine/topiramate	-8.80 (-9.62, -7.98)	9.10 (7.68, 10.78)	2.32 (1.86, 3.89)
Naltrexone/bupropion	-4.95 (-5.54, -4.36)	3.90 (2.91, 5.22)	2.60 (2.15, 3.14)
Liraglutide	-5.24 (-5.6, -4.87)	5.09 (4.07, 6.37)	2.82 (2.10, 3.77)

JAMA. 2016;315(22):2424-34.

36



### Summary of Anti-Obesity Medications

- Optimal duration of use has not been established
- Long-term outcomes beyond 2 to 4 years has not been studied
- Medication selection should be based on efficacy, tolerability, and patient's comorbidities
- Use of more than one weight loss medication concurrently has not been studied
- No clinical trials to date evaluating mortality

38

### Endocrine Society Recommendations

- Pharmacotherapy should be considered for obesity management for BMI ≥ 30 (Or BMI ≥ 27 with comorbidity)
- Assess for efficacy monthly for first 3 months, and at least every 3 months thereafter
- Discontinue if patient does not achieve weight loss ≥ 5% at 3 months
- Suggest against off-label use of medications approved for other disease states for sole purpose of weight loss

*Endocr Pract. 2016;22(3):1-203.  
J Clin Endocrinol Metab. 2013;100(2):342-62.* 39

### Patient Case Continued

After describing all the FDA approved anti-obesity medications to JG, she asks "Which drug has demonstrated the greatest weight loss effects?"

- Liraglutide
- Lorcaserin
- Naltrexone/Bupropion SR
- Orlistat
- Phentermine/Topiramate ER

40

Agent	MOA	Year	Intended Duration	Dosing	AWP (30 day supply)
Phentermine (Adipex, Lomaira)	indirect sympathomimetic	1959	12 weeks	Adipex: 15-37.5 mg daily Lomaira: 8 mg 3x/day	\$52
Orlistat (Xenical, Alli)	lipase inhibitor, ↓ absorption of fat	Rx: 1999 OTC: 2007	Chronic use	Rx: 120 mg 3x/day OTC: 60 mg 3x/day	\$703 OTC \$53
Lorcaserin (Belviq)	selective serotonin 5HT-2C receptor agonist	2012	Chronic use	IR: 10 mg 2x/day ER: 20 mg daily	\$239
Phentermine/Topiramate ER (Qsymia)	sympathomimetic with anticonvulsant	2012	Chronic use	Initial: 3.75/23 mg daily Max: 15/92 mg daily	\$318
Naltrexone/Bupropion SR (Contrave)	dopamine & NE reuptake inhibitor with opioid receptor antagonist	2014	Chronic use	Weekly titration over 4 weeks up to 2 tabs 2x/day	\$290
Liraglutide (Saxenda)	glucagon-like peptide 1 receptor agonist	2014, 2017	Chronic use	Daily SubQ inj 0.6 mg → 3 mg	\$1,385

41

### Barriers to Use

- Less than 2% of eligible patients in the US are prescribed anti-obesity medications
- Why are anti-obesity drugs prescribed so infrequently?
  - Safety concerns
  - Lack of guideline recommendations
  - Relatively modest benefits
  - Insurance coverage
  - Cost-effectiveness
  - Perceptions of obesity

*Clev J Med. 2017;84(1):539-546.* 42

# Dietary Supplements

43

## Dietary Supplements

- Approximately 15% of US adults used at least one supplement for weight loss within the last year
- Americans spend almost \$2.1 billion a year on weight-loss supplements in pill form
- May contain up to 90 separate ingredients

Prim Care. 2017;44(2):217-227. 44

## Dietary Supplement Health and Education Act (DSHEA)

- Legislation passed in 1994
- Allows supplements to be marketed without evidence to support efficacy or safety
- Definition of dietary supplement  
 "Product (other than tobacco) intended to supplement the diet that bears one or more ingredients including a vitamin, mineral, herb or other botanical, amino acid... or combination of any of the aforementioned ingredients"

Am J Clin Nutr. 2004;79:529-36. 45


## Lack of Regulation

- Claims must be limited to "general structure function" and may not assert that a product prevents or treats disease
- No system in place for FDA to inspect supplements for purity or quality prior to marketing
- FDA maintains adverse event reporting reported by consumers

Am J Clin Nutr. 2004;79:529-36. 46

## Ephedra (ephedrine)

- Derived from *Ephedra sinica* (Ma Huang)
- Many supplements started adding extracts of ephedra alkaloids in high quantities
- Adverse reactions:
  - Arrhythmia, palpitations, increased heart rate
  - Stroke, MI
  - Sudden death from cardiomyopathy
- Not banned as a supplement until 2004



Phytother Res. 2016;30(5):732-40. 47

## Weight Loss Supplements Recently Removed from Market

• QuickTrim	• A1 Slim	• Slim Fit X
• Xendarine	• Physic Candy	• X-celerated Weight Loss Ultra
• One a Day Weight Smart	• Slimming Plus Advanced	• Dream Body Advanced
• CortiSlim	• Platinum Weight Loss Solution	• Extra Slim Plus
• TrimSpa	• Lean Extreme	• ZlimXter Capsules
• Fastin	• ABX Weight Loss	• Eradicate
• Stimerex-ES	• Ultimate Body Tox	• Jenesis
• Lipodrene	• Skinny Bee Diet	• Lipo Escultura
• Ultimate Lean	• Accelerator Boost	• Perfect Slim

FDA Medication Health Fraud Page 2017. 48



## USP Dietary Supplement Verification

- Voluntary and open to manufacturers worldwide
- Rigorous testing and auditing process confirms standards of quality, purity, potency
- Enforcement of good manufacturing practices (GMP)



*Phytother Res. 2016;30(5):732-40.*

49

### Common Ingredients in Weight-Loss Supplements


Ingredient	Proposed MOA	Evidence of Efficacy	Reported Adverse Effects
Bitter orange ( <i>Citrus aurantium</i> L.)	Increased lipolysis, mild appetite suppressant	Small trials, poor methodologic quality Inconclusive effects	Chest pain, anxiety, headache, increased BP and HR
Caffeine	CNS stimulant	Short term trials Possible modest weight reduction	Generally safe <400 mg/day Nervousness, increased HR
Capsaicin	Increased satiety and lipid oxidation	Several trials, no effect on body weight	GI distress, increased insulin levels, decreased HDL
<i>Garcinia cambogia</i>	Inhibits lipogenesis	Several short-term trials, varying methodology Little to no effect on body weight	Headache, nausea, GI distress, liver damage
Green tea extract	Increased energy expenditure and lipid oxidation	Several trials, good quality Possible modest effects	Constipation, abdominal pain, nausea, liver damage (rare)
Raspberry ketones	Lipid metabolism	Several clinical trials No effect on body weight	Tolerable upper intake 4,000 IU/day Polyuria, increased calcium levels, arrhythmic
White kidney bean	Interferes with carbohydrate absorption	Several clinical trials, varying methodological quality Possible modest effects	Few safety concerns up to 3,000 mg/day for up to 12 weeks Headache, soft stools, flatulence

NIH Dietary Supplements for Weight Loss, Nov 2017.

50

## Chitosan

- Derived from shells of crustaceans
- MOA: binds dietary fats and bile acids
- 4 RCTs conducted to date
- Modest but statistically significant weight loss demonstrated in 3 out of 4 RCTs



*J Obes. 2011. Doi:10.1155/2011/297315.*

51

## Chitosan

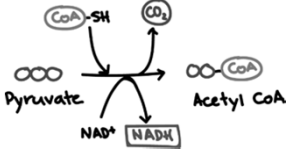
Trial	Avg BMI (kg/m <sup>2</sup> )	Treatment	Length of Treatment	Results
Pittler et al. (1999).	26	Chitosan 1 gram vs. placebo twice daily	28 days	No difference in body weight or BMI
Schiller et al. (2001)	32	Chitosan 1500 mg vs. placebo twice daily	8 weeks	↓ Body Weight 1 kg (P < 0.005) ↓ BMI 0.03 kg/m <sup>2</sup> (P < 0.01)
Ni Mhurchu et al. (2004)	35-36	Chitosan 3 grams daily vs. placebo	24 weeks	↓ Body Weight 0.39 kg (P = 0.03)
Kaats et al. (2006)	Not Reported	Behavior modification + Chitosan 3 grams daily or + placebo	60 days	↓ Body Weight 2.8 lbs (P = 0.03) ↓ Percent Body Fat 0.8% (P = 0.003)

Adverse effects: Flatulence, bloating, constipation, heartburn

*Curr Obes Rep 2016;5:262-70.*

52

## Pyruvate



- Byproduct of glucose metabolism
- MOA: unknown
- 3 RCTs conducted to date
- Modest but statistically significant weight loss demonstrated in 2 out of 3 RCTs

*J Obes. 2011. Doi:10.1155/2011/297315.*

53


## Pyruvate

Trial	Avg BMI (kg/m <sup>2</sup> )	Treatment	Length of Treatment	Results
Stanko et al. (1992)	27.8-52.7	Pyruvate 30 grams/day and calcium pyruvate 16 grams/day or placebo	21 days	Pyruvate vs placebo ↓ Body Weight 0.22 kg vs. 0.17 kg (P < 0.05) ↓ BMI 2.2 kg/m <sup>2</sup> vs. 1.5 kg/m <sup>2</sup> (P < 0.05) ↓ Fat 7.3% vs. 5.4% (P < 0.05)
Kalman et al. (1998)	>25	Pyruvate 6 grams/day; placebo or nothing (control)	6 weeks	↑ LBM 2.4% (P = 0.001) ↓ Fat Mass 12.2% (P < 0.001) ↓ Body Fat 12.4% (P < 0.001)
Kalman et al. (1999)	>25	Pyruvate 6 grams/day vs placebo	6 weeks	↓ Body Weight 1.6% (P < 0.001) ↓ Body Fat 14% (P < 0.001) ↓ Percent Body Fat 11.7% (P < 0.001)

Adverse effects: Diarrhea, gas, bloating

*J Obes. 2011. Doi:10.1155/2011/297315.*

54



### *Irvingia gabonensis*

- Mango-like fruit native to western and centra Africa
- Proposed MOA: down regulation of PPAR-gama
- Proprietary extract IGOB131 formulated as 150 mg daily

J Obes. 2011. Doi:10.1155/2011/297315.

55

### *Irvingia gabonensis*

Trial	Avg BMI (kg/m <sup>2</sup> )	Treatment	Length of Treatment (weeks)	Results
Ngondi et al. (2005)	Not Reported	<i>Irvingia gabonensis</i> 350 mg/day vs. placebo	4	↓ Body Weight 5.6% (P < 0.001) ↓ Hip Circumference 3.42% (P < 0.001)
Ngondi et al. (2009)	26-40	<i>Irvingia gabonensis</i> 150 mg/day vs. placebo	10	12.8 kg vs 0.7 kg placebo (P < 0.01) ↓ Percent Body Fat 6.3% (P < 0.05)

Adverse effects: Headache, insomnia, flatulence, gas

J Diet Suppl. 2013;10(1):29-38.

56

# Herbal Medicine

57

## What is herbal medicine?

- Also known as botanical medicine
- System based on the use of plants or plant extracts that may be ingested or applied topically
- Many different cultural systems
  - Traditional Chinese Medicine
  - Traditional Indian Medicine (Ayurveda)
  - Western herbalism
- In many of these systems the line between food and medicine is blurred

Prim Care. 2017;44(2):217-227.

58

## Forms of herbal medicine

- Extracts
- Tinctures
- Elixers
- Capsules
- Tablets
- Teas
- Pastes/Salves
- Infused Oils



Prim Care. 2017;44(2):217-227.

59

## Who regulates herbal medicine?

- Practice of herbal medicine is not a licensed profession in the US
- Herbs can be prepared and sold as "dietary supplements" in the US by anyone
- Organizations attempting to solidify best practices and promote self-regulation
  - Association of Naturopathic Physicians
  - American Herbalist Guild

Prim Care. 2017;44(2):217-227.

60

## If your patient has decided to use herbal medicine...

- Share reputable resources the patient can read for further education
- Encourage use of brands adhering to good manufacturing practices
- Recommend sharing list of ALL supplements and herbs taken with their providers
- Reinforce that plants and plant parts may contain ACTIVE INGREDIENTS and therefore can have side effects and interactions

61

## Herbal Medicine Resources for Providers

- American Botanical Council (<http://abc.herbalgram.org>)
  - Monographs
  - Adulterant monitoring program
  - Commission E Monographs
- Natural Medicines Database (formerly Natural Standard)
- PubMed "Dietary Supplement Subset" filter

62

## Free Herbal Medicine Resources for Patients

- University of Maryland Medical Center  
<http://www.umm.edu/health/medical/altmed>
- NIH Dietary Supplement Label Database  
<https://dslid.nlm.nih.gov/dslid/index.jsp>
- Examine.com  
Links to evidence and summary tables

63

## Patient Case Continued



JG was prescribed Qsymia (after proper enrollment in REMS) for one year and had good results. She stopped taking the medication when her insurance changed and no longer covered it. She soon regained the weight, developed depression, and started taking sertraline 150 mg daily.

In clinic today her mood is stable and latest A1c is 6.3%. She would like to restart a weight loss medication to assist her renewed lifestyle modification efforts.

Is Qsymia still a good option?

If not what would you recommend next?

64

## Patient Case Continued

JG is now 34 years old, she stopped taking the medication previously prescribed due to unpleasant side effects.

While dutifully performing medication reconciliation, she mentions recently starting an herbal tea her Aunt suggested that is "an old family recipe."

What would be the best counseling advice for her?

- Discontinue using herbal tea immediately.
- Great idea! See if her aunt can also provide something for her pre-diabetes.
- Encourage her to find out the ingredients of the tea. Offer to help her look up more information if she can provide names of the plants used.
- Say nothing since tea has no drug or disease interactions.

65

## Summary

- BMI is a screening tool that should be utilized in context of other factors
- Six current FDA approved weight loss medications in use
- Multiple barriers to use
- Select dietary supplements and herbs have growing clinical evidence
- Dietary supplements and herbs are not regulated

66

## References

- Apovian CM, Aronne LJ, Bessesen DH, et al. Pharmacological Management of Obesity: An Endocrine Society clinical practical guideline. *J Clin Endocrinol Metab.* 2015;100(2):342-362.
- Arena Pharmaceuticals GmbH. Belviq/Belviq XR [package insert]. Zoltingen, Switzerland: 2017, November.
- Burguera B, Ali KF, Brito JP. Antiobesity drugs in the management of T2DM: a shift in thinking? *Clev J Med.* 2017;84(1):339-346.
- Centers for Disease Control and Prevention. Prevalence of overweight, obesity, and extreme obesity among adults: obesity prevalence maps. (<http://www.cdc.gov/obesity/data/prevalence-maps.html>). Accessed October 10, 2017.
- Dombrowski SJ, Knittle K, Avenell A, et al. Long term maintenance of weight loss with non-surgical interventions in obese adults: systematic review and meta-analyses of randomized controlled trials. *BMJ.* 2014;348:g2646-58.
- Egus AM, Hamilton WR, Lenz TL. An evidence based review of fat modifying supplemental weight loss products. *J Obes.* 2011. Doi:10.1155/2011/297315. Epub 2010 Aug 10.
- Faizon CC, Balabanova A. Phytotherapy: An Introduction to Herbal Medicine. *Prim Care.* 2017;44(2):217-227.
- Garvey WT, Mchanick JI, Brett EM, et al. American Association of Clinical Endocrinologists and American College of Endocrinology comprehensive practice guidelines for medical care of patients with obesity. *Endocr Pract.* 2016;22 Suppl 3:1-203.

67

## References

- Genentech USA, Inc. Xenical [package insert]. South San Francisco, CA: 2016, August.
- Greenberg AS, Obin MS. Obesity and the role of adipose tissue in inflammation and metabolism. *Am J Clin Nutr.* 2006;83:461S-5S.
- Hainer V. Overview of new antiobesity drugs. *Expert Opin Pharmacother.* 2014;15(14):1975-78.
- Hall DMB, Cole TJ. What use is the BMI? *Arch Dis Child.* 2006;91(4):283-286.
- Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American college of cardiology/ American Heart Association task force on practice guidelines and The Obesity Society. *Circulation.* 2014;129(25 Suppl 2):S102-38.
- Kang JG, Park CY. Anti-Obesity Drugs: A review about their effects and safety. *Diabetes Metab J.* 2012; 36(1):13-25.
- Khera R, Murad MH, Chandar AK, et al. Association of pharmacological treatments for obesity with weight loss and adverse events: A systematic review and meta-analysis. *JAMA.* 2016; 315(22):2424-2434.
- Novo Nordisk Inc. Saxenda [package insert]. Plainsboro, NJ: 2017, April.
- Orexigen Therapeutics, Inc. Contrave [package insert]. La Jolla, CA:2017, May.
- Ogden CL, Carroll MD, Kit BK, and Flegal KM. Prevalence of obesity among adults: United States, 2011-2012. *NCHS Data Brief.* 2013;131:1-8.

68

## References

- Pfitter MH, Ernst E. Dietary supplements for body-weight reduction: a systematic review. *Am J Clin Nutr.* 2004;79:529-36.
- Rodgers RJ, Tschop MH, Wilding JPH. Anti-obesity drugs: past, present, and future. *Dis Model Mech.* 2012; 5(5):621-626.
- Smith SM, Meyer M, and Trinkley KE. Phentermine/topiramate for the treatment of obesity. *Ann Pharmacother.* 2013;47(3):340-49.
- Sloths SJ, Bodmaev V. A review of natural stimulant and non-stimulant thermogenic agents. *Phytother Res.* 2016;30(5):732-40.
- Tainted Products Marketed as Dietary Supplements. US Food and Drug Administration Medication Health Fraud Page. ([https://www.accessdata.fda.gov/scripts/sda/ sdNavigation.cfm?sd=tainted\\_supplements\\_cder](https://www.accessdata.fda.gov/scripts/sda/ sdNavigation.cfm?sd=tainted_supplements_cder)). Accessed 20 November 2017.
- Trust for America's Health and the Robert Wood Johnson Foundation. Updated 31 August 2017. Adult obesity in the United States. (<https://stateofobesity.org/adult-obesity/>). Accessed 20 November 2017.
- Vivus, Inc. Qsymia [package insert]. Mountain View, CA: 2014, October.
- World Health Organization. Obesity and overweight fact sheet no 311. (<http://www.who.int/mediacentre/factsheets/fs311/en/>). Accessed September 27, 2017.

69

## Questions?

Andrea Chase, Pharm.D.  
PGY-1 Pharmacy Resident  
Iowa City Veterans Affairs Health Care System  
December 12, 2017