

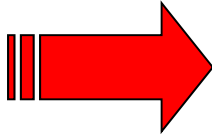
What is the global nutrition transition?

- In the same countries, one finds malnutrition and obesity. The appearance of obesity in these locales has been called the “Nutrition Transition”
- What underlies this transition are changes in diet resulting from the introduction of Western foods in place of traditional plant-based diets.

Plant-Based Diets



Subsistence Agriculture
Food Scarcity
Malnutrition



Western Diet Pattern



Industrial Agriculture
Government Subsidies
Increased Availability
Poor Food Quality
Obesity and Chronic Diseases

What are the differences ?



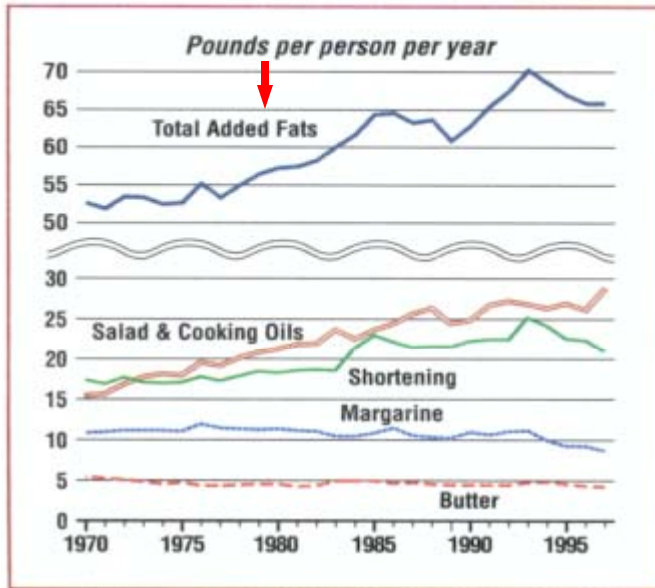
VS.



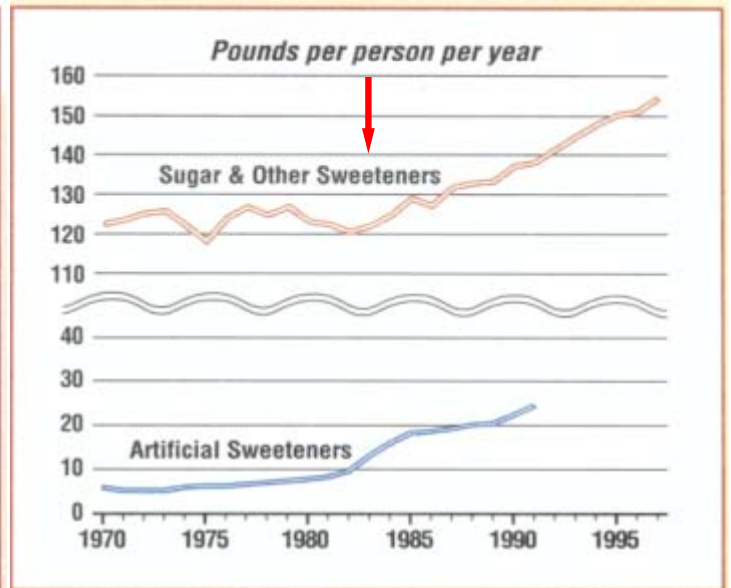
1. 10% Fat
2. Omega-6/omega-3 ratio 3:1
3. Good Fructose with Antioxidants
Fiber, Water, Few Calories
4. Plant Proteins with lower calories
can be prepared with little fat.
5. Rich in Vitamins, Minerals,
and Micronutrients

1. 35 to 50% Fat Calories
2. Omega-6/omega-3 ratio 10-30:1
3. Bad Fructose as HFCS with High
Calories, Low Fiber, Low Antioxidants
4. Animal Protein with Saturated Fat
and Increased Calories
5. Poor in Vitamins, Minerals and
Micronutrients

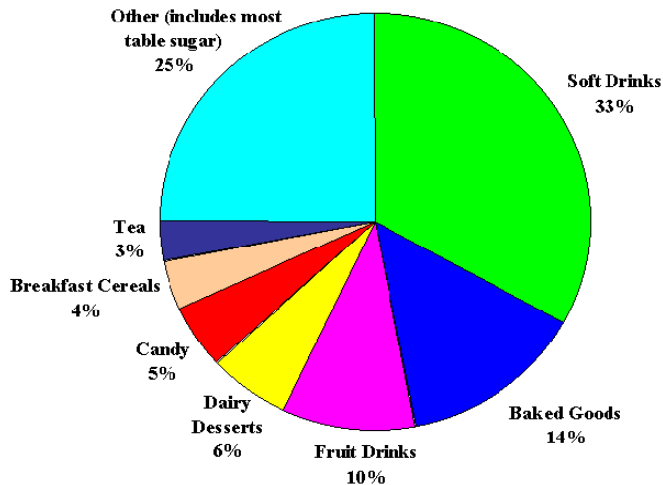
Fat Increases after 1980



Sweetener Increases after 1985

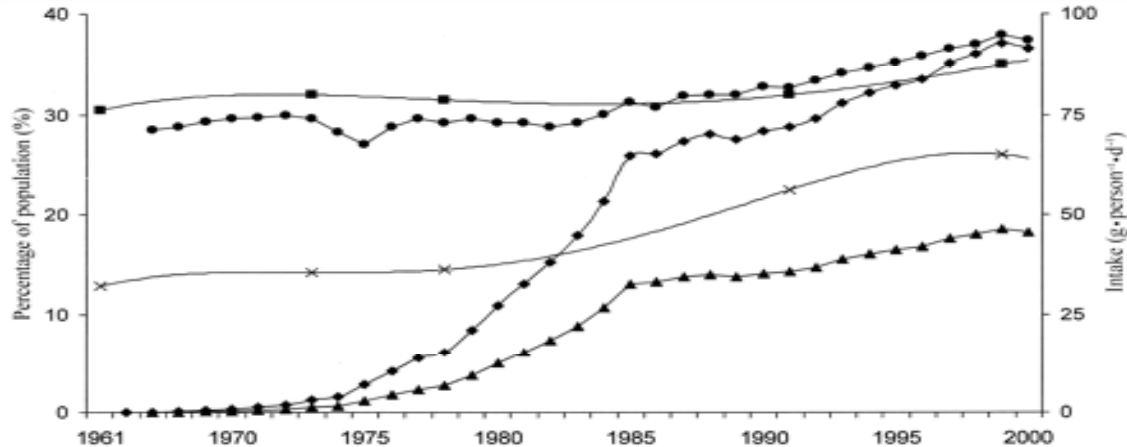


High Fructose Corn Syrup (HFCS)



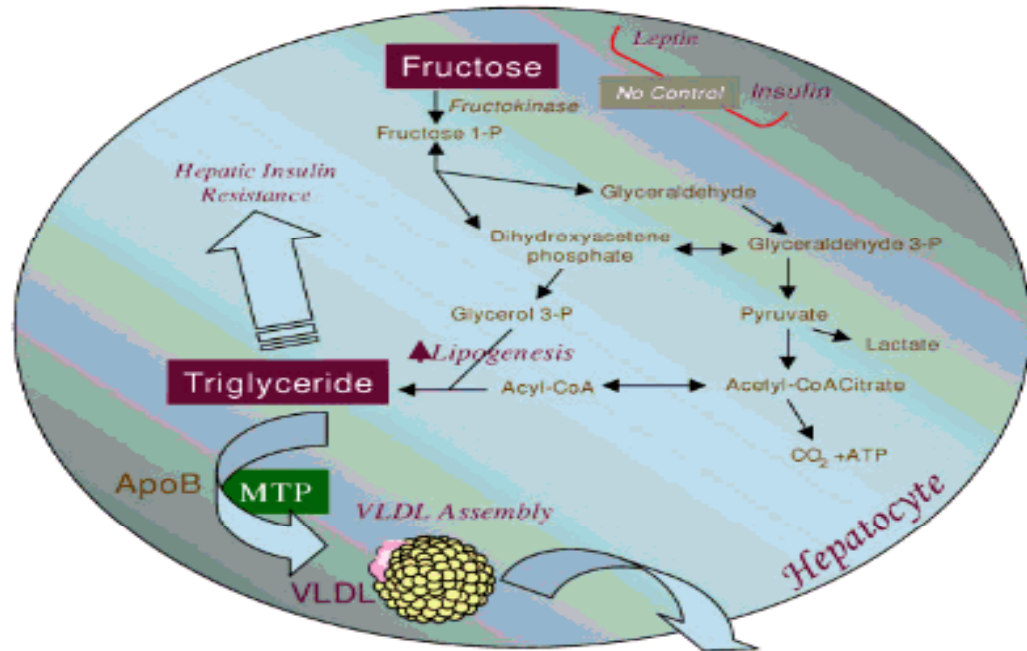
HFCS was rapidly introduced to many processed foods and soft drinks in the U.S. from about 1975 to 1985. High-fructose corn syrup is produced by milling corn to produce corn starch, then processing that starch to yield corn syrup, which is almost entirely glucose, and then adding enzymes that change most of the glucose into fructose. The resulting syrup (after enzyme conversion) contains approximately 90% fructose and is HFCS 90. To make the other common forms of HFCS (HFCS 55 and HFCS 42) the HFCS 90 is mixed with 100% glucose corn syrup in the appropriate ratios to form the desired HFCS.

Consumption of high-fructose corn syrup in beverages may play a role in the epidemic of obesity

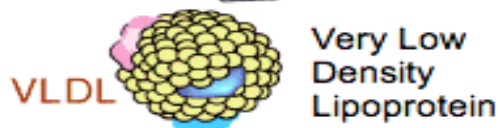


Estimated intakes of total fructose (•), free fructose (▲), and high-fructose corn syrup (HFCS, ◆) in relation to trends in the prevalence of overweight (■) and obesity (x) in the United States

Source: George A Bray, Samara Joy Nielsen and Barry M. Popkin, *American Journal of Clinical Nutrition*, Vol. 79, No. 4, 537-543, April 2004.



Fructose in the Liver



Good Fructose vs. Bad Fructose

Good Fructose

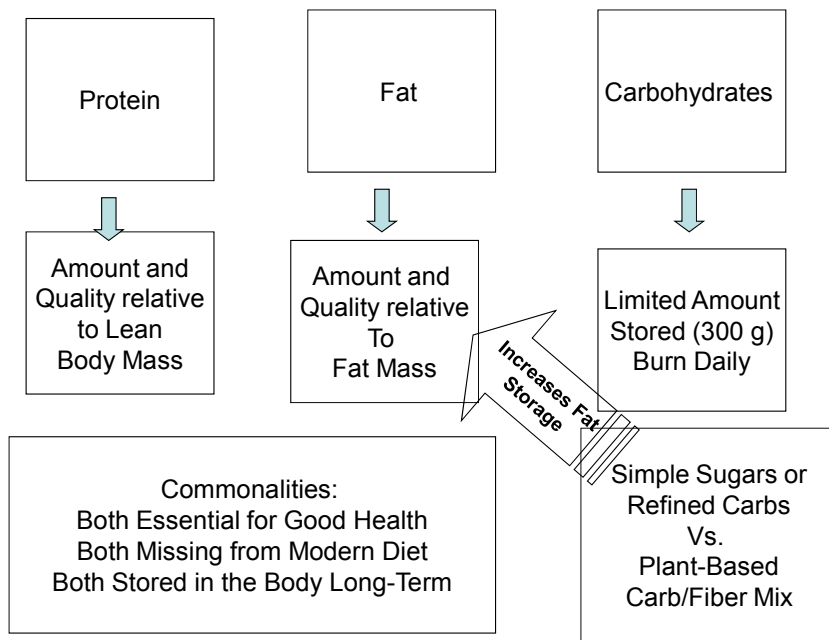
- Fruits**
- Vegetables**
- Whole Grains**

****Antioxidants and Fiber,
Nutrient Dense
and Lower Calories**

Bad Fructose

- Soft Drinks
 - Snack Foods*
 - Candy*
 - Pastries, Cakes*
- *With hidden fats

Nutrition 101

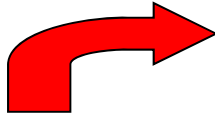


Healthy Active Lifestyle Lessens the Impact of Poor Diet

What are the results?

- Worldwide epidemic of obesity and overweight.
- Increases in type 2 diabetes.
- Association with multiple inflammatory diseases such as asthma, arthritis, heart disease, and common forms of cancer.
- Increased health care costs due to overutilization of services.

BODY MASS INDEX (W/H^2) UNCOVERS THE USA EPIDEMIC OF OBESITY



... AND,
THE USA EPIDEMIC IS
SPREADING
INTERNATIONALLY
WITH RURAL TO URBAN
MIGRATION

AMERICA EXPORTS OBESITY TO THE WORLD !!!

Definition of obesity

- § **Obesity is defined as excess body fat (not simply excess weight.)**



BMI is an Index of Obesity

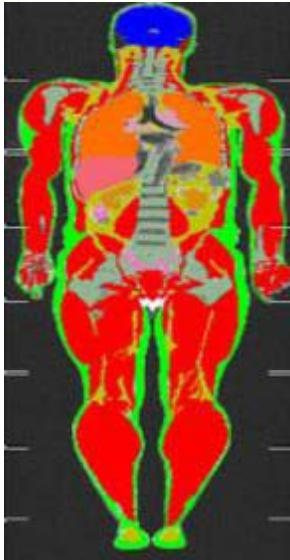


Height
Weight
BMI

6'0"
225 lbs
31 kg/m²

5'4"
180 lbs
31 kg/m²

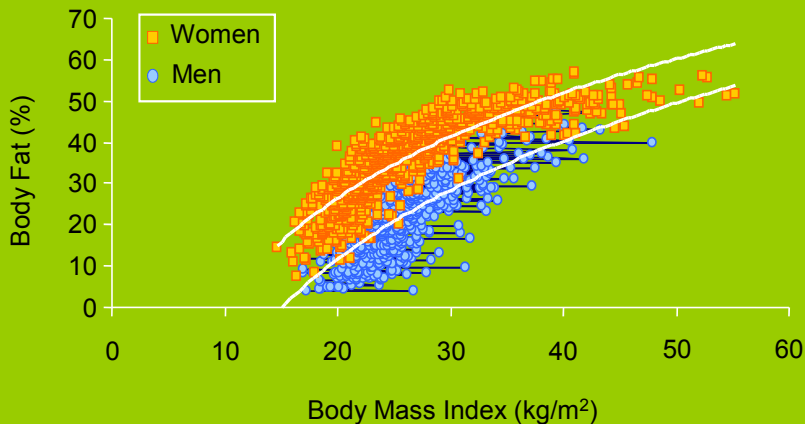
Even if you are thin you can be fat



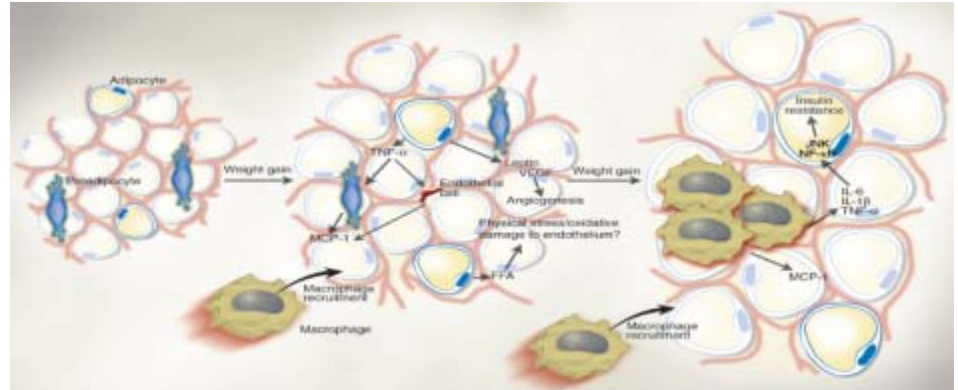
MRI reveals fat around the Heart, Liver and Intestine in Individuals with Normal Waist Circumference

Of the women scanned by Bell and his colleagues, as many as 45 percent of those with normal BMI scores (20 to 25) actually had excessive levels of internal fat. Among men, the percentage was nearly 60 percent.

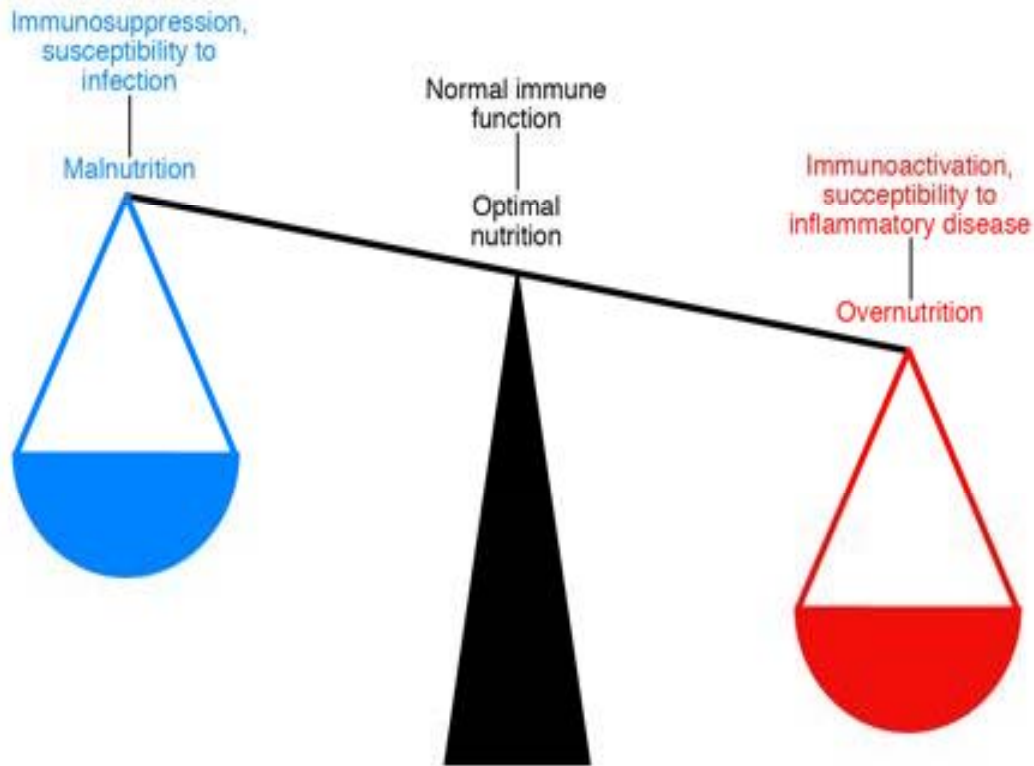
Relationship Between BMI and Percent Body Fat in Men and Women

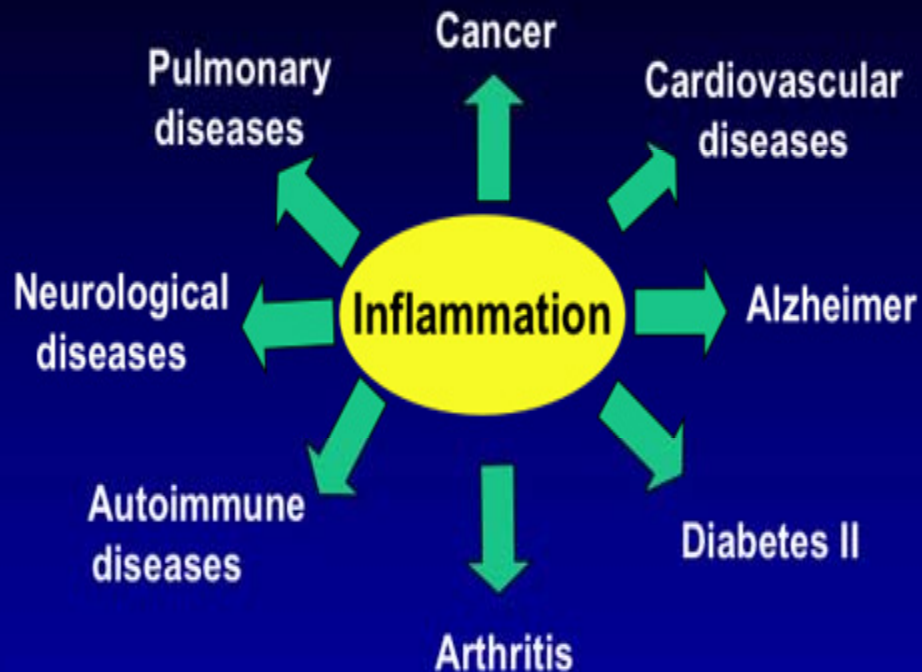


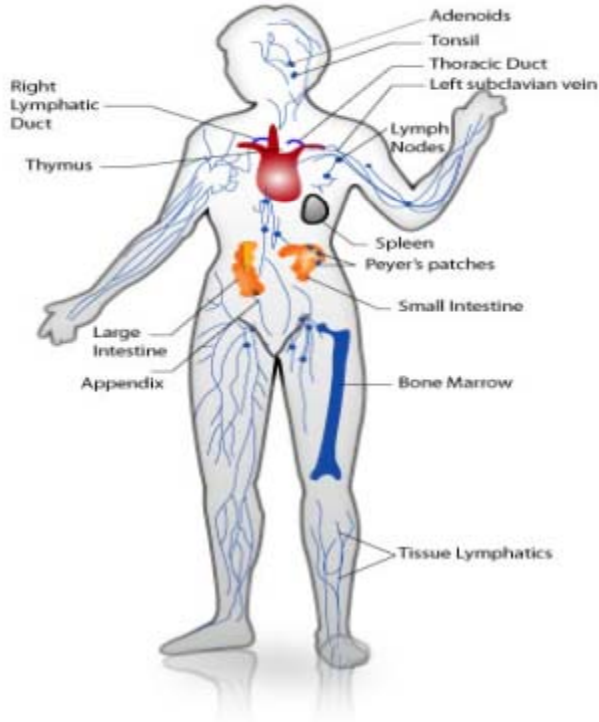
Intra-Abdominal fat



Macrophage and the Innate Immune System
Pro-Inflammatory Cells Ingress Mediates the
Inflammatory State of Adipose Tissue

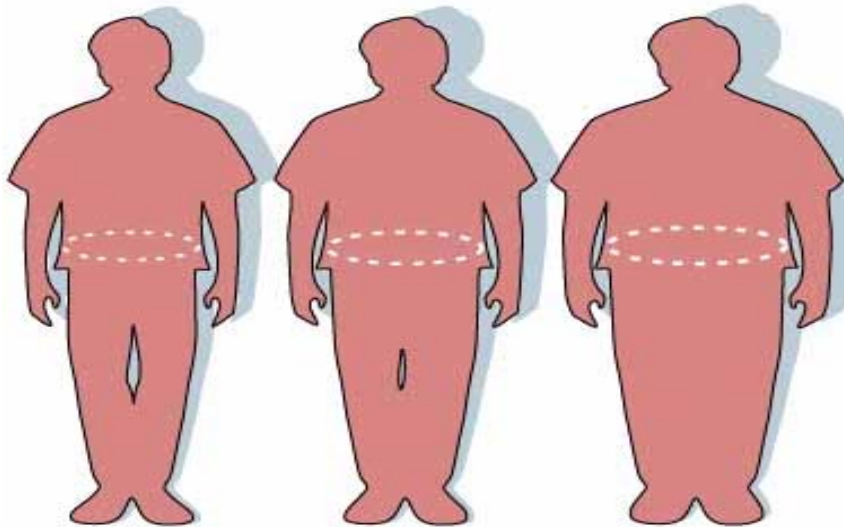






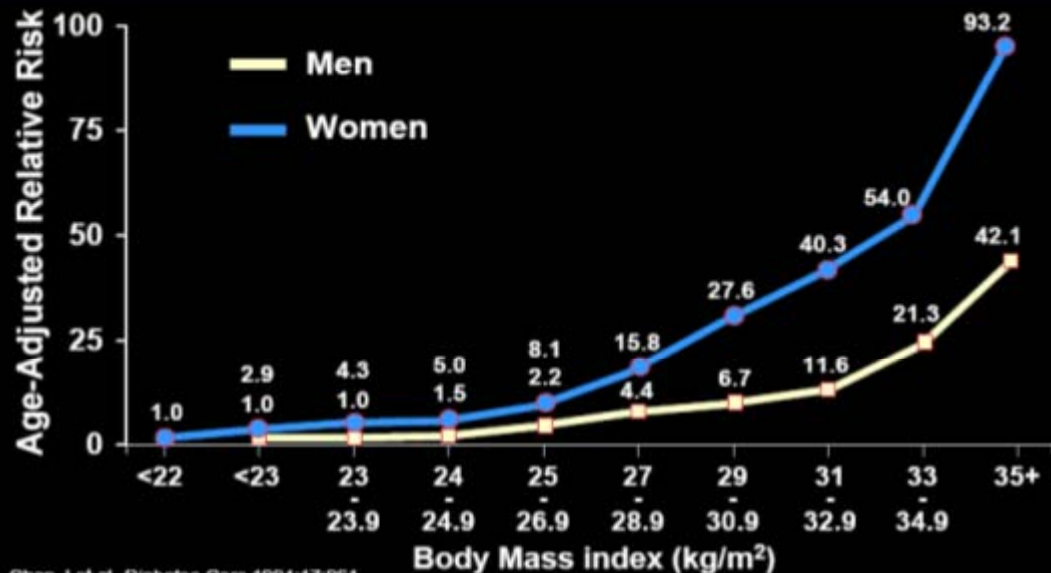
The Immune System comprises

1. Tonsils and Adenoids
2. Lymph Nodes
3. Spleen
4. Peyer's Patches
5. Appendix
6. Bone Marrow
7. Tissue Lymphatics

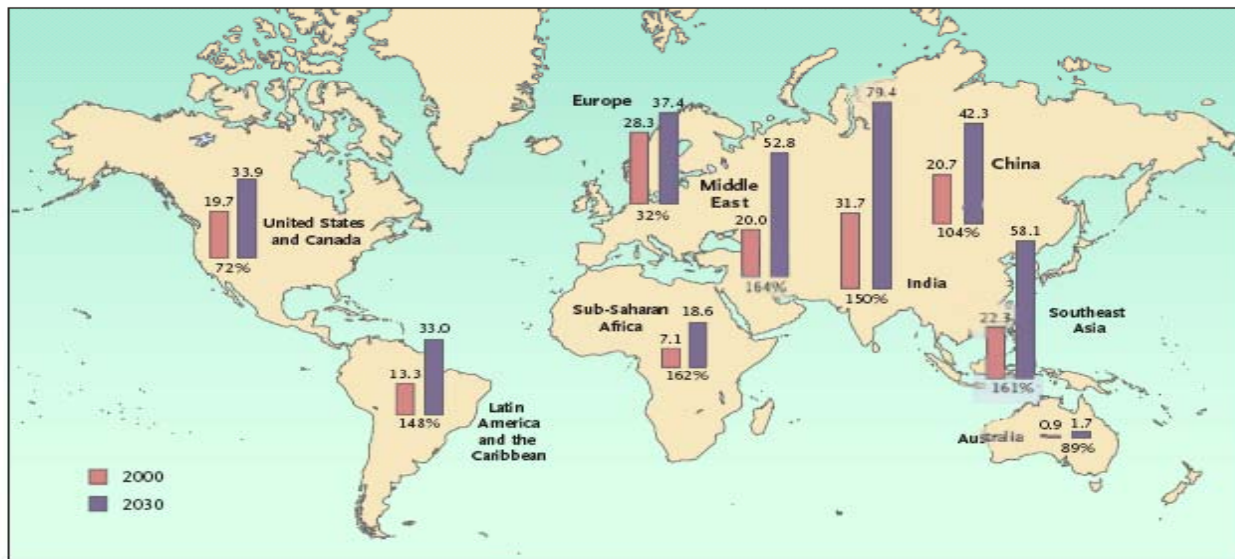


**FOCUS ON ABDOMINAL OBESITY ESPECIALLY
IN ASIANS AND IN LEAN AND OVERWEIGHT NON-OBESE**

Relationship Between BMI and Risk of Type 2 Diabetes



Millions of cases of diabetes around the world In 2000 with projections for 2030 and % increase



Millions of Cases of Diabetes in 2000 and Projections for 2030, with Projected Percent Changes.

Phytochemicals, Phytonutrients

Polyphenols

Glucosinolates

Phenolics (e.g. ferulic acid, caffeic acid)

Ellagic acid/ellagitannins

Isoflavones
(genistein, daidzein)

Flavonoids

Flavonols (e.g. quercetin)

Flavanones
e.g. hesperidin

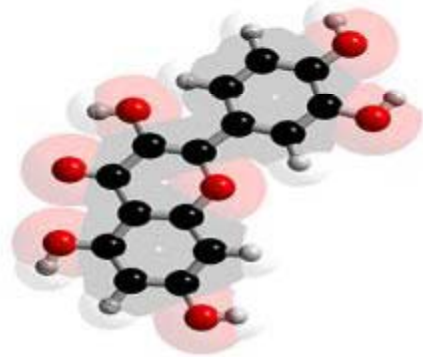
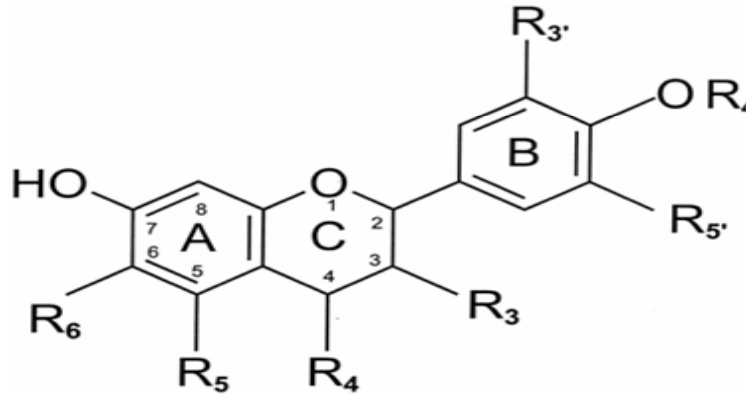
Flavanols

Anthocyanins

Catechins

Pro(antho)cyanidins

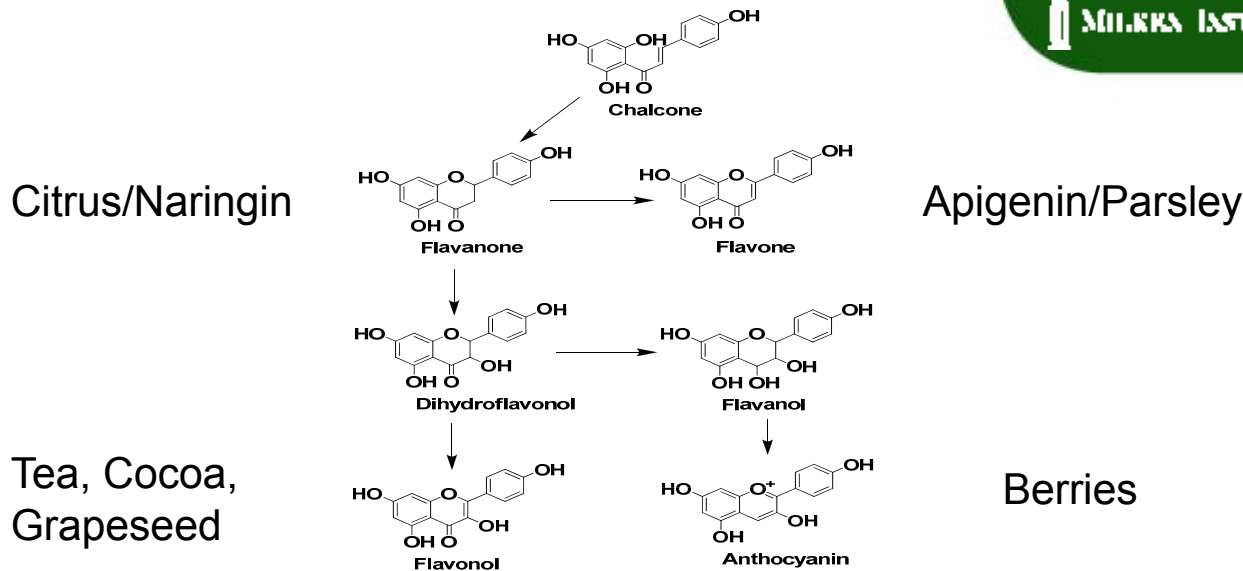




ABOVE FIGURE IS A FLAVONE

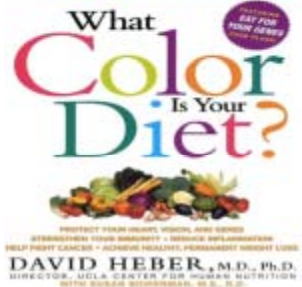
IF R₄ is a Ketone group then this is a Flavonoid

IF R₃, R₄, and double bond C₁-C₂ = anthocyanin



Relationships Among Flavonoid Structures
Analogous Structures in Different Species

THIS IS AN EXTENSIVE BOOK... HIGHLY RECOMMENDED!
—DEAN GORDON, M.D.
LOSE WEIGHT—LOOK GREAT
EAT THE 7 COLORS OF HEALTH!



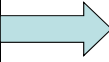
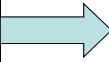



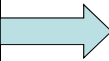
Color Code for Fruits and Vegetables

- **Red** - Tomato products, soups, sauces, juices
- **Red/Purple** - Red Wine, Grapes, Berries, Plums
- **Orange** - Carrots, Mango, Apricot, Sweet Potato
- **Orange/Yellow** - Citrus Fruits, Papaya, Peaches
- **Yellow/Green** - Spinach, Corn, Avocado, Green Beans
- **Green** - Broccoli, Brussels Sprouts, Cabbage
- **White/Green** - Garlic, Onions, Chives, Asparagus

THE COLOR WHEEL OF FOODS



Total Nutrition Solution

Balance Energy Intake and Expenditure to Reduce Abdominal Fat		Protein-Rich Shakes, Healthy Meals and Snacks and Activity/Exercise
Increase ω -3 Fatty Acids Decrease ω -6 Fatty Acids		Ocean Fish and Fish Oils Eat Less Hidden Fat
Increase Good Fructose and Limit Refined Sugars		Limit Soft Drinks, Cakes, Pastries, Cookies, Candy
Increase Antioxidants and Phytochemicals		7 Servings Per Day of Colorful Fruits &Vegetables
Increase Fiber Intake for Digestive Health		25 grams of fiber Soluble and Insoluble
Multivitamin/Multimineral Calcium and Vitamin D Targeted Supplements		Personalized Nutrition

What is the Solution?

The Mission for Nutrition

- International efforts at lifestyle change through the provision of healthy nutritional products and education in healthy active lifestyles.
- Grassroots efforts at the community level.
- Medical and Healthcare Industry understanding of the issues involved to enable leadership in prevention efforts.

The Pathway to scientific credibility

- Identify the structures of multiple constituents in supplements and explore their mechanisms of action in well-defined biological systems.
- Standardize and optimize contents and use GMP and ongoing quality assurance methods.
- Conduct pre-clinical studies (cell culture and animals) to establish science basis.
- Conduct phase I /II clinical studies.
- Assess the bioavailability/bioactivity of supplements including drug interactions.

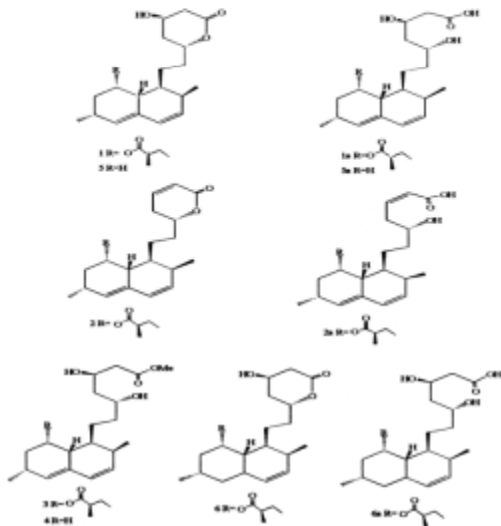
Background on Chinese red yeast rice dietary supplement

- Traditional Chinese Food Spice Shown to Lower Cholesterol in Human



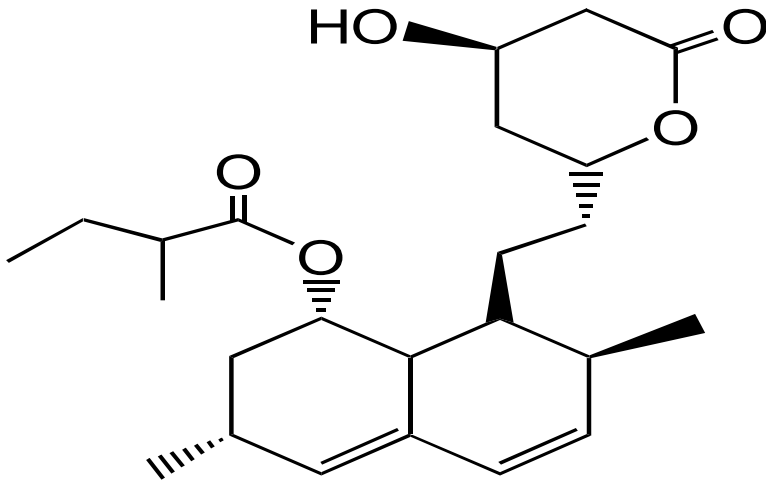
- First U.S. Trial published in AJCN 2/99 by Heber et al.
- RYR is a mixture of Monacolins one of which is identical in structure to Mevinolin

NMR Structure of Monacolins



- Compound 2 is an analog of 1
- Compound 3 is the methyl ester of ring-opened monacolin K
- Compound 4 is an analog of dihydromonacolin K
- Compound 6 is the methyl ester of the lactone ring-opened monacolin L

Monacolin K is Identical to Mevacor (Lovastatin)
Derived from another Species (Aspergillus fungus)

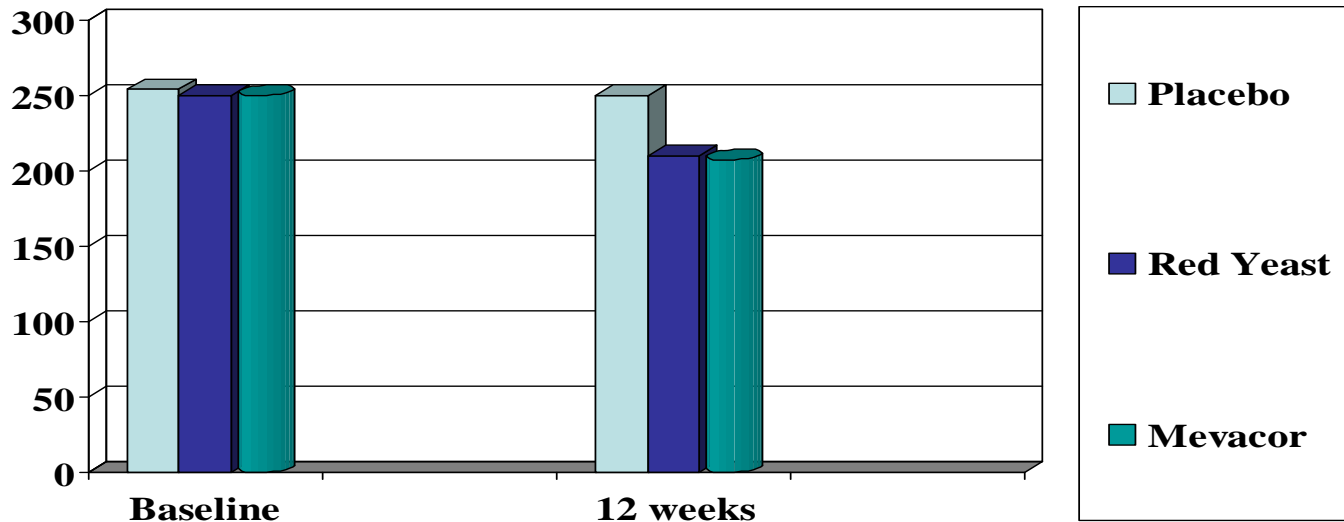


Results of Clinical Trial

	Chol	Trig	HDL	Chol
Baseline				
Control	254 + 29	143 + 46	46 + 10	
Red Yeast		250 + 30	133 + 48	50 + 13
Week 12				
Control	250 + 36	146 + 47	46 + 11	
Red Yeast		210 + 31*	124 + 44*	50 + 14

* $p < 0.05$ vs. baseline Heber et al. AJCN Feb. 1999

Effects of red yeast rice and Mevacor on total cholesterol



Results of AFCAPS Trial

- 5608 men and 997 women with moderate hypercholesterolemia in Texas (Cholesterol of 221 ± 21 mg/dL, LDL 150 ± 17 mg/dL Triglycerides 158 ± 76 mg/dL) given 20 or 40 mg of Mevacor or placebo.
- After follow-up of 5.2 years, 63% RR the incidence of first acute major coronary events (183 vs 116), 60% RR of myocardial infarction (95 vs 57), 67% RR of revascularization procedures (157 vs 106). Lovastatin (20-40 mg daily) reduced LDL-C by 25% on average.

Significance

- Over 30 million Americans have hypercholesterolemia but only 4 million take prescription cholesterol-lowering drugs.
- Affordability of botanical diet supplements promises to provide a major public health benefit, since prevention trials have shown benefits of statins in hypercholesterolemia.

Statins and cancer

- An analysis of the use of HMGCoA reductase inhibitors (statins) in a cohort of 6721 Canadian patients who developed cancer (n = 542) using a nested case control design demonstrated a 28% decreased risk of cancer (RR 0.72, 95%CI 0.57-0.92) associated with statin use by comparison to bile-acid binding resin use. (*L. Blais et al, Arch Int Med 2000, 160:2362-68*)
- In lipid-depleted media, statins kill cancer cells by inhibiting normal oncogene function.

Why red yeast?

- Statins inhibit the farnesylation of oncogenes, and synthesis of dolichol required for oncogene and IGF-1 receptor anchoring in the cell membrane.
- The development of drugs for the purpose of inhibiting this pathway is limited by toxicity considerations and so the safety of RYR at high doses makes it an excellent candidate for the development of herbal anti-cancer drug approaches.
- Other phytochemicals in the RYR may interact synergistically to inhibit tumor growth.

Regulations overview

Regulations are implicated in the following areas:

- Product Development
 - Label Claims
- Manufacturing
 - Good Manufacturing Practices (GMPs)
 - Site Licenses
- Adverse Events Reporting

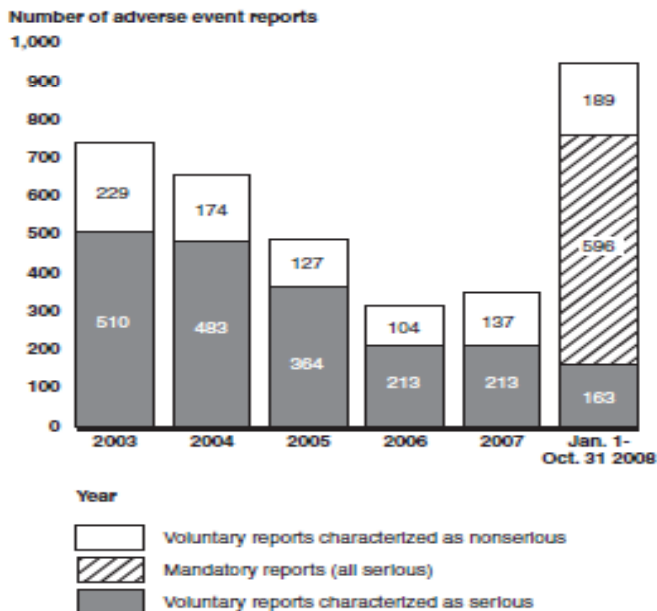
Product development/claims

- The development of claims must balance:
 - Effective marketing
 - Regulatory risk
- The level of risk is dependent on both the claim and the sales channel
- In general, DTC (direct mail) and HCP are considered low-risk channels; HFS is medium-risk; and internet/TV is highest risk
- Successful direct mail requires the highest level of claim; HFS and HCP require a medium-risk claim; while internet claims must be maintained at a low risk level
- There are also different requirements depending on the country

Adverse events reporting

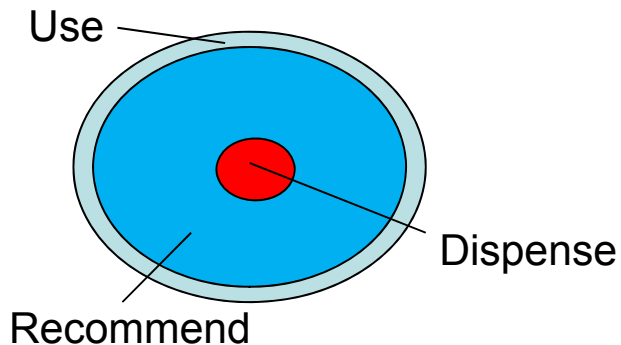
- **The reporting of serious adverse events is mandatory**
 - “Serious Adverse Event” is defined by FDA as an event that results in death; a life-threatening experience, inpatient hospitalization (regardless of duration); a persistent or significant disability or incapacity; a congenital anomaly or birth defect; or an event that requires medical intervention or surgery in order to avoid the aforementioned outcomes
- **Industry data** (2008, see Appendix)
 - 1080 total AEs reported, 672 serious, 11 deaths
 - In comparison for the same year, ~300,000 serious events associated with pharmaceuticals; 50,000 deaths

Appendix: DS industry-wide adverse event reports (2008)



Source: GAO analysis of FDA data.

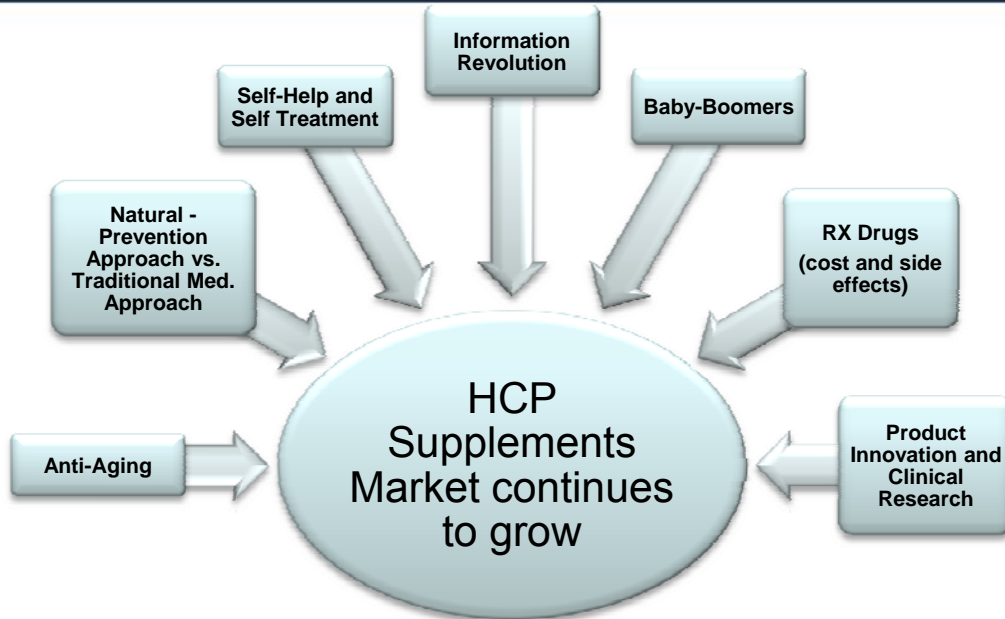
Defining the HCP channel



- ~80% of U.S. doctors and nurses use dietary supplements
- Similar % recommend use to patients
 - Difficult to quantify sales
- HCP channel- dispensing

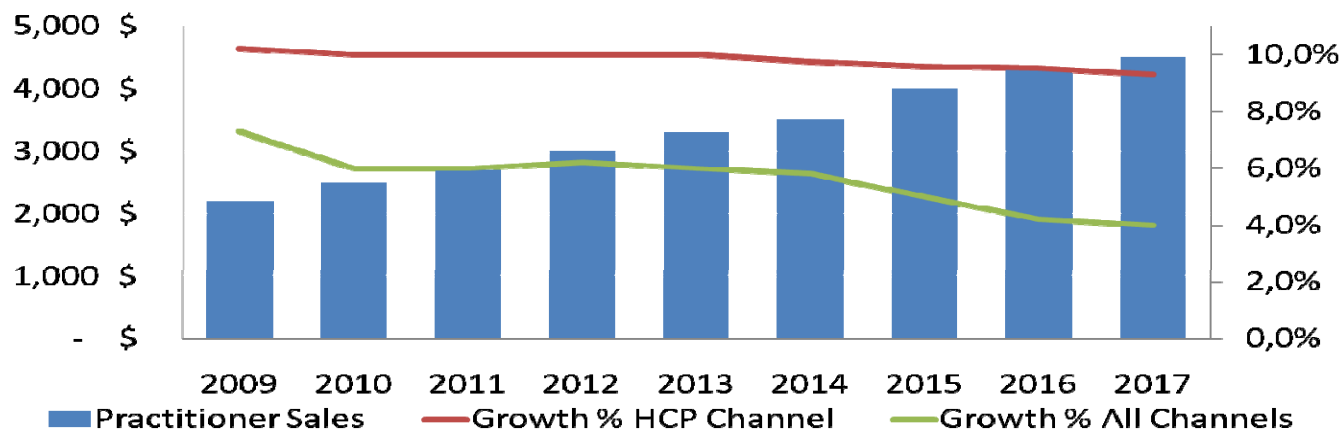


Drivers promoting HCP channel growth



HCP channel forecast

**U.S. HCP Sales Forecast (MM USD)
and Growth vs. Other Channels**



Research in Metabolic Syndrome

- Encompasses weight, inflammation, oxidative stress, etc.
- Provides biomarkers of effect that can be effectively modulated by nutritional interventions
- Regulatory pressure to study non-disease populations
- Emerging international policy
 - Healthy subjects
 - Cannot address disease outcome; instead must address:
 - Management of symptoms
 - Interventions to decrease risk (example, lower markers of inflammation known to be associated with cardiovascular disease)

Supplement sales by specialty

Type of medical professional	Total number of professionals	% selling products	# selling products
Chiropractor	79,000	72%	57 528
Chinese Medicine	33,950	78%	26 481
Naturopath	27,379	87%	23 819
MD/Nurse	717,590	4%	28 704
Acupuncturist	35,710	78%	27 854
Homeopath	9,280	91%	8 445
Ayurvedic Practitioner	1,500	91%	1 350
Osteopathic Physician	57,347	15%	8 620
Massage therapist	298,330	7%	20 883
Total	~1.3 million	17%	~200,000

Source: Internal source and NBJ 2009.

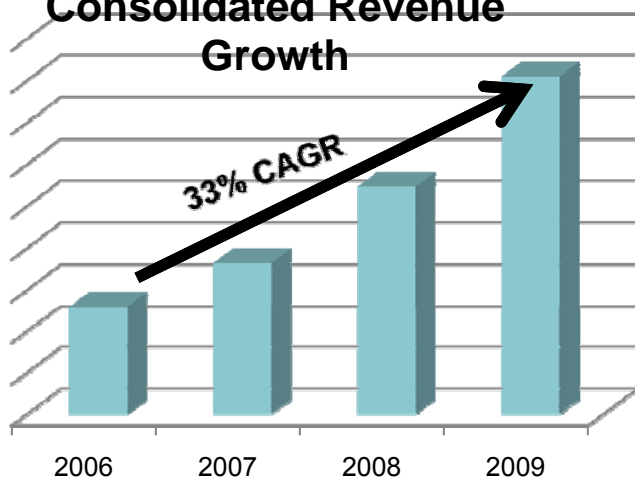
Yoga in America Study

- 2008 Study conducted by Harris Interactive Service Bureau
- About 15.8 million Americans (6.9%) characterize themselves as current yoga practitioners
- About 9.4 million non-practitioners say they will **definitely try** yoga in the next 12 months
- 18.3 million non-practitioners are **very or extremely interested** in yoga
- 98% of Americans are aware of the benefits of yoga. Awareness is strong and the perception is positive.
- Yoga Spending **nearly doubled** since 2004

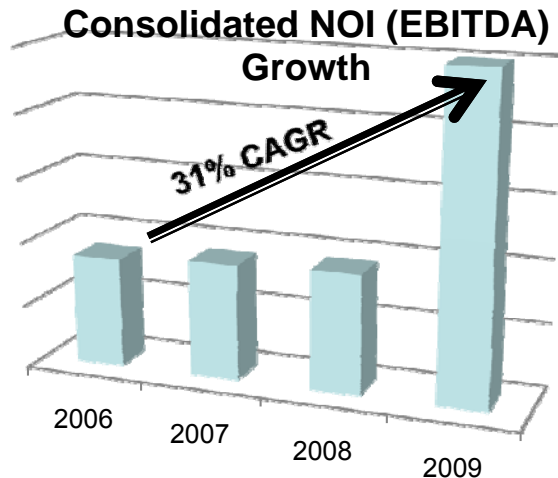


2009 Financial Highlights

**Consolidated Revenue
Growth**



**Consolidated NOI (EBITDA)
Growth**

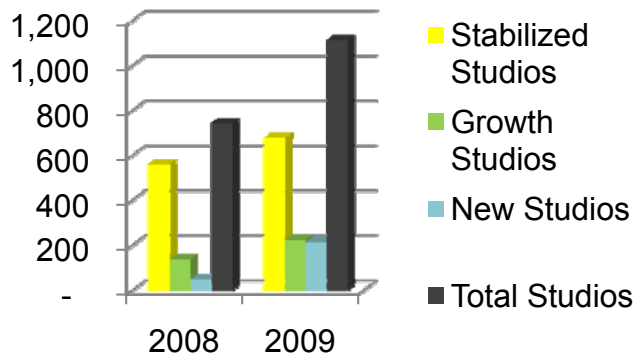


Total Company: Yoga and Attendance

Over 1 million class visits

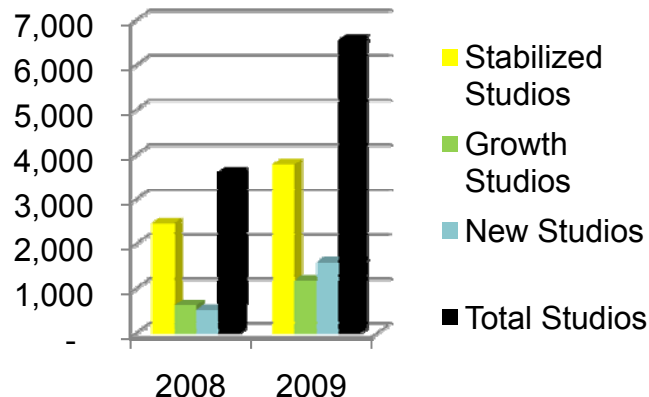
Number of Yoga Class Visits

(in 000's)



Over six thousand members

Number of Members at Year-end



Total Company: Programming Revenue by Product

Significant Increase in Programming Revenue over 2008

