



Natural Health Research Institute: Scientific Symposium

The Effectiveness of Natural Products for Women's Health



8th Annual **NHRI**
Scientific Symposium

Presented by:

UIC COLLEGE OF
PHARMACY



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Managing Obesity with Natural Dietary Supplements: Lessons Learned from Clinical Research Studies



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OBESITY

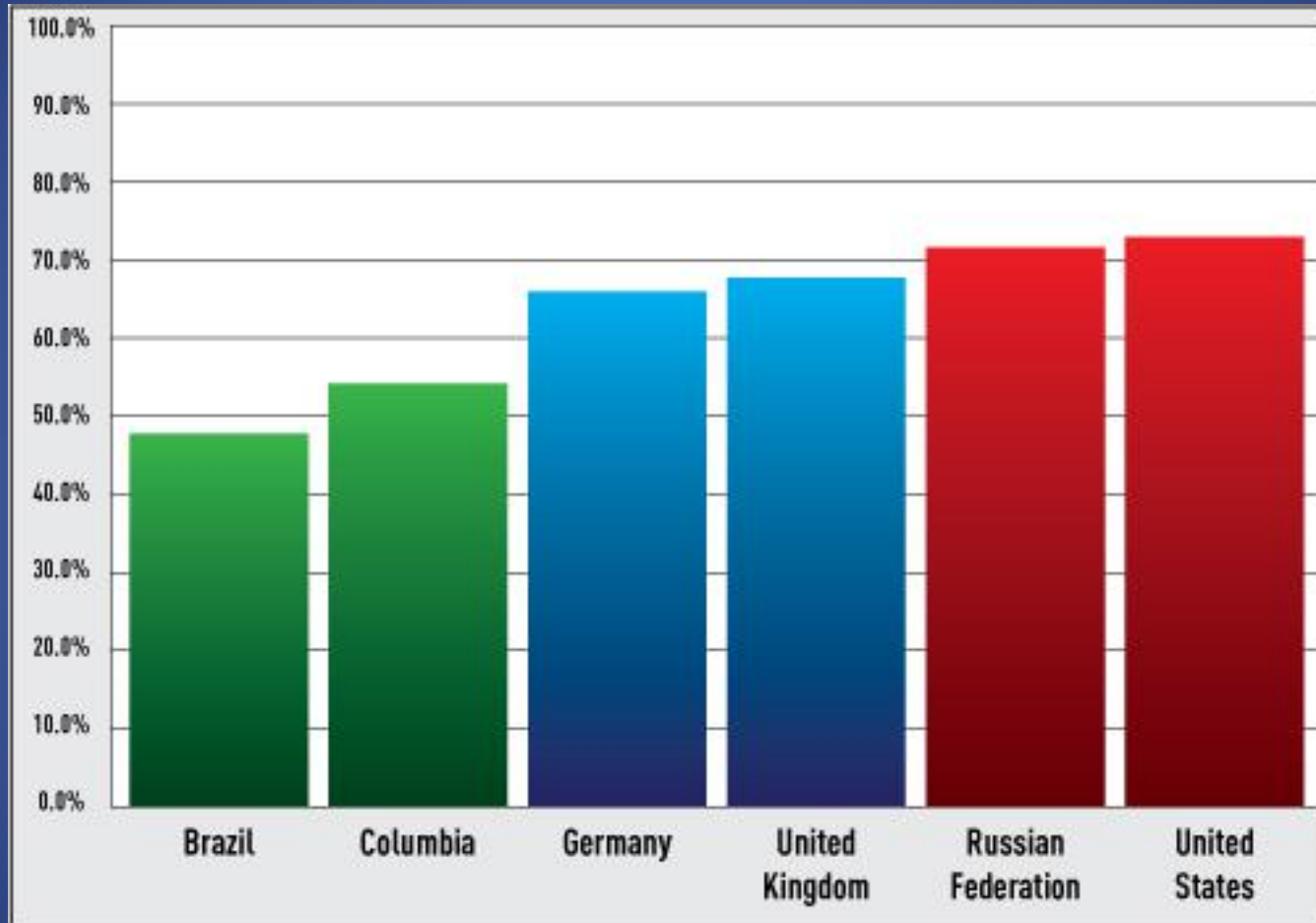
Millions of adults & children are overweight or obese -

- Overweight BMI $25 - 29.9 \text{ kg/m}^2$
- Obese $30 - 39.9 \text{ kg/m}^2$
- Extreme Obesity $\geq 40 \text{ kg/m}^2$

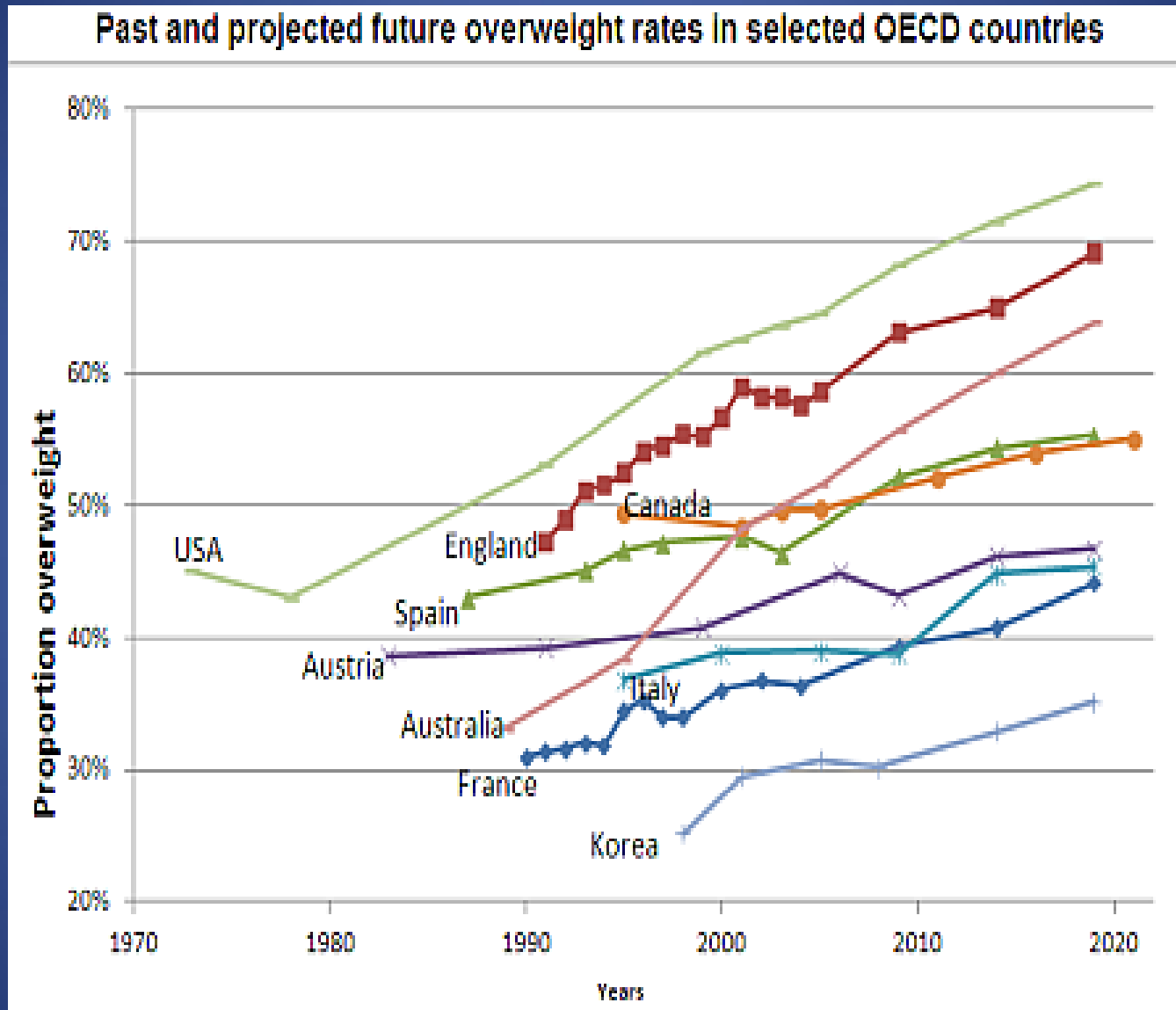
Waist: Males $> 40 \text{ in. (102cm)}$
 Females $> 35 \text{ in. (88cm)}$

Obesity: accumulation
of excess body fat, not
excess body weight

Estimated % of Overweight Adults in Foreign Countries

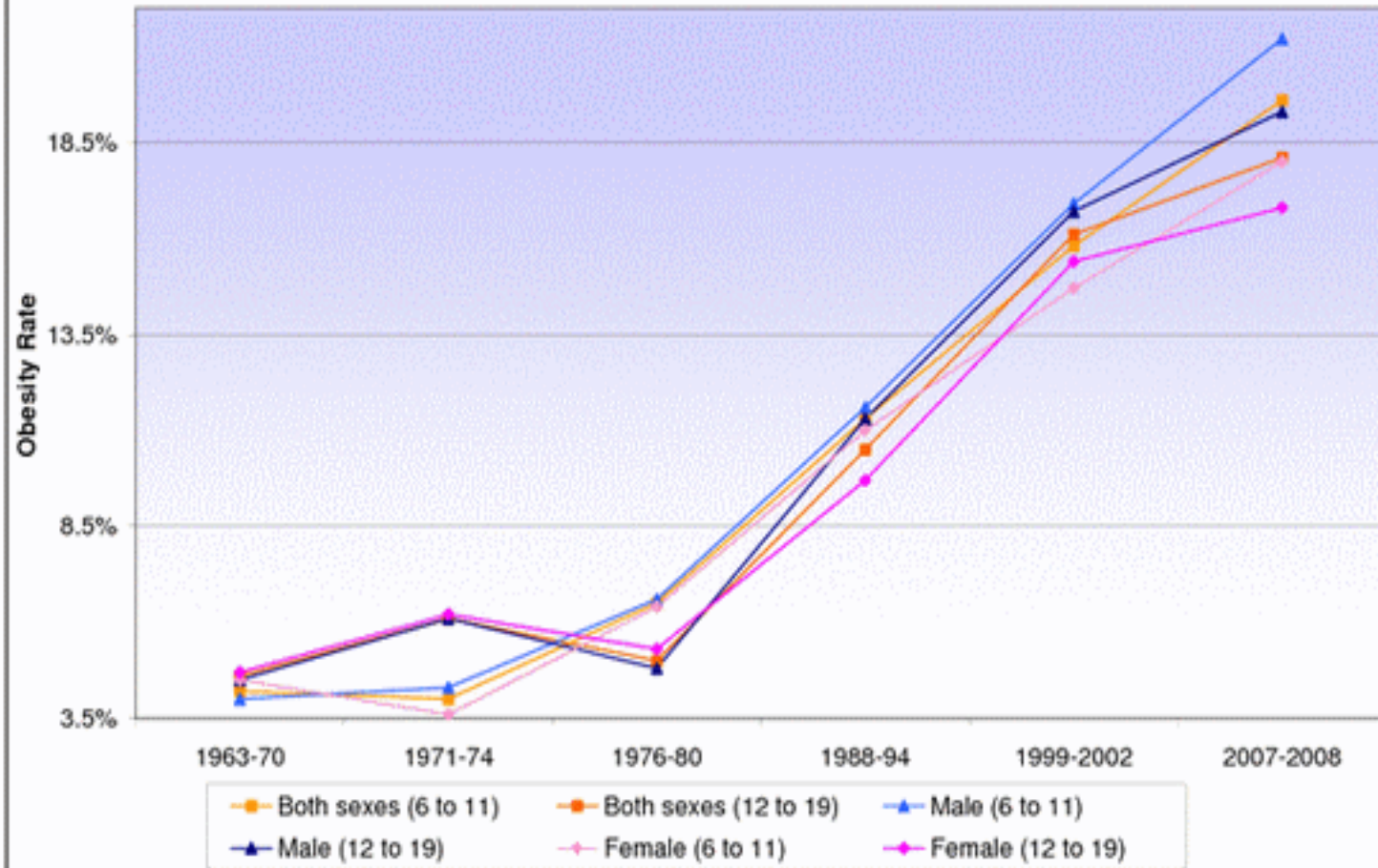


World Obesity Statistics for OEC Countries 2010



<http://www.hivehealthmedia.com/world-obesity-stats-2010/>

Child Obesity Statistics & Teenage Obesity Statistics by Age and Gender



<http://www.bariatric-surgery-source.com/child-obesity-statistics.html>

Strength Training (Anaerobic) Accelerates Fat Loss

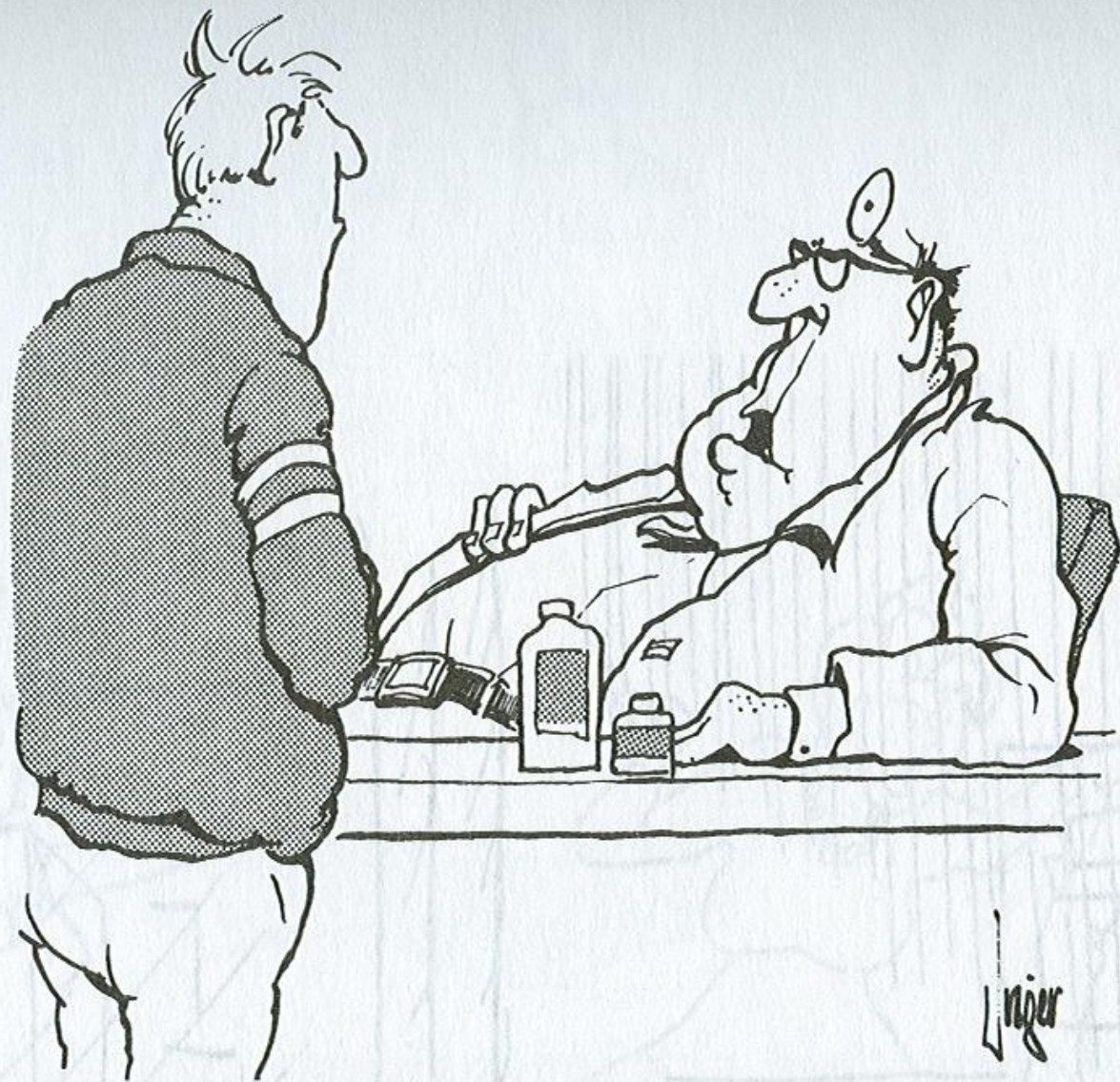
1. Burn calories during workout
2. Burn substantial number of calories after each training session to replenish anaerobic energy system
3. Additional muscle gain from exercise burns calories*
4. Overcomes insulin resistance

* One pound muscle consumes 35-40 calories per day

* Three pounds of muscle increases BMR 120 calories per day = 1 pound fat loss per month

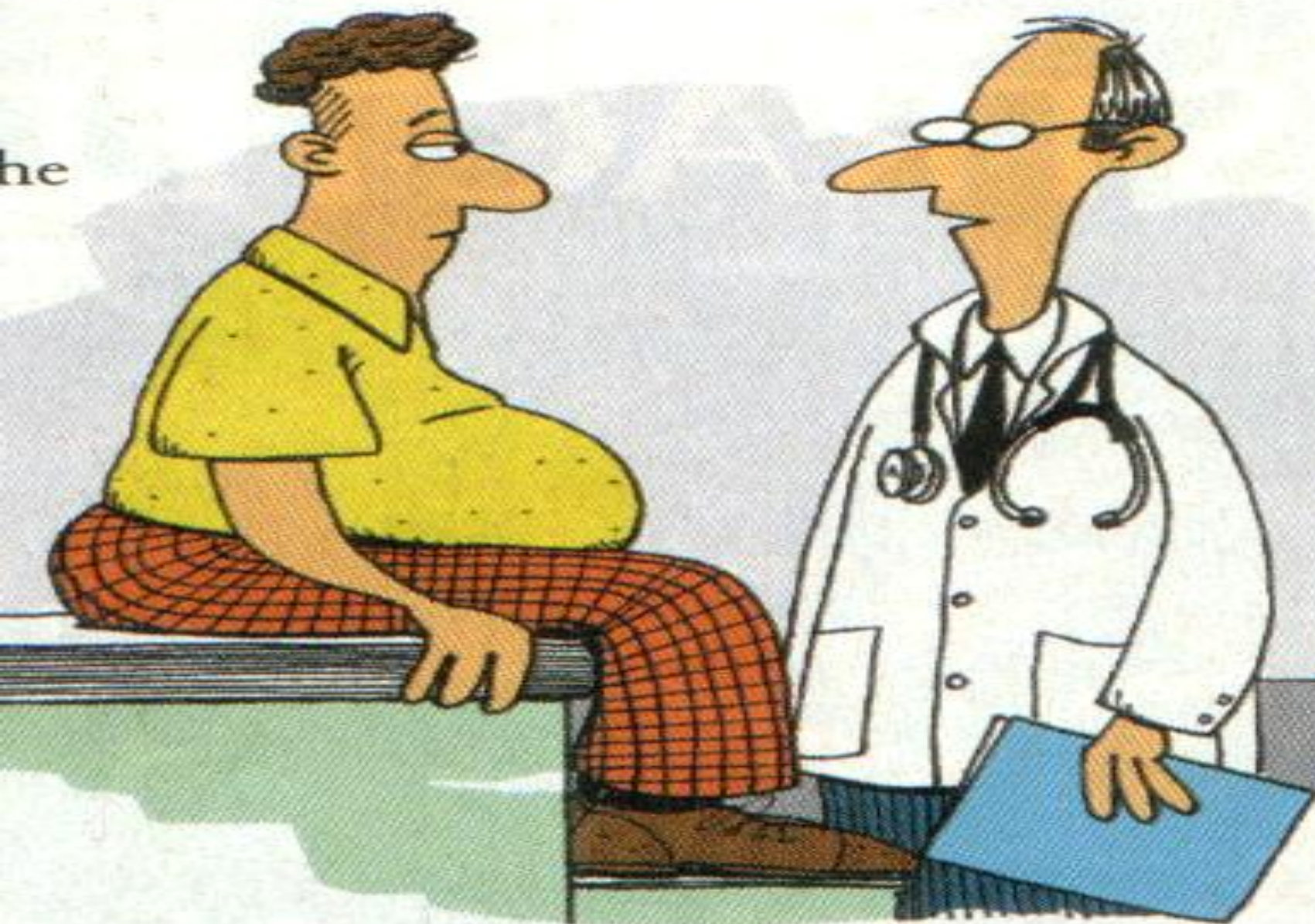
Facts About Diet Restriction Plans

- The average American consumes over 200 more Kcal a day than 10 years ago.
- If all Americans achieved normal body weight, it has been estimated there would be a three year increase in life expectancy, 25% less coronary disease, and 35% less congestive heart failure and stroke.
- One out of two Americans on calorie restriction diet plan (USPHS).
- Thirty billion dollars spent on diet plans in 2002.

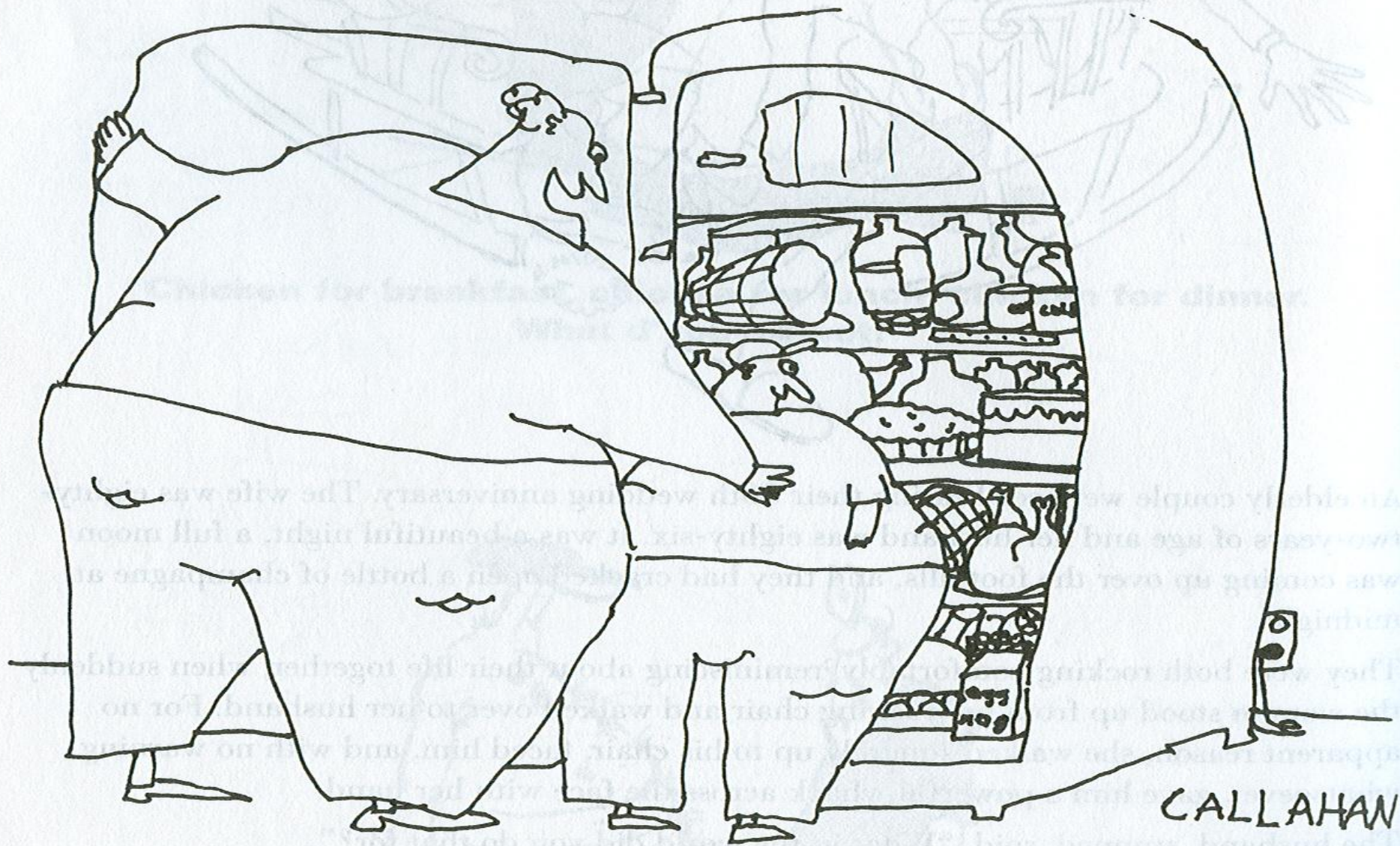


"Are you eating properly and getting plenty of exercise?"

he



**“You need to lose
twenty cable channels.”**



"Someday, son, all this will be yours!"



I'm Starving.



**"If you remember,
I did mention possible side-effects."**

Diseases Related to Excess Weight

❑ Obesity is clearly associated with prevalence of

- Hypertension
- Coronary artery disease
- Diabetes mellitus
- Left ventricular hypertrophy
- Congestive heart failure
- Almost all forms of cancer

New England Journal of Medicine. 2002;347:305-313

❑ Other studies have found that obesity is associated with:

- Liver disease
- Urinary Incontinence
- Sleep apnea
- Depression
- Osteoarthritis
- Sarcopenia

Obesity Research. 2002;10:767-773.

Clinical Studies on Obesity – Supplements

1. Quality
2. Dose
3. Body Composition vs Weight
4. Compliance

LESSON 1: *NOT ALL
SUPPLEMENTS, EVEN SEEMINGLY
SIMILAR ONES, ARE EQUAL*

Efficacy of Various Chromium Compounds

Ligand	↓SBP	↑Insulin Sens
Citrate	-	-
Amino Acid Chelate	-	-
Chelavite	-	+
Polynicotinate	+	+
Nicotinate	-	-
Picolinate	+	+

LESSON 2: *DOSING IS IMPORTANT*

Heymsfield SB et al. JAMA 280:1596, 1998
Garcinia Cambogia (HCA) as a potential
antiobesity agent! A randomized control
study

1. 135 Subjects : Placebo = 69, HCA = 66
2. 1500 mg HCA
3. 1200 Kcal Diet
4. 12 Weeks

Body Weight Loss

Placebo

n = 66

-3.2 Kg \pm 0.4

Treatment

n = 69

-4.1 \pm 0.5

Questions?

1. What type of HCA?
2. Proper Dose?
3. 1200 K Cal Diet
4. Compliance

Preuss HG et al. Int J Chem Pharm – 25:133,
2005. Efficacy of a novel Ca/K salt of HCA in
weight control

1. 90 Subjects – 8 Weeks
2. 2,000 Kcal diet
3. Food and pills delivered
4. 2800 mg HCA per day

	Group A (HCA – SX, n=29)	Group C (Placebo, n=25)
Body Weight (lbs)**	-10.78 (0.687)	-3.35 (0.740)
BMI***	-1.86 (0.115)	-0.616 (0.124)
Triglycerides***	-8.38 (2.88)	+0.64 (3.10)
VLDL****	+0.10 (1.09)	-0.44 (1.18)
LDL***	-14.31 (2.37)	+2.60 (2.55)
HDL***	+2.69 (0.50)	-1.2 (0.53)
Total Cholesterol***	-11.17 (2.61)	+0.96 (2.81)
Serotonin**	+105.9 (17.33)	+36.10 (18.67)
Leptin***	-13.50 (1.44)	-0.38 (1.56)
Remaining Food***	+142.07 (33.14)	+26.40 (35.69)

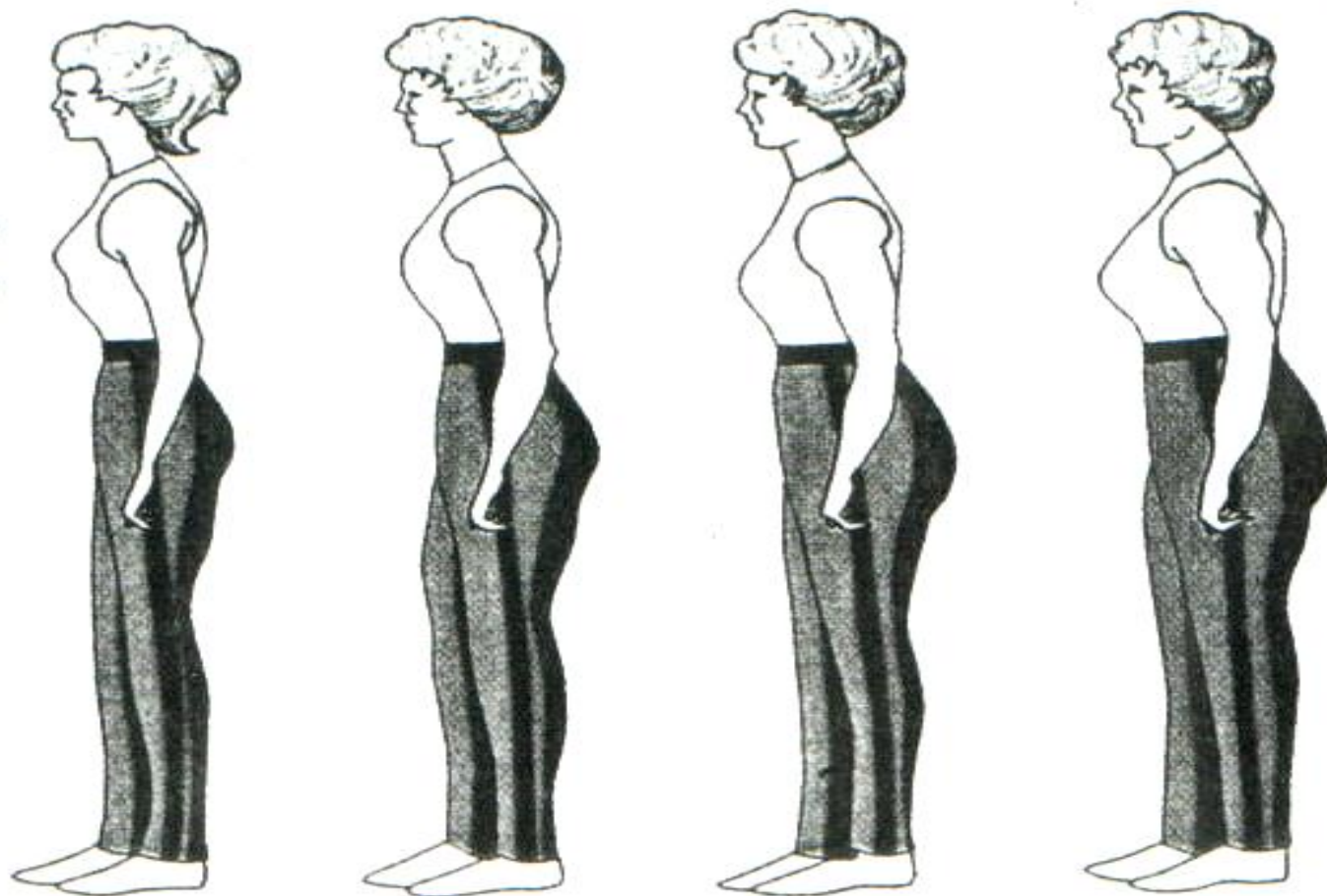
BODY PROPORTIONS

Lesson 3: *It's fat not scale weight that is important in "weight loss"*

Obesity: accumulation
of excess body fat, not
excess body weight



Figure 1. Body weight and body composition changes during adult life.



Age:	20	30	40	50
Bodyweight (lbs.)	126	136	146	156
Muscle (lbs.)	45	40	35	30
Fat (lbs.)	29	44	59	74
Percent Fat (%)	23	32	40	47

Change in Body Composition During Aging

Chromium Study

- Crossover Study with 10 in 2 Groups
- Advice on Diet and Exercise
- Two Month Test Periods
- One Month Wash Out
- Scale and Impedance Measurements

Weight Loss Study Result

Body Weight Loss (lbs)

P to T	-2.6 ± 1.0	-2.8 ± 1.1
T to P	-2.5 ± 0.4	-4.0 ± 0.8

Body Fat Loss (lbs)

P to T	-0.2 ± 0.6	-1.8 ± 0.9
T to P	-2.1 ± 0.4	-3.5 ± 0.4

LBM Loss (lbs)

P to T	-2.5 ± 0.9	-0.9 ± 1.0
T to P	-0.4 ± 0.3	-0.5 ± 0.7

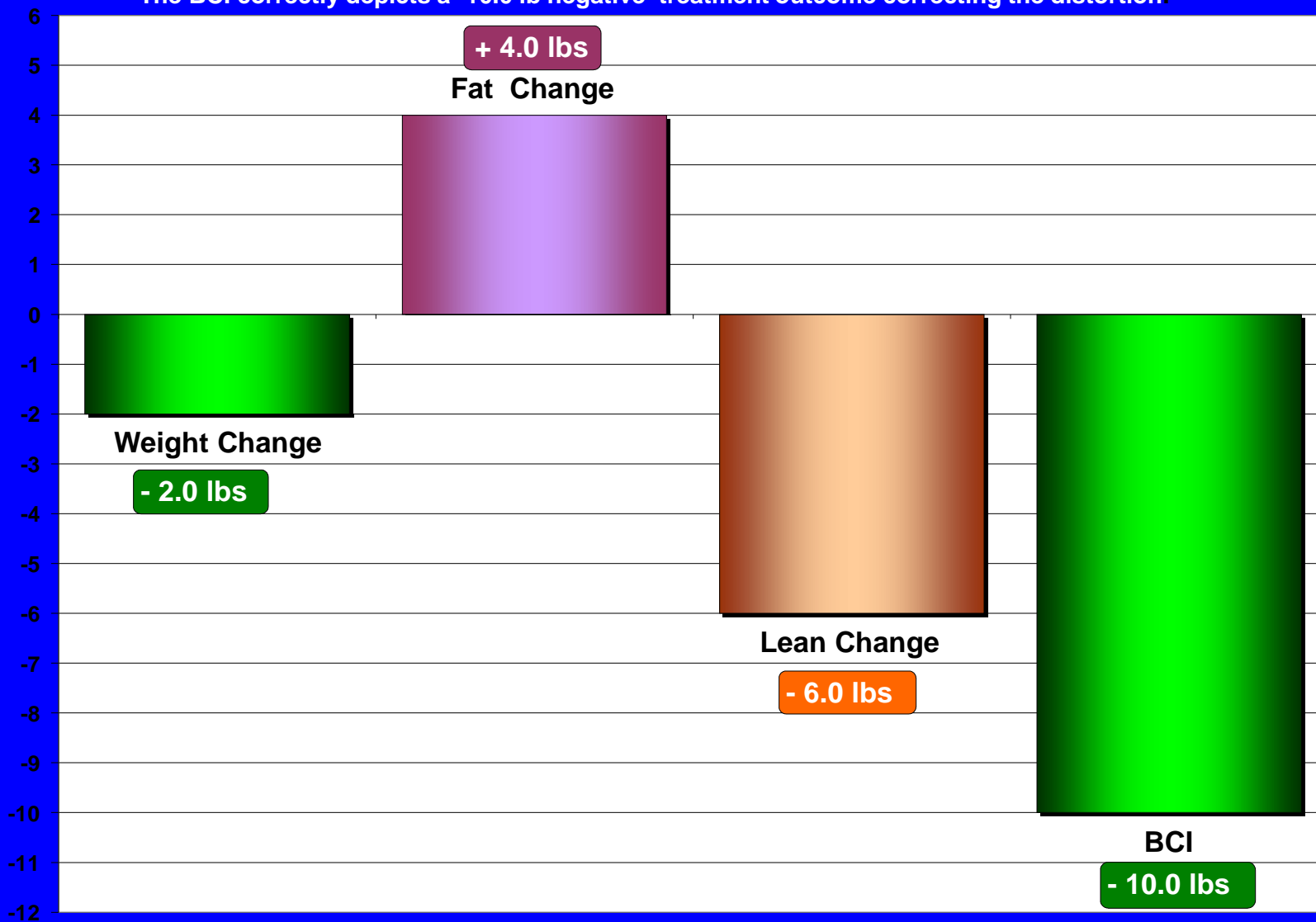
The Body Composition Improvement (BCI) index—A Paradigm Shift in Assessment

The litmus test for the safety and efficacy of weight loss interventions is not how much weight is lost, but rather what kind of weight is lost. Reductions in scale weight and Body Mass Index can lead to erroneous conclusions with regard to the safety and efficacy of an intervention since neither depict the kind of weight that was lost. Weight loss that depletes lean and bone mass can increase risk factors, while weight loss that adds lean and bone can decrease risk factors—both of which would depict opposite outcomes when using scale weight or body mass index. The BCI resolves these distortions by calculating the net result of scoring:

- gains in lean & losses of fat as positive outcomes
- losses of lean & gains of fat as negative outcomes

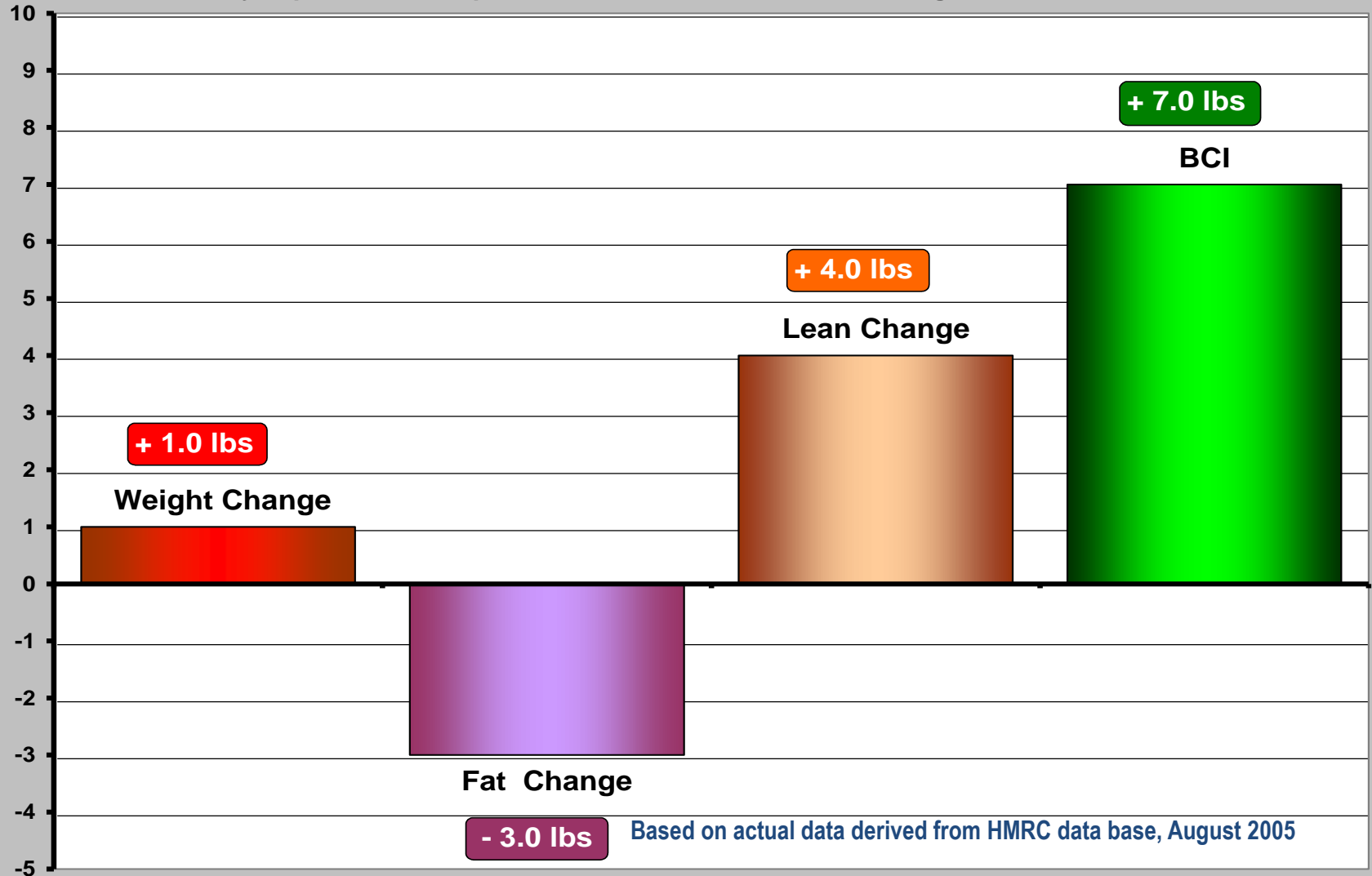
When a 2 lb “success” Masked a 10 lb Failure

The scale weight suggests a -2.0 lb positive treatment outcome. But the weight loss resulted from a - 4.0 lb increase on body fat and a decrease of - 6.0 lbs of lean mass--both negative treatment outcomes. The BCI correctly depicts a -10.0 lb negative treatment outcome correcting the distortion.



When a 1 lb “failure” Masked a 7 lb Success

The scale weight suggests a 1.0 lb negative treatment outcome. But the weight gain was the result of a - 3.0 lb loss of body fat and a gain of 4.0 lbs of lean mass--both positive treatment outcomes. However, the BCI correctly depicts a +7.0 lb positive treatment outcome correcting the distortion.



The Magnitude of the Distortion—An Analyses of a 14,000 changes in body composition tests in the data base

Using the BCI as a standard, the following errors can be made when interpreting outcomes of weight loss interventions:

Scale weight changes suggests

+ A loss of scale weight

- A gain of scale weight

No change in scale weight

The BCI suggests:

- A negative BCI

+ A positive BCI

+ or - BCI

The Magnitude of the Problem:

- 40.3% Lost Weight Suggesting a Successful Treatment Intervention

But a Negative BCI Suggests an Unsuccessful Treatment Intervention

- 45.3% Gained Weight Suggesting a Failed Treatment Intervention

But a Positive BCI Suggests a Successful Treatment Intervention

Thus, 85.6% of subjects were misled with an average error of an 8.0 lb difference between weight loss changes and the BCI

Lesson 4: *Compliance is
necessary for success but
weighing scales could make it
harder to persevere*

Compliant Subjects in Glucomannan Study Groups

	<u>N</u>	<u>Time & Amount</u>
Placebo	42	18 (42.9%)
Active	38	16 (42.1%)

Baseline between Active Group (A) and Placebo (P) Groups before any Corrections

Parameter	Active (38)	Placebo (42)	A-P ¹	p
Age (yrs)	46.4 \pm 2.2	47.6 \pm 2.1	-1.2	0.7
Weight (lbs)	176.3 \pm 6.6	180.5 \pm 5.7	-4.2	0.6
BMI (Kg/M ²)	29.2 \pm 1.2	29.1 \pm 0.8	0.1	1.0
Body Fat (%)	40.0 \pm 1.3	38.3 \pm 1.4	1.7	0.4
Fat Mass (lbs)	72.0 \pm 4.5	70.0 \pm 3.7	2.0	0.7
FFM (lbs)	104.2 \pm 3.5	110.5 \pm 3.7	-6.3	0.2
Bone Density	122.0 \pm 0.018	1.226 \pm 0.020	-0.006	0.8

Comparison of Changes Between Treatment Group (A) and Placebo Group (P) After Two Months of Study: No Corrections

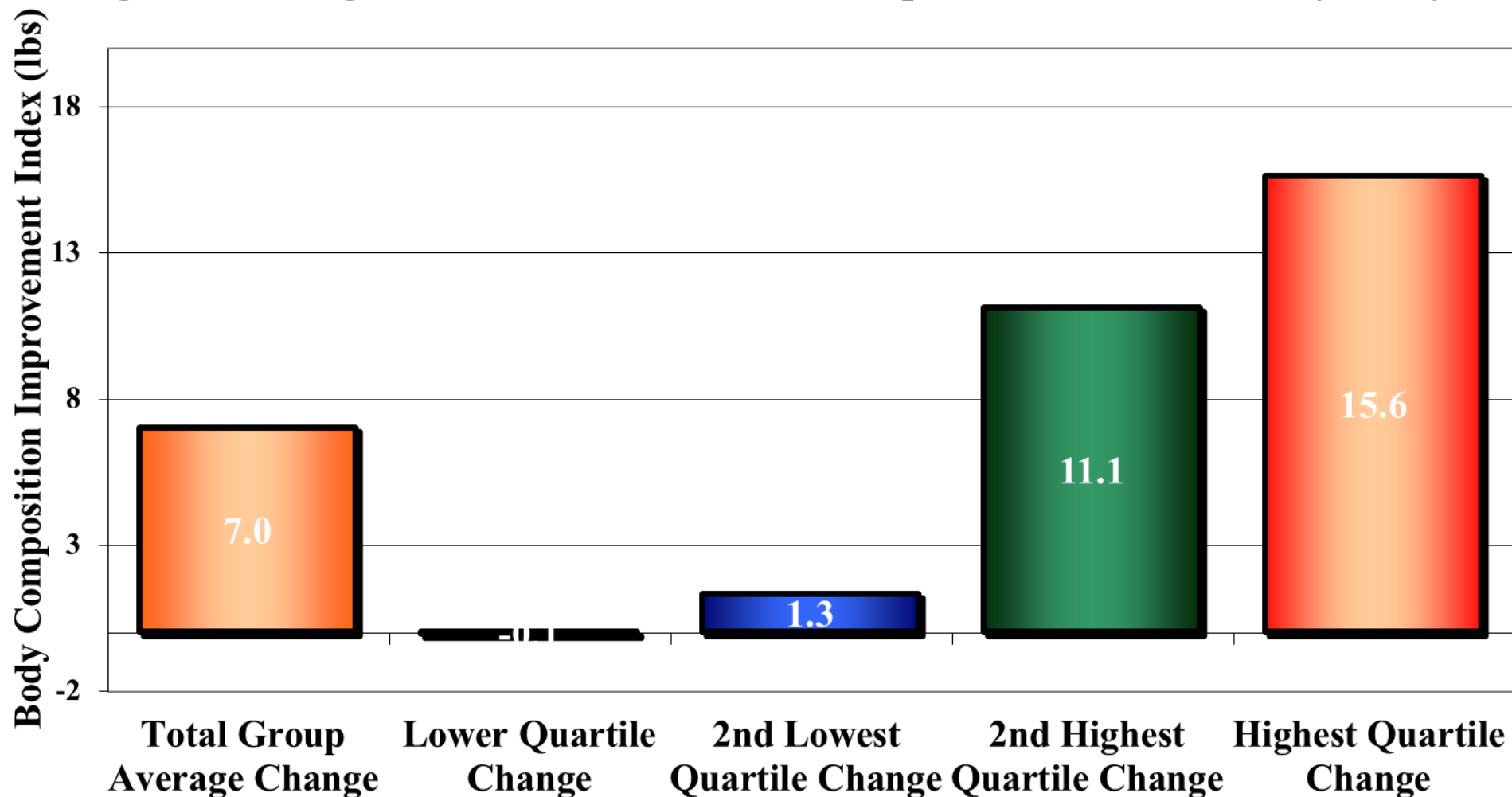
Parameter	Active (38)	Placebo (42)	A-P ¹	p
Weight (lbs)	0.55±0.77	1.21±0.73	-0.66	0.53
Body Fat (%)	0.02±0.27	0.53±0.25	-0.51	0.18
Fat Mass (lbs)	0.16±0.63	1.10±0.60	-0.94	0.28
FFM (lbs)	0.39±0.52	0.11±0.50	0.28	0.70
Bone Density	-0.59±0.33	-0.14±0.31	-0.45	0.32

Changes (delta) after 2 Months on Protocol between Treatment Group and Placebo Groups According to Compliance

Parameter	Treat (16)	Plac (18)	A-P	p
Weight (lbs)	-2.87 \pm 0.80	3.97 \pm 0.80	-6.84	<0.001
Body Fat (%)	-0.83 \pm 0.30	0.87 \pm 0.30	-1.70	<0.001
Fat Mass (lbs)	-2.49 \pm 0.64	2.81 \pm 0.6	-5.29	<0.001
FFM (lbs)	-0.38 \pm 0.67	1.17 \pm 0.67	-1.55	0.11
Bone Density	-0.36 \pm 0.51	-0.83 \pm 0.51	0.47	0.52

Average \pm SEM depicted. Number in each group shown in parentheses.

Changes in the Body Composition Improvement Index as a Function of Four Levels of Compliance in a Group of 52 Subjects Following a Pedometer-Based Weight Loss Program That Included a Meal Replacement for a 90-Day Study



FAT-LOSING SUPPLEMENTS

- Calorie Burners
- Appetite Suppressants
- Insulin Sensitizers
- GI Blockers (CHO, Fat)
- Miscellaneous

The Multi-Mechanistic Fat Loss Plan

To improve body composition (lean to fat ratios) through the use of four ingredients designed to facilitate the loss of body fat Trivalent Chromium, Bean Extract, Green Tea Extract, Hydroxycitric Acid, and CLA to preserve or increase lean.

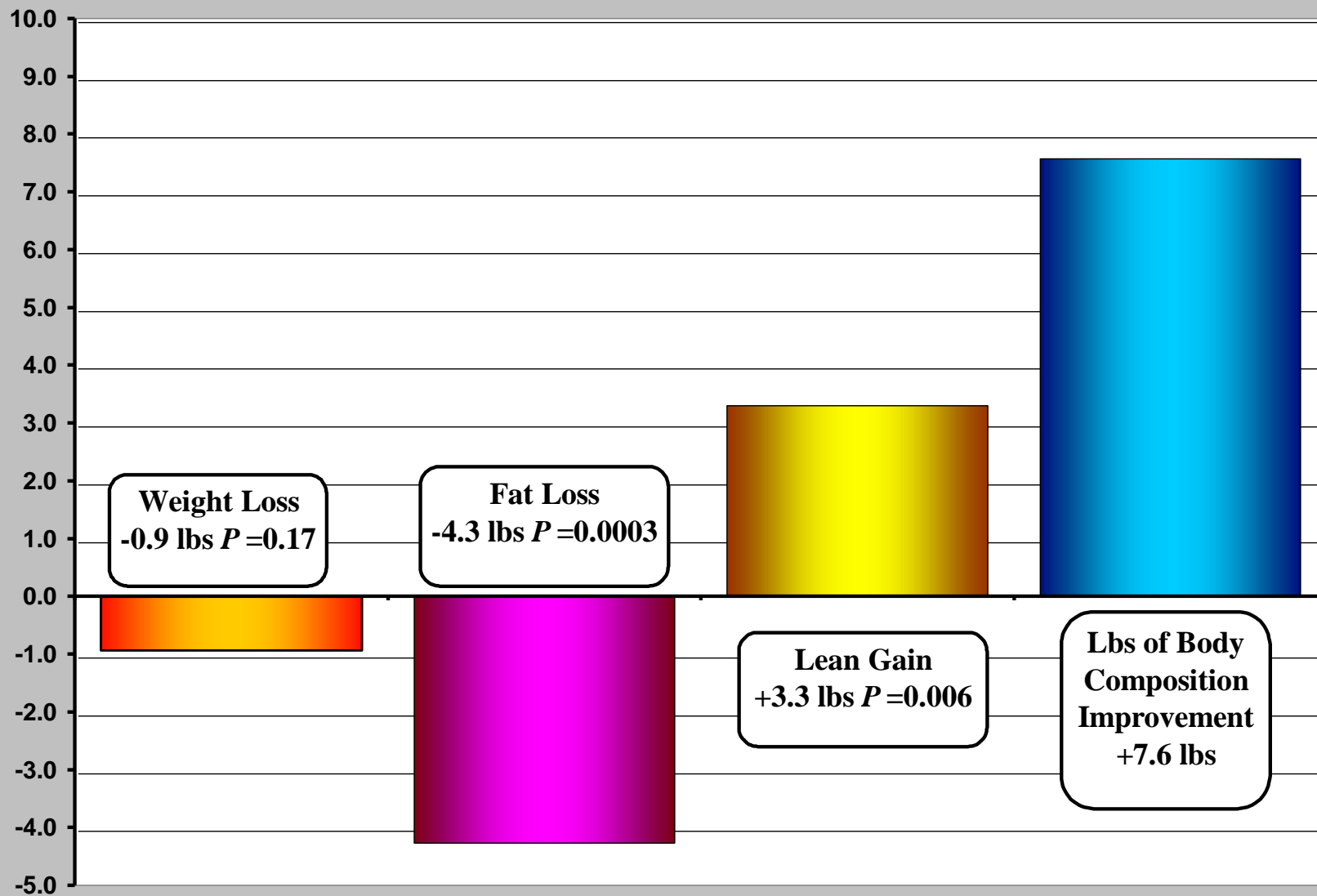
FAT BURNER – Trivalent Chromium: This ingredient does more than just burn fat. When you start to lose weight it makes sure weight loss comes from fat, not muscle. In one study, in which two groups lost the same weight, the chromium group lost 84% fat and 16% muscle. The placebo group lost 92% muscle and 8% fat!

CARB BLOCKER – Bean Extract: An FDA reviewed product that has been proven to neutralize the starch found in foods like potatoes, breads, pasta, rice and corn. In a recent UCLA study, the group that received the bean extract lost twice as much weight as the placebo group.

CALORIE BURNER - Green Tea Extract: Proven to burn up to 5% more calories per day – which equals one meal per week! It also helps keep off the weight! In a recent study, a group that had lost 13 lbs was divided in two groups. One received green tea extract, the other a placebo. The green tea group continued to lose weight while the placebo group actually regained 40% of the weight they had lost!

APPETITE CONTROL – Trivalent Chromium: We added extra strength doses of this product that is proven to suppress appetite as well as reduce conversion of carbs to fat. In an 8-week study, the trivalent chromium group lost an average of 12 pounds each compared to 3 pounds for the placebo group.

LEAN ENHANCEMENT – Conjugated Linoleic Acid: Decades of research indicate that conjugated linoleic acid (CLA) actually changes body composition by reducing body fat and increasing or preserving lean muscle mass. Derived from natural safflower oil, CLA inhibits lipoprotein lipase, an enzyme that breaks down fat from our diets. Once the fat is broken down, it is stored in the body. By suppressing this enzyme, CLA helps reduce the amount of fat that is broken down and, therefore, the amount of fat that is stored



Positive Changes (lbs) in Body Composition During a 60-day Clinical Trial

Lessons from Clinical Weight Loss Studies

1. Dose
2. Quality
3. Body Composition vs Weight
4. Compliance