GAO's 2006 Investigation of Four Genetic Testing Web Site Services

Workshop on Direct-to-Consumer Genetic Testing
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Discussion Agenda

- Background
- Discussion of GAO's 2006 Investigation
  - Objective
  - Methodology
  - Results
- Questions

Background:
Who We Are and What We Do

- The Forensic Audits and Special Investigations (FSI) unit was formed in May 2005 to bring GAO's related anti-fraud and other investigative activities together in one organization.

- FSI work addresses
  - fiscal challenges facing our nation,
  - organizational and individual ethics,
  - stewardship over government resources,
  - control environment at federal agencies, and
  - issues related to homeland and national security.

- FSI has the authority to perform undercover tests to identify vulnerabilities or areas lacking oversight.

Objective

- "Nutrigenetic" tests purport to analyze a limited number of genes to provide personalized nutritional and lifestyle recommendations. Companies that market this type of test claim to provide consumers with the information needed to tailor their diet and exercise programs to address their genetically determined health risks.

- The Senate Special Committee on Aging requested that FSI investigate the "legitimacy" of claims made by these companies.

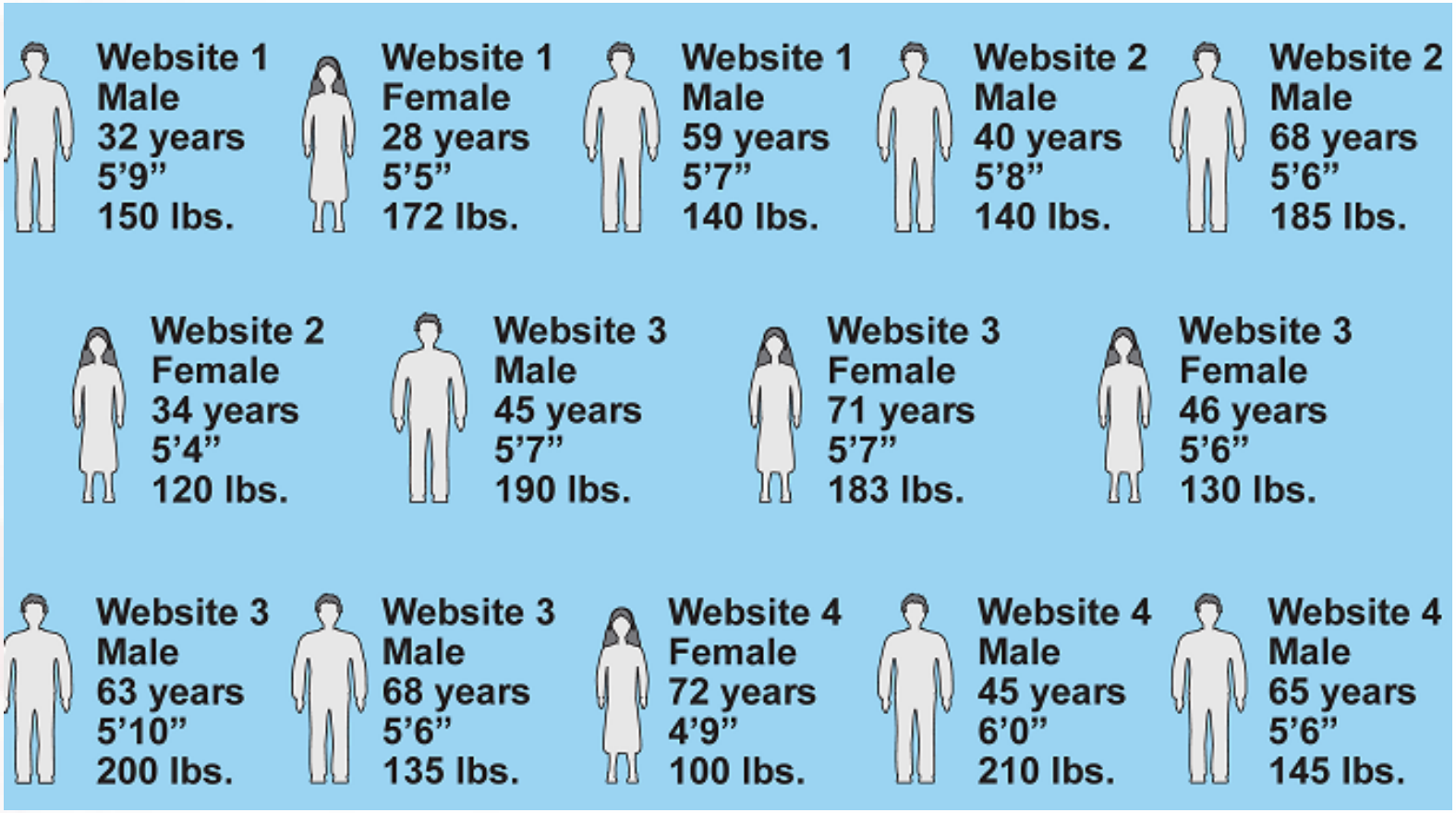
Methodology

- We chose a nonrepresentative selection of four Web sites selling nutrigenetic tests:
  - All claimed to analyze a limited number of genes to create personalized dietary and other lifestyle recommendations.
  - All stated that their products would not test for disease or predisposition for disease.
- We purchased several tests from each site (14 in total) so that we could compare a variety of results.
- Tests ranged in price from $89 to $395.

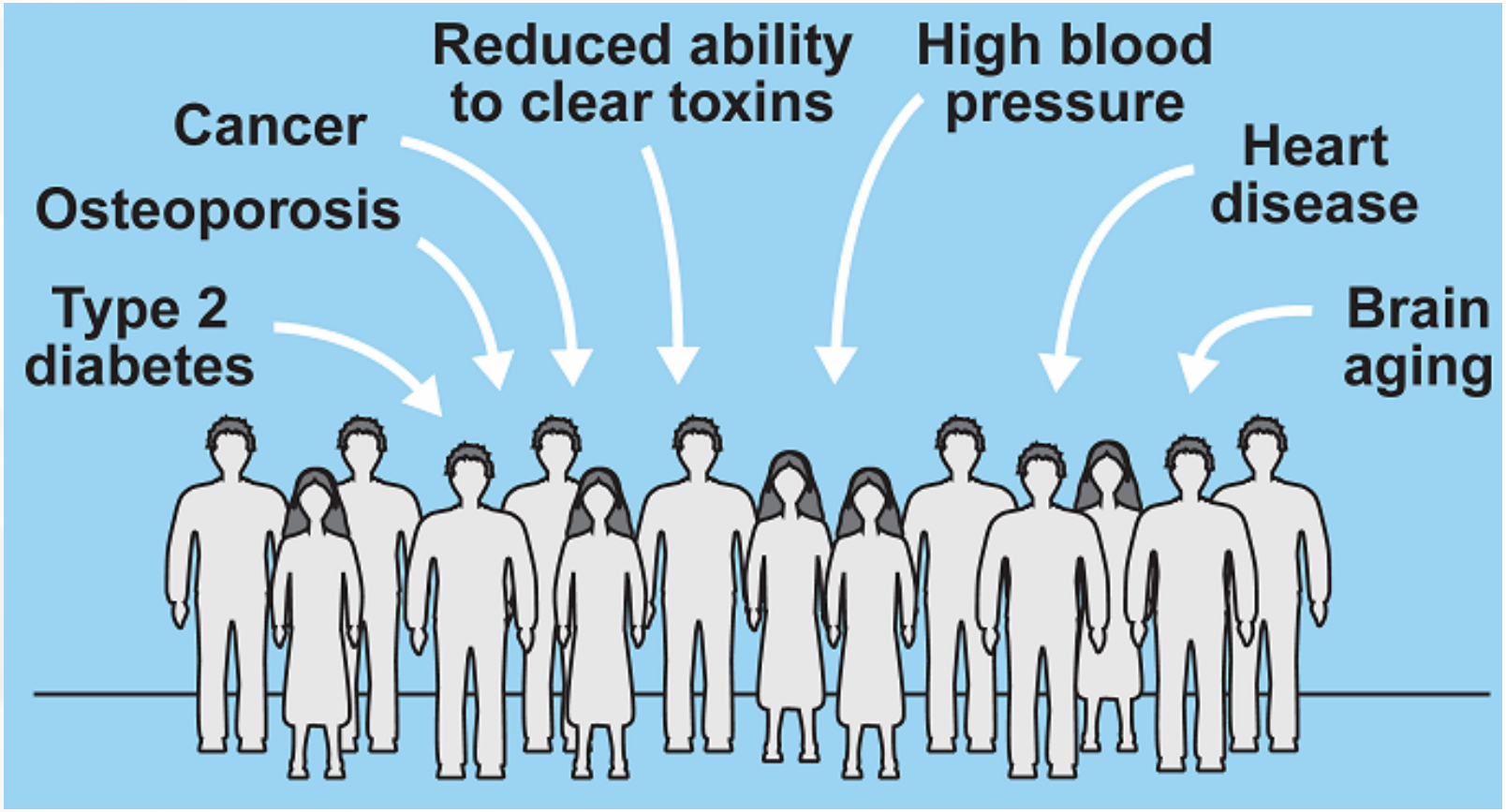
Methodology

- We created "fictitious consumers" by submitting 12 DNA samples taken by cheek swab from a 9-month-old female, with consent from her parents, and 2 DNA samples from an unrelated 48-year-old male.
- On questionnaires included with the tests, we described the DNA as coming from adult men and women of various ages, weights, and lifestyle descriptions.
- We consulted with experts to help analyze the test results we received.

Methodology:
Fictitious Profiles Submitted for Testing



Results:
Health Risks Found in Fictitious Profiles



Results: Medically Unproven and Ambiguous

- Specific test result examples:
  - You have “gene variations that may alter the body’s ability to metabolize cholesterol” and variations that may affect “mineral absorption and bone metabolism.”
  - You have “faulty methylation patterns” which may lead to “an above average risk for developing cardiac aging, brain aging, and cancer” and “sub-optimal glycation,” which can lead to diabetes and increased body fat.
  - You have a “significant risk of developing the age related conditions associated with elevated levels of DNA damage.”

Results: Medically Unproven and Ambiguous

- Experts informed us that these predictions could not be proven given the level of scientific evidence available at the time of our testing.

- Even if the predictions could be proven, the way they were presented renders them meaningless:
  - Many people “may” be “at increased risk” for developing heart disease or diabetes because of a variety of factors, so such ambiguous statements could apply to anyone.

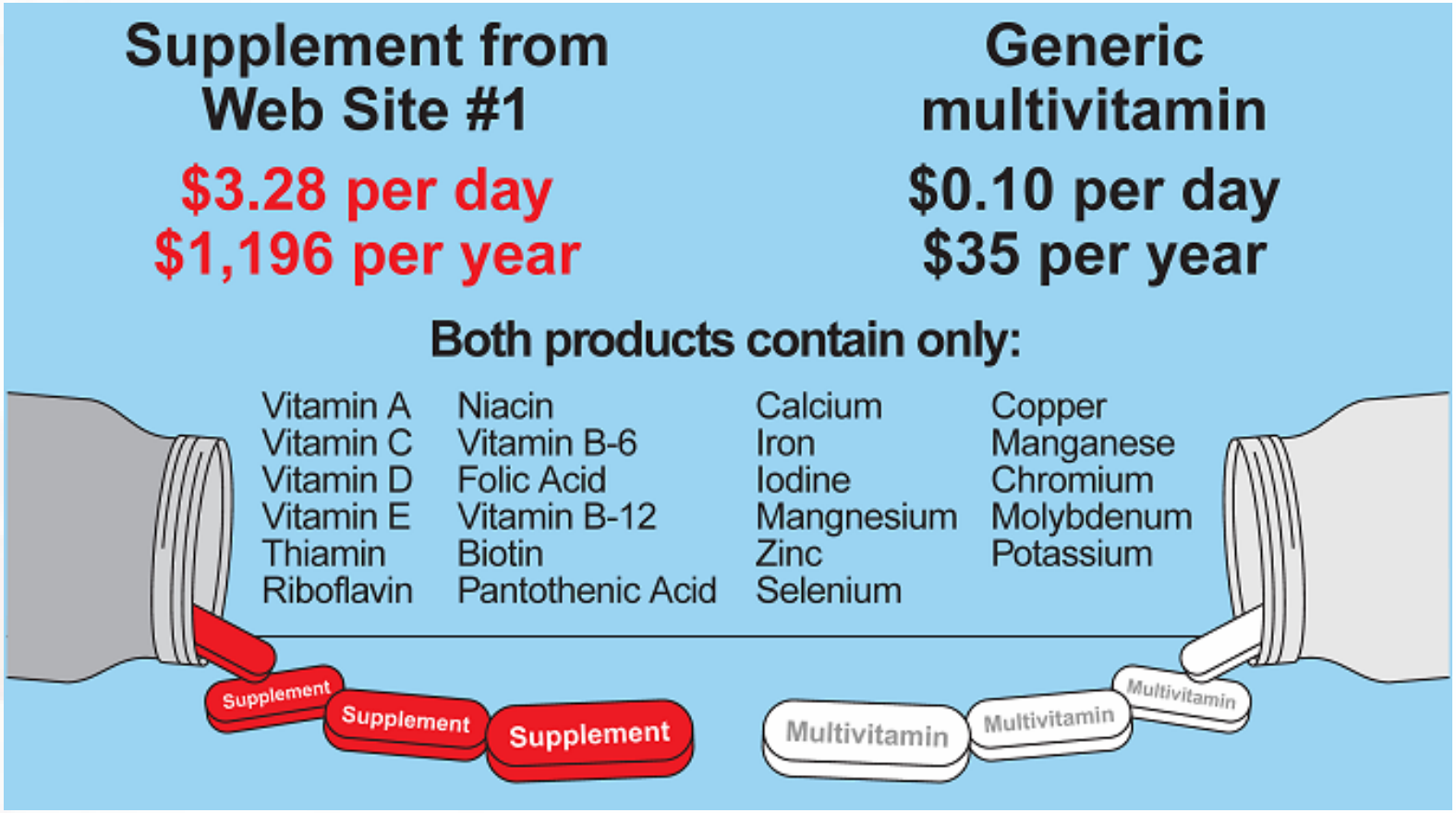
Results: Lifestyle Recommendations Not Based on DNA

- If the lifestyle recommendations were really based on DNA, then our fictitious consumers with same DNA should have received the same recommendations.
- Instead, we received generally accepted health advice linked to information we submitted via the test questionnaires.
  - If we said that our fictitious consumers smoked, they were told to stop smoking. If we said the consumers never smoked, they were told to continue to avoid smoking.

Results: Unnecessary Supplements

- Our consumers were told to buy costly supplements that were customized to their "unique" DNA and lifestyle or that could "repair" damaged DNA.
  - The pills were not unique. Our fictitious 72-year-old female nonsmoker with a diet high in protein was recommended the same supplement as our 45-year-old male smoker with a diet high in fats.
  - Experts confirmed that no pill can repair DNA.
- In reality, the supplements were standard multivitamins, although experts cautioned that taking some of the ingredients in large doses could be dangerous.

Results:
Cost and Ingredient Comparison



Question and Answer Period

Questions?