

**USDA Dietary Supplement Ingredient
Database (DSID): Adult
Multivitamin/Mineral Study**

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Why a Dietary Supplement Ingredient Database (DSID)?

Need for research on relationships between health and use of dietary supplements

Public health concerns:

- Excessive or deficient intakes of nutrients**
- Exposure to other bioactive constituents**
- Possible interaction with drugs**

Goals for Dietary Supplement Ingredient Database

- **To develop reliable estimates of nutrients and other bioactive components in Dietary Supplements**
- **To assess variability and/or possible bias in nutrient levels for DS**
- **To release and maintain publicly available on-line DS database**

Vision for DSID

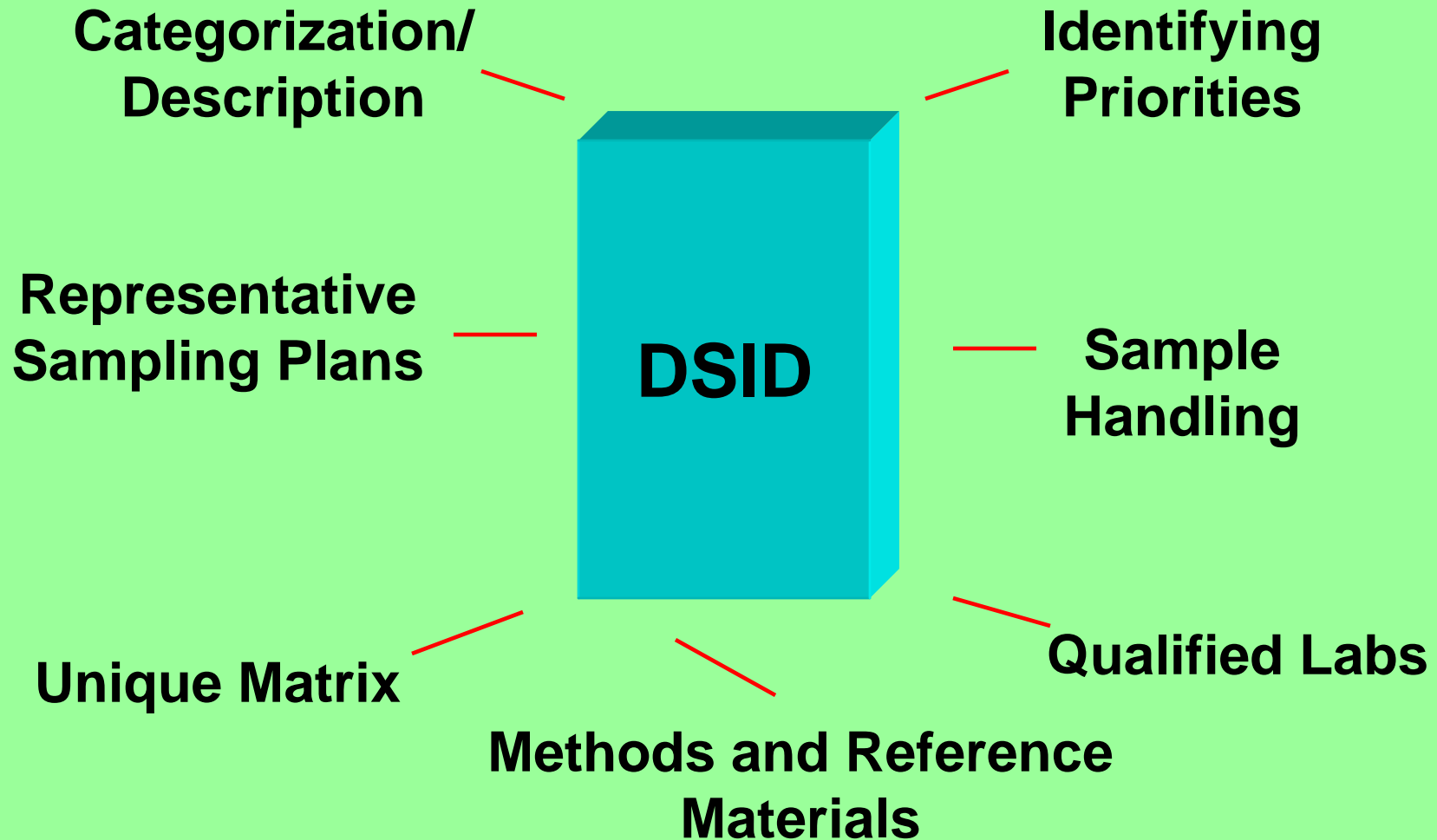
- **Data for top-reported DS products based on lab analyses**
- **Probability-based sampling plan to obtain products to be analyzed**
- **Statistical applications to products in similar categories**

Database Format

DSID vision:

- **Nutrient estimates by product name**
- **Values for individual nutrients**
- **Values for nutrients for default and generic products**
- **Mean values & indicators of variability**
- **Documented sources of data**

Key Challenges



Pilot Study Results

Set priorities for nutrients and products:

- **public health significance**
- **availability of valid methods & SRMs**
- **federal research projects**

Identified experienced labs and methods

- **assessed lab variability**

Reviewed sample handling protocols

Developed quality control materials

Defining a MVM

Definition based upon

- **Pills, capsules, tablets**
- **Number of vitamins and minerals**
- **“Specialty” MVM differentiation**
- **Functions or types of MVM**

Adult MVM Study question: How do different products labeled at the same % Daily Value (DV) level compare?

What level of confidence exists with labeled nutrient values?



Supplement Facts
Serving Size 1 Tablet

Each Tablet Contains	% DV	Each Tablet Contains	% DV
Vitamin A 3500 I.U. (29% as Beta Carotene)	70%	Magnesium 100 mg	25%
Vitamin C 60 mg	100%	Zinc 15 mg	100%
Vitamin D 400 I.U.	100%	Selenium 20 mcg	29%
Vitamin E 30 I.U.	100%	Copper 2 mg	100%
Vitamin K 25 mcg	31%	Manganese 2 mg	100%
Thiamin (Vit. B1) 1.5 mg	100%	Chromium 120 mcg	100%
Riboflavin (Vit. B2) 1.7 mg	100%	Molybdenum 75 mcg	100%
Niacin 20 mg	100%	Chloride 72 mg	2%
Vitamin B6 2 mg	100%	Potassium 80 mg	2%
Folic Acid 400 mcg	100%	Boron 150 mcg	*
Vitamin B12 6 mcg	100%	Nickel 5 mcg	*
Biotin 30 mcg	10%	Silicon 2 mg	*
Pantothenic Acid 10 mg	100%	Tin 10 mcg	*
Calcium 162 mg	16%	Vanadium 10 mcg	*
Iron 18 mg	100%	Lutein (<i>Tagetes erecta</i>) (flower) 250 mcg	*
Phosphorus 109 mg	11%	Lycopene 300 mcg	*
Iodine 150 mcg	100%		

*Daily Value (DV) not established.

INGREDIENTS: Dicalcium Phosphate, Magnesium Oxide, Potassium Chloride, Cellulose, Ascorbic Acid, Ferrous Fumarate, Calcium Carbonate, Gelatin, dl-Alpha Tocopheryl Acetate, Niacinamide, Zinc Oxide, Croscarmellose Sodium, Dextrin, Titanium Dioxide, Hypromellose, d-Calcium Pantothenate, Crospovidone, Magnesium Stearate, Calcium Silicate, Silicon Dioxide, Manganese Sulfate, Maltodextrin, Polyethylene Glycol, Corn Starch, Pyridoxine Hydrochloride, Thiamine Mononitrate, Vitamin B12, Vitamin E, Vitamin K, Vitamin D, Vitamin C, Resin, Sodium Benzoate, Lycopene, Lutein, Ascorbyl Palmitate, Ascorbyl Triphosphate, Metasilicate, Phosphorus, Nickelous Sulfate, Cyanocobalamin.

Contains: Fish Oil, Vitamin D, Vitamin E, Vitamin K, Vitamin C, Resin, Sodium Benzoate, Lycopene, Lutein, Ascorbyl Palmitate, Ascorbyl Triphosphate, Metasilicate, Phosphorus, Nickelous Sulfate, Cyanocobalamin.

IMPORTANT INFORMATION: This product contains 29% of vitamin A which may cause drowsiness or dizziness. Do not take more than the recommended dose. Do not take this product if you are taking other vitamin supplements. Do not take this product if you are taking other vitamin supplements. Do not take this product if you are taking other vitamin supplements.

WARNING: Accidental ingestion of this product may cause irritation of the mouth and throat. If you experience any symptoms of an allergic reaction, such as hives, swelling, or difficulty breathing, seek medical attention immediately.

Made in U.S. Pharmaceutical Grade. Meet or Exceeds Industry Standards. 100% Satisfaction Guarantee.

QUALITY
If you are not satisfied with your product, return it for a full refund. No questions asked.

Customer Support: 1-800-451-4515

Adult MVM “% DV” Study Objectives

- **To determine if any systematic relationship exists among MVM.**
- **To assess variability across products**
- **To evaluate the % DV approach as aid in planning future studies**

Adult MVM % DV Study Design

- Used NHANES '01-02 MVM records (n=541)**
- Chose products at 3 most common DV levels for 23 nutrients.**
- Analyzed 6 products from each DV level, total 219 products.**
- Double Lot component: Analyzed 4 key nutrients for 3 products at 3 DV levels, total 36 products.**

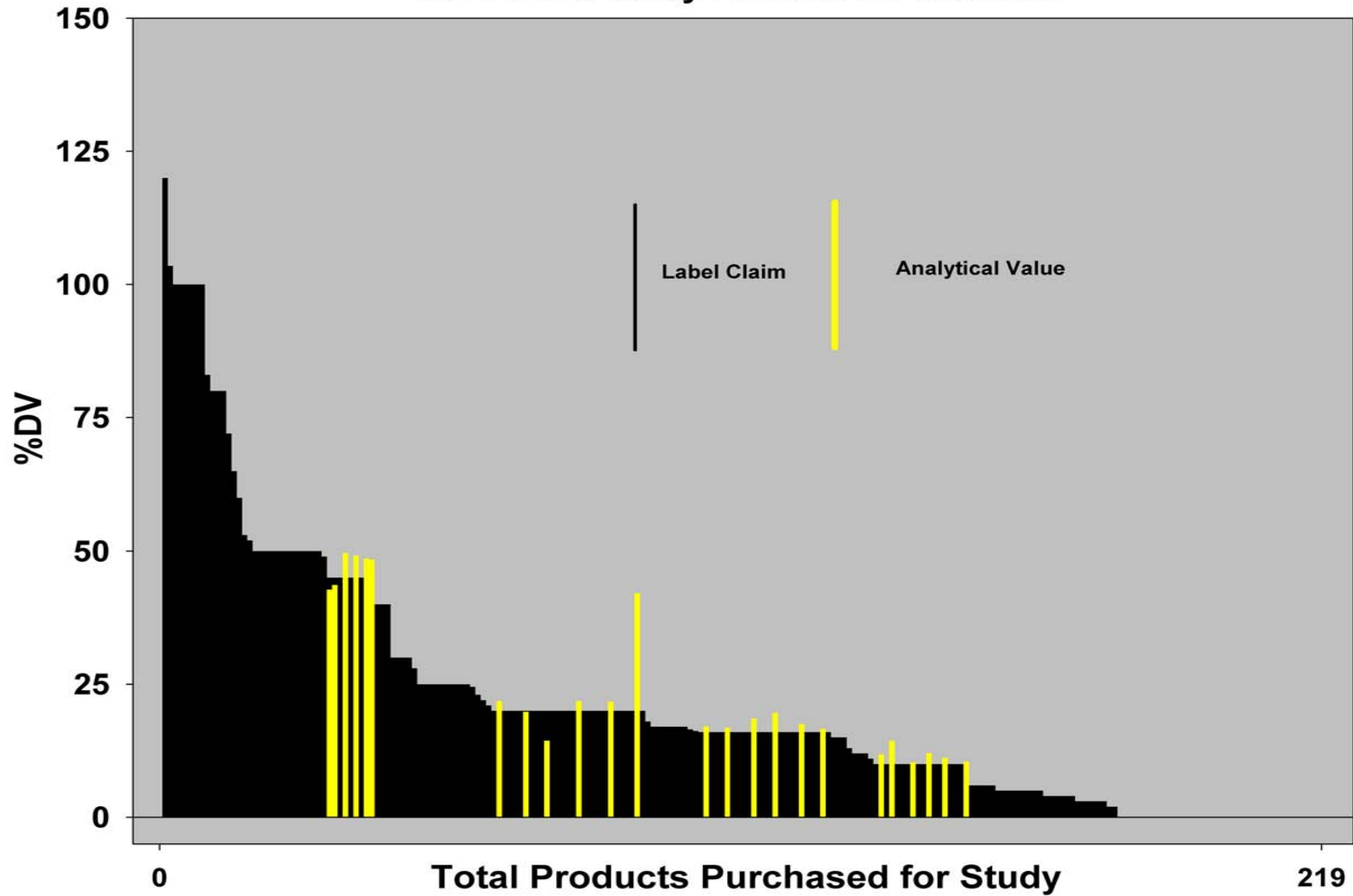
Adult MVM “% DV” Product Characteristics

- DV levels ranged from 2% to 6666%**
- Most common DV level was 100% for 16 of the 23 nutrients**
- 66% of the products were 1 pill per day, while 10% of products were 4 or more daily**

Preliminary Key Findings from % DV Study

PRELIMINARY

%DV Pilot Study Results for Calcium



Calcium Label Vs. Analyzed Value

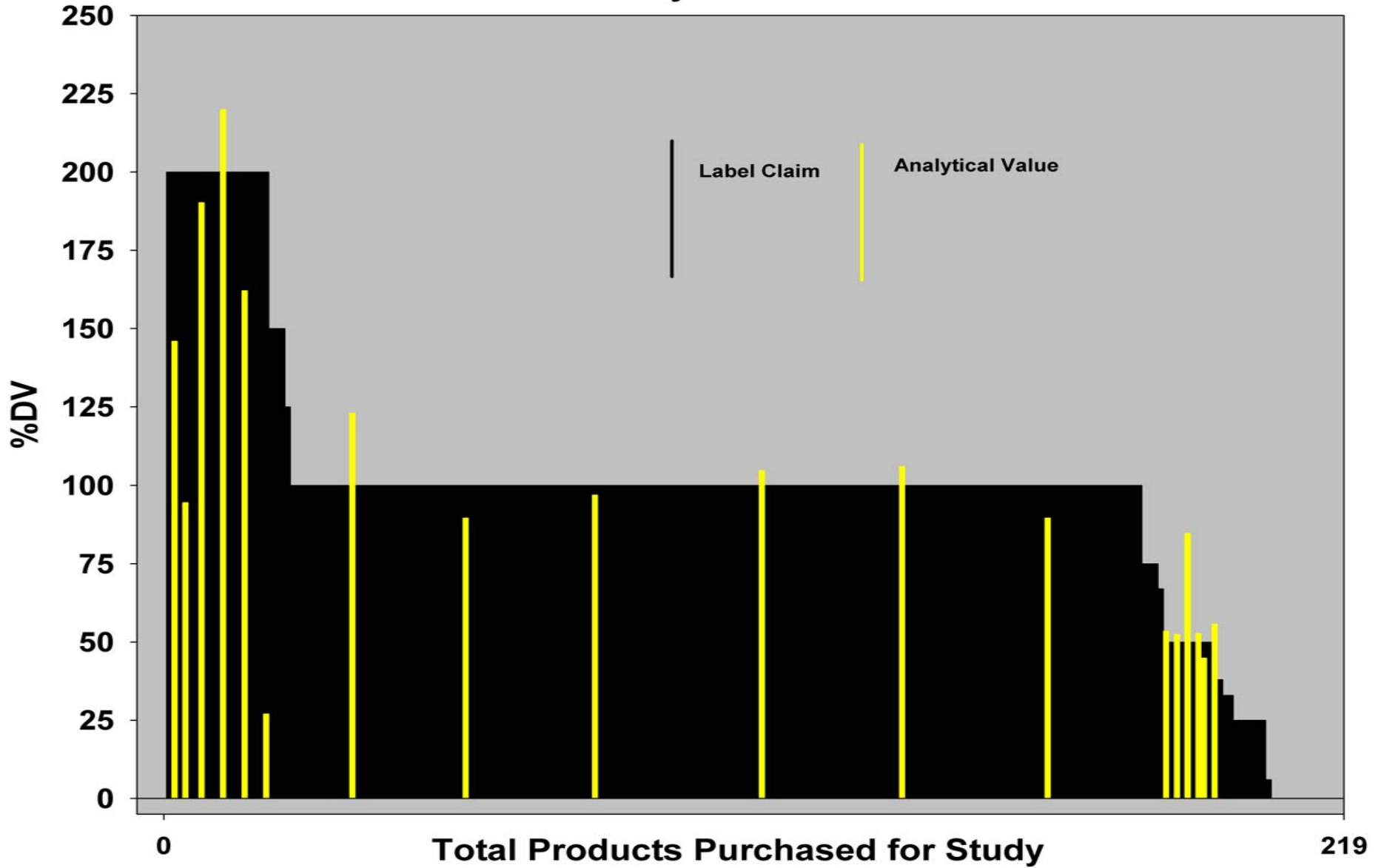
- Labeled % DV ranged from 0 to 120%
- DV levels studied were 10,16,20,40
- Analyzed values for 16 out of 24 products were within $\pm 20\%$ of labeled DV values

Folic Acid Label vs. Analyzed Value

- **Labeled % DV ranged from 0 to 200%**
- **DV levels studied were 50, 100, 200**
- **Analyzed values for 14 out of 18 products were within $\pm 20\%$ of labeled DV values**

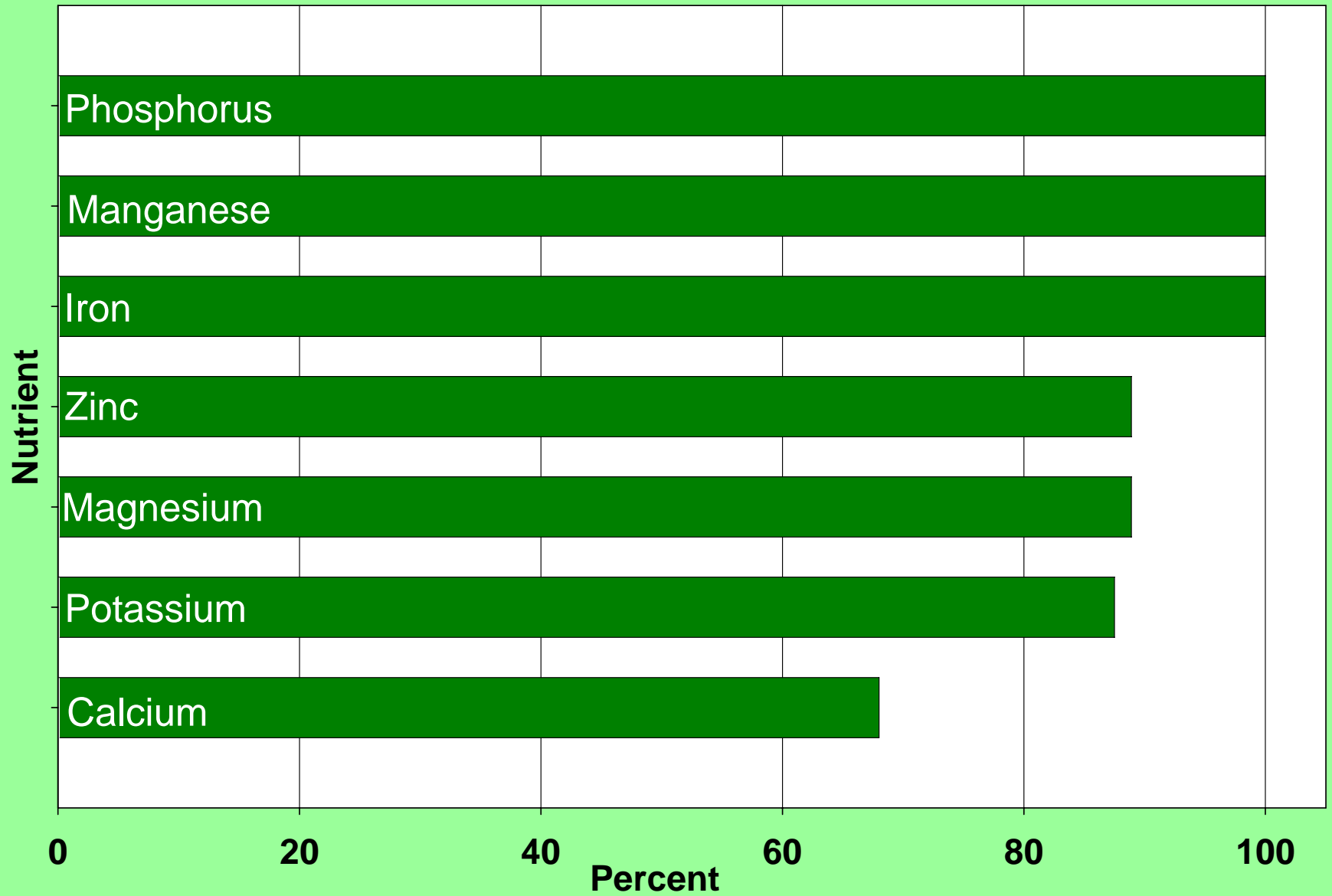
PRELIMINARY

%DV Pilot Study Results for Folic Acid

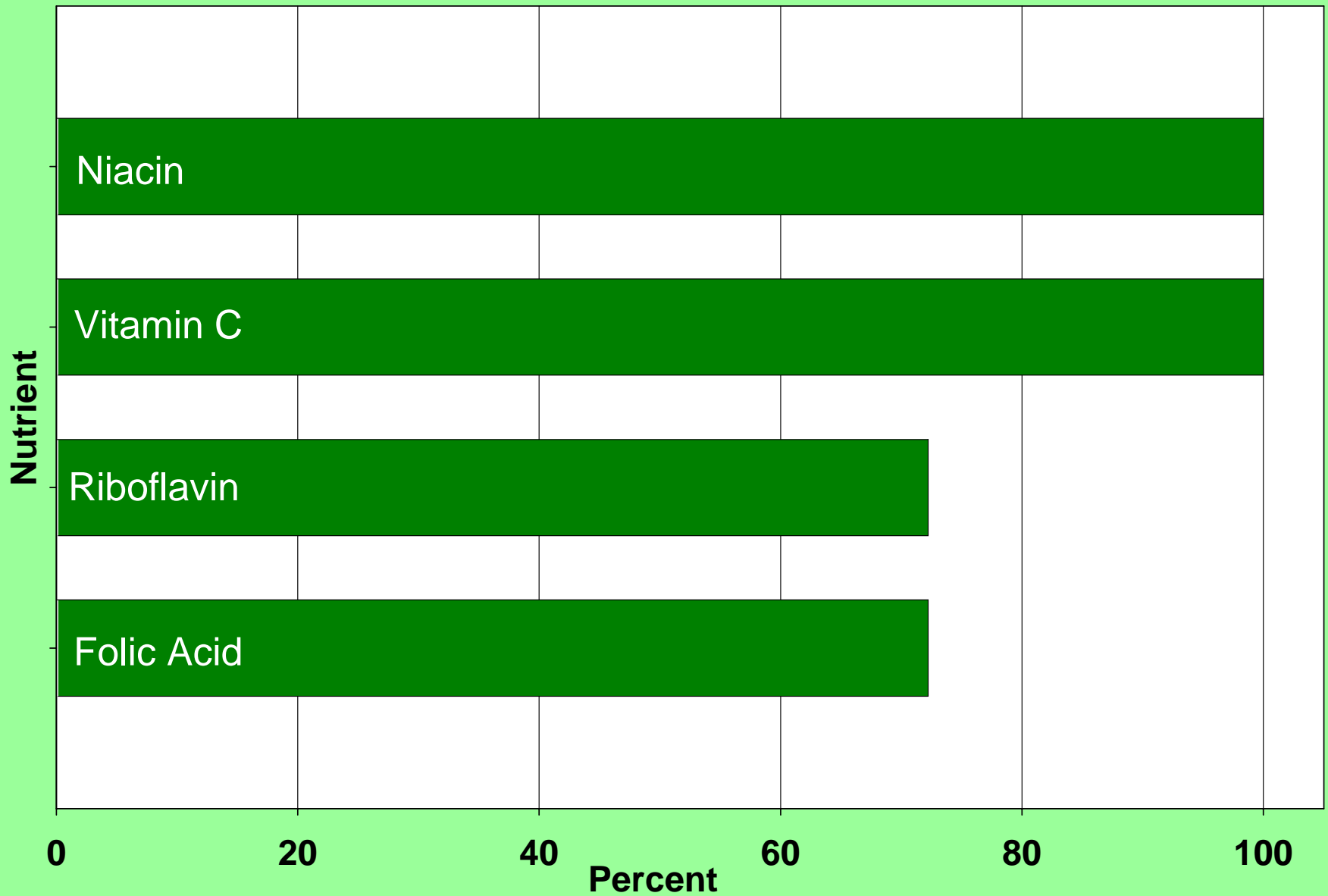


Key Findings of % DV Study

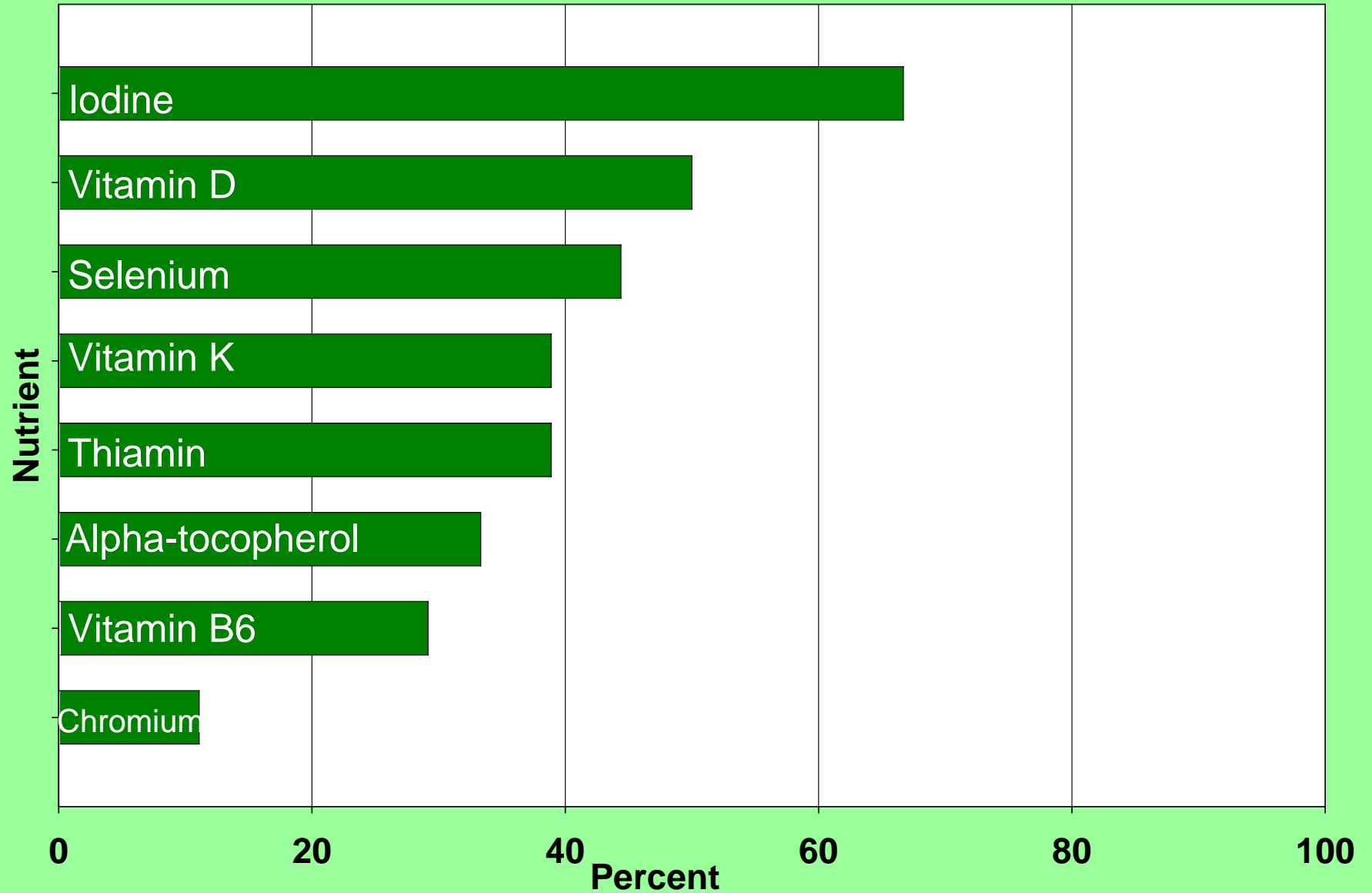
Percentage of Products Within +/- 20% of Label Claim (n = 18 or 24)



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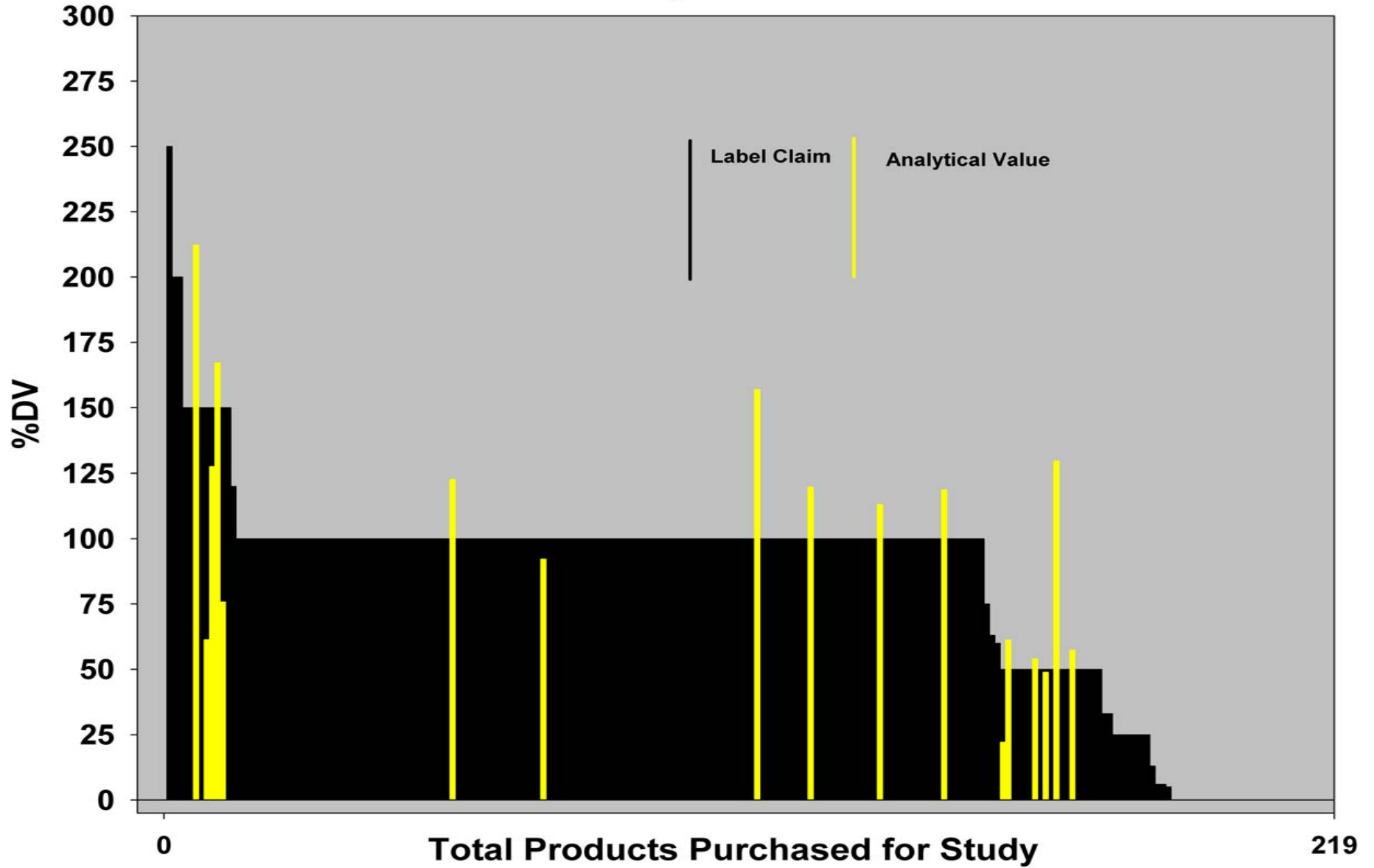


Percentage of Products Within +/- 20% of Label Claim (n = 18 or 24)



PRELIMINARY

%DV Pilot Study Results for Vitamin D



Vitamin D Label vs. Analyzed Value

- **Labeled % DV ranged from 0 to 250%**
- **DV levels studied were 50, 100, 150**
- **Analyzed values for 9 out of 18 products were within $\pm 20\%$ of labeled DV values**

**Key Findings of
Double Lot Study:
Preliminary summary**

**Lot-to-lot variability was generally
 \leq lab variability for the 4 nutrients
in the double lot study.**

Comprehensive Adult MVM Study Objectives

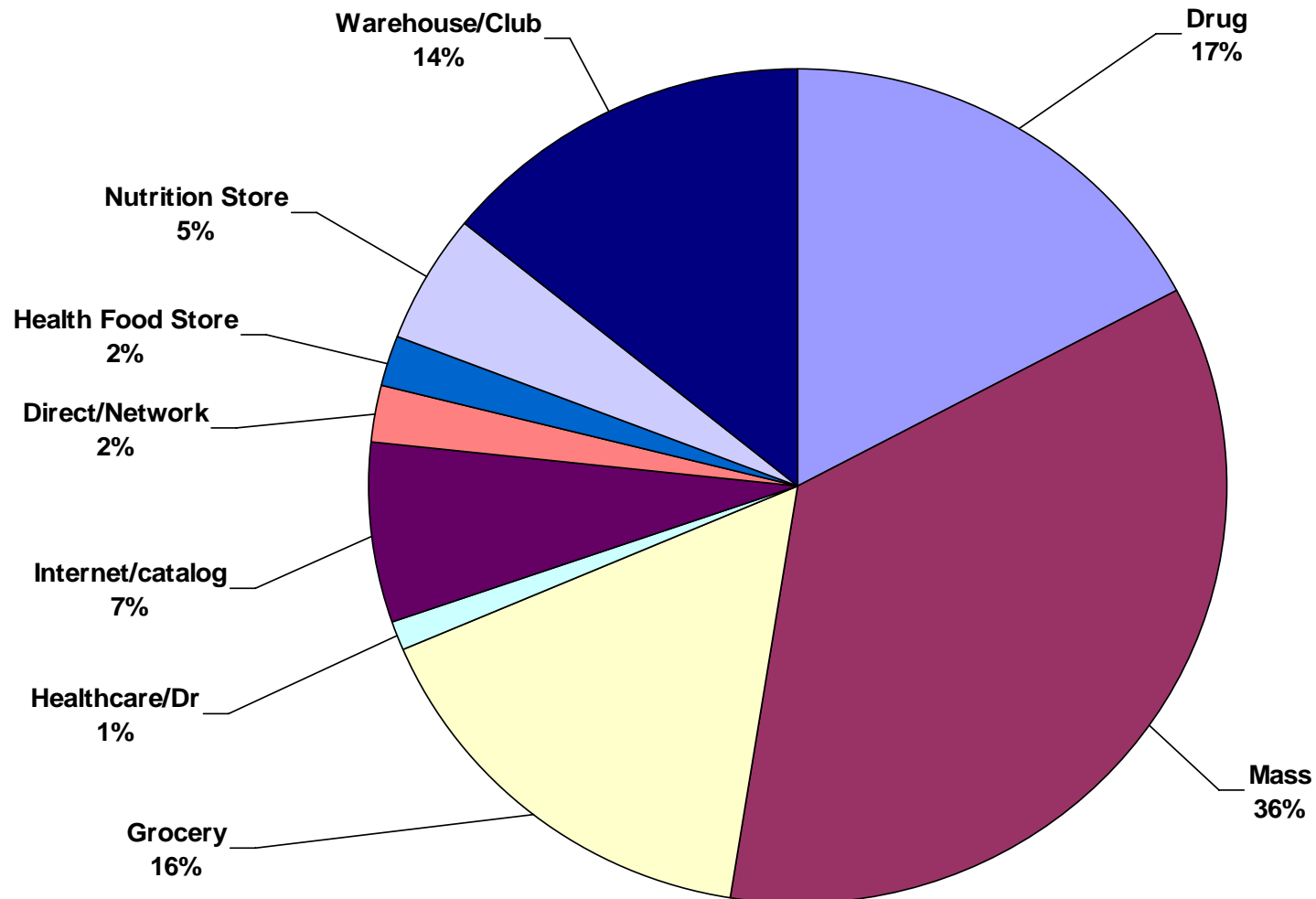
- **To provide nationally representative estimates for 22 nutrients in top products most commonly reported by the U.S. population**
- **To assess variability in specific products based upon geographic sampling plan**

Overview of Comprehensive Adult MVM Study sampling frame

- **Individual analysis (estimates) of 35 top products, basing each analysis on 6 samples distributed across marketing channels proportional to estimated product use.**
- **The top 35 products represent approximately 85% of adult MVM brands according to market share.**

Market Channels for Adult MVMs obtained from May 2006 Market Survey

Percentage of Multivitamin Purchases by Channel



DSID Future Plans

- **Review and analyze nation-wide adult MVM study data.**
- **Release data as DSID 1.**
- **Future areas of study: childrens MVM, prenatal MVM, calcium- and Vitamin D-containing supplements, others**

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