

# MEVACOR™ Daily A Public Health Opportunity

Edwin L. Hemwall, PhD  
Merck Research Laboratories

# OTC Indication and Target Population

- Lovastatin 20 mg once-daily
  - *“To help lower cholesterol which may prevent a first heart attack”*
- Target population based on National Cholesterol Education Program (NCEP) ATP III Guidelines
  - Men  $\geq 45$  / Women  $\geq 55$
  - Moderately-high LDL (130 mg/dL-170 mg/dL)
  - One additional CHD risk factor

# MEVACOR™ Daily Appeals to a Unique Population

Motivated, Health-Conscious Consumers

- Regularly visit doctor
  - 70-80% at least yearly and discussed cholesterol
  - 70-80% had cholesterol test within year
- Know they have a cholesterol problem
- Committed to lifestyle changes
- Use consumer products for heart health
  - Aspirin, vitamin E, fish oil, garlic
- Supplements ↔ Prescription

Sources: CUSTOM 02-03, Segmentation 03, NLA 04, SELECT 06, Gallup 06, GK Study 07, CAB Study 07.

# FDA Agreements Following 2005 Advisory Committee

- Target population can benefit
- Safety and efficacy is appropriate for OTC
- Actual use behavior is satisfactory
  - CUSTOM showed
    - 21% LDL reduction
    - Follow-up cholesterol testing and goal
    - Diet and exercise
    - Compliance and persistence
    - Interaction with doctor & pharmacist

# FDA Recommendations for Additional Study

- Improve and test label
- Maintain strong safety seen in CUSTOM
- Improve communication of
  - Pregnancy warning
  - Muscle safety warning
- Reduce use by
  - Women under 55
  - Consumers with lower CHD risk
- Detail consumer support/monitoring programs

# Non-prescription Statin Criteria

	Addressed
● Target population warrants treatment	2005
● Efficacy	2005
● Safety	2005
● Appropriate consumer decisions	
– Self-selection	
– Improve pregnancy & muscle warning	
– Ongoing use	2005
• Lipid lowering	2005
• Cholesterol test/achieving goal	2005
• Diet & exercise	2005
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• Interaction with healthcare professional	2005
● Consumer support program	2005
● In-market monitoring program	

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# MEVACOR™ Daily: Key Consumer Studies

- CUSTOM: Actual Use Study (2005)
- SELECT: Self-Selection Study (2007)
- Label Comprehension Studies
  - Pivotal SELECT Label Study
  - Muscle Safety Warning Study



# Commitment to Responsible Marketing

- Represents a new approach to life-saving medicines
- GSK experience and track record
- Comprehensive educational program
- Sold only in stores with pharmacies
  - Provides access and enhanced support
  - Optimizes public health opportunity

# Today's Speakers

## **Introduction**

Edwin Hemwall, PhD  
Merck Research Laboratories

## **Public Health Opportunity**

Valentine Burroughs, MD, MBA  
Mount Sinai Medical School

## **Lovastatin Safety and Efficacy**

Ingrid Adamsons, MD, MPH  
Merck Research Laboratories

## **CUSTOM**

Jerry Hansen, RPh  
Merck Research Laboratories

## **SELECT**

Edwin Hemwall, PhD

## **Support & Monitoring Program**

Saul Shiffman, PhD  
University of Pittsburgh

## **Responsible Marketing**

George Quesnelle  
GlaxoSmithKline Consumer Healthcare

## **Conclusion**

Edwin Hemwall, PhD

# Invited Consultants

## **Elizabeth Barrett-Connor, MD**

Professor and Chair  
Department of Family and Preventive Medicine  
Chief, Division of Epidemiology  
Univ. of California San Diego School of Medicine

## **Jerome Cohen, MD**

Professor of Internal Medicine/Cardiology  
Director, Preventive Cardiology Programs  
St. Louis University School of Medicine

## **Antonio M. Gotto, Jr., MD, DPhil**

Dean of the Weill Medical College  
Cornell University

## **Steven Mann, MD**

Mann Healthcare Ltd.  
United Kingdom

## **Jeremy Nobel, MD, MPH**

Department of Health Policy and Management  
Harvard School of Public Health

## **Anthony Scialli, MD**

Vice President, Sciences International  
Adjunct Professor of OB/GYN, Molecular Biology  
Georgetown University Medical Center

## **Paul Watkins, MD**

V. S. Caviness Distinguished Professor of Medicine  
Professor of Pharmacotherapy  
University of North Carolina

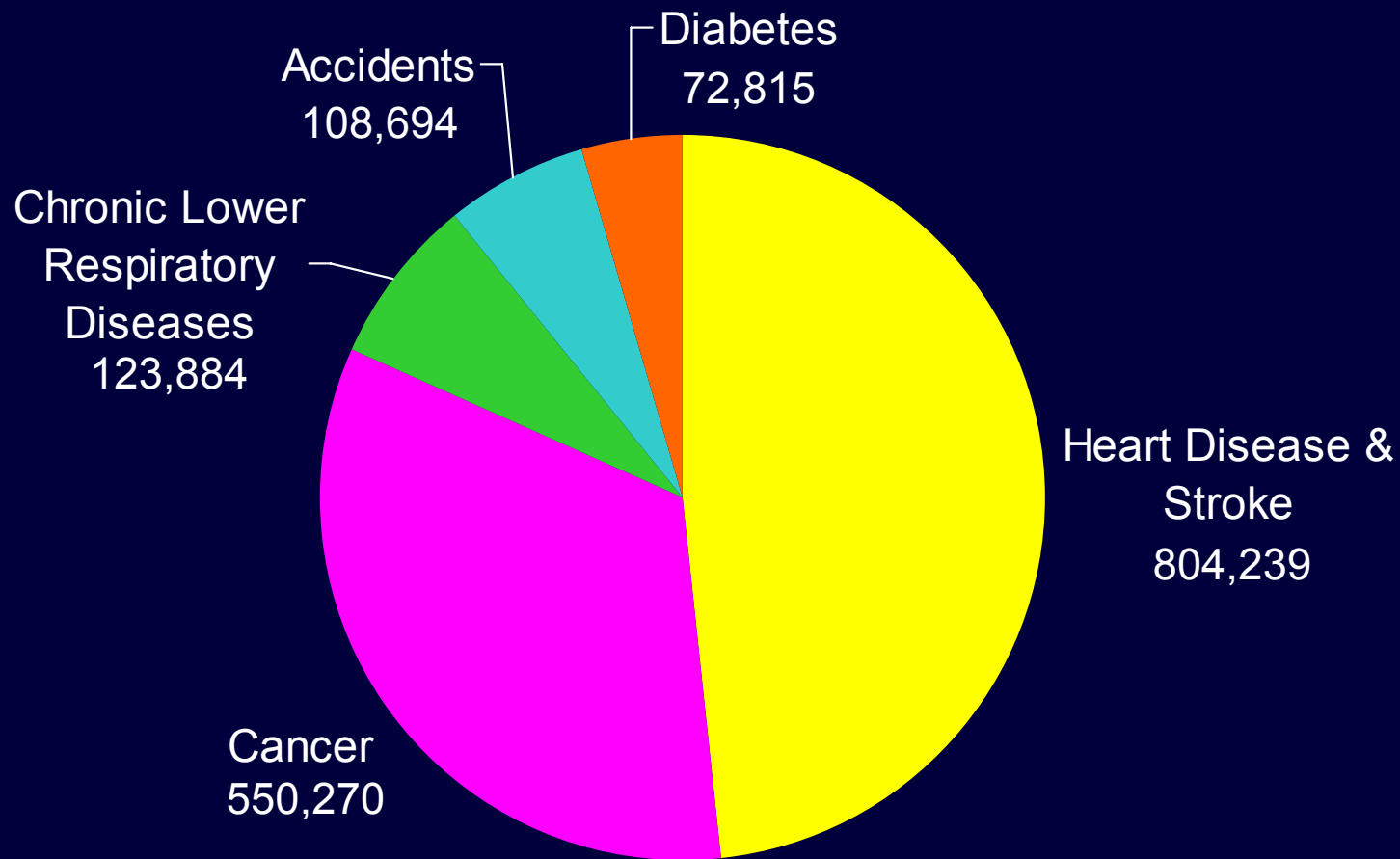
## **Robert L. Wortmann, MD**

Professor of Medicine  
Dartmouth Hitchcock Medical Center

# Nonprescription MEVACOR™ Daily Public Health Benefit

Valentine Burroughs, MD MBA  
*Associate Professor of Medicine*  
Mount Sinai Medical School, New York City

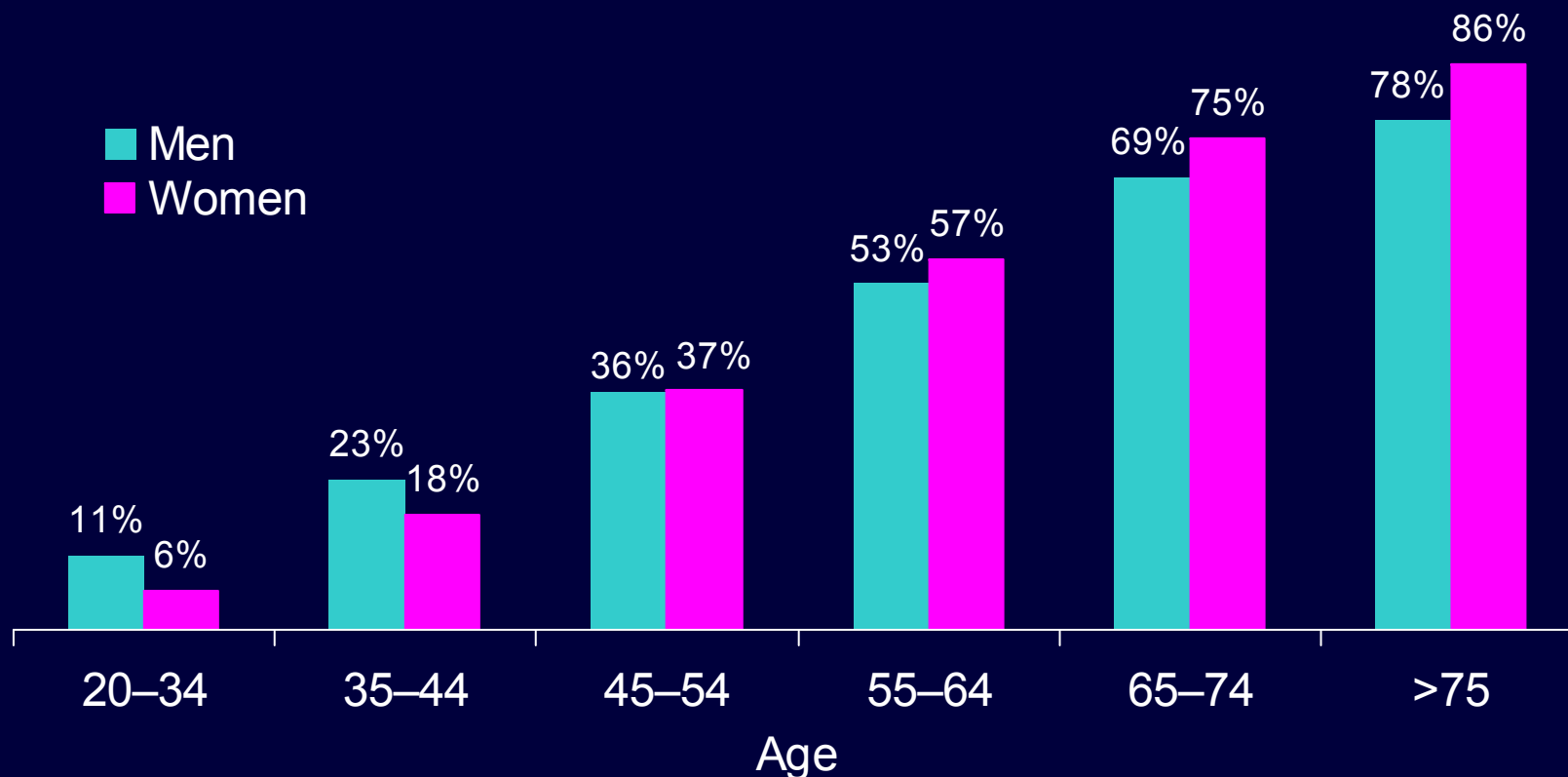
# Cardiovascular Disease Kills More Americans Than Any Other Disease



Source: National Vital Statistics Reports, Vol. 54, No. 19, June 28, 2006.  
Data for 2004.

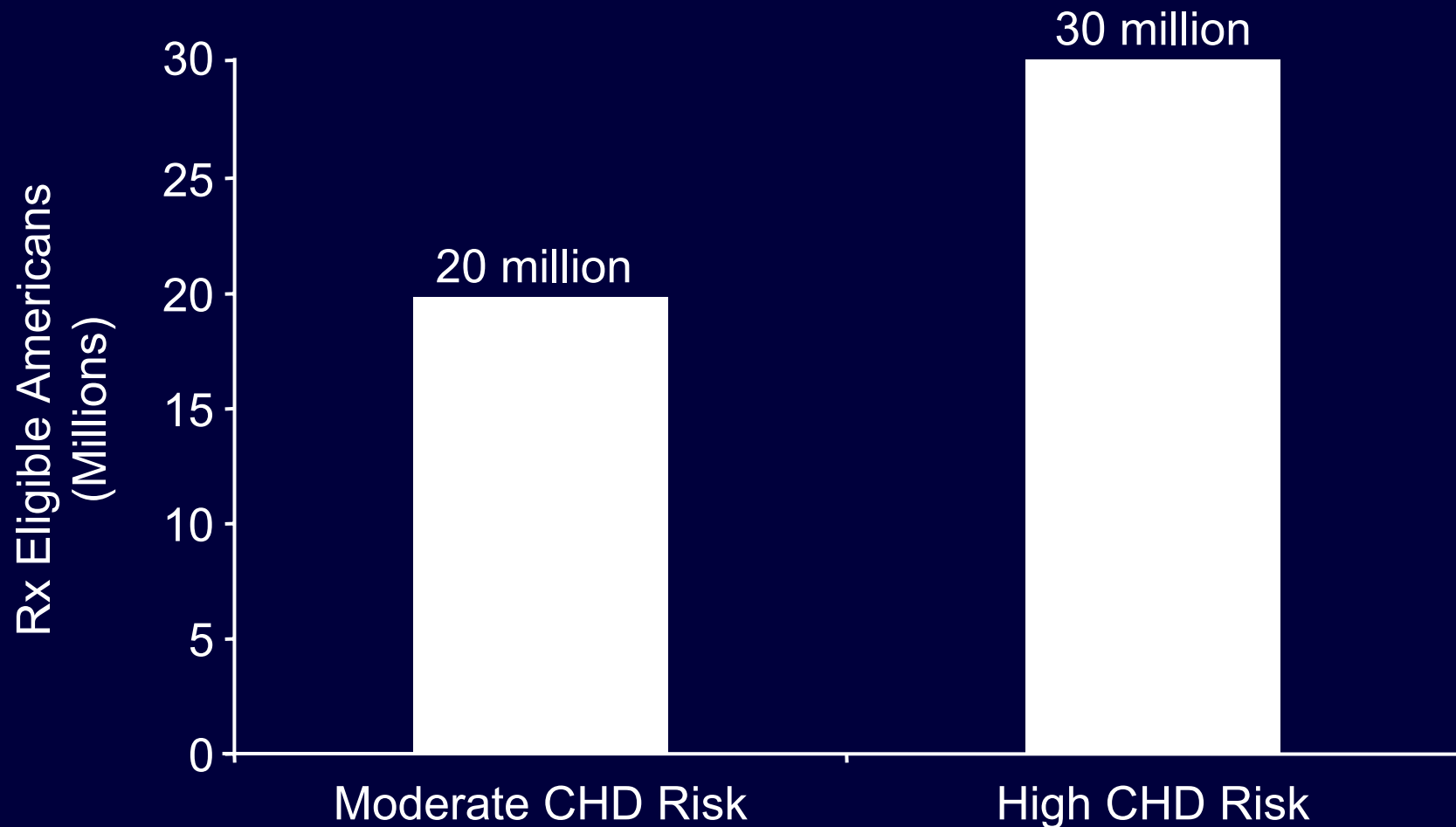
# Prevalence of Cardiovascular Disease Remains High in U.S.

Percent of Population With Cardiovascular Disease  
by Age and Gender, U.S.: 1999–2002



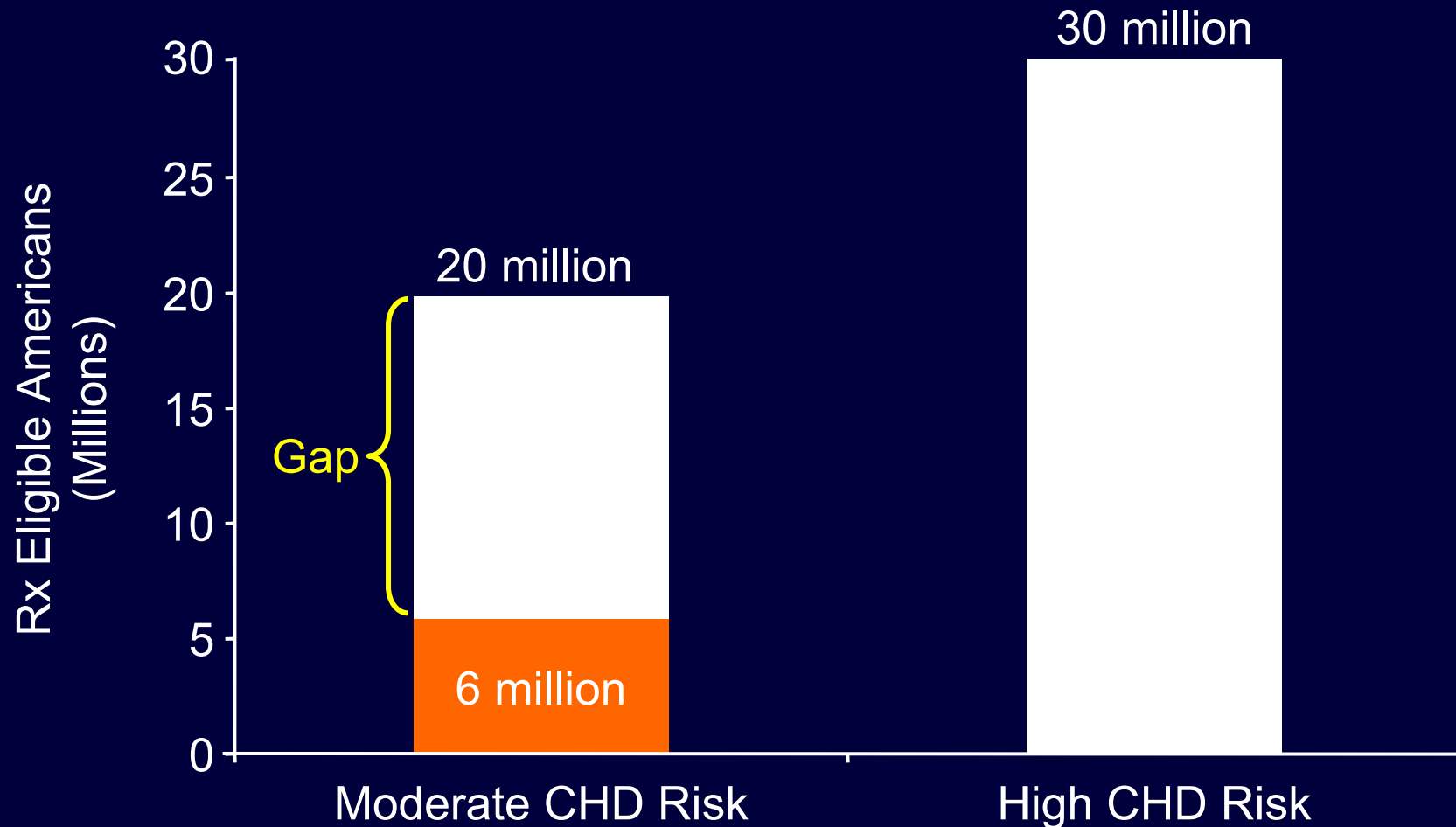
AHA Heart Disease and Stroke Statistics—2006 Update.

# OTC Statin Therapy Could Help Reduce Cholesterol Treatment Gap



NHANES 1999 - 2002, Gallup Study of Cholesterol-Lowering Options 2005.

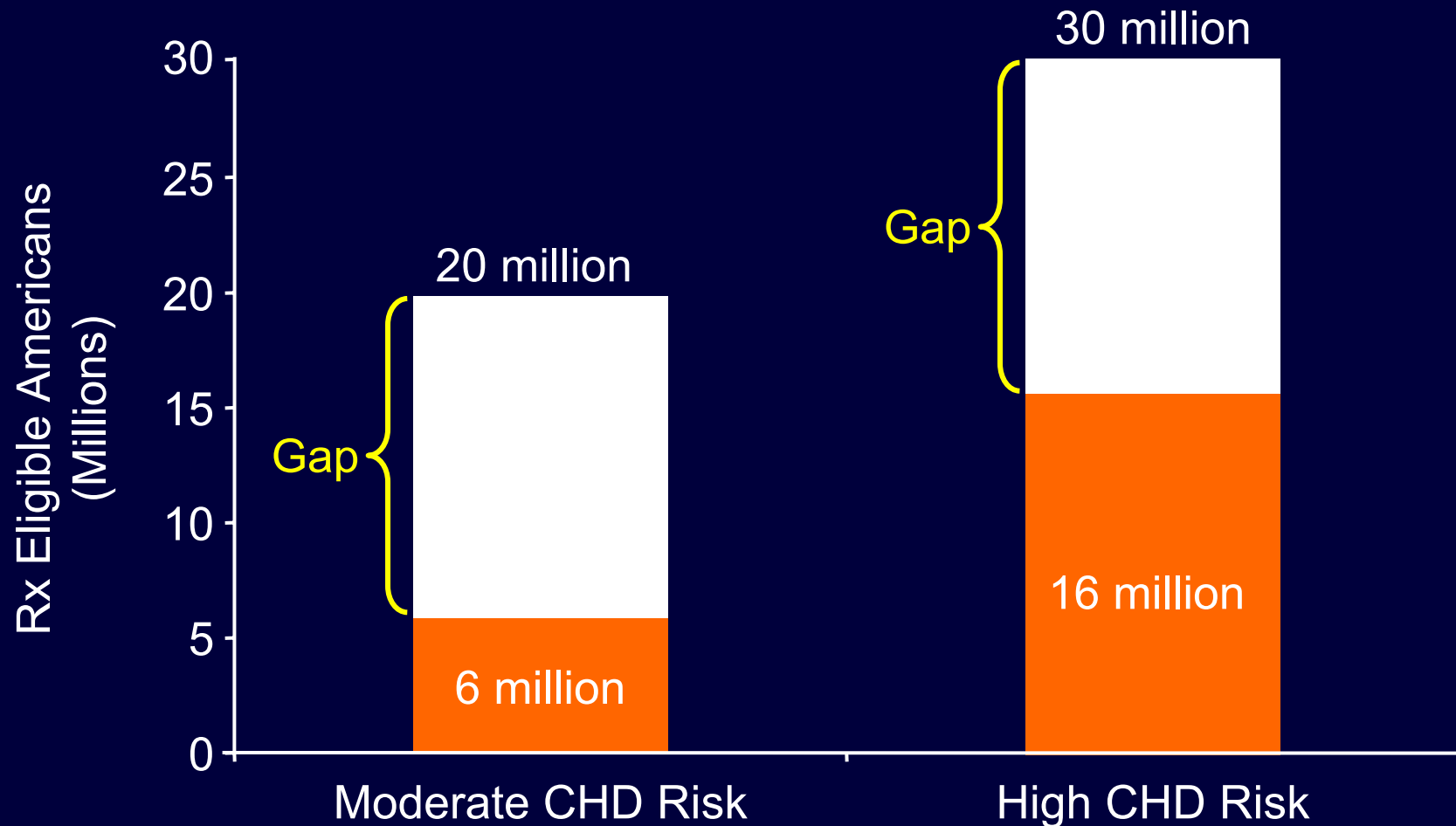
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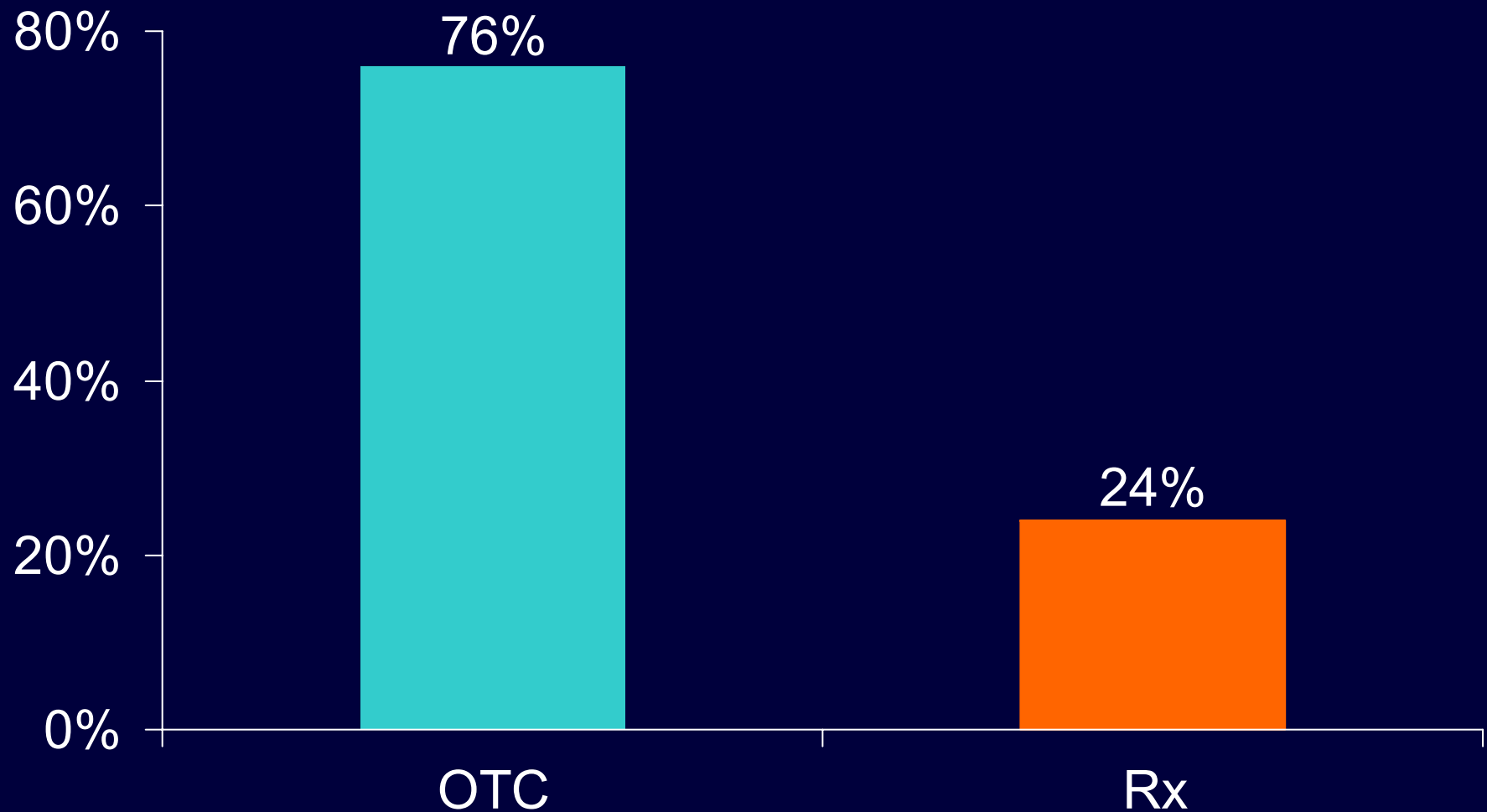
# Potential Public Health Benefit of OTC Statin Can Be Estimated

- Based on CUSTOM data (Brass, et al.<sup>†</sup>)
  - 23,000-33,000 CHD events would be prevented per million people over 10 years
- Based on U.S. population (Gemmell, et al.<sup>‡</sup>)
  - 185,000 CHD events would be prevented in moderate-risk people in the U.S. over 5 years

<sup>†</sup> *Am J Cardiol* 2006;97:851-856.

<sup>‡</sup> *Am J Cardiovasc Drugs* 2007;7:299-302.

# Many Moderate Risk Consumers Prefer OTC vs. Rx Cholesterol Medication (N=710)



National Consumers League/Harris Interactive 2007 Survey, Q 610/611.

# Why Moderate Risk Population Prefers OTC to Rx (N=710)

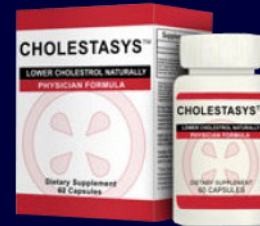
- OTC
  - 80% said more suitable for those who take charge of their health
  - 70% said more suitable for someone with their health care needs
- Rx
  - 86% said more suitable for someone in poor health

# Many People Take Dietary Supplements to Lower Cholesterol

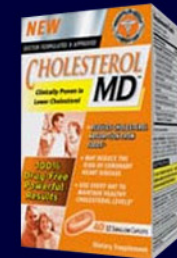
*“Lower LDL and Triglycerides Without Exercise or Change in Diet”*



*“Drop Your Cholesterol 30 points in 30 Days or It's FREE”*



*“97.6% Experience Positive Results”*



*Discover how you can lower your BAD CHOLESTEROL safely and naturally... without expensive prescriptions and their harmful side effects.*

*“SAFE and Effective... All Natural... No Side Effects”*



*Cholesterol Care™ Reduce Your Cholesterol Quickly and Easily.*

*“Causes Zero negative side effects, only positive benefits!”*



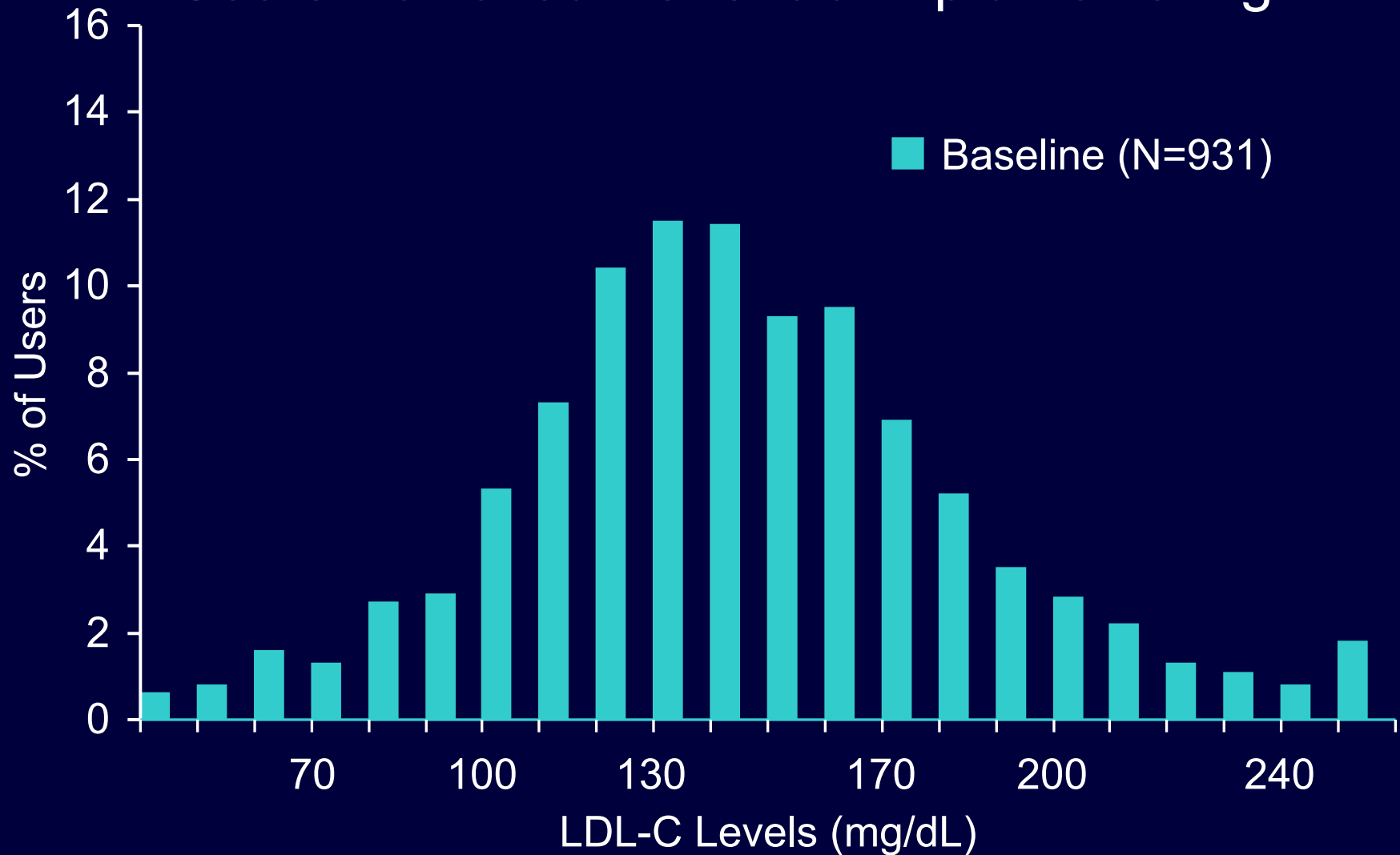
*Red Rice Yeast Healthier than Lipitor® for Lowering Your Cholesterol.*



# Lovastatin 20 mg OTC Can Help Shift Curve

CUSTOM Data

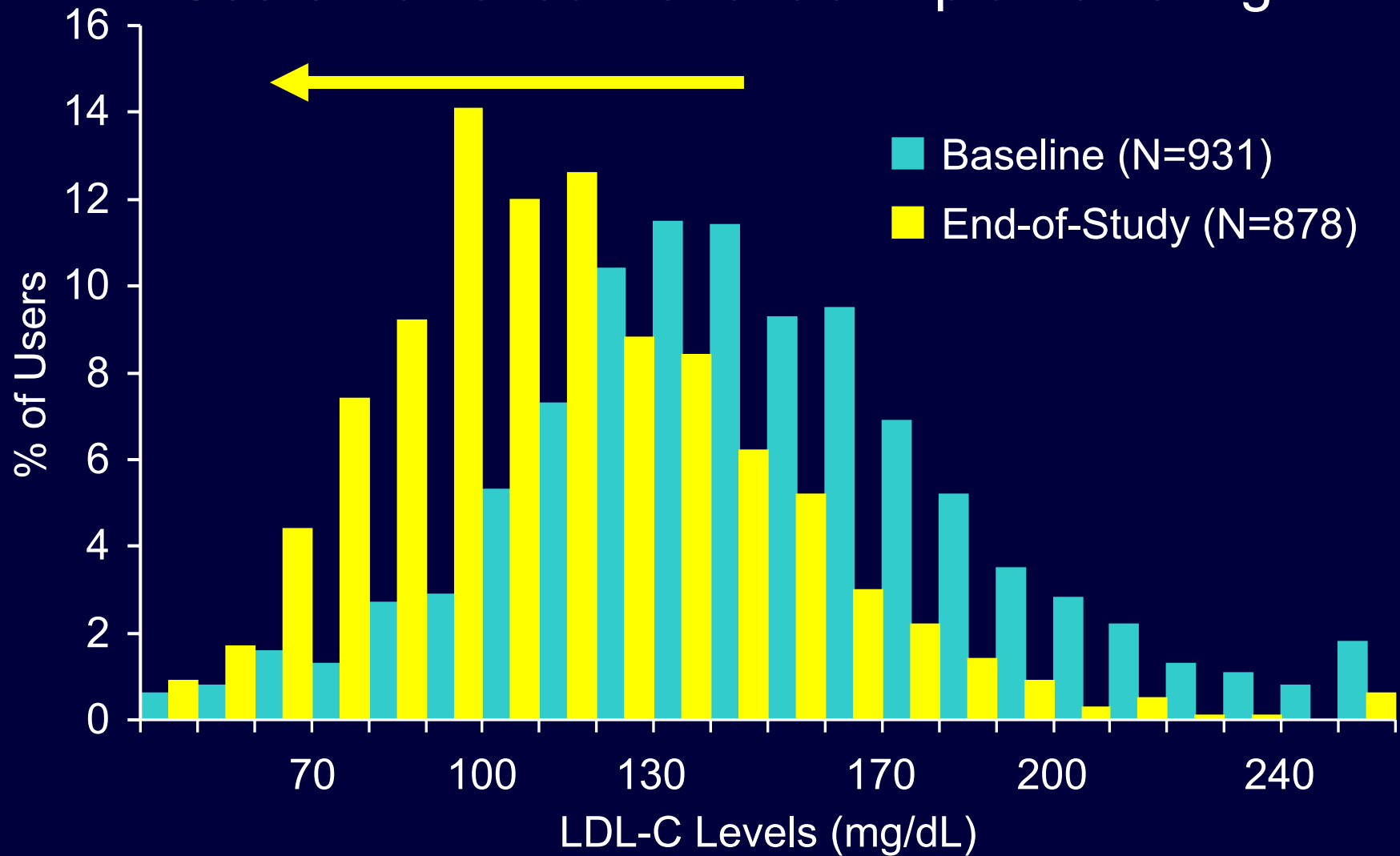
Users Achieved Beneficial Lipid Lowering



# Lovastatin 20 mg OTC Can Help Shift Curve

CUSTOM Data

Users Achieved Beneficial Lipid Lowering



**MEVACOR™ Daily can help address  
an important public health need.**

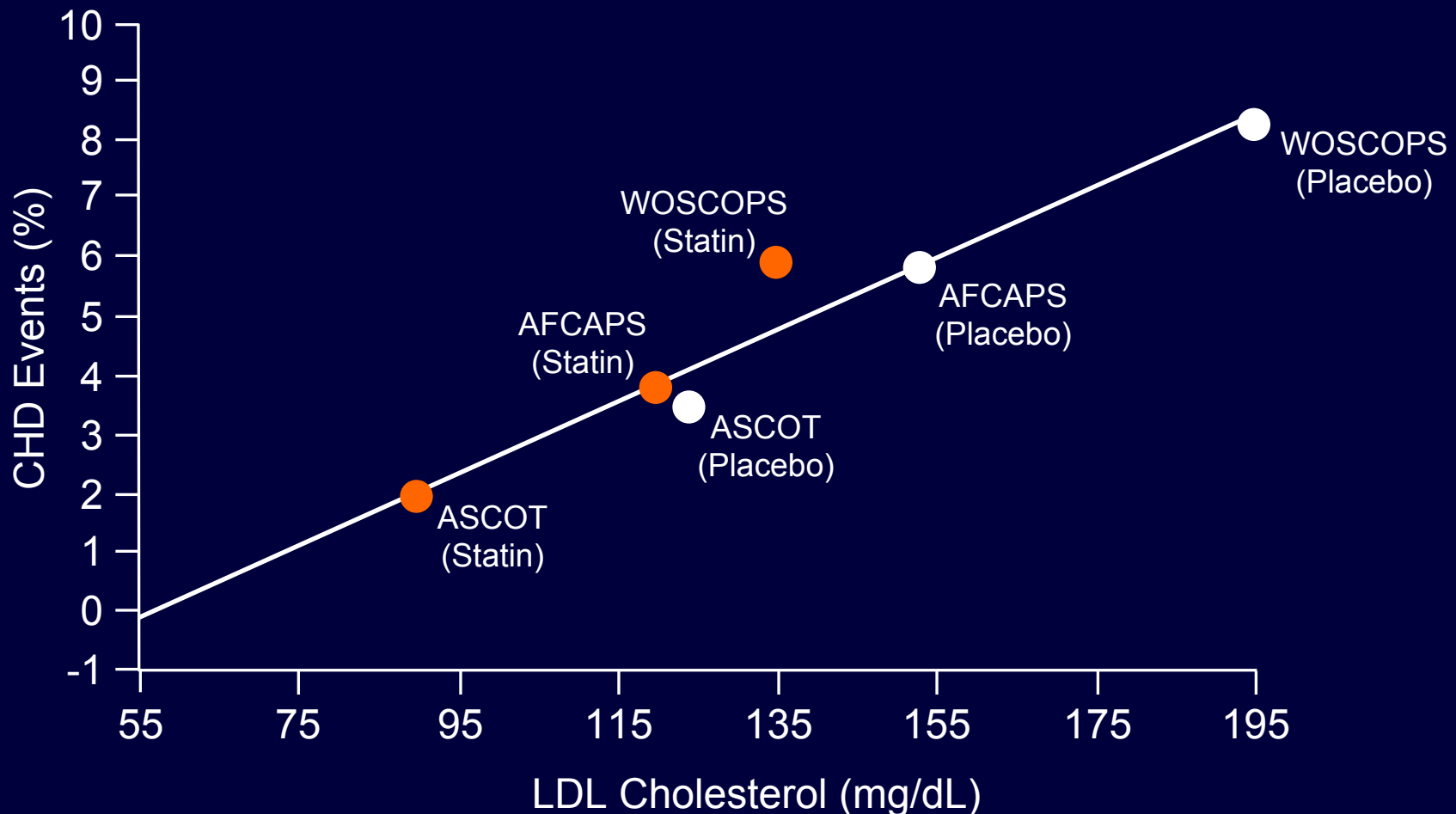


# Lovastatin: Efficacy and Safety

Ingrid Adamsons, MD, MPH  
Merck Research Laboratories

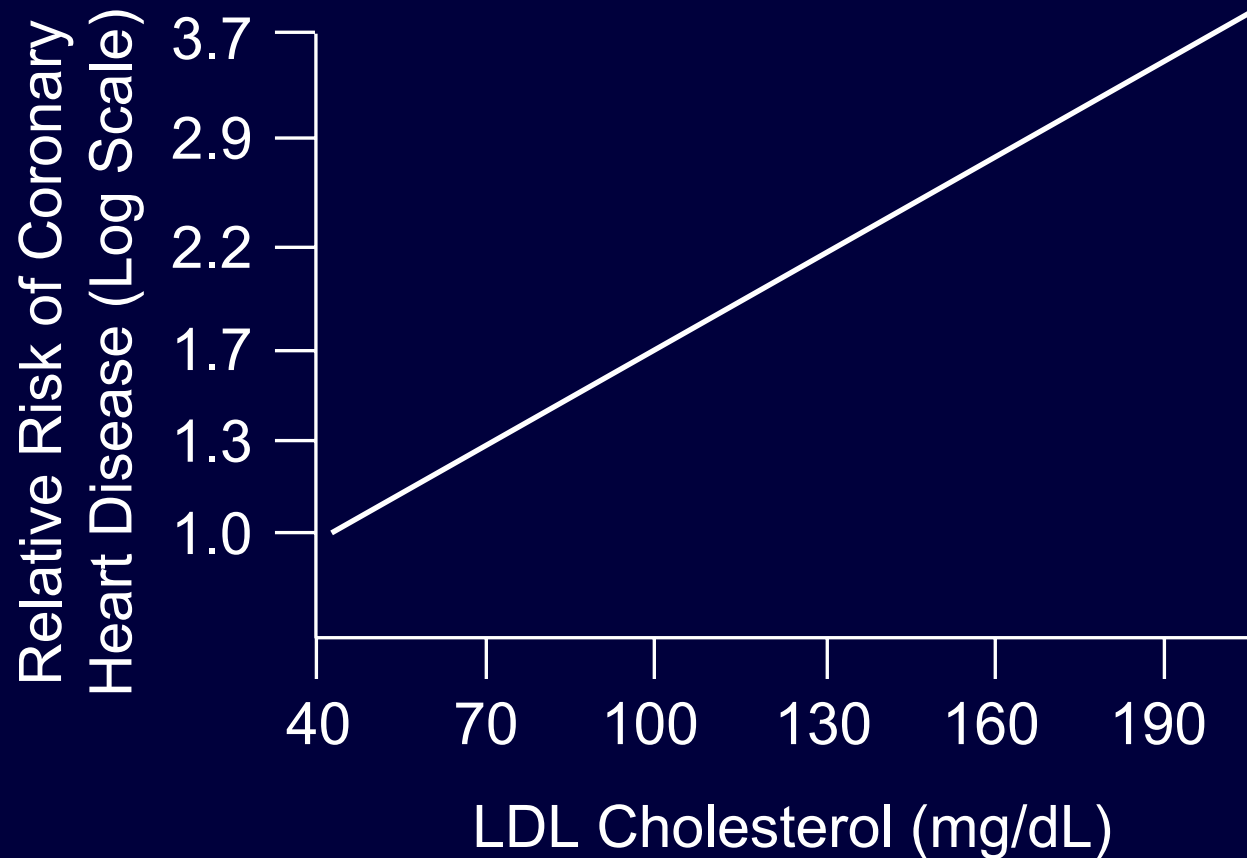
# Lower LDL-Cholesterol Results in Lower Cardiac Event Rates

Primary Prevention Studies: Mean Values on Treatment



O'Keefe et al. *J Am Coll Cardiol* 2004;43:2142-2146.

# LDL Cholesterol: Lower Is Always Better



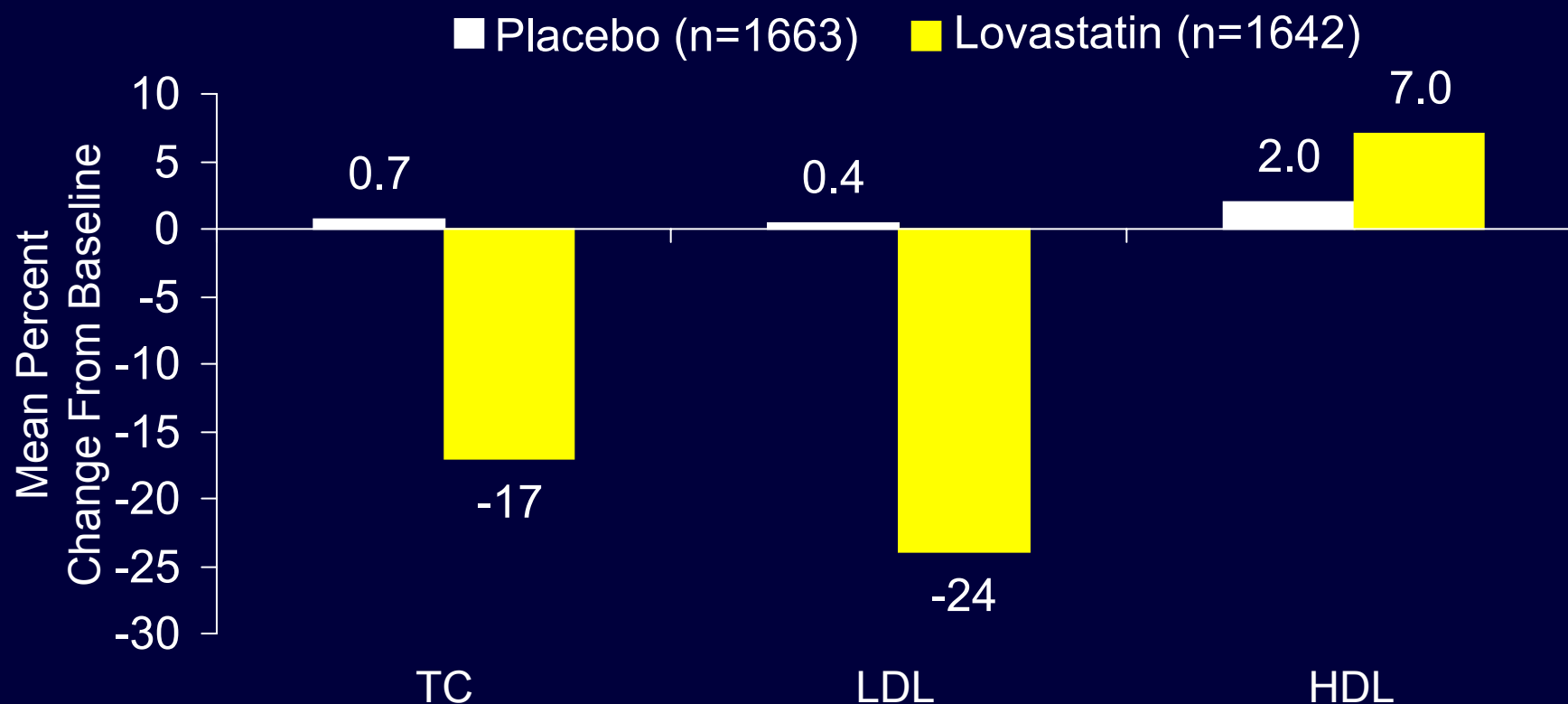
Grundy et al. *Circulation*. 2004.

# MEVACOR™ (Lovastatin): Demonstrated Efficacy and Safety

- First FDA approved statin (1987)
- Extensive marketed use
  - 35+ million patient treatment-years
- Well studied in many clinical trials including
  - EXCEL: 48 week clinical study
    - 8245 patients
  - AFCAPS/TexCAPS: 5+ year endpoint study
    - 6605 patients

# Lovastatin Effective in Lowering LDL-C

Expanded Clinical Evaluation of Lovastatin (EXCEL) Study  
Lovastatin 20 mg Daily

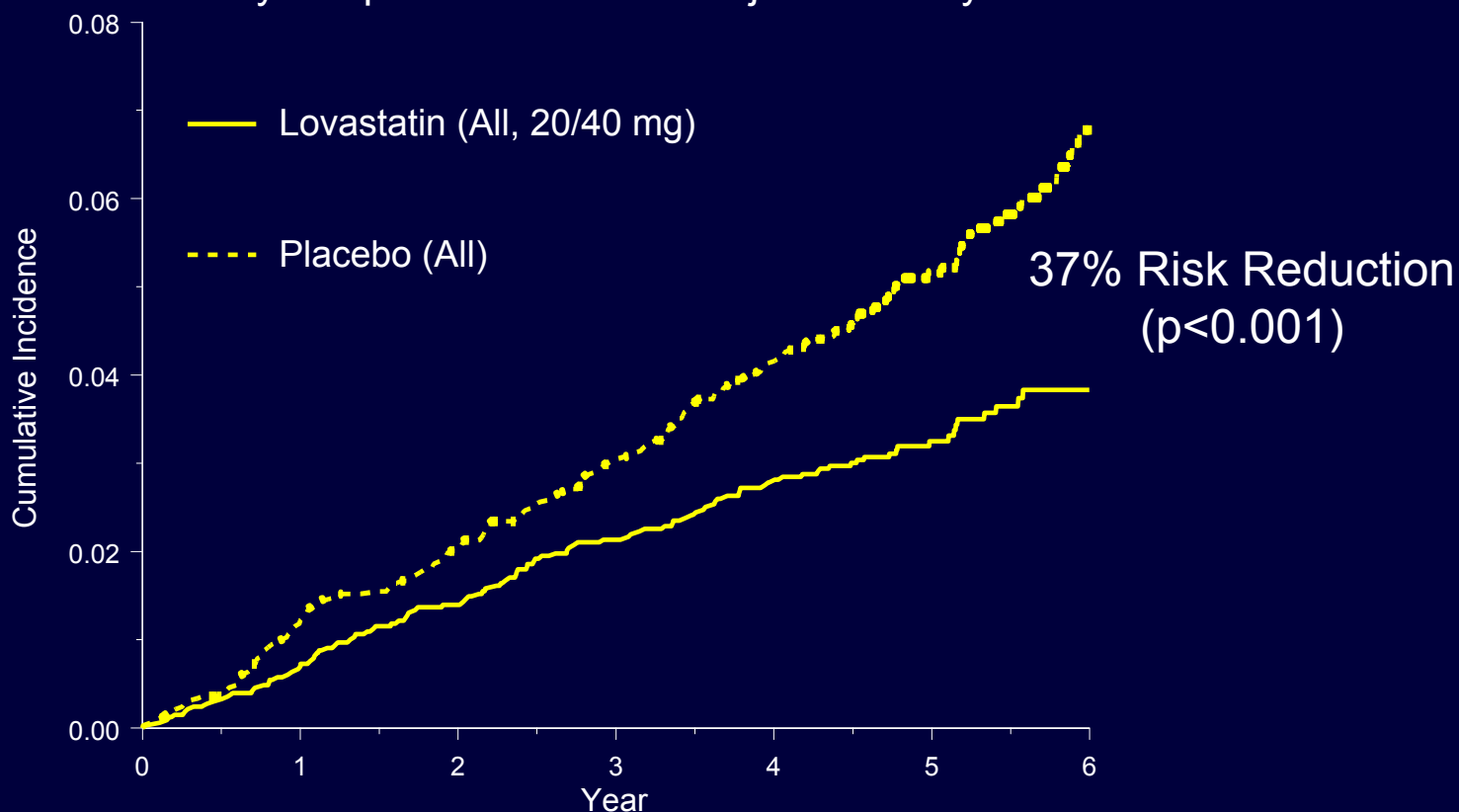


p-Value <0.001 for all lipid parameters: between group differences and changes on lovastatin from baseline to Week 48.

# Lovastatin Effective in Reducing Coronary Events

Air Force/Texas Coronary Atherosclerosis Prevention Study (AFCAPS/TexCAPS)

Primary Endpoint: First Acute Major Coronary Event



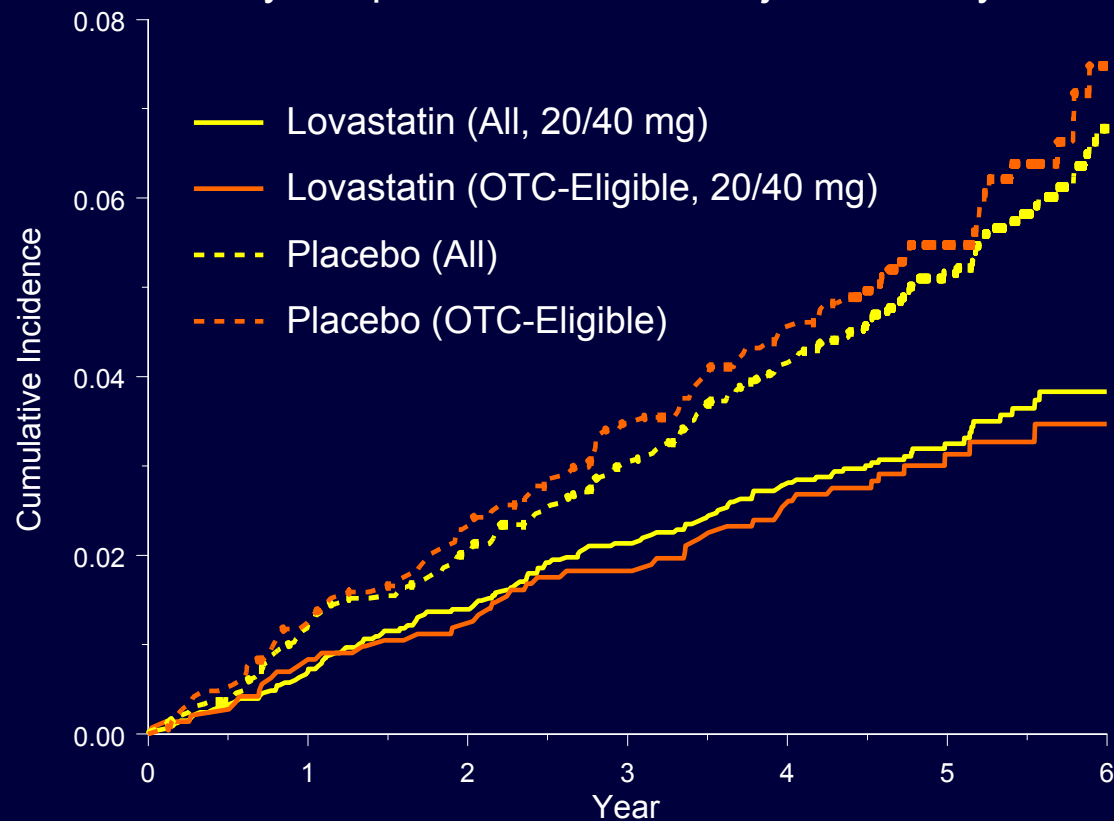
No. at risk:						
Lovastatin N=	3,304	3,270	3,228	3,184	3,134	1,688
Placebo N=	3,301	3,251	3,211	3,159	3,092	1,644

Downs JR et al. *JAMA* 1998;279:1615-1622.

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# Lovastatin Similar to Placebo in Key Safety Parameters

AFCAPS/TexCAPS (5+ years)

	Placebo N=3248 %	20 mg N=1586 %	40 mg N=1657 %
Muscle enzymes (CPK>10x ULN)	0.6	0.7	0.6
Liver enzymes: ALT (Consecutive elevations 3x ULN)	0.3	0.7	0.4
Muscle pain (Myopathy-myalgia with CPK>10x ULN)	0	0	0
Rhabdomyolysis (Myopathy with end-organ damage)	0.06	0.07	0
Hepatic failure	0	0	0



# No Increase in Muscle AEs With Strong CYP3A4 Inhibitors

Subset of AFCAPS/TexCAPS Patients

	Lovastatin 20 to 40 mg (N=535 <sup>†</sup> )		Placebo (N=511)	
	n	(%)	n	(%)
Myopathy/rhabdomyolysis	0	(0)	0	(0)
Muscle weakness	1	(0.2)	2	(0.4)
Myalgia	3	(1)	4	(1)
Any musculoskeletal AE	42	(8)	39	(8)

<sup>†</sup> Erythromycin (387), clarithromycin (107), ketoconazole (42), itraconazole (51).

# Lovastatin Use With Liver Disease

- Database study of patients with liver dysfunction or disease
  - 93,106 total in study
  - 13,491 received lovastatin
- Exposure to lovastatin associated with substantially reduced risk of adverse hepatic outcomes
- FDA Briefing Document concludes†
  - “...sufficient evidence that the risk of hepatotoxicity is minimal in patients with common asymptomatic liver diseases to address the safe use of this product in the nonprescription setting.”

† Attachment 3, page 8.

# No Increased Incidence of ALS

- FDA Briefing Document<sup>†</sup>
  - Clinical trials: Similar incidence for statin and placebo
    - ~4.4 cases per 100,000 PTY
  - No increased incidence in U.S. in past 20 years
- Lovastatin clinical trials of 6+ months duration (48 weeks to 5.2 years)
  - No reports with lovastatin (n=10,171) or placebo (n=5280)

<sup>†</sup> Attachment 3, page 56.

# Lovastatin: Effective Treatment for Primary Prevention

- Effectively decreases LDL-C and CHD risk
- Excellent safety profile
- Demonstrated
  - With OTC dose
  - In OTC population

MEVACOR™ Daily

CUSTOM:  
Consumer Use Study of OTC MEVACOR

Jerry Hansen, RPh  
Merck Research Laboratories

# CUSTOM: Key Objectives

- Determine if consumers could appropriately self-select and use MEVACOR™ Daily
- Determine level of LDL reduction OTC
- Collect data on key questions
  - Compliance
  - Diet and exercise
  - Physician interaction

# CUSTOM Study Overview (N=3346)

- Simulated OTC setting
- 1059 purchased and used
- 6-month actual use trial
- Consumer support program

# Two-Step Consumer Support Program

In-Store Support

Ongoing Support



Promotes Diet & Exercise and  
Healthcare Provider Interaction



# Key Results of CUSTOM Consistent With Prescription Experience

CUSTOM  
Results  
%

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Rx Care  
(Statins)  
%

---

# Key Results of CUSTOM Consistent With Prescription Experience

	CUSTOM Results %	Rx Care (Statins) %
Obtained LDL-C goal	62	57 <sup>a</sup> - 68 <sup>b</sup>

<sup>a</sup> Frolkis, et al. *Am J Cardiol* 2004; 94:1310-1312. <sup>b</sup> Pearson, et al. *Arch Intern Med* 2000; 160:459-67.

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Persistence	62	43 <sup>c</sup> - 68 <sup>d</sup>

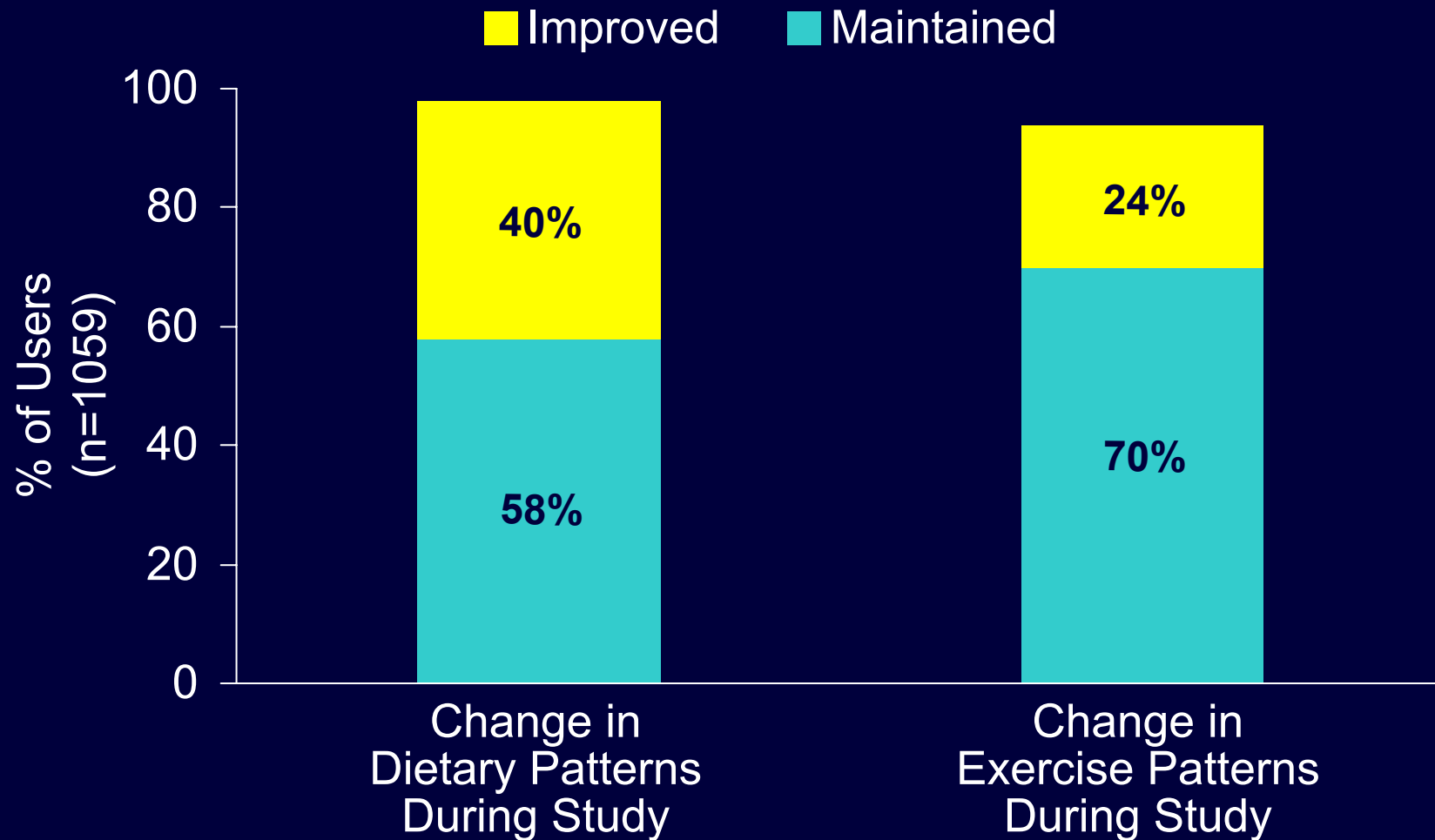
<sup>a</sup> Frolkis, et al. *Am J Cardiol* 2004; 94:1310-1312. <sup>b</sup> Pearson, et al. *Arch Intern Med* 2000; 160:459-67.  
<sup>c</sup> Benner, et al. *JAMA* 2002;288:455-461. <sup>d</sup> Grant, et al. *Arch Intern Med* 2004; 164:2343-2348.

# Key Results of CUSTOM Consistent With Prescription Experience

	CUSTOM Results %	Rx Care (Statins) %
Obtained LDL-C goal	62	57 <sup>a</sup> - 68 <sup>b</sup>
Persistence	62	43 <sup>c</sup> - 68 <sup>d</sup>
Average LDL-C reduction	21	24 <sup>e</sup> - 25 <sup>f</sup>

<sup>a</sup> Frolkis, et al. *Am J Cardiol* 2004; 94:1310-1312. <sup>b</sup> Pearson, et al. *Arch Intern Med* 2000; 160:459-67.  
<sup>c</sup> Benner, et al. *JAMA* 2002;288:455-461. <sup>d</sup> Grant, et al. *Arch Intern Med* 2004; 164:2343-2348.  
<sup>e</sup> EXCEL data. <sup>f</sup> AFCAPS data.

# MEVACOR™ Daily Program Promotes Lifestyle Changes

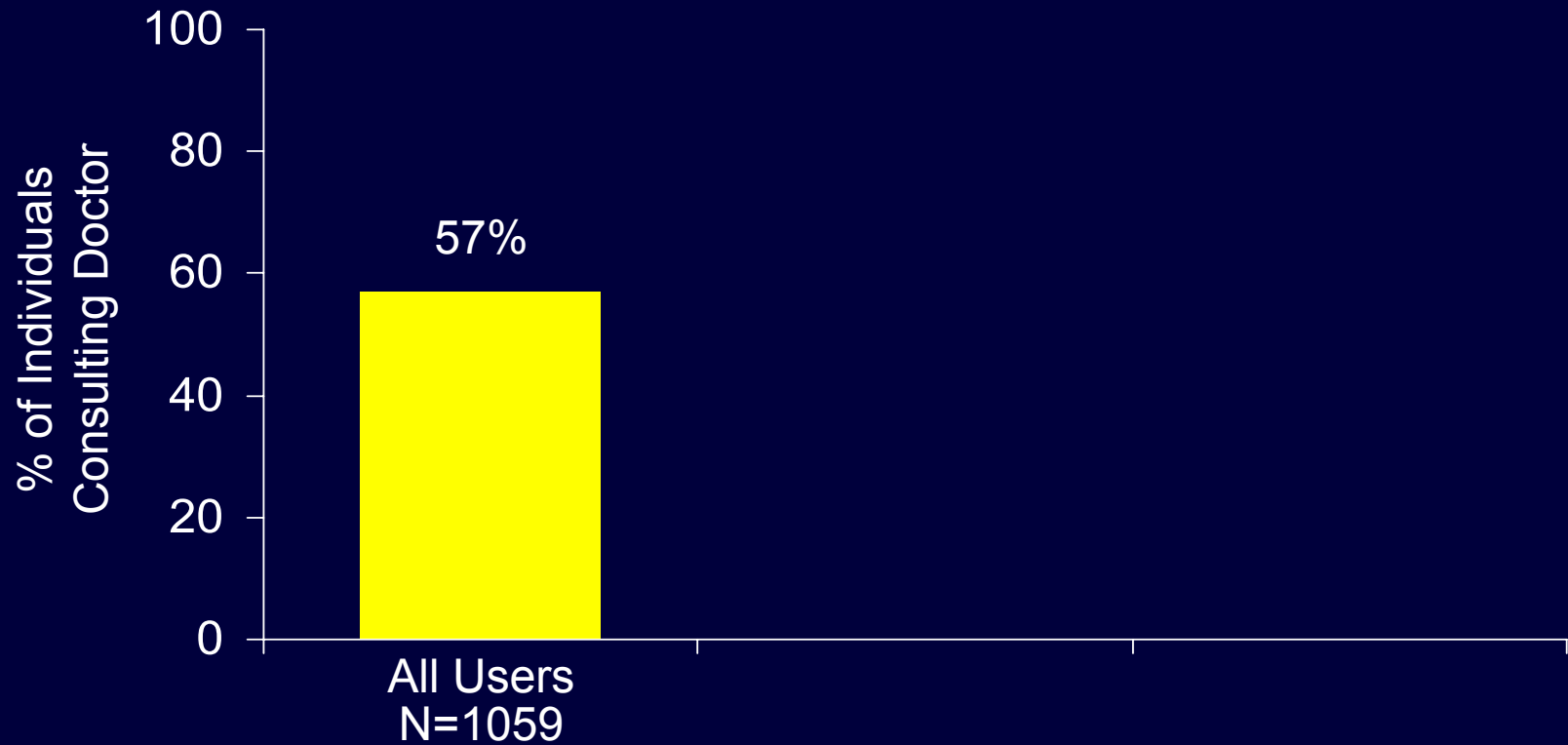


# MEVACOR™ Daily Program Drives Healthcare Professional Interaction

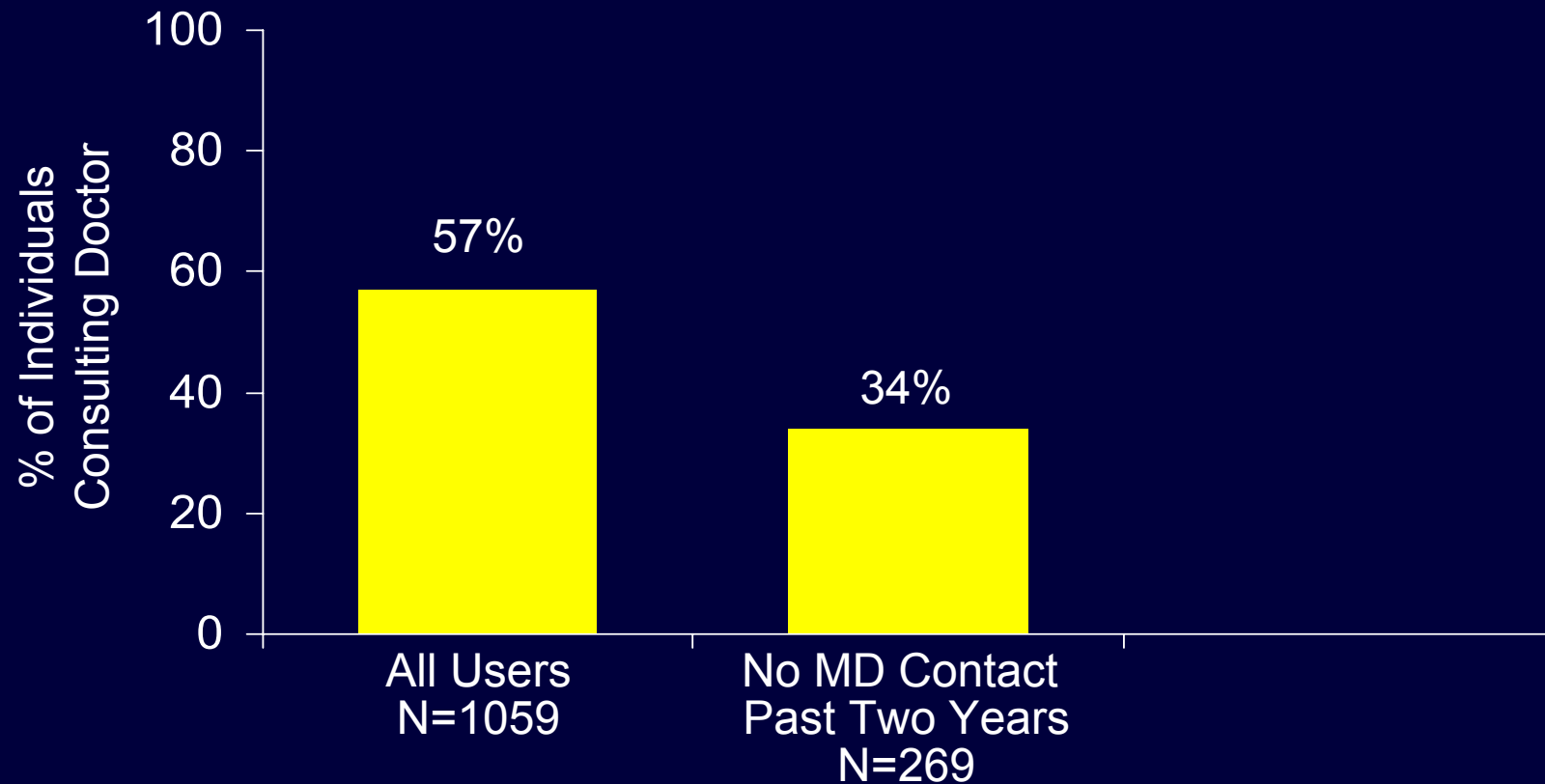
- Emphasized throughout program
- High-Risk Referral System



# MEVACOR™ Daily Program Encourages Interaction With Physician

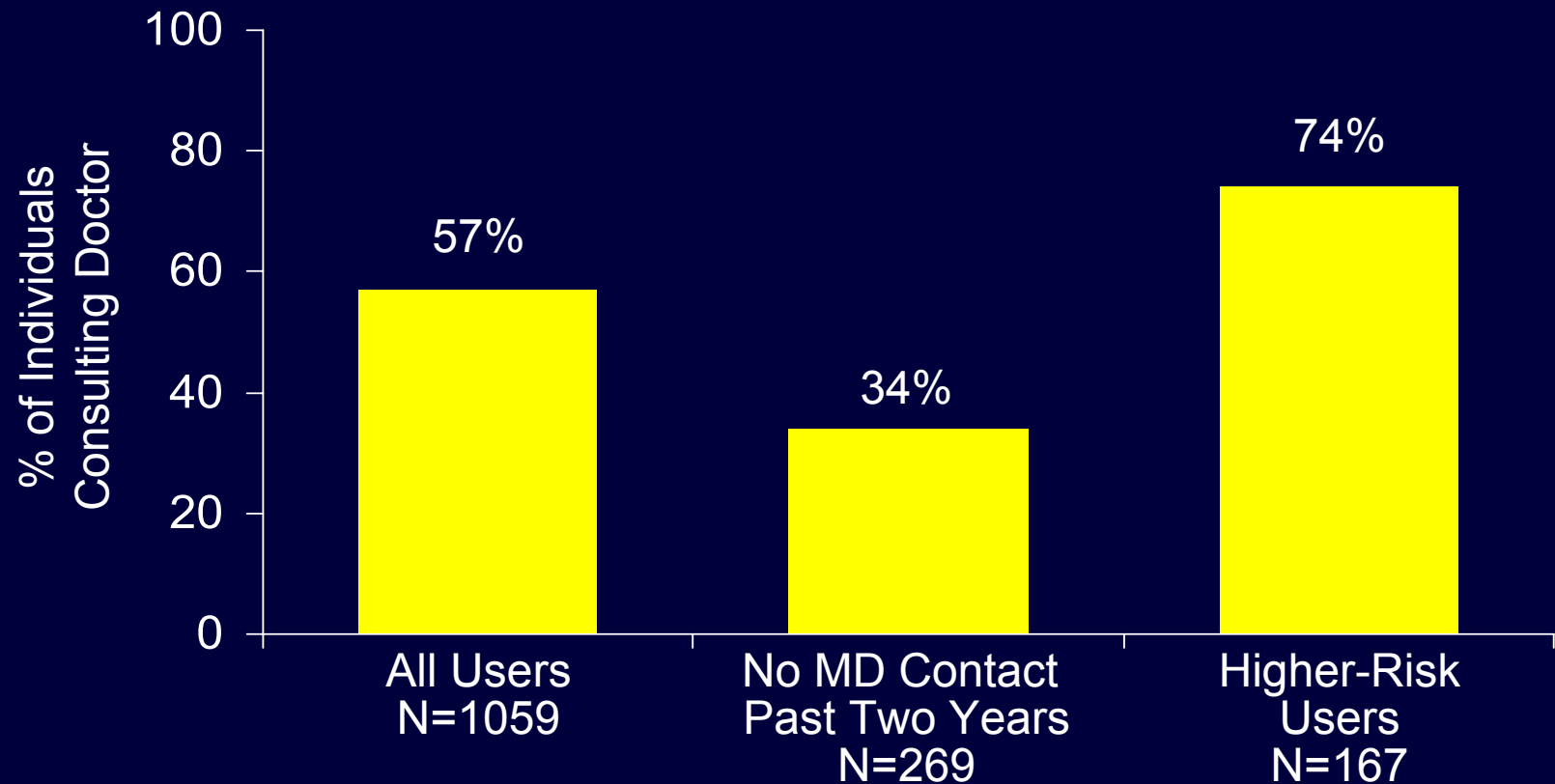


# MEVACOR™ Daily Program Encourages Interaction With Physician





# MEVACOR™ Daily Program Encourages Interaction With Physician



# CUSTOM Summary

- CUSTOM Consumer Results
  - Reduced LDL 21%
  - Maintained/improved diet and exercise
  - Appropriately interacted with physician
- Consumer Support Program
  - Responsible, comprehensive, tested

# MEVACOR™ Daily

## SELECT: Self-Evaluation of Lovastatin to Enhance Cholesterol Treatment

Edwin L. Hemwall, PhD  
Merck Research Laboratories

# SELECT: Key Objectives

- Maintain high safety scores achieved in CUSTOM
- Improve self-selection in
  - Women less than 55 years of age
  - Women of childbearing potential
  - People with lower CHD risk

# New Front Panel Emphasizes Age Requirement



# MEVACOR<sup>TM</sup>

Lovastatin 20 mg **Daily**  
CHOLESTEROL REDUCER

This Product is **only for:**



**WOMEN** age 55 and older



**MEN** age 45 and older

If you meet these age requirements,  
read back for more information.

45 TABLETS



# New Front Panel Emphasizes Age Requirement



The image shows a box of Mevacor Daily (Lovastatin 20 mg) with a new front panel overlay. The box features a photograph of an elderly couple and the text: **MEVACOR™**, Lovastatin 20 mg, CHOLESTEROL REDUCER, and **Daily**. The new front panel, which is blue, contains the following text:

**This Product is only for:**

-  **WOMEN** age 55 and older
-  **MEN** age 45 and older

If you meet these age requirements, read back for more information.

On the original box, the text "only for:" is partially visible above a pink box containing "age 55 and older" and a light blue box containing "5 and older". Below this, it says "ese age requirements, more information." and "45 TABLETS" next to a tablet icon.

# New Back Panel Highlights What to Do Before Purchasing

MEVACOR™ Daily

## Before buying:

- You must have tried a healthy diet and exercise to reduce your cholesterol.
- You must have had a fasting cholesterol test and know your cholesterol numbers.
- Your LDL “bad” cholesterol must be 130 to 170.

### Drug Facts

#### Active ingredient (in each tablet)

Lovastatin 20 mg.....

#### Purpose

.....Cholesterol reducer ▶

You must read the entire Drug Facts label inside

LIFT THIS FLAP

▶ READ LABEL WARNINGS CAREFULLY ▶

LIFT  
▶  
HERE

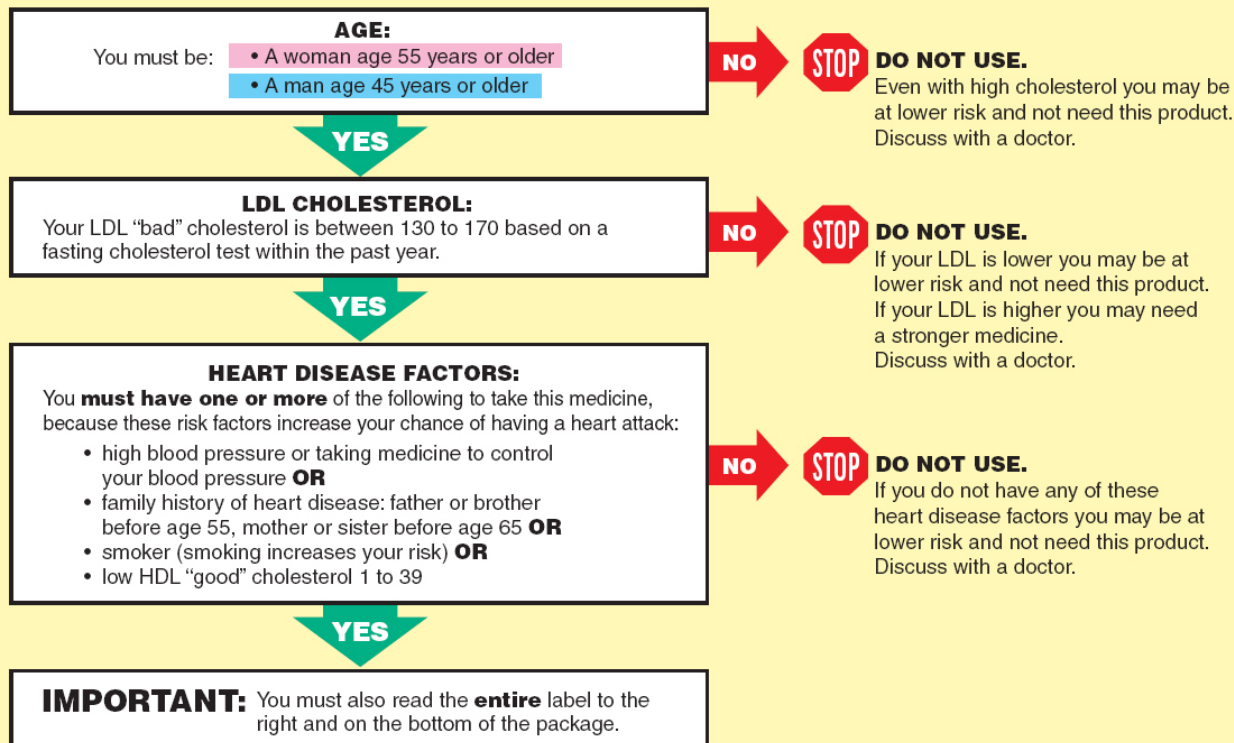
# Redesigned Package Includes Decision Tree to Aid in Self-Selection

**Drug Facts** (continued)

**Use** To help lower cholesterol, which may prevent a first heart attack. ▶

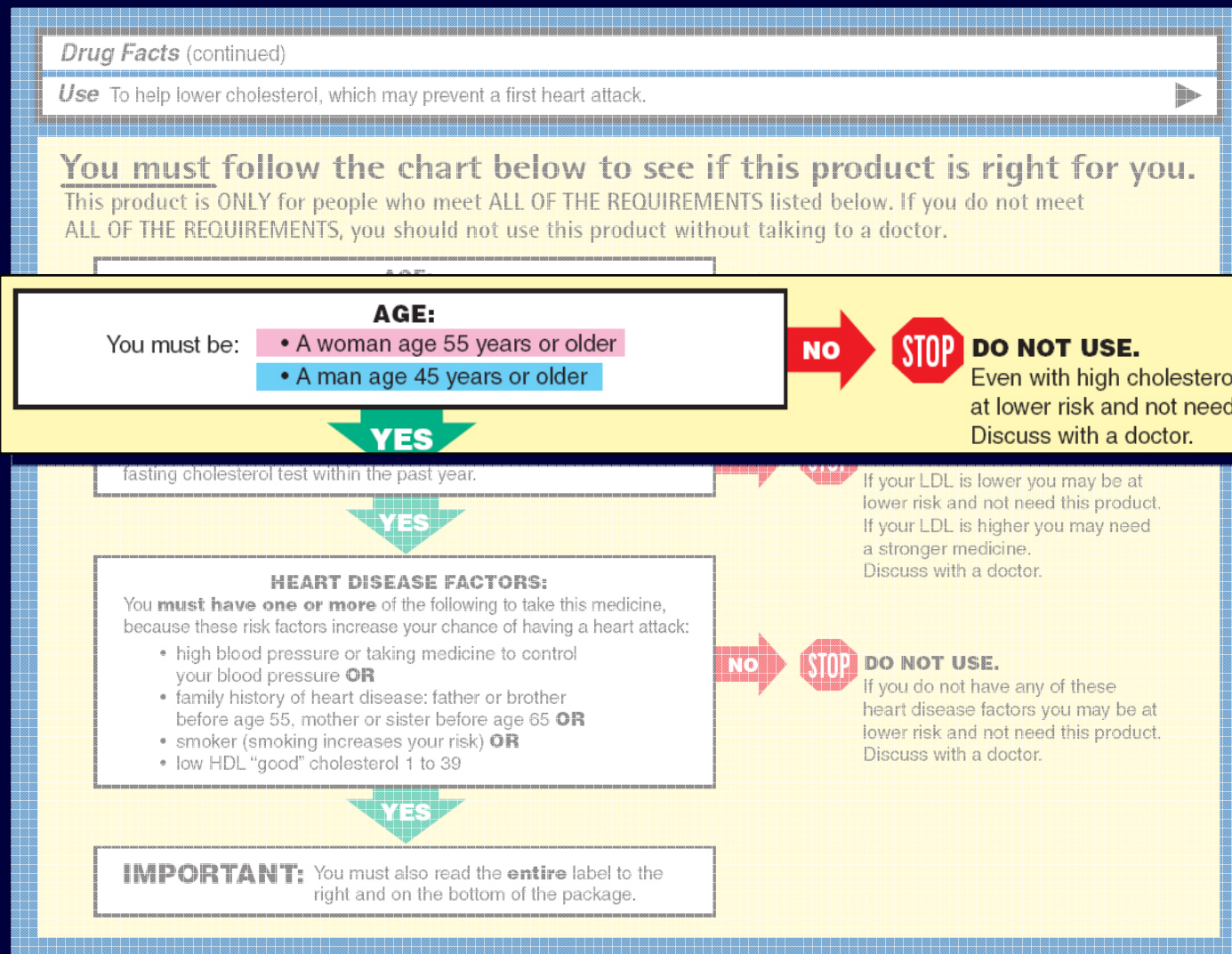
## You must follow the chart below to see if this product is right for you.

This product is **ONLY** for people who meet **ALL OF THE REQUIREMENTS** listed below. If you do not meet **ALL OF THE REQUIREMENTS**, you should not use this product without talking to a doctor.

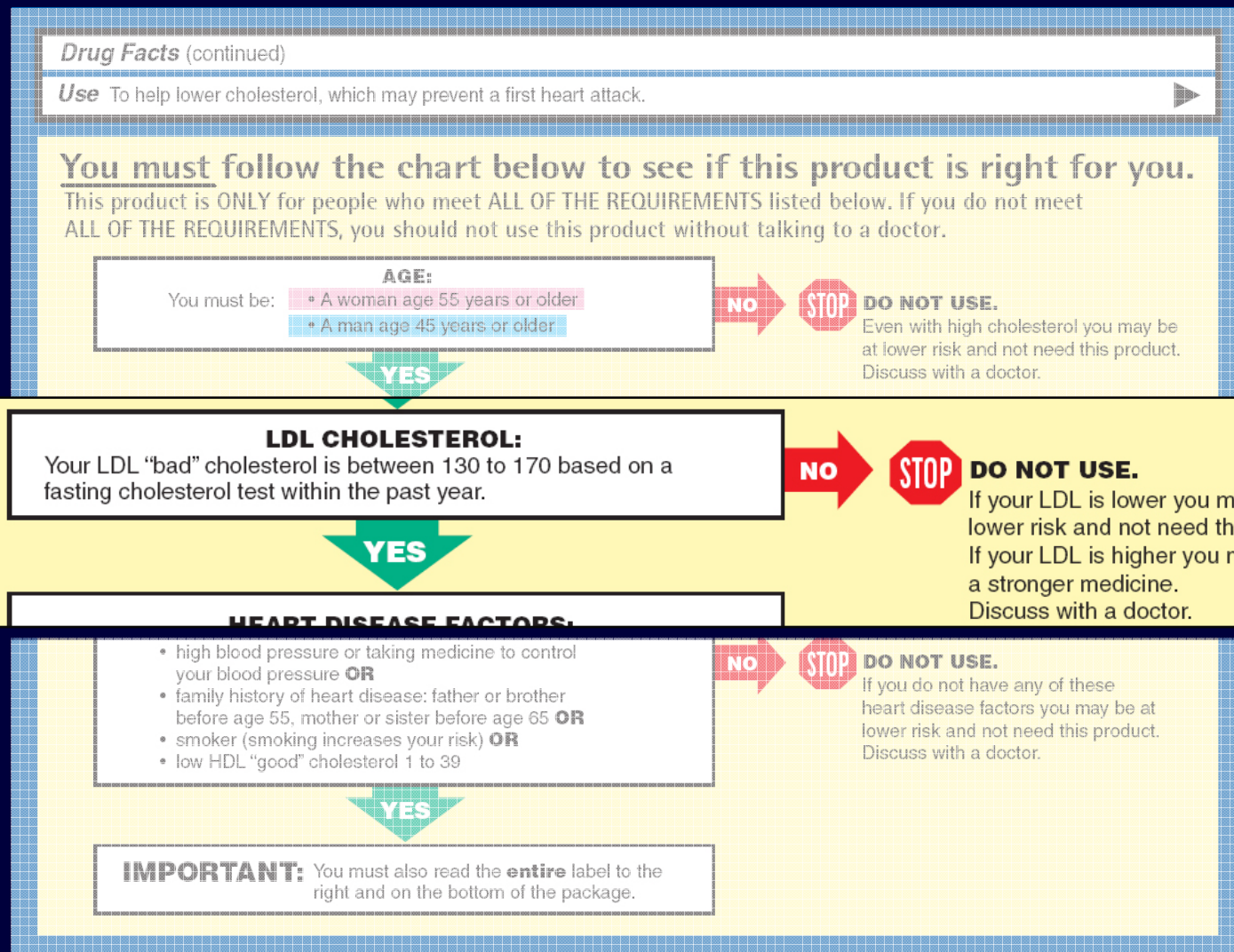




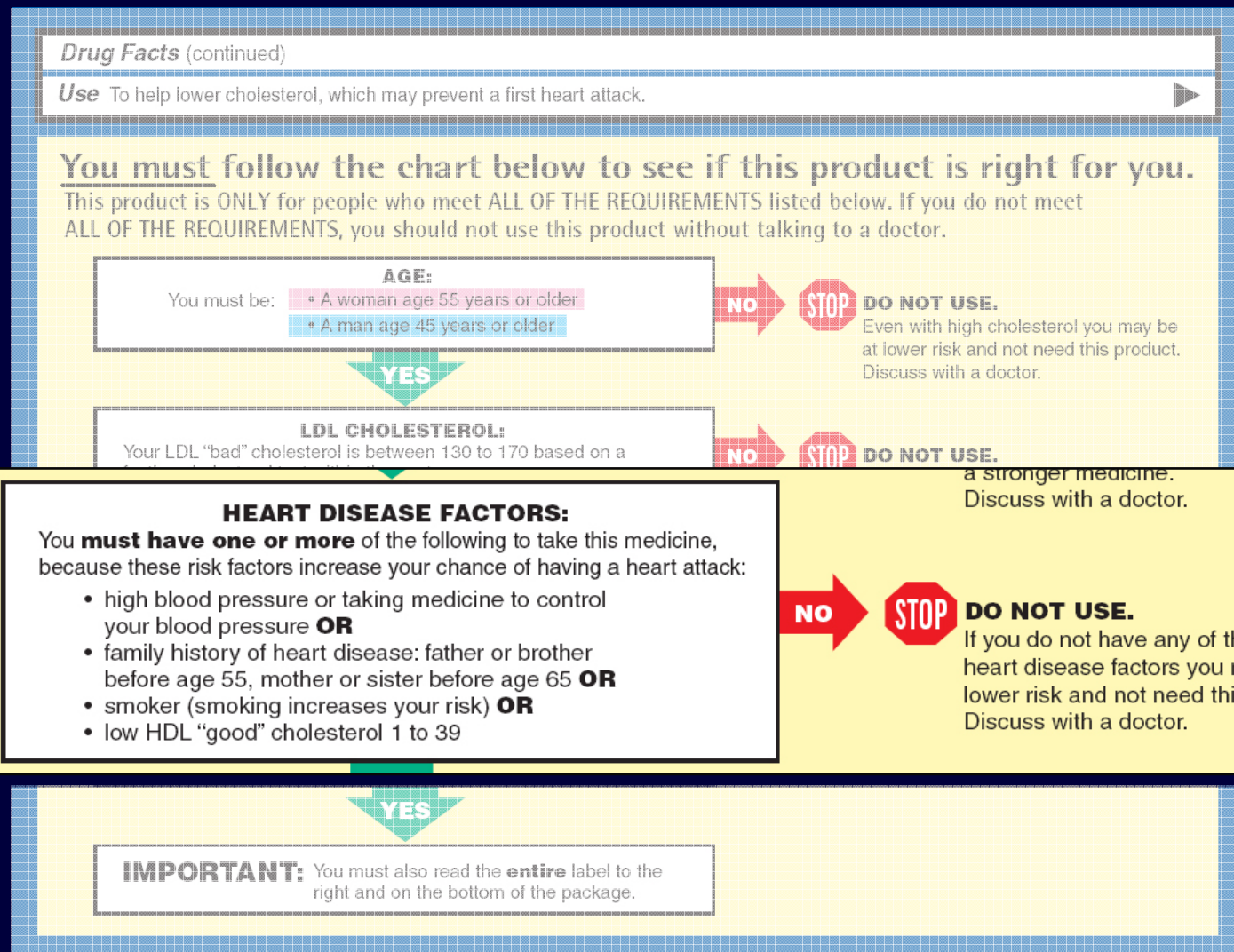
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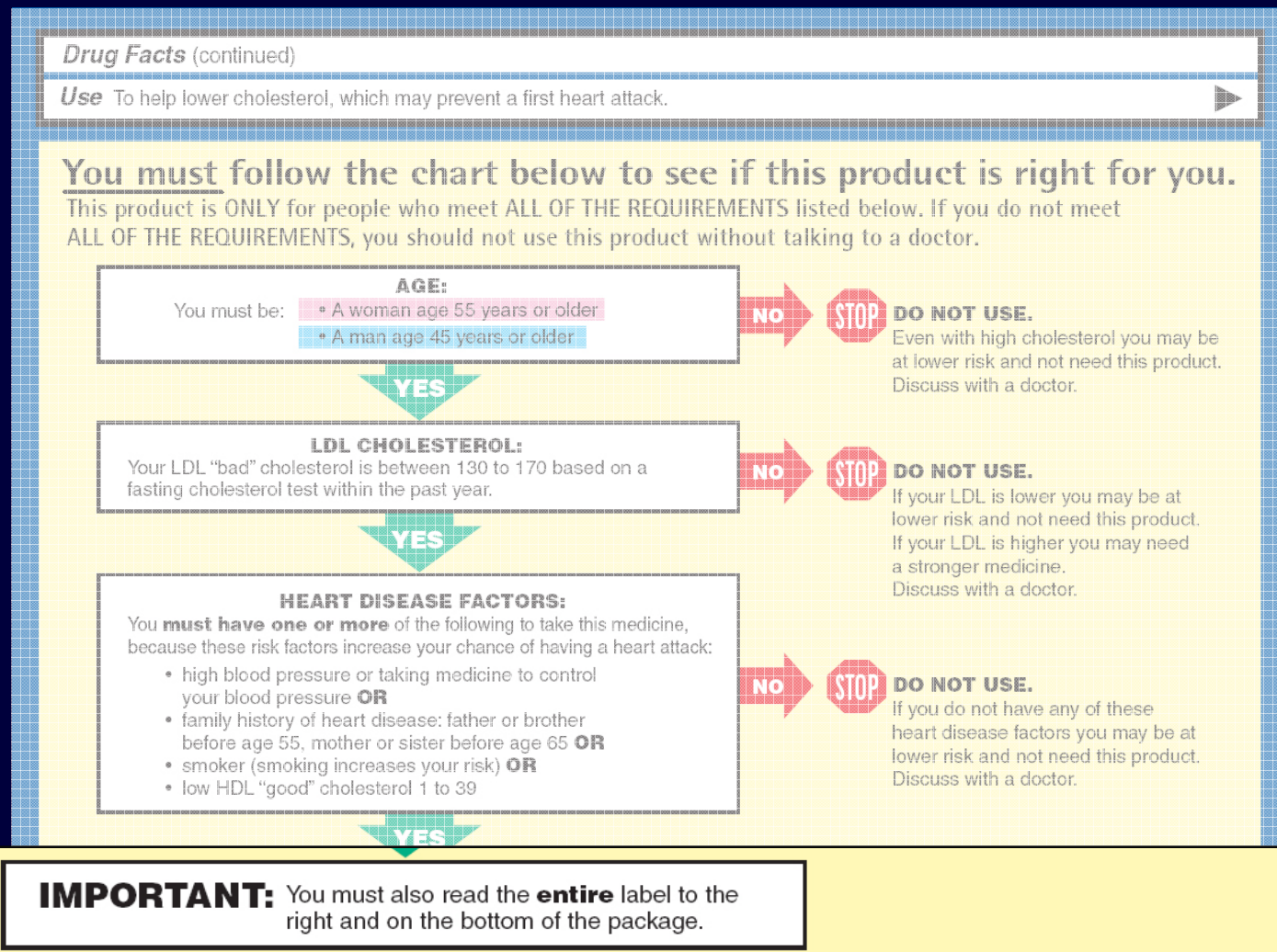
# Redesigned Package Includes Decision Tree to Aid in Self-Selection



# Redesigned Package Includes Decision Tree to Aid in Self-Selection



# Redesigned Package Includes Decision Tree to Aid in Self-Selection



# New Label Has Expanded Pregnancy Warning

OLD

*“If pregnant or breast-feeding do not use.”*

NEW

*“If pregnant or breast-feeding, **or think you may become pregnant**, do not use.”*

# Label Comprehension Studies: FDA Reviews

- Pivotal Label Comprehension Study
  - General agreement with analysis and conclusions
  - Strong scores in key safety areas
  - Most lower scores related to ongoing use
- Muscle Warning Comprehension Study
  - General agreement with analysis and conclusions
  - Strong understanding of muscle warning

# SELECT Objectives

- 1) Evaluate consumers' ability to make appropriate self-selection decisions
  - Self-assessment (SA)
  - Purchase decision (PD)
- 2) Provide insights on the reasoning behind the self-selection decisions

# SELECT Study Design

## **Study Recruitment**

- TV and Radio
- 14 sites in 7 geographic areas
- Minority ads
- No specific label eligibility guidelines



# SELECT Study Design

## Study Recruitment

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## Site Visit



- Simulated retail setting
- All comers accepted

## Product Evaluation

- Review of package label
- Pharmacist available to answer questions

# SELECT Study Design

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## Questions

### Self-Assessment

*“Based on this label, is this product appropriate for you to use right now or not?”*

### Purchase Decision

*“Would you like to pay for this right now for your own use or put it back in the display?”*

# SELECT Study Design

## Study Recruitment

- TV and Radio
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## Questions

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*"Based on this label, is this product appropriate for you to use right now or not?"*

### Purchase Decision

*"Would you like to pay for this right now for your own use or put it back in the display?"*

## Eligibility Assessment

- Medical history
- In-depth questioning on reasons for decisions
- Cholesterol testing

# SELECT Demographics

All Participants (N=1497)

Gender (%)	
Male	48
Female	52
Median age (yr.)	
Male	52
Female	53
Low health literacy (%)	13
Racial origin (%)	
White	63
Black	24
Hispanic	8
Other	5
Median household income (\$)	44K

# SELECT Participants Evaluated 15 Label Elements

- **Absolute Safety Warnings** (*Do Not Use*)
  - Allergy to lovastatin
  - Pregnant or breast-feeding
  - May become pregnant
- **Relative Safety Warnings** (*Ask a Doctor or Pharmacist Before Use*)
  - Have history of liver disease
  - Take potentially interacting medication
  - Take prescription lipid-lowering medication
  - Consume large quantities of grapefruit juice
- **Benefit Guidelines**
  - Age
  - LDL-C or Total-C in range
  - HDL-C in range
  - CHD risk factors
  - No heart disease
  - No stroke
  - No diabetes
  - Non-fasting cholesterol values

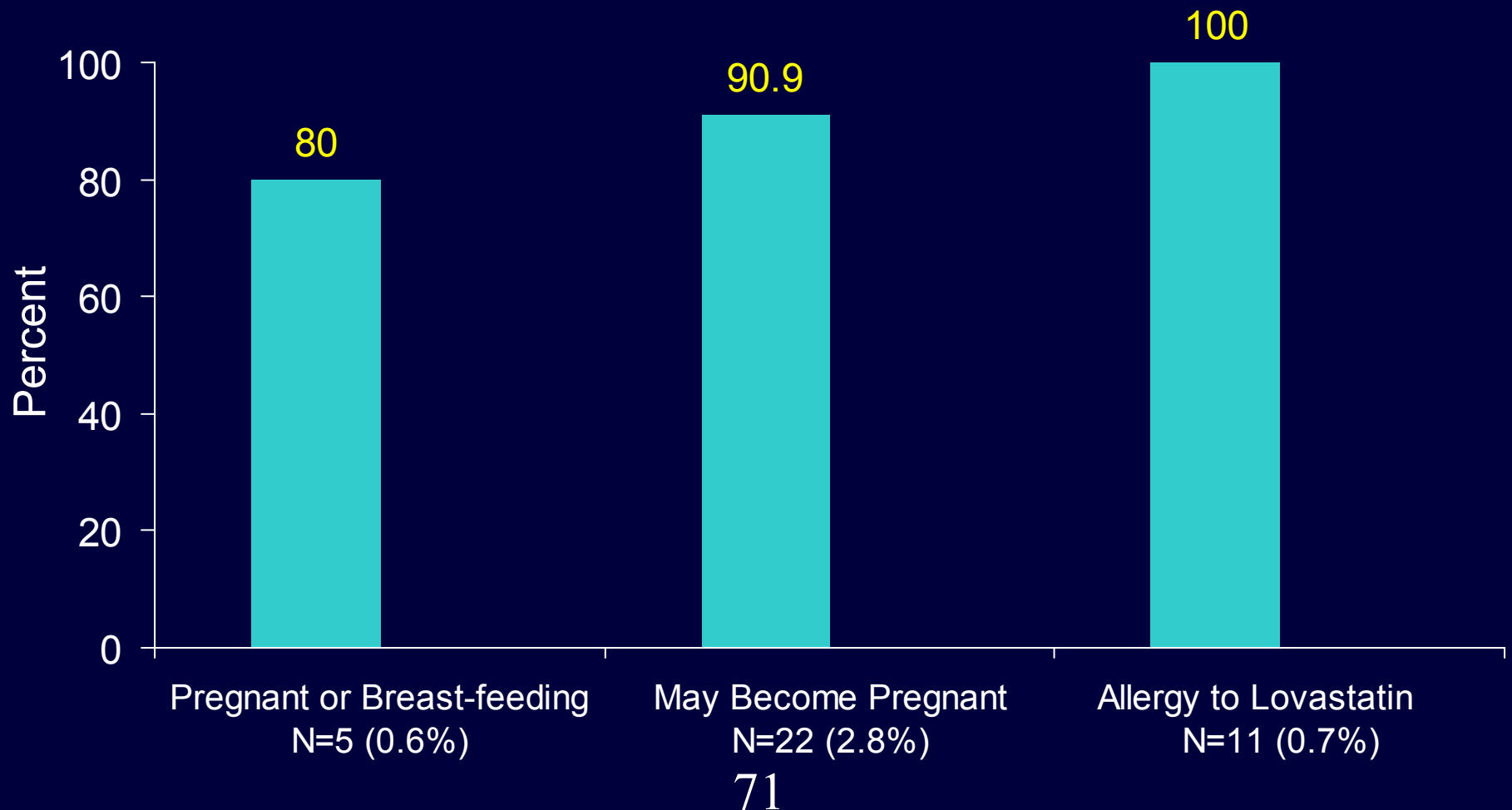
# Participants With SA=Yes Followed Most Label Elements (N=456)

	<u>Number of Label Elements</u>	<u>Average Correct (Per Participant)</u>
Entire label	15	13.5
Safety warnings	7	6.9
Benefit guidelines	8	6.6

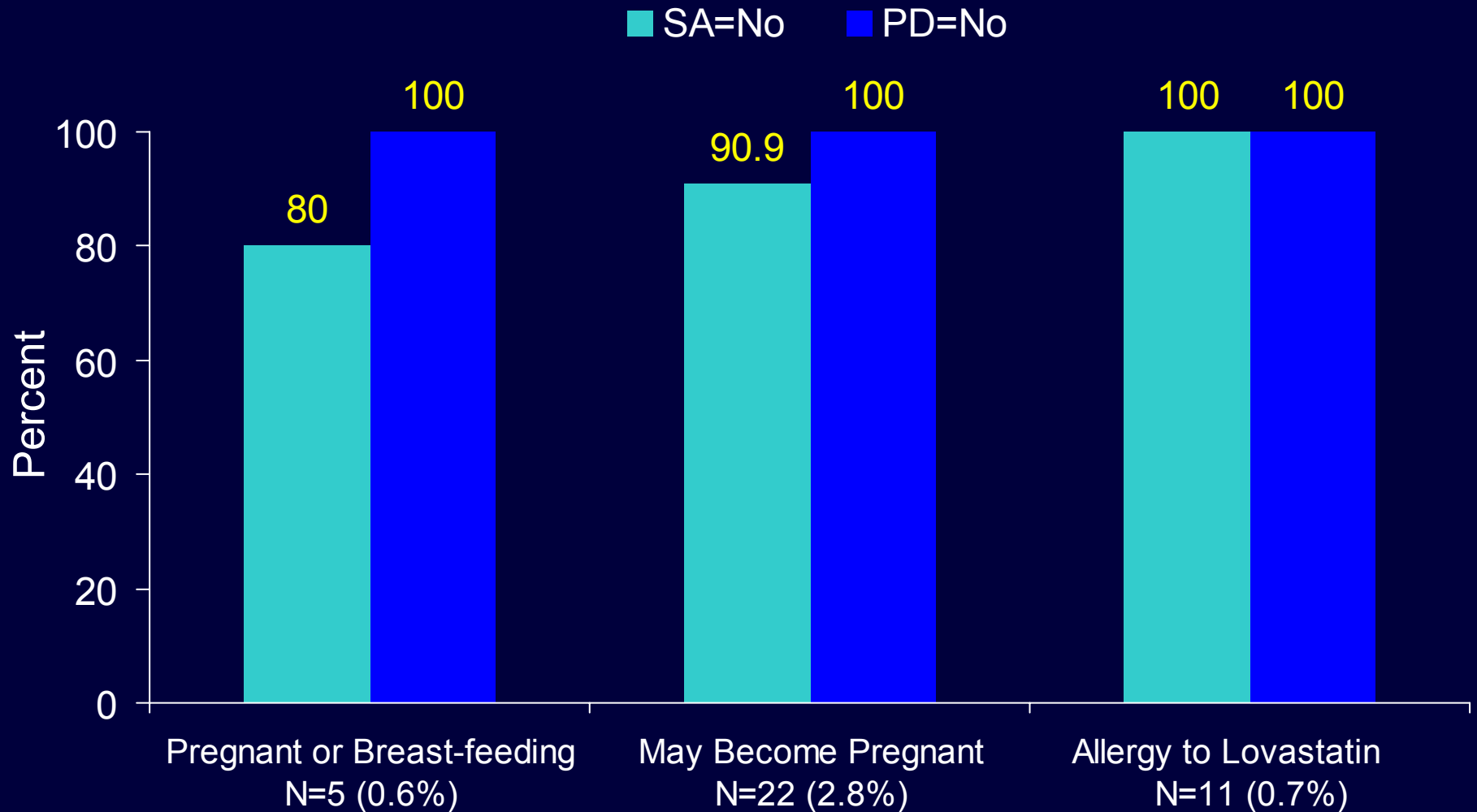
# Participants Followed Absolute Safety Warnings

## Combined LDL/TC Paradigms

■ SA=No

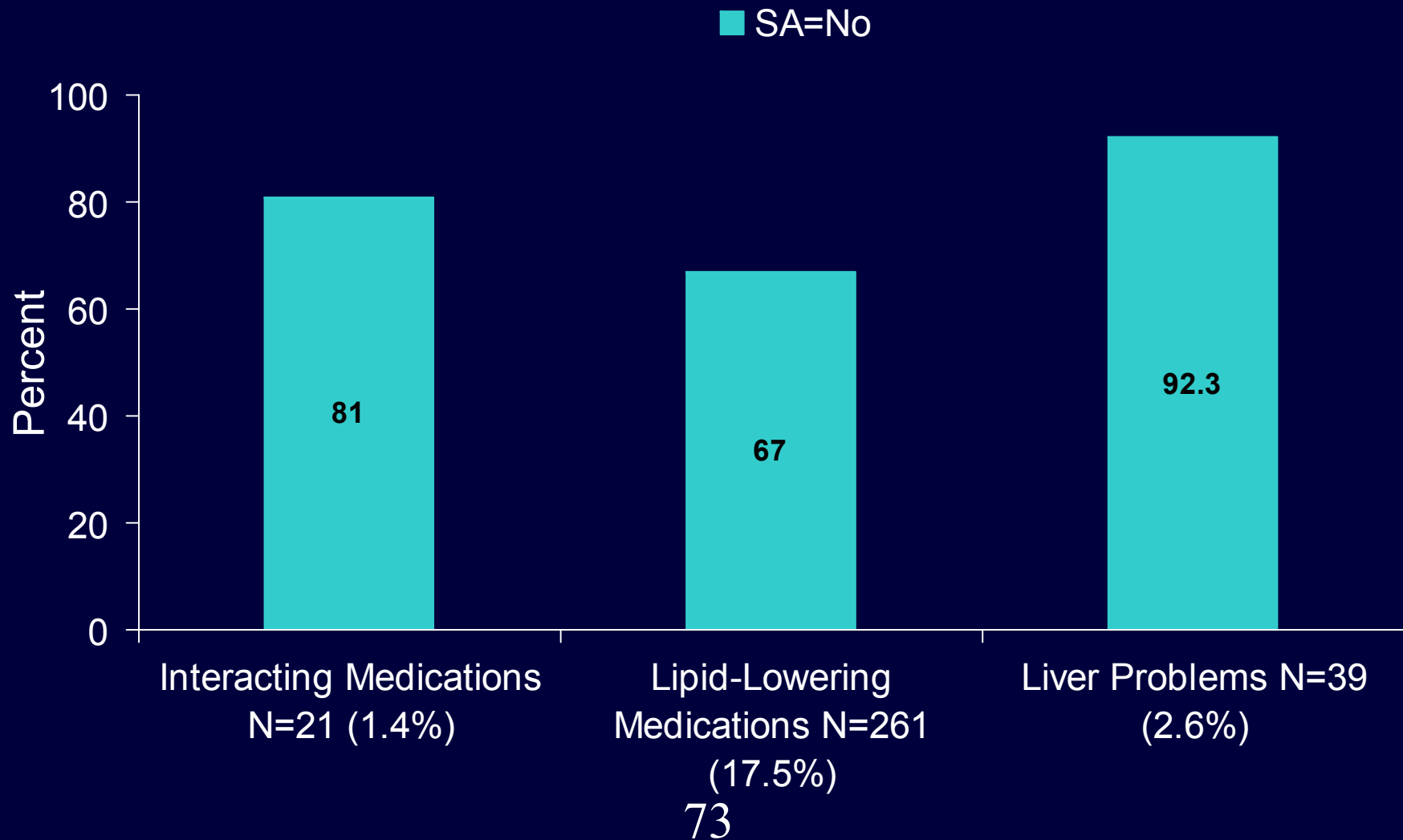


# Absolute Safety Warnings: 100% Did NOT Purchase Combined LDL/TC Paradigms

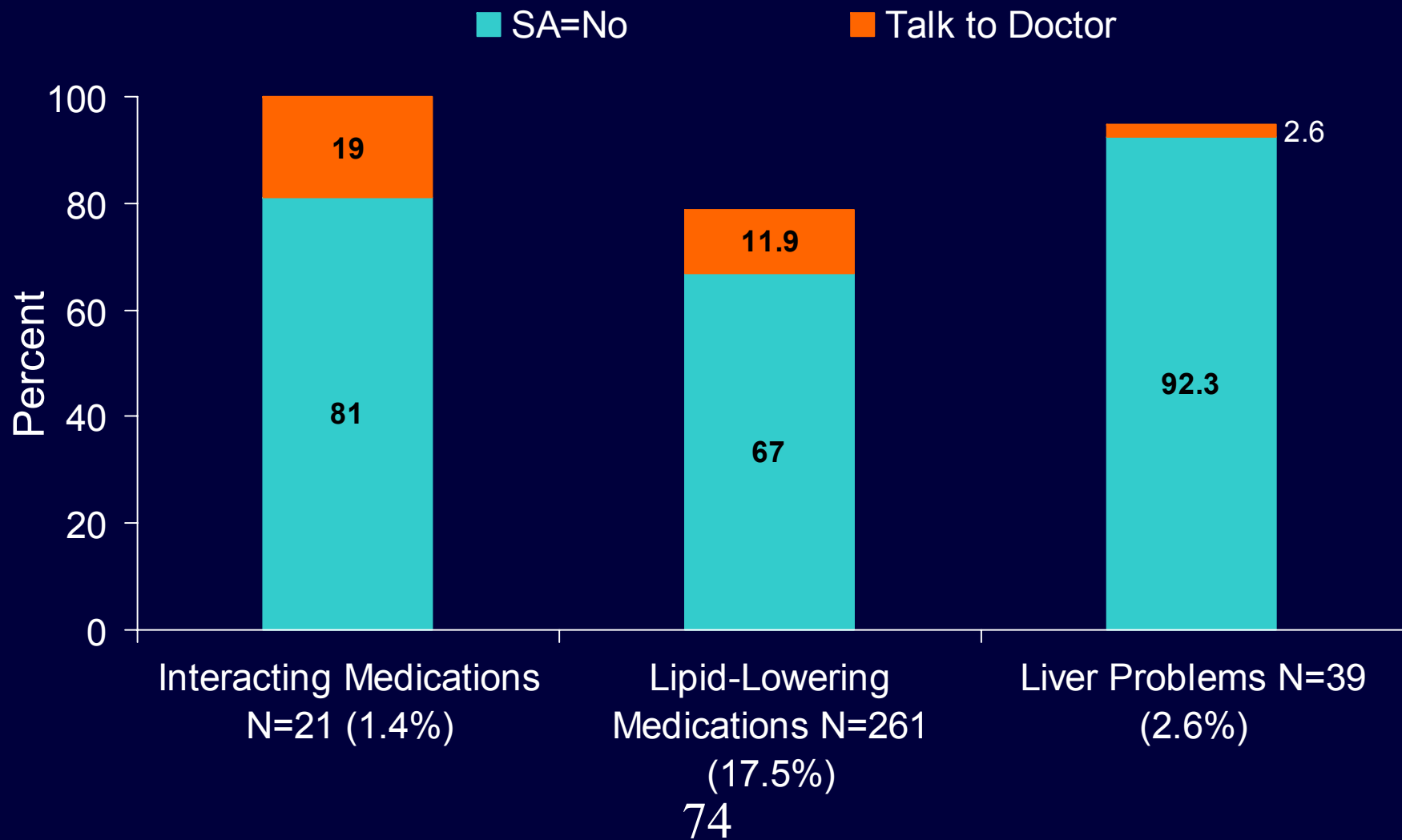




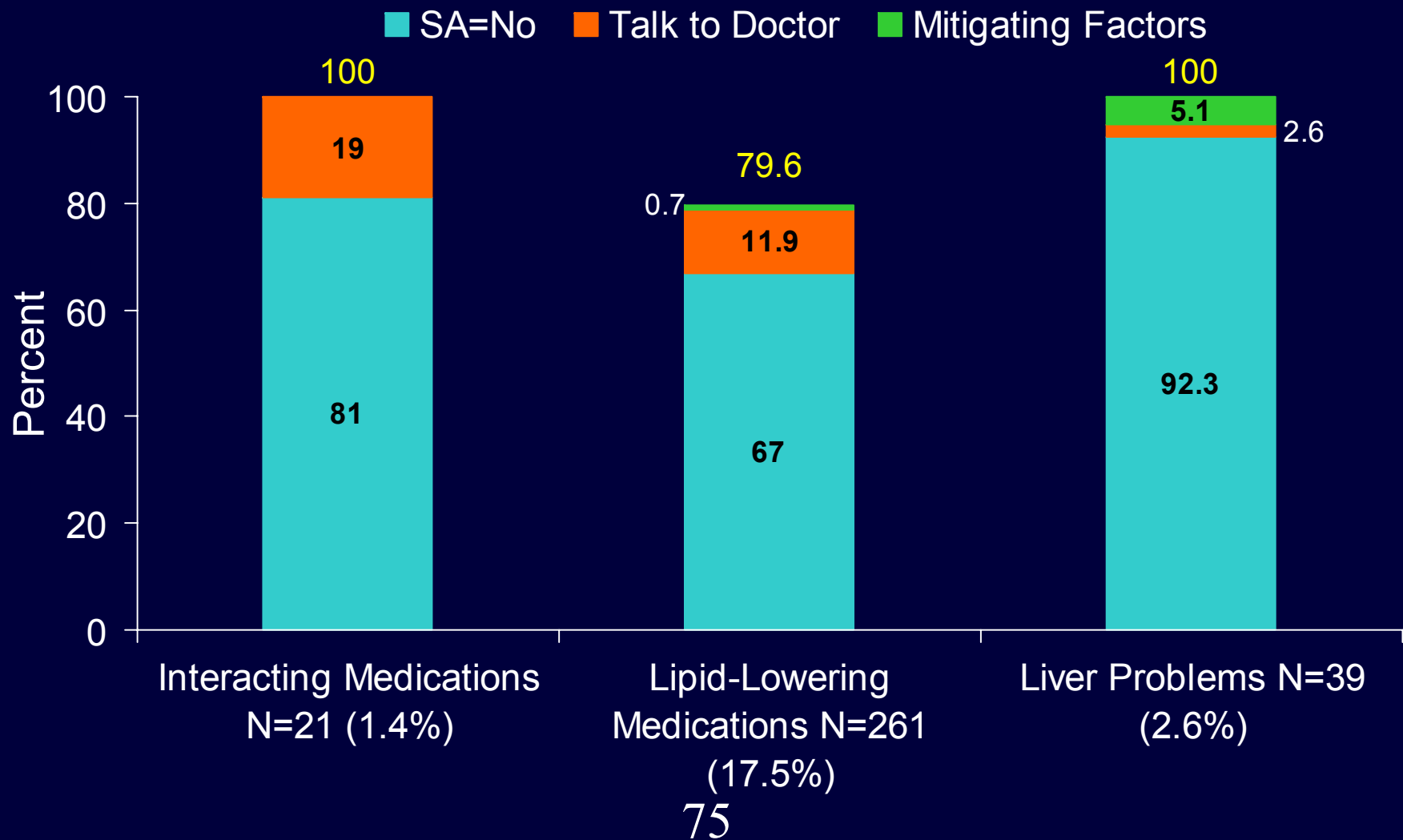
# Relative Safety Warnings: Most Participants Follow Label Combined Paradigms



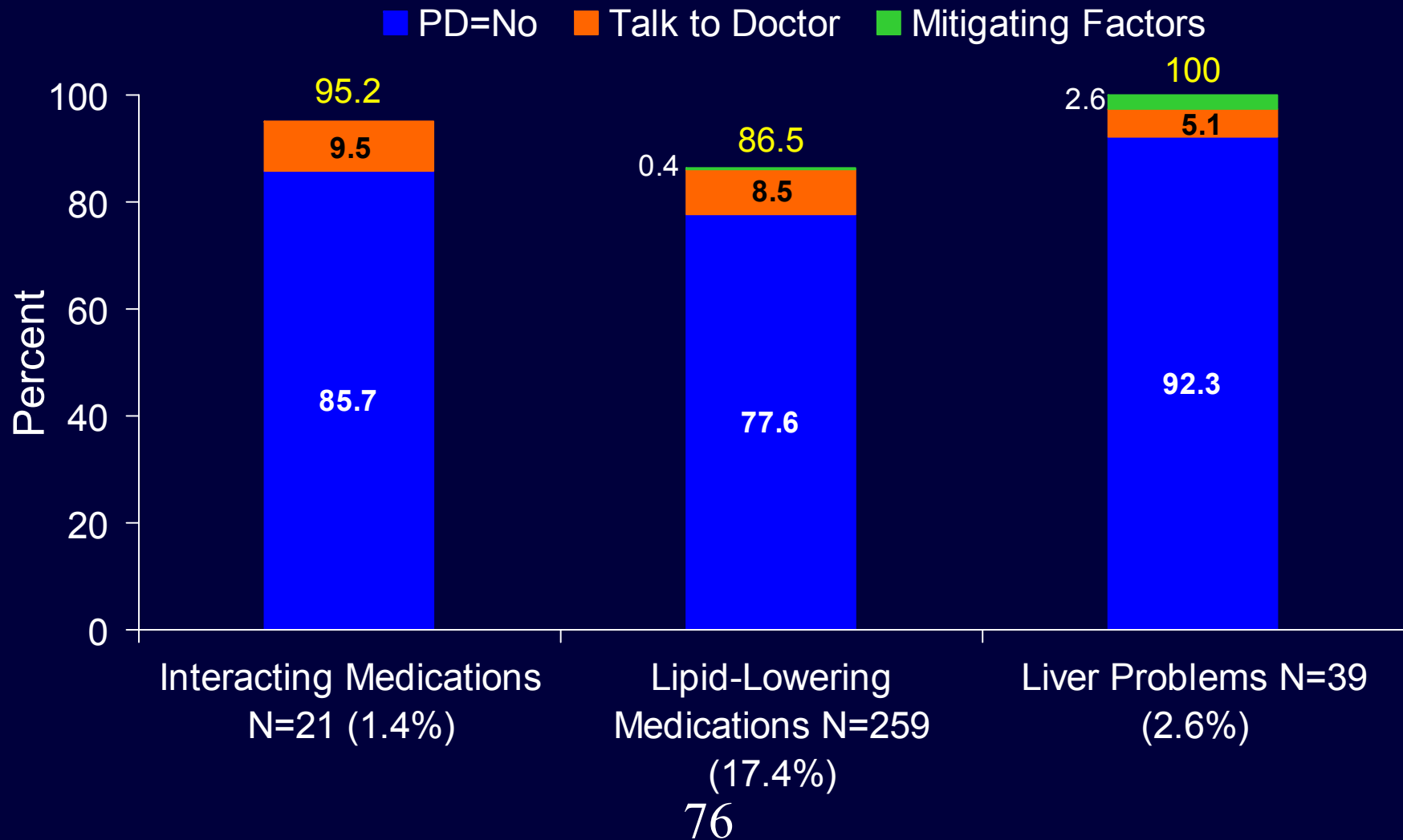
# Relative Safety Warnings: Most Participants Follow Label Combined Paradigms



# Relative Safety Warnings: Most Participants Follow Label Combined Paradigms



# Relative Safety Warnings: Most Participants Did Not Purchase Combined Paradigms



# SELECT Maintained Strong Safety Scores

Percent Who Followed Label

	<u>SELECT</u> %	<u>CUSTOM</u> %
Absolute safety	100	100
Relative safety		
History of liver disease	100	95
Potentially interacting medicine	95	90
Taking Rx for lipids	87	87

For SELECT: Includes PD=No, Talk to Doctor and Mitigating Reasons.  
For CUSTOM: Includes PD=No and Talk to Doctor.

# Label Guidelines Designed to Optimize Benefit of MEVACOR™ Daily

- Age: Men  $\geq 45$ , women  $\geq 55$
- LDL-C: 130-170 mg/dL or Total-C 200-240 mg/dL
- HDL-C:  $< 60$  mg/dL for women
- Presence of CHD risk factors
  - High BP, smoker, family history, HDL  $< 40$  mg/dL
- No history of heart disease, stroke, or diabetes

# Participants With SA=Yes Decisions: Consistent With Benefit Guidelines

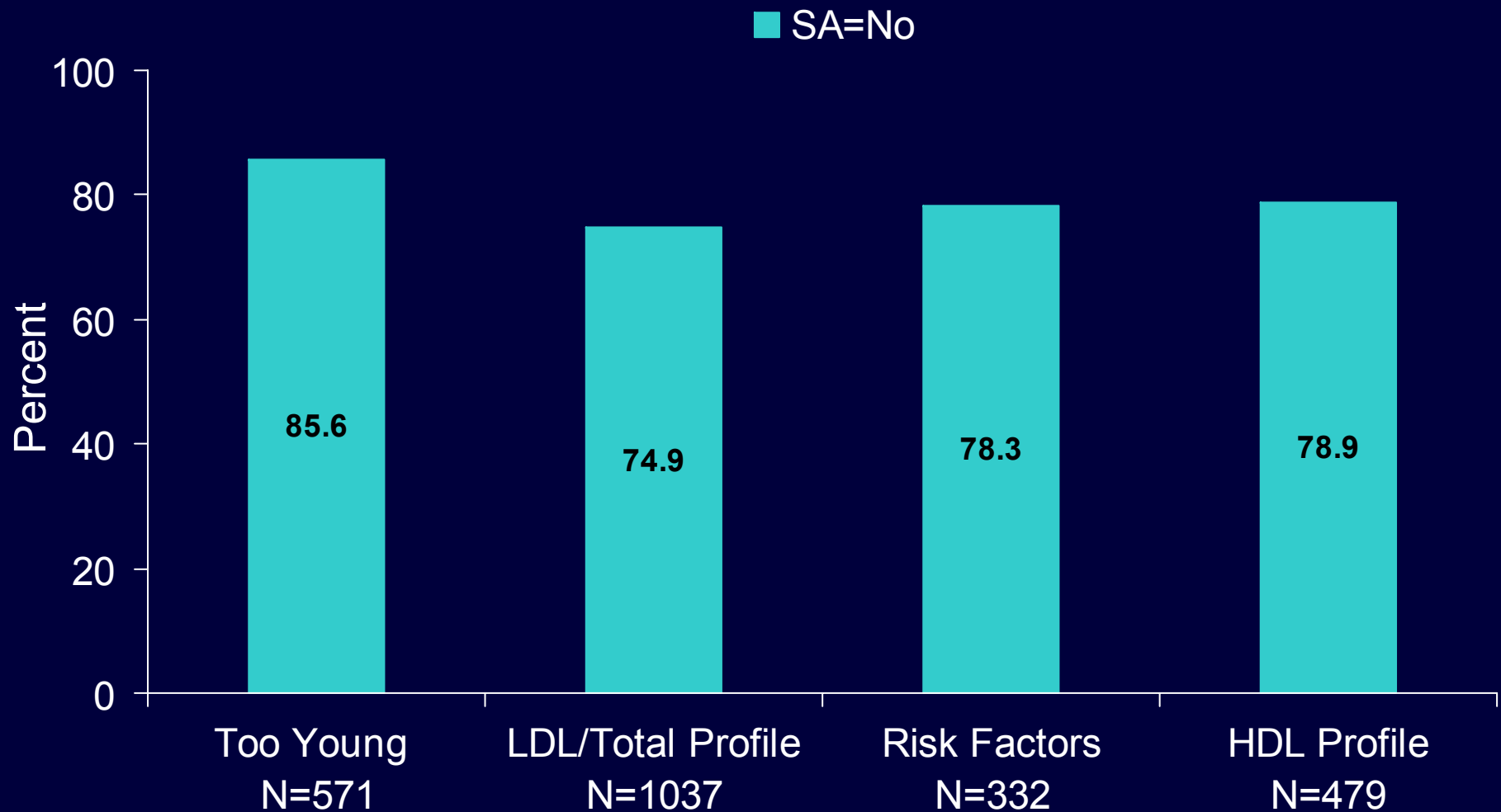
		Results From SELECT (Mean)	
	<u>Label</u>	<u>Men</u>	<u>Women</u>
Age: Men (years)	45+	54.2	-
Age: Women (years)	55+	-	59.2
LDL-C (mg/dL)	130-170	154	155
CHD risk factor	$\geq 2$	2.0	1.9

# FDA Identified SELECT Results of Concern: Outside of Benefit Guidelines (SA=Yes) Combined Paradigms

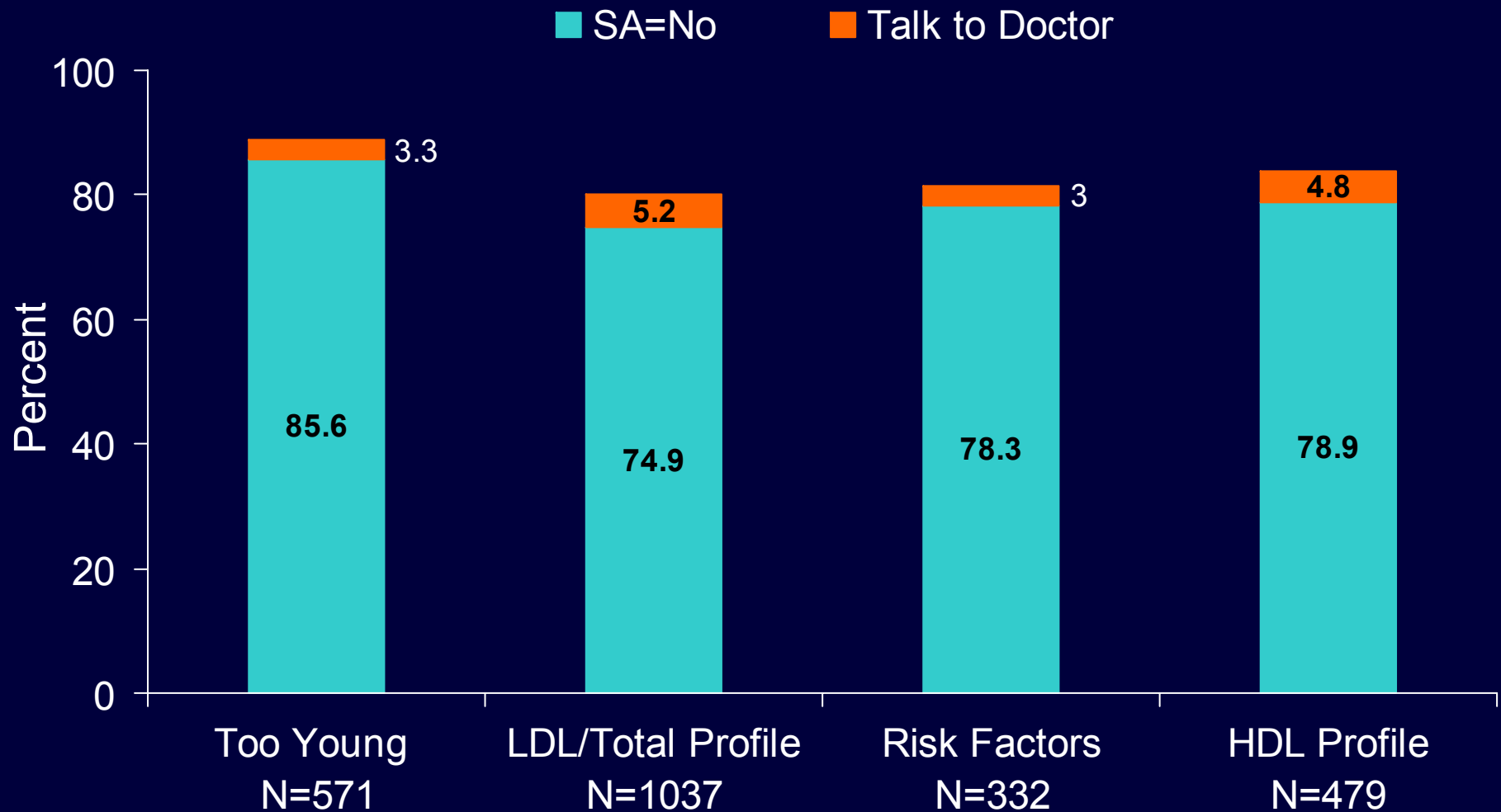
- 11% of women under age 55 said product appropriate
- 16% had lipid levels below label guideline range
- 38% had lipid levels above label guideline range
- 35% with CHD, stroke, or diabetes said product appropriate
- 25% were lower CHD risk per Framingham (<5%)
  - Most were women



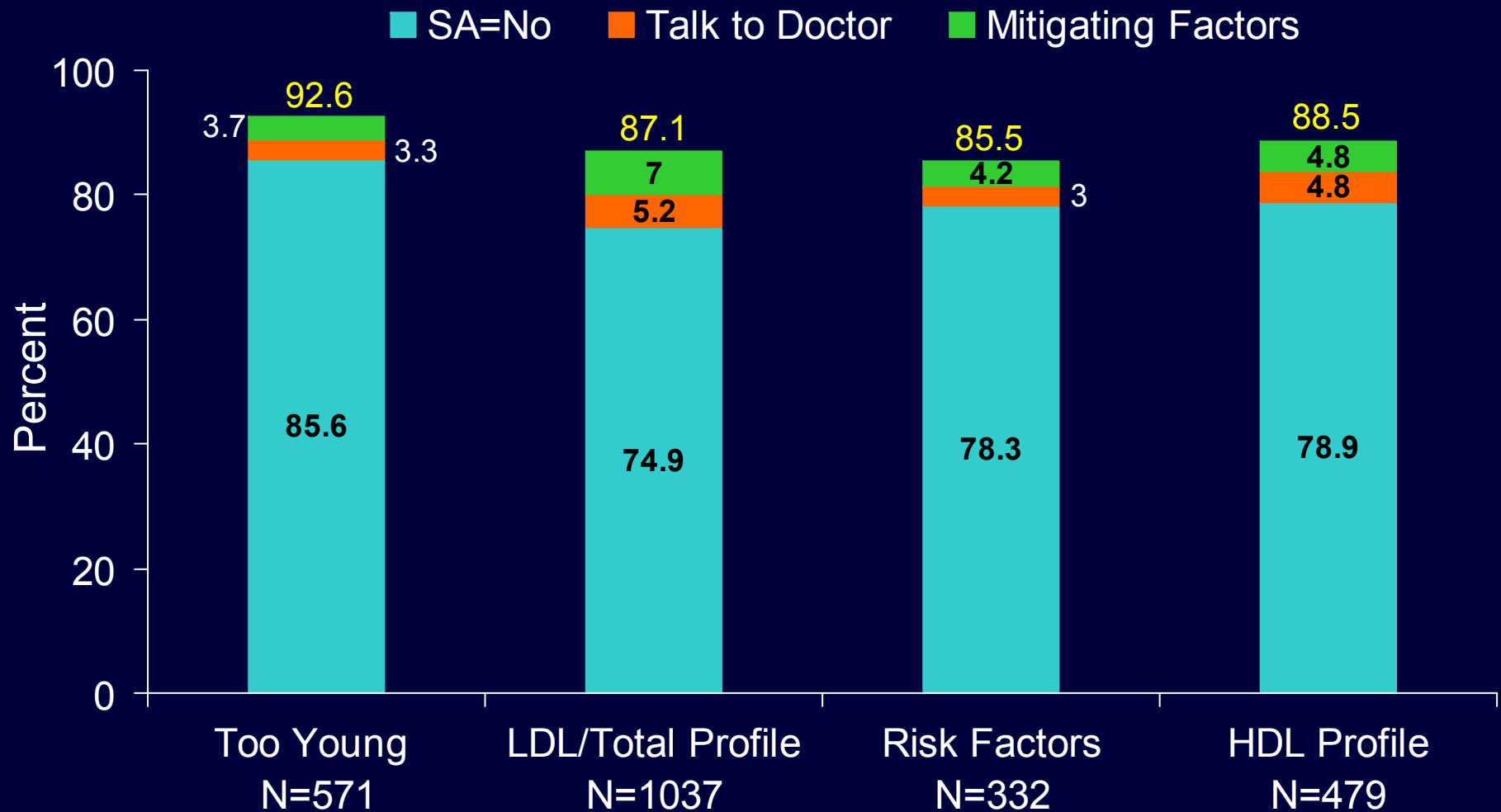
# Participants With SA Decisions Consistent With Benefit Guidelines Combined Paradigms



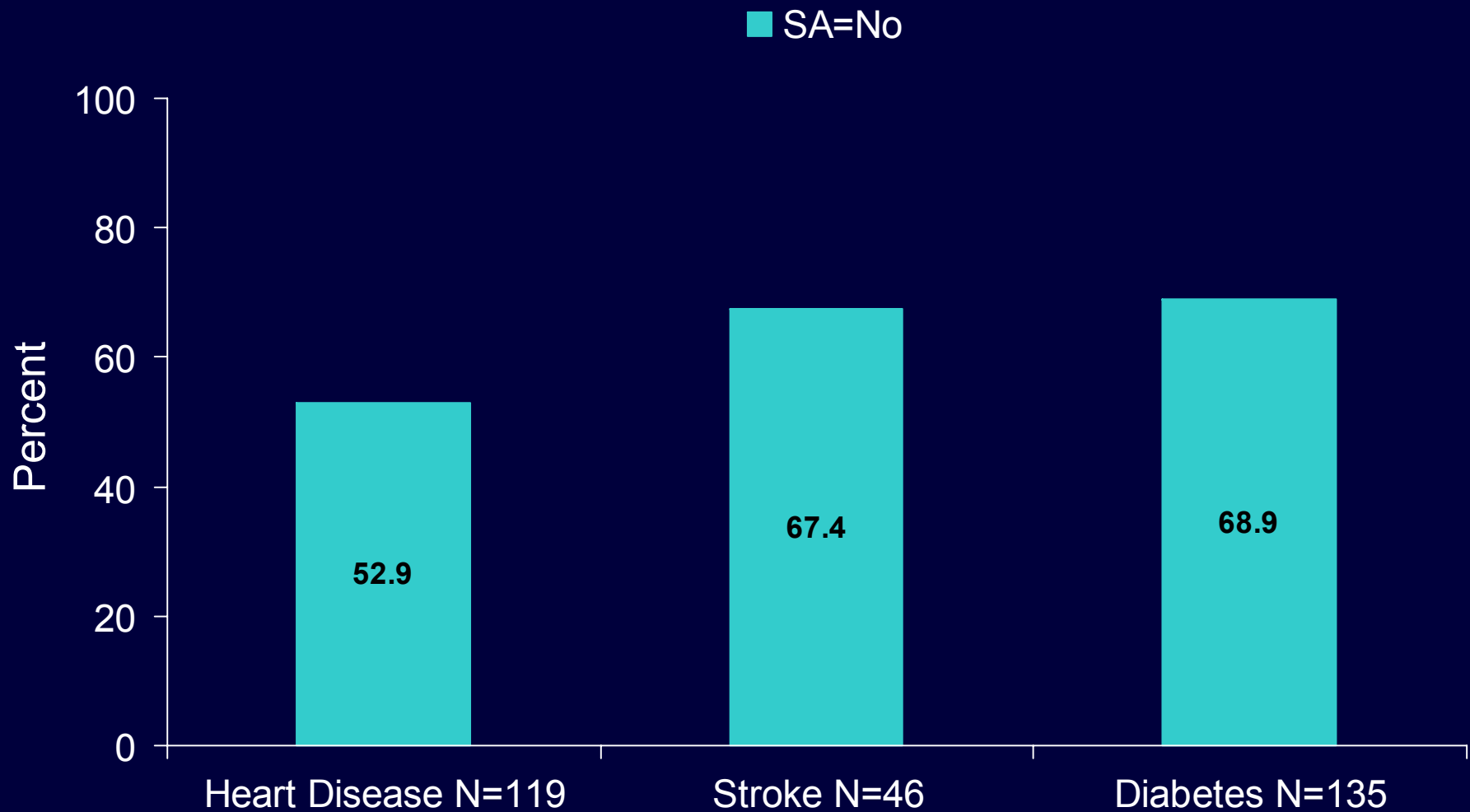
# Participants With SA Decisions Consistent With Benefit Guidelines Combined Paradigms



# Participants With SA Decisions Consistent With Benefit Guidelines Combined Paradigms

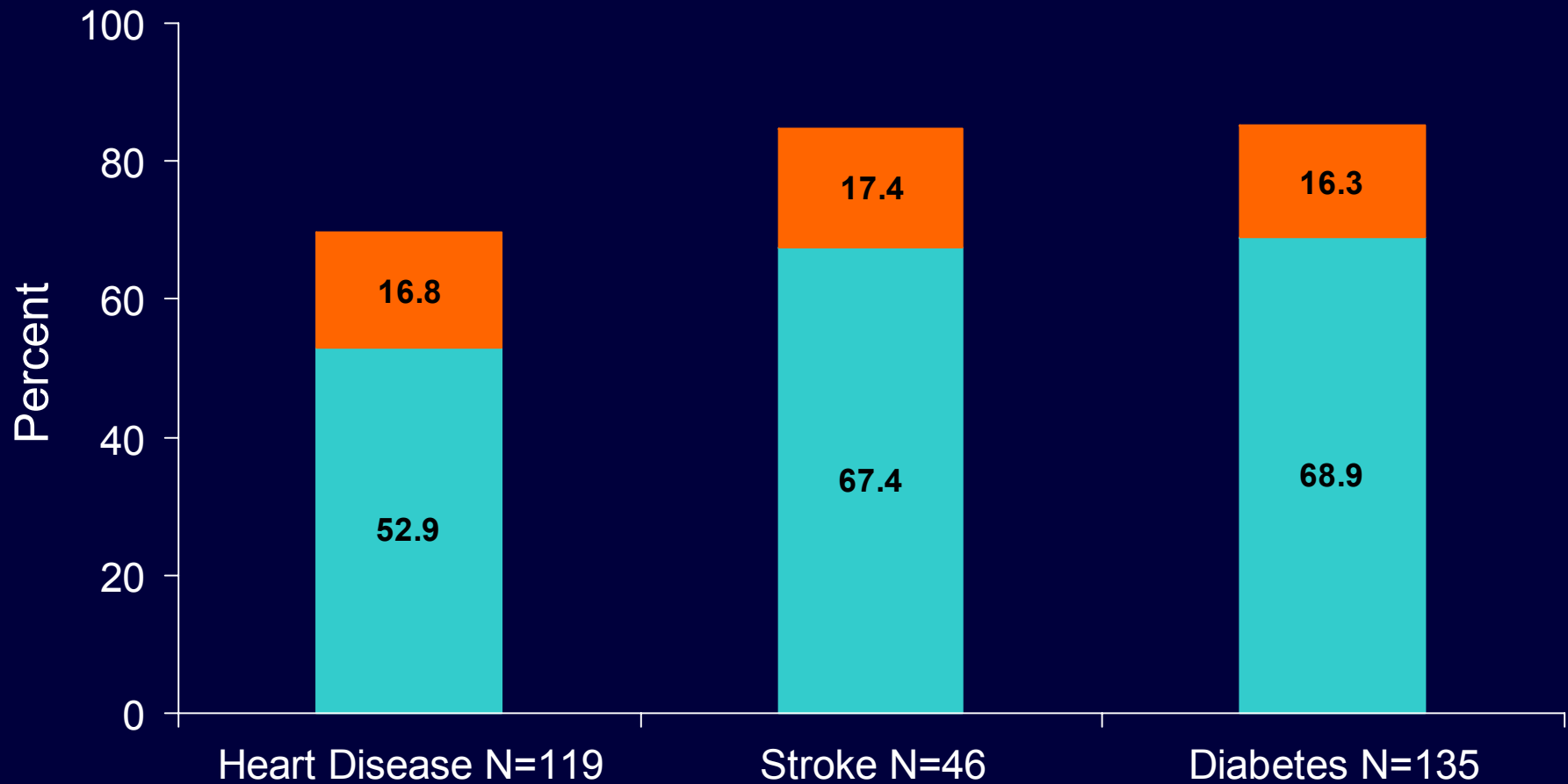


# Participants With SA Decisions Consistent With Benefit Guidelines Combined Paradigms



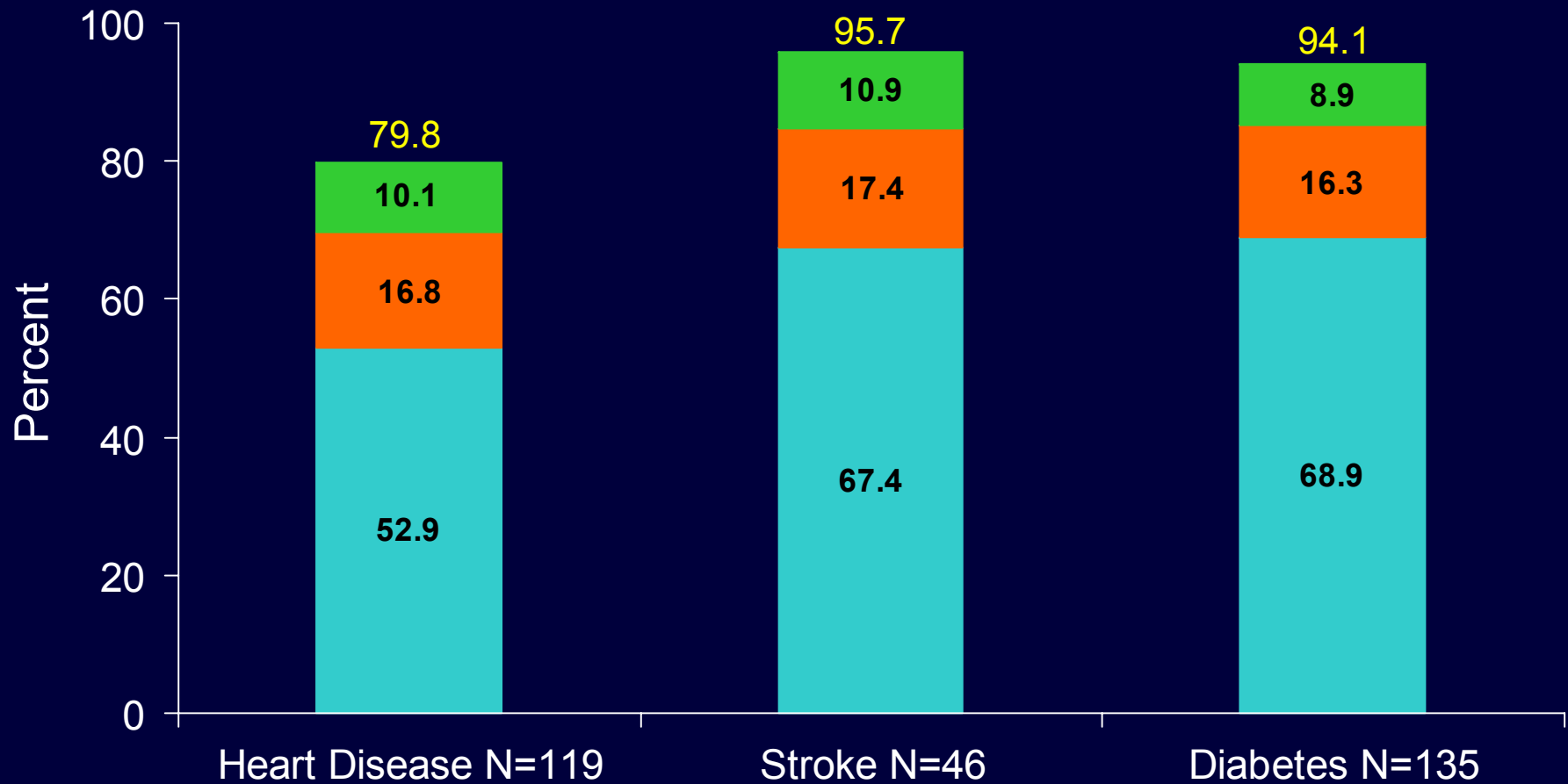
# Participants With SA Decisions Consistent With Benefit Guidelines Combined Paradigms

■ SA=No      ■ Talk to Doctor



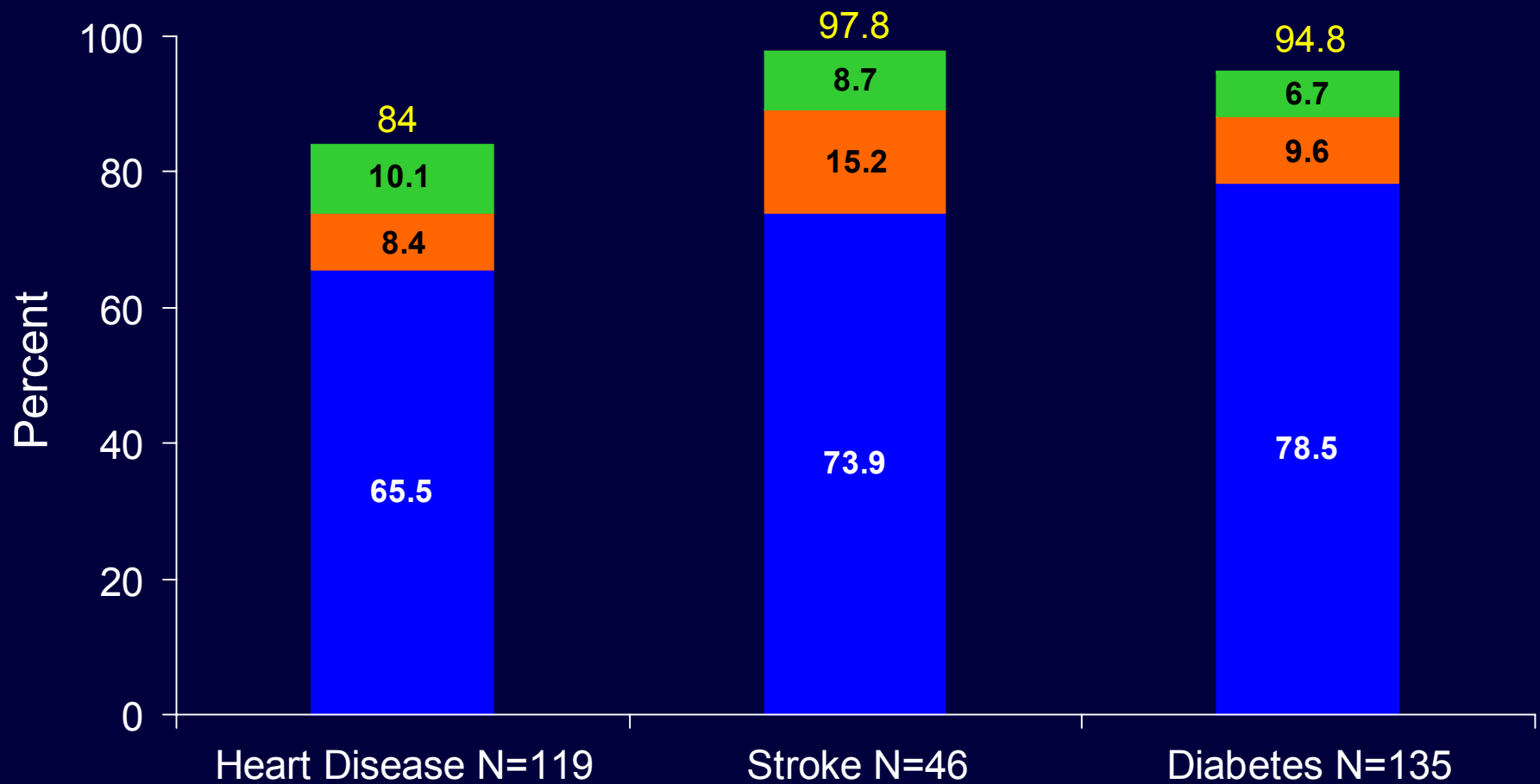
# Participants With SA Decisions Consistent With Benefit Guidelines Combined Paradigms

SA=No    Talk to Doctor    Mitigating Factors



# Participants With PD Decisions Consistent With Benefit Guidelines Combined Paradigms

■ PD=No ■ Talk to Doctor ■ Mitigating Factors



## Most Women <55 Years Made Appropriate Decisions

- 89% (335/377) said MEVACOR™ Daily NOT appropriate
- 88% (339/387) did NOT want to purchase
  - Improved from 76% in CUSTOM
- Of the 42 who said SA=Yes
  - 74% Over 45 years of age
  - 83%  $\geq 1$  CHD risk factor
  - 64% LDL  $\geq 130$  mg/dL
  - 33% Wanted to talk to doctor per label

**93% were consistent with the label**



# Most With Low LDL-C Made Appropriate Decisions

## LDL Paradigm

- 83% (127/153) said MEVACOR™ Daily NOT appropriate
- 86% did NOT want to purchase
- Of the 26 who said SA=Yes
  - 100%  $\geq 1$  CHD risk factors
  - 89%  $\geq 2$  CHD risk factors
  - 42% LDL  $\geq 110$  mg/dL
  - 46% Wanted to talk to doctor per label

**91% were consistent with the label**

# Label Benefit Guidelines Discourage Use by Participants With Lower CHD Risk<sup>†</sup>

## Combined Paradigms

- 78% (407/520) said MEVACOR™ Daily NOT appropriate
- 79% did NOT want to purchase
- Of the 113 who said SA=Yes
  - 74% Had LDL-C  $\geq$ 130
  - 91% Had Total-C  $\geq$ 200
  - 91%  $\geq$ 1 CHD risk factors
  - 52%  $\geq$ 2 CHD risk factors
  - 69% Met age guidelines
  - 83% Within 5 years

<sup>†</sup> Lower risk is defined as a Framingham 10-year risk score <5%.

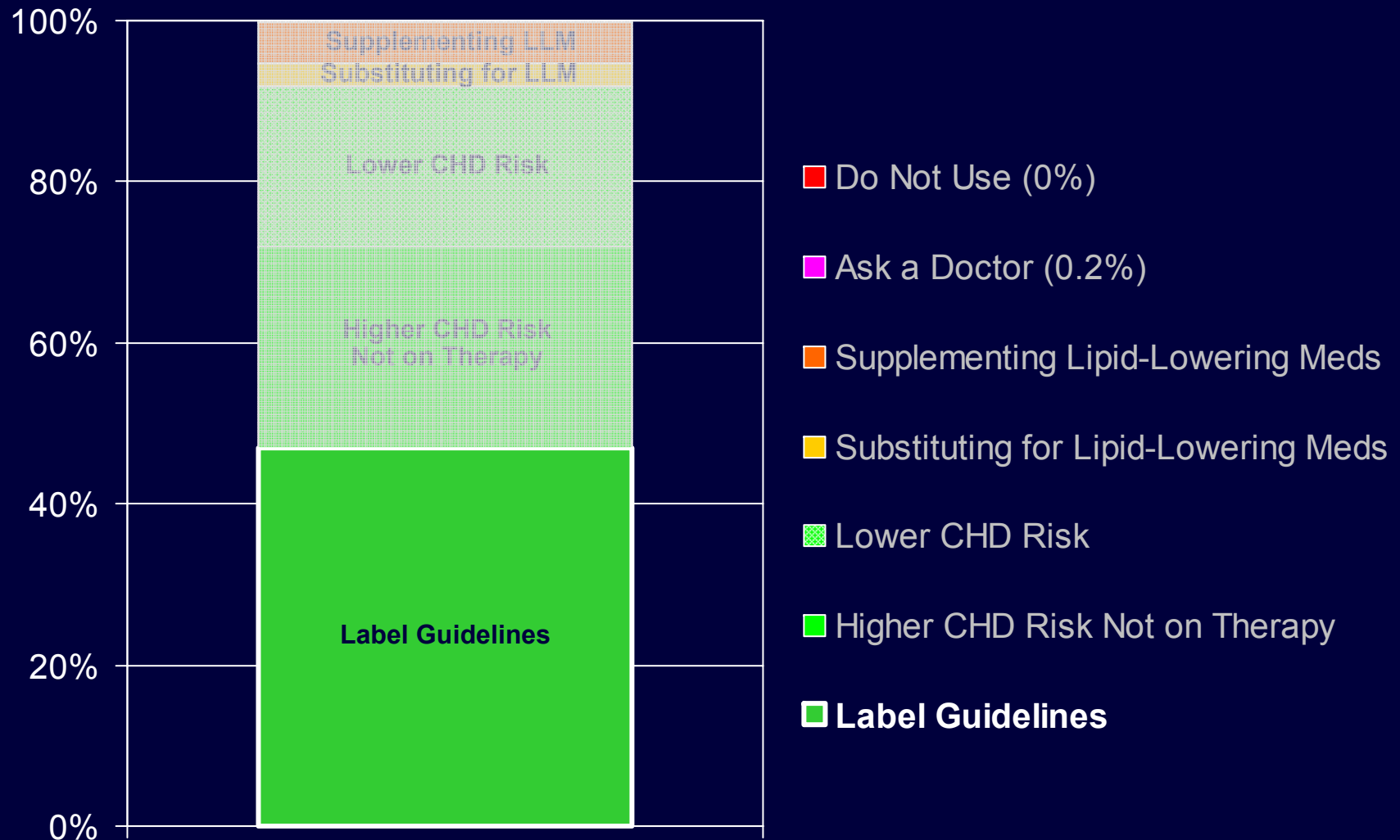
# Many People at Higher CHD Risk Not on Lipid-Lowering Therapy

- Framingham Score >20%
  - 53% wanted to purchase
    - 100% not on Rx
- CHD/stroke/diabetes
  - 35% said appropriate
    - 67% not on Rx
- Cholesterol above label guideline
  - 38% said appropriate
    - 89% not on Rx
- All will benefit from reduced LDL or High-Risk Referral System

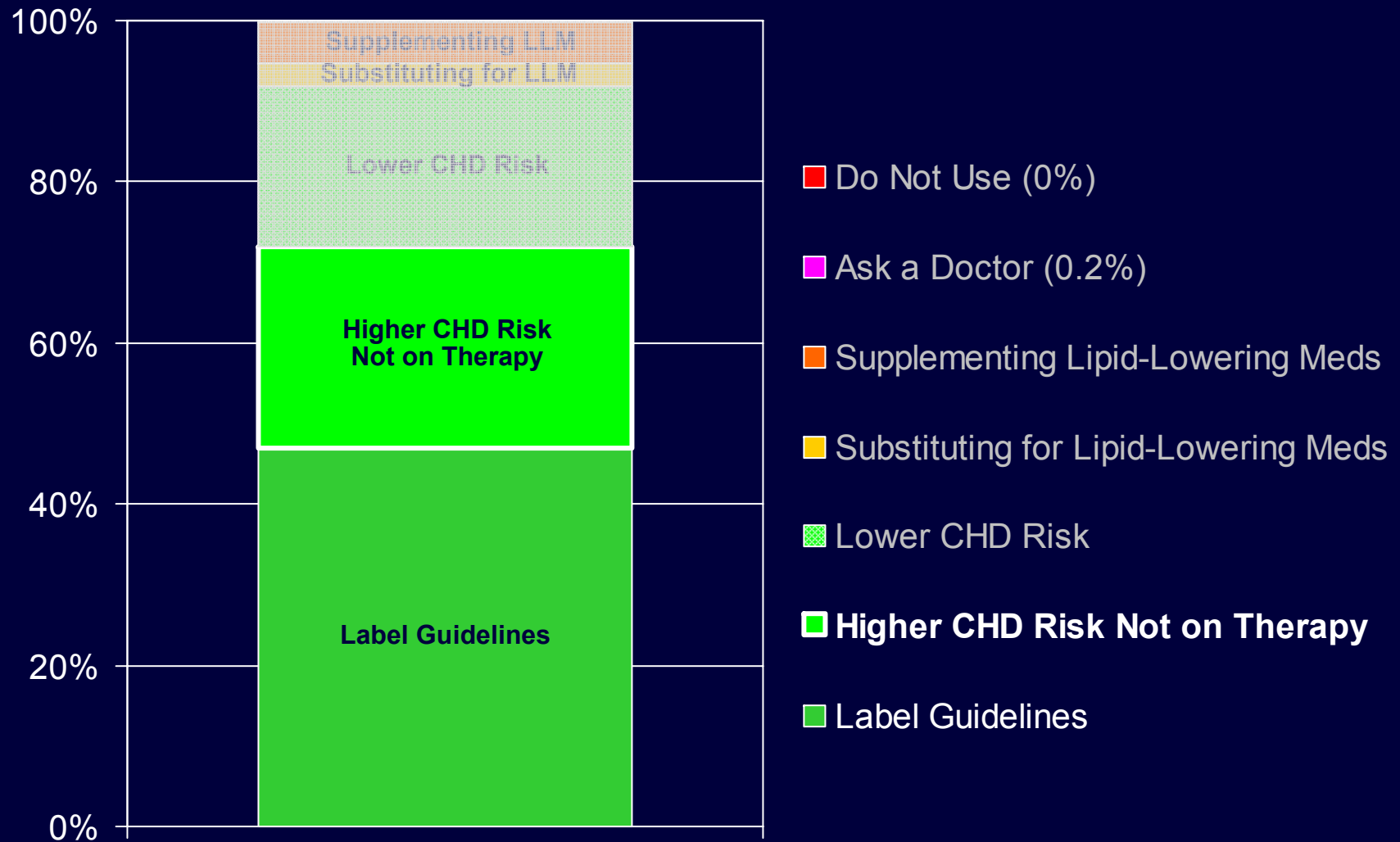
# SELECT: Summary

- Maintained strong safety scores
  - 100% followed absolute safety warnings
  - 100% followed liver disease warning
  - 95% followed interacting medication warning
  - 87% followed lipid-lowering medication warning
- Reduced use by women <55 years
  - 88% did not want to buy
- Label prevented use by people with lower CHD risk
  - 79% did not want to buy
- Interviews reveal informed decisions
- Benefit-Risk relationship favorable

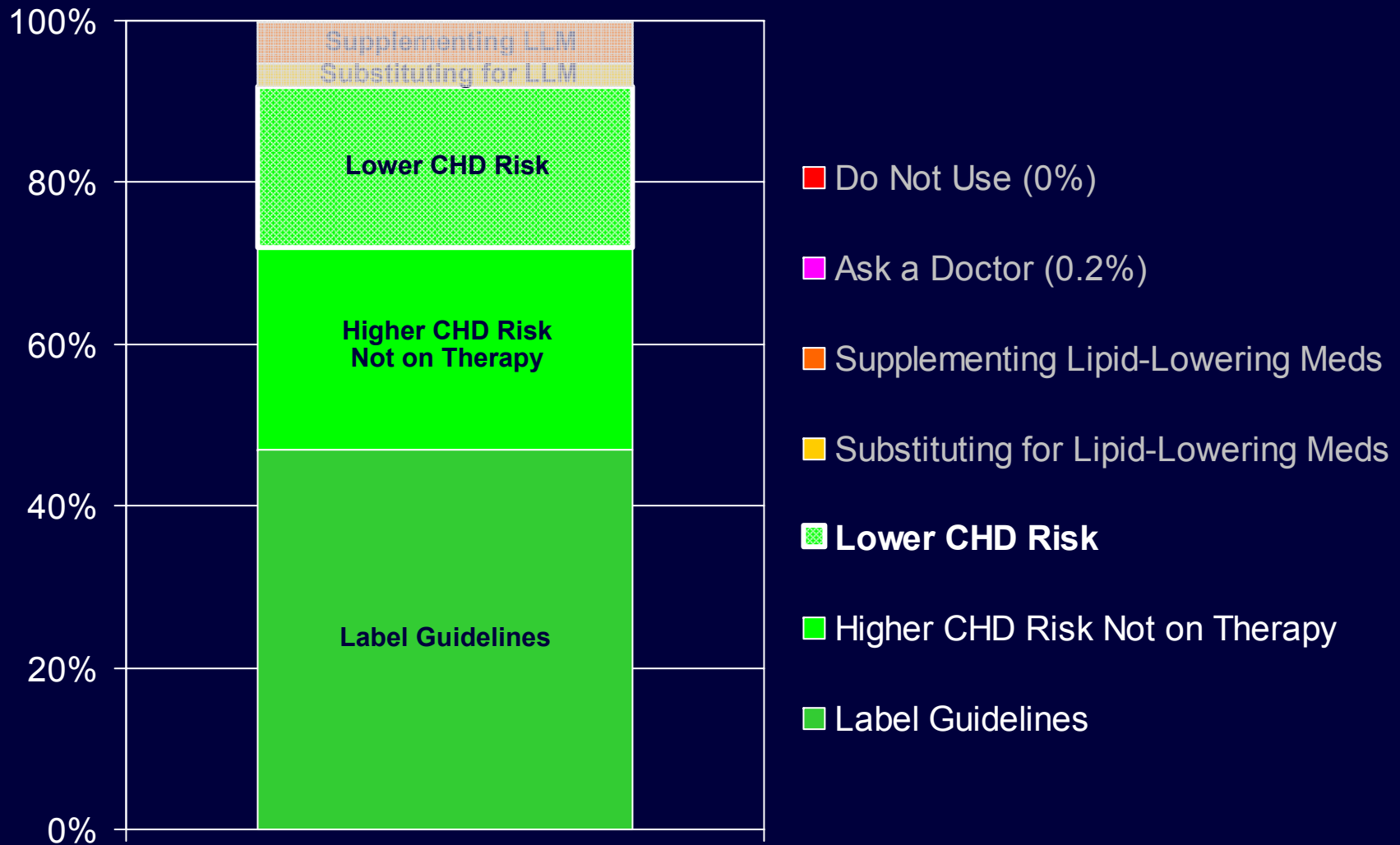
# Labeling Hierarchy of Purchasers in SELECT



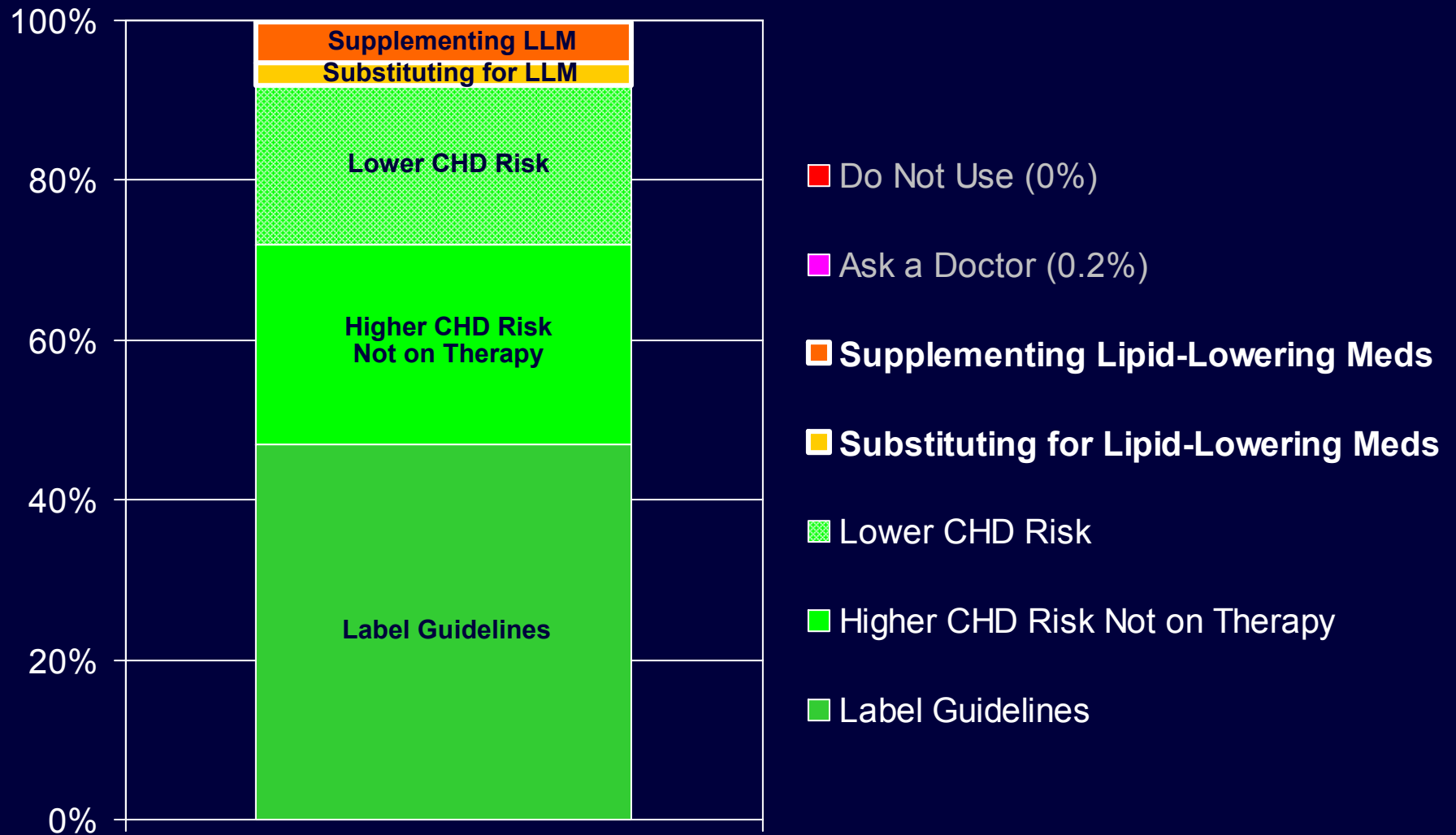
# Labeling Hierarchy of Purchasers in SELECT



# Labeling Hierarchy of Purchasers in SELECT

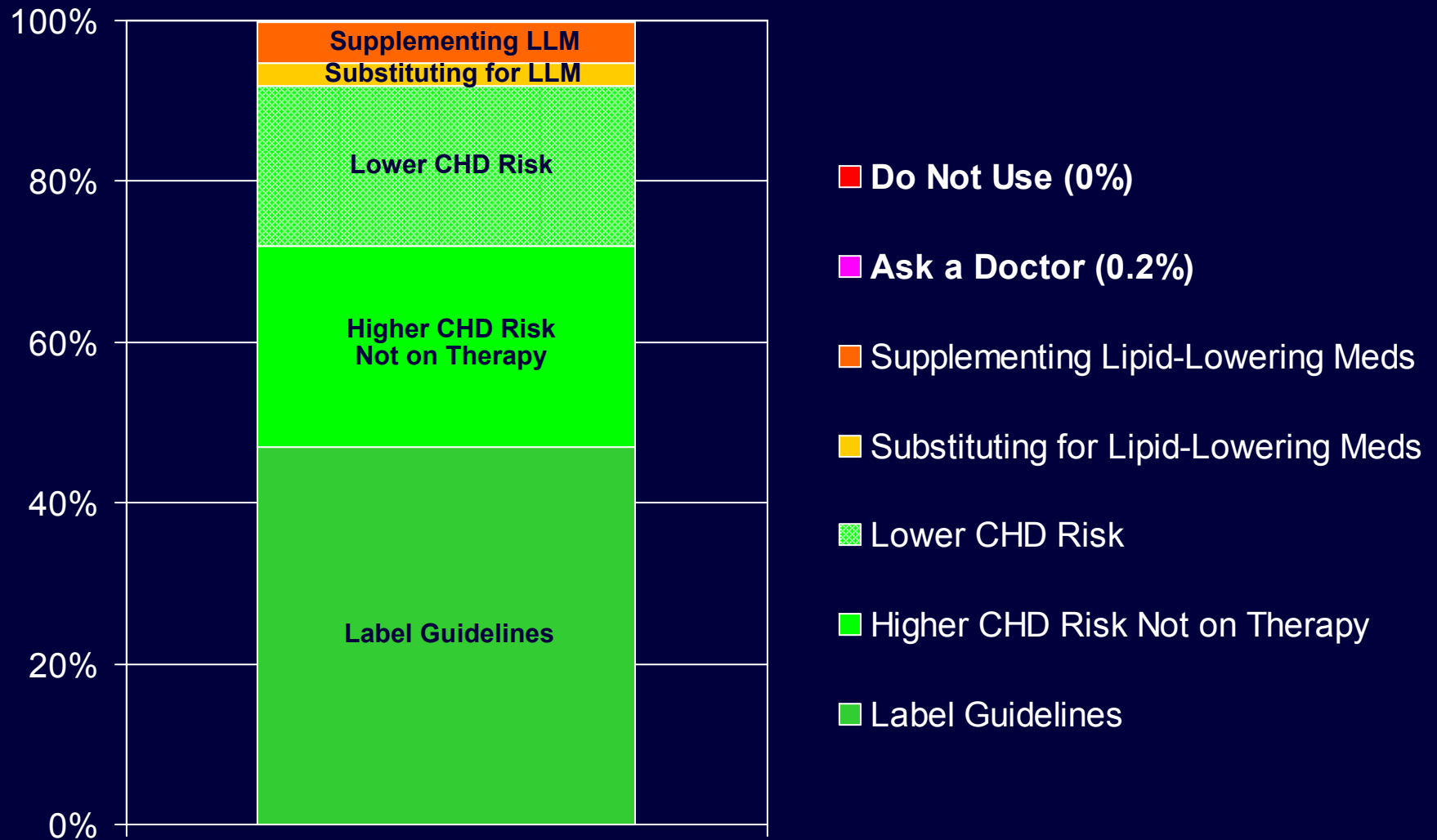


# Labeling Hierarchy of Purchasers in SELECT

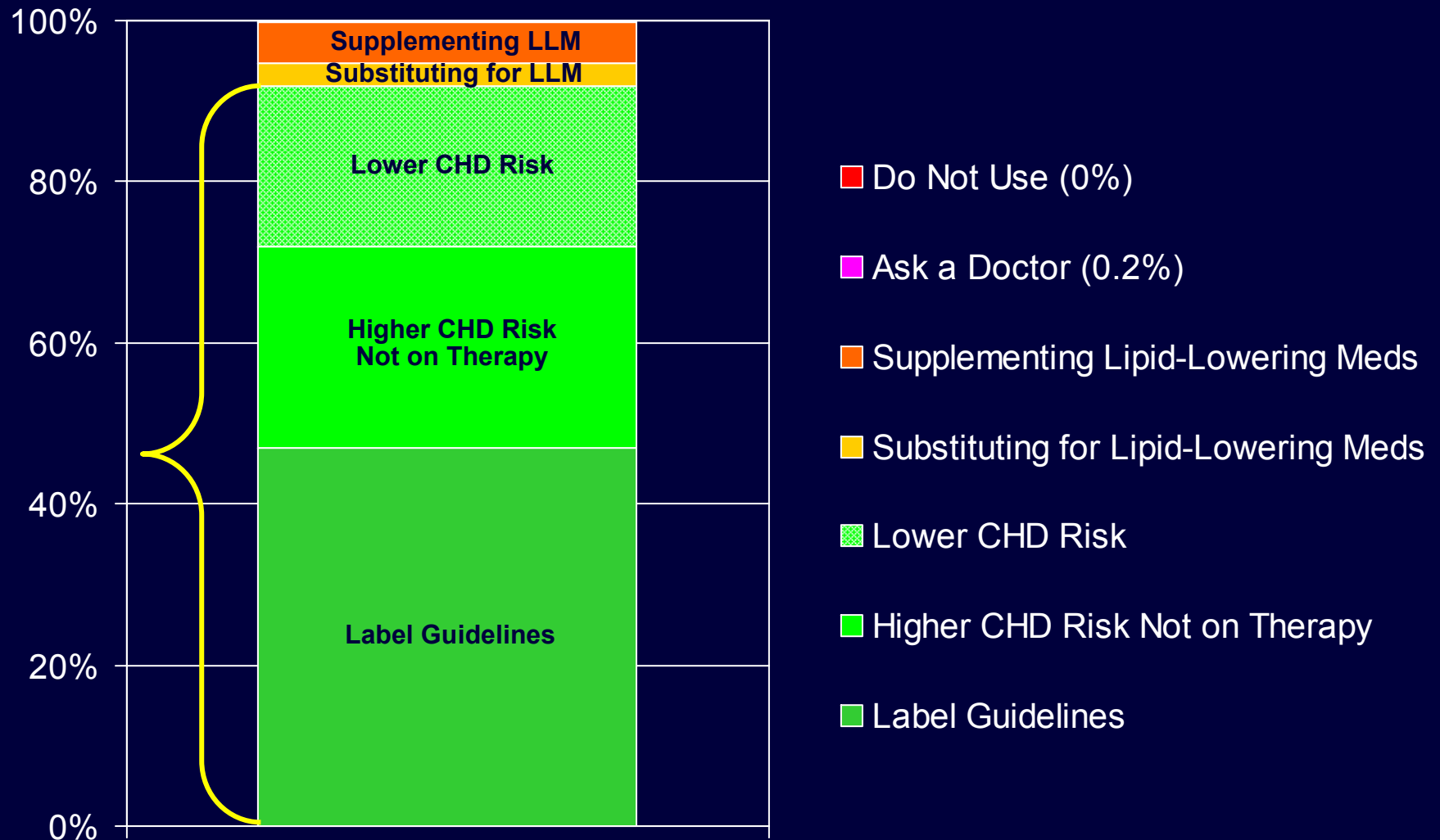




# Labeling Hierarchy of Purchasers in SELECT



# Labeling Hierarchy of Purchasers in SELECT



MEVACOR™ Daily

Consumer Support and Monitoring Program

Saul Shiffman, PhD

*Professor Psychology, Psychiatry, & Pharmaceutical Sciences*  
University of Pittsburgh

# Consumer Support & Monitoring Program

Based on Sound Principles for Behavior Change

- Draws from recent GSK OTC switch programs
  - Nicotine Replacement Therapy (to quit smoking)
  - alli<sup>®</sup> (to lose weight)
- Designed to help consumers
  - Appropriately select whether to use product
  - Use product according to label
  - Change behavior/adopt healthier lifestyles

# Consumer Guidance and Support Three-Step Program

## Pre-Purchase Guidance



## In-Store Guidance



## Ongoing Guidance



- Promotes:**
- Appropriate self-selection
  - Appropriate use
  - Healthy lifestyle
  - Healthcare provider interaction

# Pre-Purchase Guidance

## Assists Consumer Self-Selection

- Advertising drives consumers to web and 1-800 number
  - To determine eligibility per label
  - To assess cardiovascular risk



# In-Store Guidance

## Store-Shelf Communication Engages and Educates Consumer

**First-Time Buyers** Should you take it?

**Repeat Buyers** Did you make it?

**Important TAKE ONE**

**Should you take it?**

1. **Total Cholesterol**

2. **LDL "bad" Cholesterol**

3. **HDL "good" Cholesterol**

4. **Diagnosis**

**Did you make it?**

1. **Did you get a fasting cholesterol test at 4 weeks?**

2. **Did you get to the required 4 week goal: LDL 1-129?**

**Lower your cholesterol... and keep it down!**

## See if it's right for you. Turn all 5 wheels!

1  
4 choices

1 Man, 44 Yrs. or younger STOP

**Gender & Age?**

2  
4 choices

1 1-129 mg/dL STOP

**LDL "bad" Cholesterol?**

3  
5 choices

1 None apply STOP

**Any conditions that increase heart risk?**

4  
9 choices

1 Pregnant or breast-feeding STOP

**Any warnings apply to you?**

Should you take it?

5

**ANY ANSWERS DO NOT BUY**

**MEVACOR® Daily may not be right for you.**

Ask your doctor or study personnel.

# Post-Purchase: In-Package Materials

## Direct Appropriate Self-Selection and Use

The collage features several key pieces of in-package material:

- Decision Tree:** A flowchart titled "Should you take it?" with two main paths:
  - 1 Double-check to make sure it's right for you:** A flowchart for LDL cholesterol. It asks if the user's LDL is 129 or below. If yes, it says "You're on your way." If no, it asks if the user is taking MEVACOR Daily. If yes, it says "You must follow the chart below to see if this product is right for you." If no, it says "You should not take MEVACOR Daily." The chart includes boxes for "ASPIRIN", "LDL CHOLESTEROL", and "HEART DISEASE FACTORS".
  - 2 Test at 6 weeks:** A card titled "You're on your way." It says "After 6 weeks of daily use, MEVACOR Daily will have lowered your LDL cholesterol." It includes a small image of the MEVACOR Daily bottle and a "Quick Start Guide" icon.
- Quick Start Guide:** A blue card with a yellow header that says "IMPORTANT... Read This First!". It includes the text "Should you take it?", "Did you make it?", and "It's the way to a heart-healthy life." It also features the MEVACOR Daily logo and the text "Get your LDL cholesterol to 129 or below, and keep it down."
- Informational Leaflets:** Several smaller cards with text and graphics. One titled "Did you make it?" discusses LDL test results and provides instructions on when to take the medication. Another titled "Should you take it?" provides detailed instructions on how to use the product. A third titled "MEVACOR Daily" provides information about the medication's benefits and safety.
- Heart Healthy Living Guide:** A blue booklet titled "Your Guide to Heart Healthy Living" featuring a photo of a family walking on a beach. It includes the text "Get your LDL cholesterol to 129 or below, and keep it down."



# Ongoing Guidance

## Promotes Appropriate Self-Selection

- MEVACOR™ Daily Interactive Consumer Support Program
  - Incentive to enroll
  - Interactive self-selection
- Return/refund if product not appropriate



# Ongoing Guidance

## Promotes Appropriate Use

- Encourages diet and exercise
- Actively prompts for cholesterol re-testing
- Interactive, tailored, web-based program
  - Provides phone/print if no web access



# Ongoing Guidance

- Tailored
  - Addresses individual's motivations and preferences
  - Enhances program effectiveness
- Proactive
  - Prompts for engagement in program
  - Reminds users to have cholesterol re-tested

# In-Market Monitoring Program

## Confirms Appropriate Use

- Adverse Event Reporting per NDA regulations
- Proactive monitoring of consumer behavior
  - Studies of MEVACOR™ Daily users
  - Surveys of physicians & pharmacists
- Timely data on real-world use
- Overseen by an Expert Advisory Board
- Results reported to FDA

# In-Market Monitoring Program

## Assess Appropriate Self-Selection and Use

- Studies of MEVACOR™ Daily users
- Objectives
  - Assess consumer self-selection
  - Assess on-going use
- Sample interview questions
  - Age, gender, CHD risks
  - Baseline LDL-C level
  - Medications at baseline
  - Use of MEVACOR™ Daily
  - Repeat cholesterol test at 6 weeks

# In-Market Monitoring Program

## Assess Appropriate Population and Disposition

- Profile interested consumers against target population
  - Population surveys
  - Profile screening contacts
- Disposition of screen-outs to assess heeding and referral
  - Follow-up surveys

# In-Market Monitoring Program

## Assess Appropriate Self-Selection and Use

- Self-selection and appropriate use in
  - Users enrolled in registry
    - Longitudinal panel
  - Users identified through national household panel
  - Enrollees in Consumer Support Program
- Repeated series identify trends over time

# In-Market Monitoring Program

Collects Physician and Pharmacist Observations

- Physicians
  - Contact with MEVACOR™ Daily users
  - Possible areas of concern
- Pharmacists
  - Contact with consumers considering MEVACOR™ Daily
  - Questions consumers are asking
  - Counseling activities
  - Cholesterol and MEVACOR™ Daily knowledge



# Consumer Support and Monitoring Program

Overseen by Expert Advisory Board

- Multi-disciplinary
- Analyzes and assesses performance
- Recommends program improvements
- Reports provided to FDA

# MEVACOR™ Daily Consumer Support & Monitoring Program

- Consumer Support Program
  - Pre-purchase
  - Point-of-purchase
  - Ongoing use
- In-Market Monitoring Program
  - MEVACOR™ Daily user studies
  - Physician and pharmacist surveys
- Independent Expert Advisory Board
- Reporting to FDA

# MEVACOR™ Daily

## Consumer Support and Marketing Program

George Quesnelle  
*President*

GlaxoSmithKline Consumer Healthcare  
North America

# GSK Consumer Healthcare

## Experienced in Successful Rx-to-OTC Switches

- Nicotine Replacement Therapy – 1996
  - Smoking cessation therapy
  - Behavioral support program
- alli® – 2007
  - Weight loss therapy
  - Behavioral support program



# Nicotine Replacement Therapy

## OTC Switch Challenges

- Nicotine is addictive
- Potential teen misuse/abuse
- Professional intervention in OTC setting
- Marketing practices

# Nicotine Replacement Therapy

## OTC Switch Challenges

- Nicotine is addictive
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- Professional intervention in OTC setting
- Marketing practices

## GSK Commitments

- In-market monitoring
- Labeling, in-market monitoring
- HCP engagement
- Responsible marketing
  - Education
  - Guidance
  - Support

# Nicotine Replacement Therapy

## OTC Switch Challenges

- Nicotine is addictive
- Potential teen misuse/abuse
- Professional intervention in OTC setting
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## GSK Commitments

- In-market monitoring
- Labeling, in-market monitoring
- HCP engagement
- Responsible marketing
  - Education
  - Guidance
  - Support

➤ 7.6 million people quit with OTC Nicotine Replacement

# alli<sup>®</sup> Weight Loss Therapy

## OTC Switch Challenges

- Requires behavior change (diet/exercise)
- Potential teen misuse/abuse
- Professional intervention in OTC setting
- Proper self-selection
- Marketing practices



# alli® Weight Loss Therapy

## OTC Switch Challenges

- Requires behavior change (diet/exercise)
- Potential teen misuse/abuse
- Professional intervention in OTC setting
- Proper self-selection
- Marketing practices

## GSK Commitments

- Behavior support program
- In-market monitoring
- HCP engagement
- Guide self-selection
- Responsible marketing

# alli® Weight Loss Therapy

## OTC Switch Challenges

- Requires behavior change (diet/exercise)
- Potential teen misuse/abuse
- Professional intervention in OTC setting
- Proper self-selection
- Marketing practices

## GSK Commitments

- Behavior support program
- In-market monitoring
- HCP engagement
- Guide self-selection
- Responsible marketing

➤ 2 million consumers using alli® to lose weight

# Right Positioning for Consumers in Advertising

- Appropriate target audience
- Science-based messaging
- Educational and supportive tonality



# Education to Promote Heart-Healthy Lifestyle

- Educate consumers on importance of high cholesterol and knowing numbers
- Non-branded communications—advertising, public relations, web

## Heart-Healthy Lifestyles Pre-launch Web Program

Do you have the  for it?



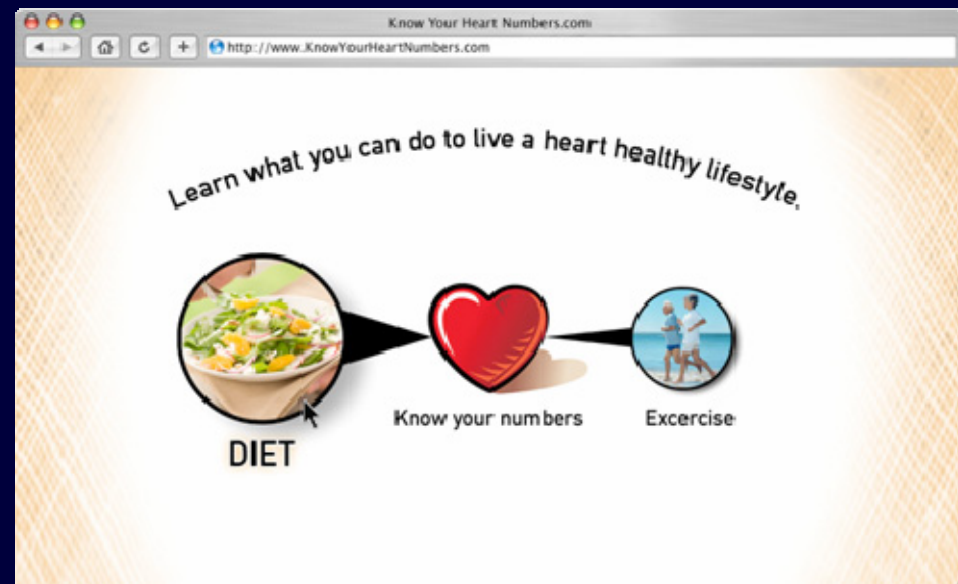
150<sup>LDL</sup>  
45<sup>HDL</sup>

Knowing your numbers can save your life.



150<sup>LDL</sup>  
45<sup>HDL</sup>

Find out more at [KnowYourHeartNumbers.com](http://KnowYourHeartNumbers.com)



# Cholesterol Education Programs

## Collaboration With the American Heart Association

- Website
- 1-800 number
- In-store heart-health education
- Healthcare professional education
- Cholesterol education & screening events

# Face-to-Face Consumer Support

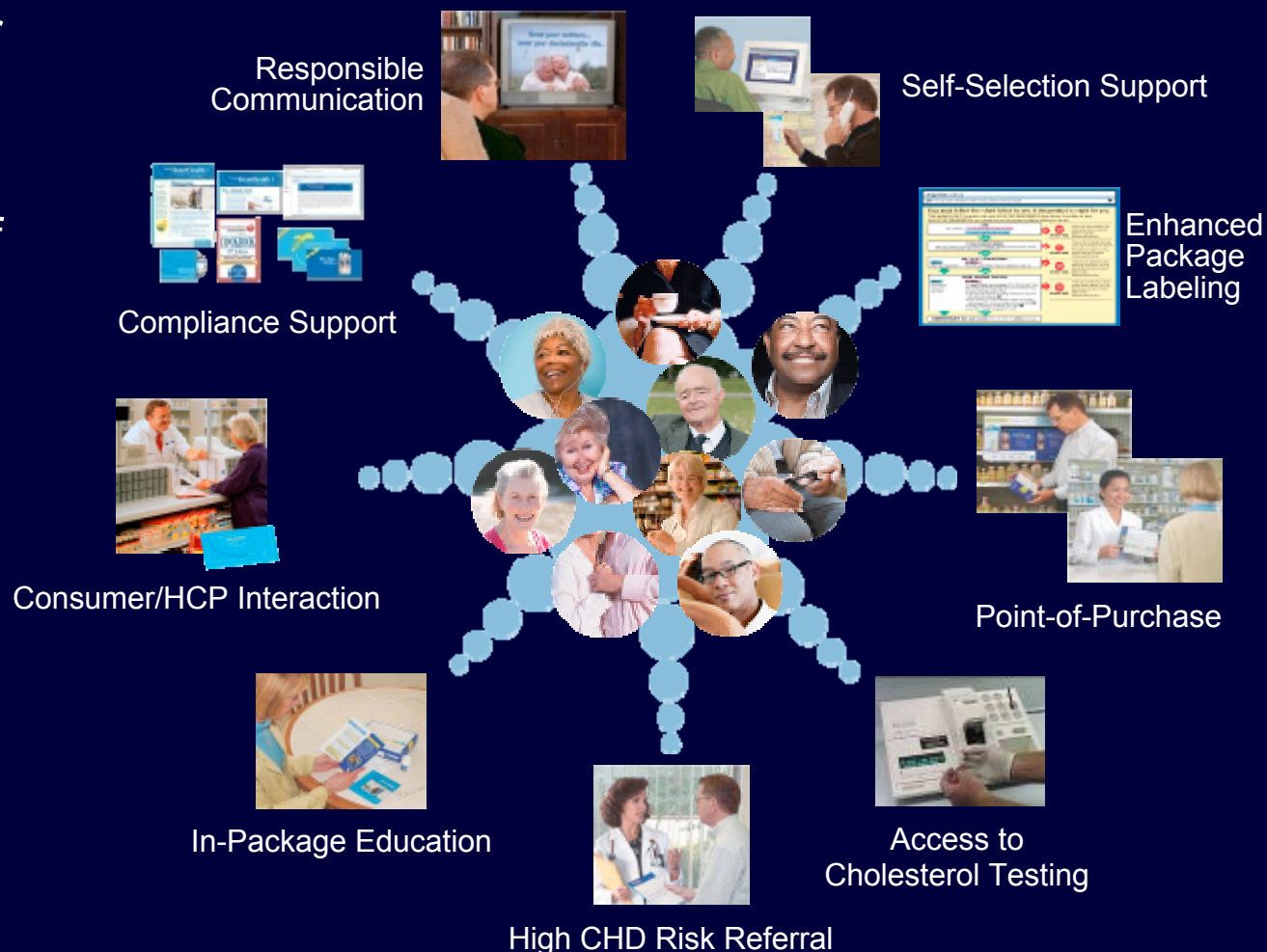
## Example Smoking Cessation Counseling

- One-on-one with trained counselors
- Heart-healthy lifestyle tips
- Cholesterol testing events



# Consumer Support at MEVACOR™ Daily Launch

- Support consumer before and after purchase
- Multiple formats of support
- Science-based messaging



# GSK Responsible Marketing Commitments for MEVACOR™ Daily

- Educate consumers on cholesterol
- Help people adopt heart-healthy lifestyle
- Help people appropriately select
- Monitor appropriate use
- Make adjustments when necessary
- Included programs in NDA



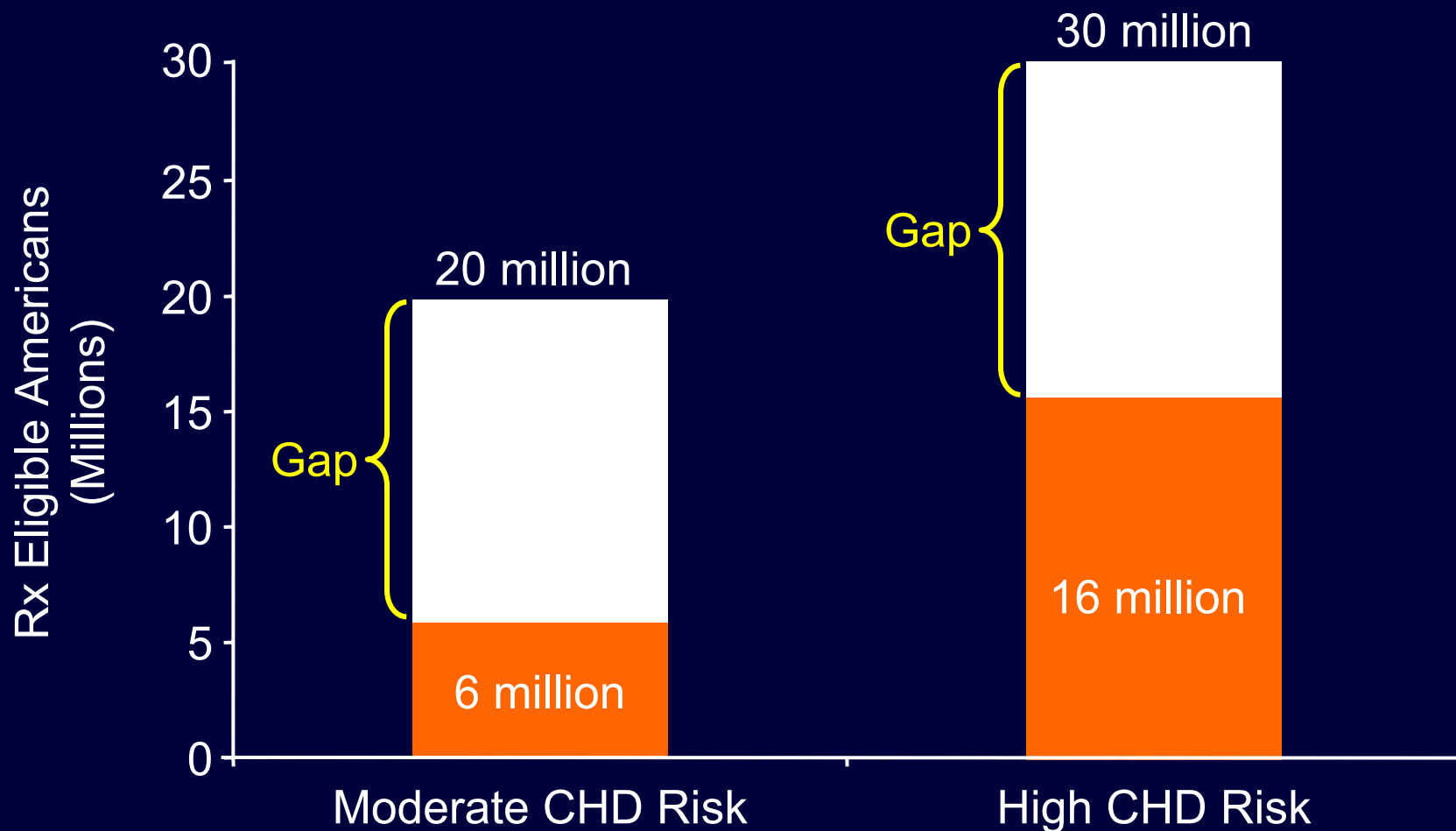
**MEVACOR™ Daily**  
**A Public Health Opportunity**

Edwin L. Hemwall, PhD  
Merck Research Laboratories

# Non-prescription Statin Criteria

	Addressed
● Target population warrants treatment	2005
● Efficacy	2005
● Safety	2005
● Appropriate consumer decisions	2007
– Self-selection	2007
– Improve pregnancy & muscle warning	2007
– Ongoing use	2005
• Lipid lowering	2005
• Cholesterol test/achieving goal	2005
• Diet & exercise	2005
• Compliance/persistence	2005
• Interaction with healthcare professional	2005
● Consumer support program	2005
● In-market monitoring program	2007

# Current Cholesterol Treatment Gap

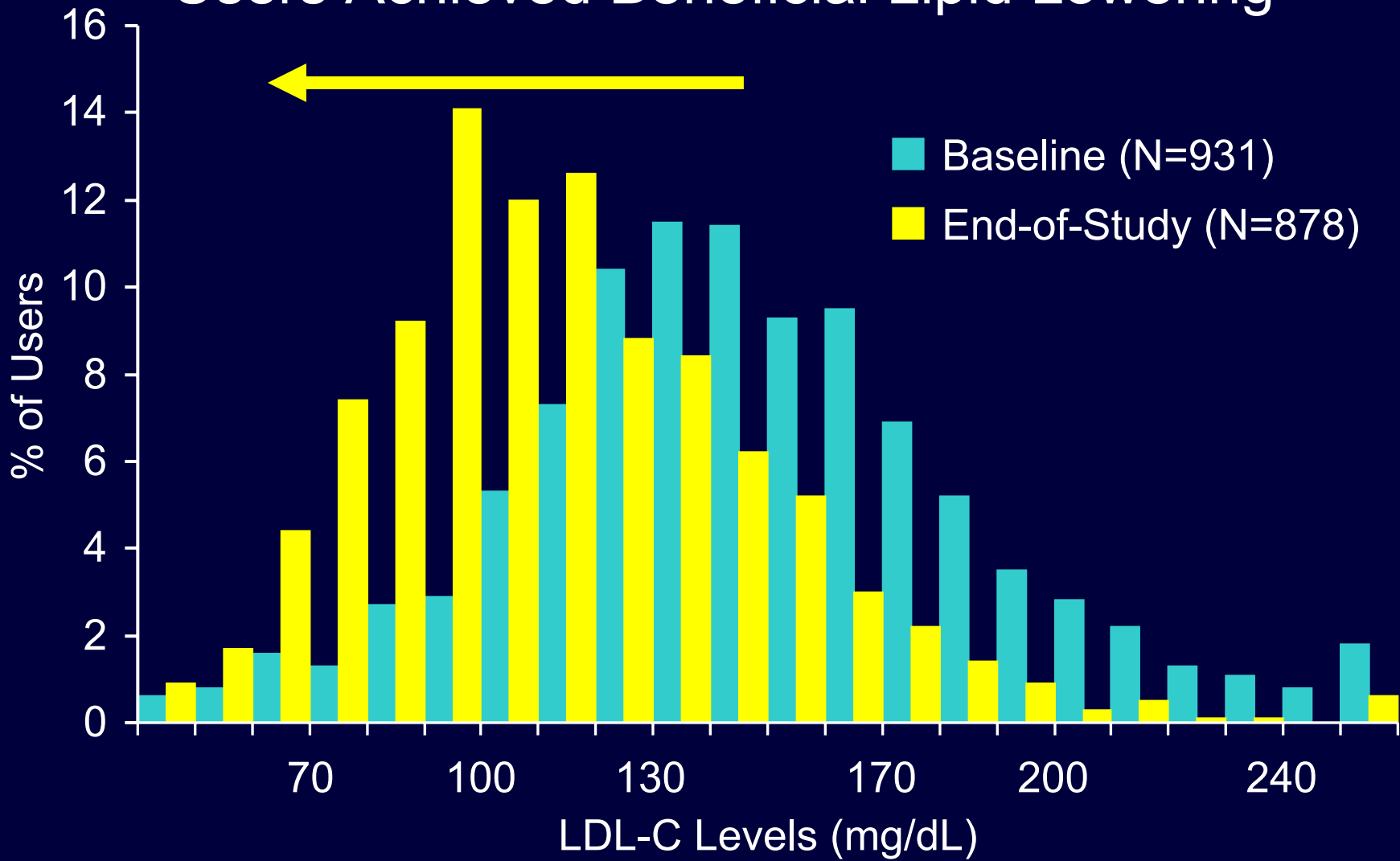


NHANES 1999 - 2002, Gallup Study of Cholesterol-Lowering Options 2005.

# OTC Can Help Shift the Curve

CUSTOM Data

Users Achieved Beneficial Lipid Lowering





# MEVACOR<sup>TM</sup>

Lovastatin 20 mg **Daily**  
CHOLESTEROL REDUCER

This Product is **only for:**



**WOMEN** age 55 and older



**MEN** age 45 and older

If you meet these age requirements,  
read back for more information.

45 TABLETS



