

CENTER FOR DRUG EVALUATION AND RESEARCH

**ADVISORY COMMITTEE: JOINT MEETING of the
NONPRESCRIPTION DRUGS and the DERMATOLIC and
OPHTHALMIC DRUGS ADVISORY COMMITTEES**

DATE OF MEETING: 07/16/97

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SLIDES

**Joint Meeting of the Nonprescription
Drugs Advisory Committee
and the
Dermatologic and Ophthalmic
Drugs Advisory Committee**

ROGAINE® Extra Strength for Men

July 16, 1997



Pharmacia&Upjohn

**Joint Meeting of the Nonprescription
Drugs Advisory Committee
and the
Dermatologic and Ophthalmic
Drugs Advisory Committee**

ROGAINE® Extra Strength for Men

July 16, 1997

Michael Valentino
President

Pharmacia & Upjohn
Consumer Healthcare
North America

Pharmacia & Upjohn Consumer Healthcare

July 16, 1997 Advisory Committee Meeting

Introduction

Michael Valentino

Psychosocial Effects

Thomas Cash, PhD

Safety and Efficacy

Ronald Trancik, PhD

Labeling Studies

Stuart Rose

Risk/Benefit

Ronald Trancik, PhD

&

Conclusions

Rationale for Approval

Strong Consumer Need

- 40 million men: androgenetic alopecia
 - 6-7 million motivated
- ROGAINE OTC experience
 - Users increased 5-fold
 - Many satisfied ROGAINE 2% users
- Greater efficacy desired
 - 50% of users want more effective product
 - Non-users looking for greater efficacy

Rationale for Approval

FDA approvable letter for prescription drug:
December 21, 1996

- Established ROGAINE 5% effective for males
- Originally submitted as an Rx before 2% OTC approval
- Filed (male) OTC NDA after Rx approvable letter
- Pursuing approval of ROGAINE 5% in females

Issues

- Safety in an OTC setting for males
- Consequences should women purchase

Rationale for Approval

Meets All OTC Criteria

APPEARS THIS WAY
ON ORIGINAL

- Effective
 - 46% more hair growth than ROGAINE 2%
 - See results sooner
- Safe
 - Comparable safety profile relative to ROGAINE 2%
- Superior benefit/risk ratio
- Acceptable OTC labeling

APPEARS THIS WAY
ON ORIGINAL

Conclusion

- ROGAINE® 5% should be approved for OTC availability
 - Strong benefit to risk ratio for men
 - Labeling appropriately advises men about difference between ROGAINE 2% and ROGAINE 5%
 - Labeling appropriately deters women
- OTC status provides the opportunity for many more men to treat their hair loss with the best product available

Psychosocial Effects of Hair Loss

Thomas F. Cash, PhD
Professor of Psychology
Old Dominion University

(with Adjunct Appointment at Eastern Virginia Medical School)

Licensed Clinical Psychologist in Virginia

PhD in Clinical Psychology
MA in Clinical Psychology
George Peabody College (of Vanderbilt University)

BA in Psychology
Vanderbilt University

Psychology of Physical Appearance

- Function and appearance of body are life-shaping
- “Outside view”: interpersonal effects of human appearance
 - Social prejudice and discrimination
- “Inside view”: subjective attitudes/feelings about own looks
 - “Body image”

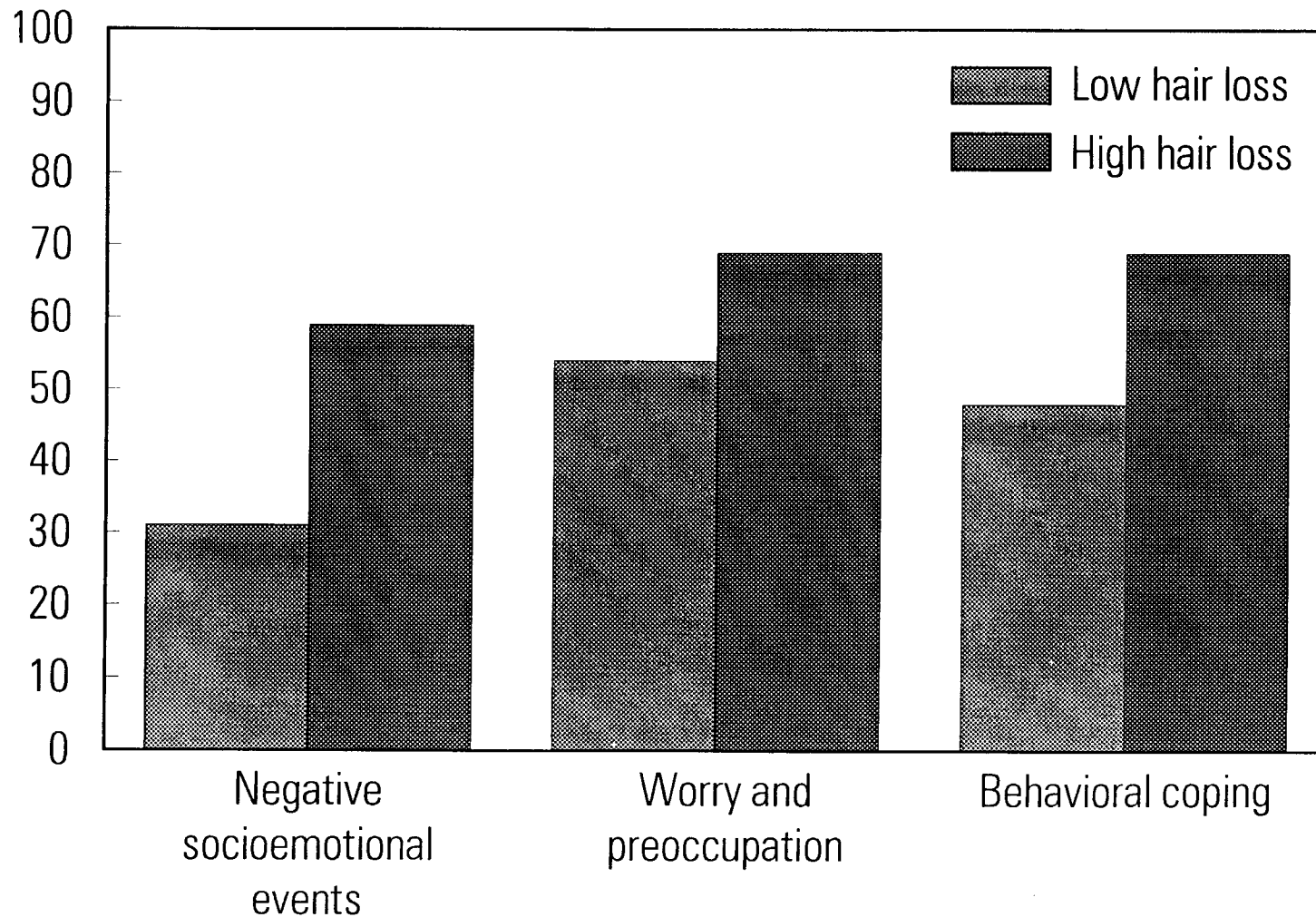
Well-Controlled Scientific Studies

- Modestly visible hair loss (n=63)
 - Significant impact on 60% of events
- More extensive hair loss (n=40)
 - Significant impact on 79% of events

Adverse Effects of Hair Loss Among Men

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Percent of men reporting adverse effects due to hair loss

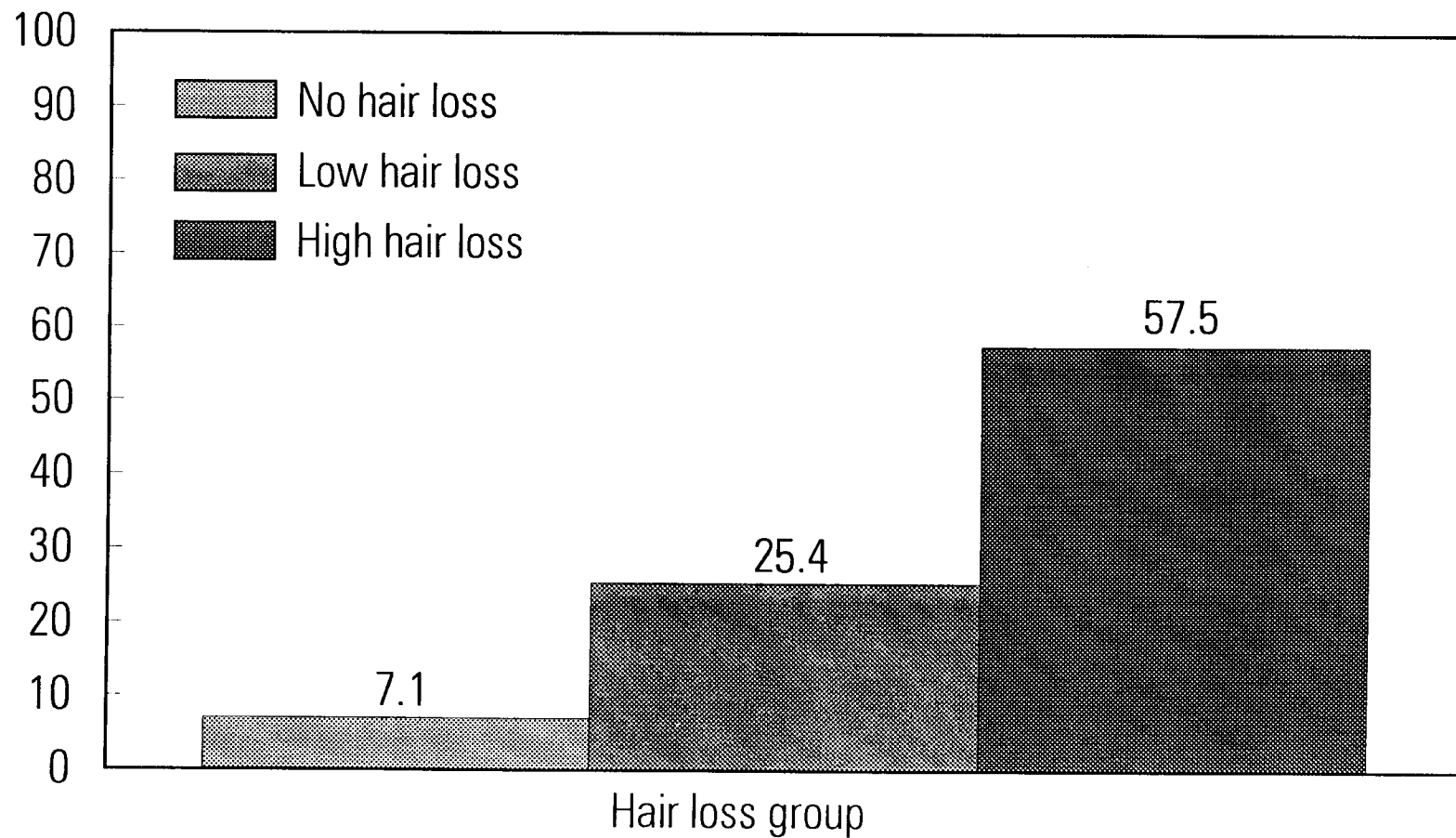


Experiences Attributed to Hair Loss Among Men

Reported event	Low hair loss	High hair loss
Wish for more hair	52%	84%
Get teased by peers	45%	79%
Feel self-conscious	42%	78%
Worry about looks	49%	68%
Worry about more balding	44%	59%
Look older than age	40%	55%
Feel helpless about hair loss	37%	56%

Dissatisfaction with Hair Among Men

Percent dissatisfied



Men Most Adversely Affected by Hair Loss

- Believe balding to be socially noticeable
- Expect further hair loss
- Are younger
- Have earlier onset
- Are single, not dating

**APPEARS THIS WAY
ON ORIGINAL**

Psychosocial Effects of Hair Loss Among Men

Worry about future hair loss	93%
Feel frustrated/helpless	88%
Self-conscious about looks	78%
Feel less attractive	73%
Look older than age	70%
Get teased/kidded	60%
Feel depressed	38%

Coping with Hair Loss Among Men

Try to hide the hair loss	63%
Try to improve hairstyle	63%
Talk to hairstylist about it	58%
Talk to spouse/partner about it	57%
Seek reassurance about looks	57%
Try to improve overall looks	55%
Talk to friends about it	52%
Try to improve physique	52%

Conclusions

APPEARS THIS WAY
ON ORIGINAL

Hair loss has a significant
psychosocial impact on men

Safe and effective treatments of hair loss
are important to men's quality of life

APPEARS THIS WAY
ON ORIGINAL

Ronald J. Trancik, PhD
Director Clinical Research

Pharmacia & Upjohn
Consumer Healthcare

Background

ROGAINE 5% relative to ROGAINE 2%

- Comparable safety
- Superior efficacy

Support the direct OTC approval of
ROGAINE Extra Strength for Men

Comparable Safety

- Pharmacokinetic studies support wide margin of safety
- 2,000+ patients in well-controlled clinical trials
- REGAINE® 5% worldwide commercial marketing experience as prescription and nonprescription
- ROGAINE 2% US experience as a prescription vs OTC

APPEARS THIS WAY
ON ORIGINAL

Superior Efficacy

APPEARS THIS WAY
ON ORIGINAL

- Clinical studies in over 700 males support superior efficacy of ROGAINE 5% over ROGAINE 2%

APPEARS THIS WAY
ON ORIGINAL

Conclusion

APPEARS THIS WAY
ON ORIGINAL

Comparable safety and superior efficacy of
ROGAINE 5% support the direct OTC approval
of ROGAINE Extra Strength for Men

APPEARS THIS WAY
ON ORIGINAL

Minoxidil History in U.S.

<u>Major Events</u>	<u>Date</u>
LONITEN® approved	November 1979
ROGAINE 2% Rx approved/males	August 1988
ROGAINE 2% Rx approved/females	August 1991
FDA meeting/pre-NDA (5%)	March 1995
NDA submitted — Rx (5%)	December 1995
ROGAINE 2% OTC approved	February 1996
Rx FDA approvable letter in males (5%)	December 1996
NDA submission — direct OTC (5%)	February 1997
NDAC meeting (5%)	July 1997

Marketing Experience

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- Regulatory/marketing status — ROGAINE 2%
 - 90 countries approved
 - 20 as nonprescription

APPEARS THIS WAY
ON ORIGINAL

Marketing Experience

- Regulatory/marketing status — REGAINE 5%
 - 19 countries approved (males and females)
 - 14 marketed
 - 2 as nonprescription
 - Denmark
 - New Zealand
 - 12 prescription approvals pending
 - 2 direct OTC approvals pending

APPEARS THIS WAY
ON ORIGINAL

Safety

APPEARS THIS WAY
ON ORIGINAL

- Comparable safety to ROGAINE 2%
- Established by
 - Pharmacokinetic studies
 - Clinical studies
 - Commercial marketing experience

APPEARS THIS WAY
ON ORIGINAL

Safety

Pharmacokinetic/Absorption

APPEARS THIS WAY
ON ORIGINAL

- Low absorption (1.7% of topical dose)
- Multiple factors studied that affect absorption
- Minimal hemodynamic effect level: 20 ng/mL
- Serum minoxidil levels in long-term clinical trials
 - ROGAINE 2%: 0.6 ng/mL
 - ROGAINE 5%: 1.2 ng/mL
- Margin of safety more than an order of magnitude

Scope of the Clinical Program: Safety

Males

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Protocol no. (population studied)	Treatment duration (weeks)	Total enrollment	No. evaluable for safety		
			ROGAINE 5%	ROGAINE 2%	PBO
0001	32	345	174	86	85
0285	48	393	157	158	78
0282	48	62	31	—	31
0275	96	27	9	8	10
Total		827	371	252	204

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ON ORIGINAL

Medical Event Occurrence/Relative Risk Assessment by Body System

Males and Females

APPEARS THIS WAY
ON ORIGINAL

Body system	Medical events* no. pts. (% occurrence)			Relative risk			
				ROGAINE 5% vs ROGAINE 2%		ROGAINE 5% vs PBO	
	ROGAINE 5% (n=672)	ROGAINE 2% (n=525)	PBO (n=365)	Estimate	95% confidence intervals	Estimate	95% confidence intervals
Dermatologic	126 (18.8)	63 (12.0)	39 (10.7)	1.57 [†]	(1.18, 2.09)	1.91 [†]	(1.37, 2.67)

APPEARS THIS WAY
ON ORIGINAL

*Includes Protocols 0001, 0009, 0275, 0285, 0286, 0279, and 0282. Protocols 0279 and 0282 did not have a ROGAINE 2% treatment arm.

[†]Relative risk significantly greater than unity (1.0) [ie, lower bound of 95% confidence interval is > 1.0].

Dermatologic Event Occurrence/Relative Risk Assessment by Body System

Males

APPEARS THIS WAY
ON ORIGINAL

Body system	Medical events* no. pts. (% occurrence)			Relative risk			
				ROGAINE 5% vs ROGAINE 2%		ROGAINE 5% vs PBO	
	ROGAINE 5% (n=371)	ROGAINE 2% (n=252)	PBO (n=204)	Estimate	95% confidence intervals	Estimate	95% confidence intervals
Dermatologic	53 (14.3)	26 (10.3)	20 (9.8)	1.47	(0.93, 2.30)	1.63	(0.98, 2.72)

APPEARS THIS WAY
ON ORIGINAL

*Includes Protocols 0001, 0285, 0275, and 0282. Protocol 0282 did not have a ROGAINE 2% treatment arm.

Treatment Discontinuations Due to a Medical Event

Males and Females

APPEARS THIS WAY
ON ORIGINAL

Type of medical event	Treatment group		
	ROGAINE 5% (n=672)	ROGAINE 2% (n=525)	PBO (n=365)
All medical events	51 (7.6%)	28 (5.3%)	9 (2.5%)
Dermatologic medical events	29 (4.3%)	10 (1.9%)	4 (1.1%)
All other medical events	22 (3.3%)	18 (3.4%)	5 (1.4%)

APPEARS THIS WAY
ON ORIGINAL

Treatment Discontinuations Due to Dermatologic Medical Events

APPEARS THIS WAY
ON ORIGINAL

Dermatologic medical events (eg, pruritus, etc.)	Treatment group		
	ROGAINE 5%	ROGAINE 2%	PBO
Male	9 (2.4%) (n=371)	2 (0.7%) (n=252)	0 (n=204)

APPEARS THIS WAY
ON ORIGINAL

Treatment Discontinuations Due to Specific Dermatologic Medical Events

Males and Females

Type of medical event	Treatment group		
	ROGAINE 5%	ROGAINE 2%	PBO
Pruritus:			
Male and female	8 (1.2) (n=672)	1 (0.2) (n=525)	3 (0.8) (n=365)
Male	4 (1.1) (n=371)	1 (0.4) (n=252)	0 (n=204)
Hypertrichosis:			
Male and female	7 (1.0) (n=672)	1 (0.2) (n=525)	0 (n=365)
Male	0 (n=371)	0 (n=252)	0 (n=204)

Hypertrichosis — Females

APPEARS THIS WAY
ON ORIGINAL

	ROGAINE 5% (n=301)	ROGAINE 2% (n=273)	PBO (n=161)
Medical event	20 (7%)	1 (<1%)	1 (<1%)
Discontinued	7 (2%)	1 (<1%)	0

APPEARS THIS WAY
ON ORIGINAL

Local Tolerance

APPEARS THIS WAY
ON ORIGINAL

- Itching, erythema, dryness
- Incidence in males
 - ROGAINE 5% \approx PBO > ROGAINE 2%
- Consistent with
 - Dermatologic medical event reports
 - Reaction to propylene glycol
- Conclusion
 - Local intolerance addressed in labeling
“increased scalp irritation may occur”

Commercial Marketing Experience — REGAINE 5%

Males and Females

- Estimated exposure
 - Approximately 60,000 users
 - 14 countries — 2 as an OTC
- 37 users reported 69 medical events
 - Most frequent dermatologic (61%)
 - None serious
- 15 users reported 38 medical events — with 5% extemporaneous topical minoxidil formulations
- Conclusions
 - No new “signals” emerging
 - Consistent with ROGAINE 2% experience

APPEARS THIS WAY
ON ORIGINAL

Medical Event Profiles for Prescription ROGAINE 2% vs Nonprescription ROGAINE 2%

Males and Females — United States Only

Body system	Number (%) of events	
	ROGAINE 2% prescription* (total number of events = 24,310)	ROGAINE 2% nonprescription† (total number of events = 15,163)
Dermatologic	14,034 (57.8)	8,943 (59.0)
Miscellaneous	3,041 (12.5)	2,106 (13.9)
Neurologic	2,142 (8.8)	1,343 (8.9)
Cardiovascular	1,062 (4.4)	715 (4.7)

- Safety profile unchanged in OTC vs prescription product

*From September 1988 (Prescription launch) through 14 April 1996.

†From 15 April 1996 (OTC launch) through 31 May 1997.

Safety — Conclusion

- Comparable safety to ROGAINE 2%
- Established by
 - Pharmacokinetic studies
 - Clinical studies
 - Commercial marketing experience
 - REGAINE 5%
 - ROGAINE 2% (prescription vs OTC)

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

Scope of Definitive Studies: Efficacy

Males

APPEARS THIS WAY
ON ORIGINAL

Protocol no. (population studied)	Treatment duration (weeks)	Total enrollment	No. evaluable for efficacy		
			ROGAINE 5%	ROGAINE 2%	PBO
0001	32	321	163	79	79
0285	48	352	139	142	71
Total		673	302	221	150

APPEARS THIS WAY
ON ORIGINAL

Summary of Primary and Secondary Endpoints

Males — Protocol 0285

Endpoints	New method (questionnaire)		
	ROGAINE 5% vs PBO	ROGAINE 5% vs ROGAINE 2%	ROGAINE 2% vs PBO
Mean change from baseline 1° nonvellus hair count	S	S	S
Patient questionnaire 1° benefit from treatment 1° change in scalp coverage	S S	S S	S S
Investigator questionnaire 2° benefit from treatment 2° change in scalp coverage	NS S	S NS	S M

S Statistical significance ($p < 0.05$).
M Marginal statistical significance ($0.05 \leq p \leq 0.1$).
NS Not statistically significant ($p > 0.1$).

Efficacy — Males

APPEARS THIS WAY
ON ORIGINAL

- Two definitive clinical studies (0285, 0001) based on hair count results
 - ROGAINE 5% > ROGAINE 2% > PBO

APPEARS THIS WAY
ON ORIGINAL

Efficacy — Males

Superior efficacy demonstrated by:

- Magnitude of effect
 - 46% increase in hair counts over ROGAINE 2% at week 48
- Time to effect
 - Response at week 8 with ROGAINE 5% equivalent to response at week 16 with ROGAINE 2%

Conclusions — Safety and Efficacy

- ROGAINE® 5% relative to ROGAINE 2%
 - Comparable safety
 - Superior efficacy
- FDA approvable letter — ROGAINE 5% male only prescription product
- Support the direct OTC approval of ROGAINE Extra Strength For Men

Stuart Rose
Director Marketing Research

Pharmacia & Upjohn
Consumer Healthcare

APPEARS THIS WAY
ON ORIGINAL

Label Testing Review

APPEARS THIS WAY
ON ORIGINAL

Gender-Specific Areas of Focus

APPEARS THIS WAY
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Men

- Label comprehension

Women

- Intent to heed warnings

APPEARS THIS WAY
ON ORIGINAL

NDAC Labeling Questions

APPEARS THIS WAY
ON ORIGINAL

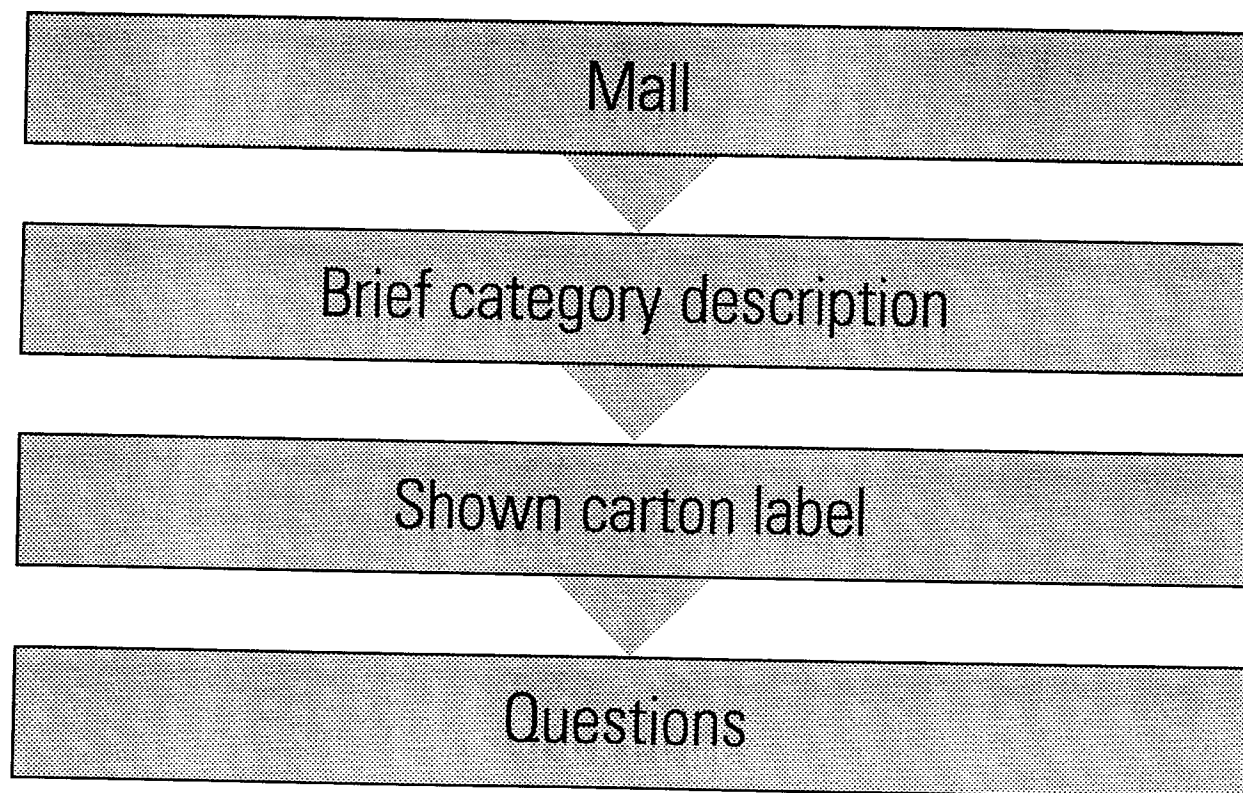
- Will men appropriately self-select?
- Will women appropriately avoid use?

APPEARS THIS WAY
ON ORIGINAL

Generalized Test Design

- Mall-intercept interviews
- 300 target audience consumers
 - 200 non-users
 - 100 users of ROGAINE/store brand
- 20-25 markets
- Broad demographic/socioeconomic representation
- December 1996 – June 1997

Basic Flow of Interview



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Objective: Label Comprehension Among Men

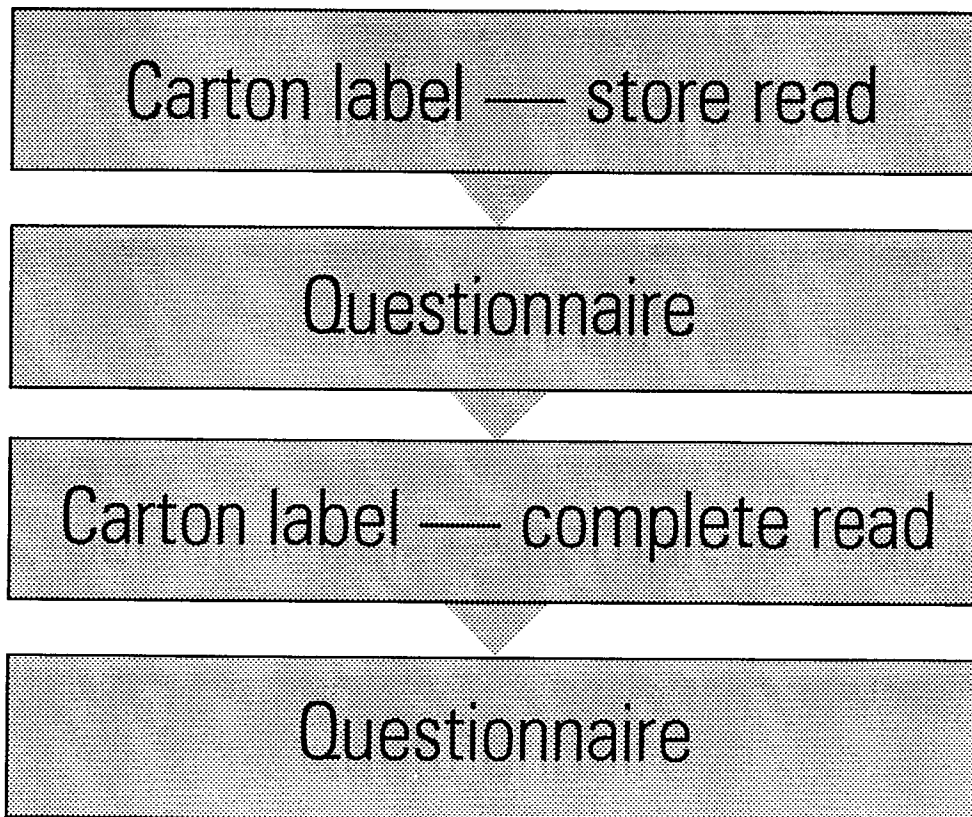
APPEARS THIS WAY
ON ORIGINAL

- Appropriate benefit/risk assessment between ROGAINE Extra Strength and Regular Strength
 - More hair growth
 - Hair regrowth sooner
 - Increased chance of minor scalp irritation

APPEARS THIS WAY
ON ORIGINAL

Interview Content and Flow

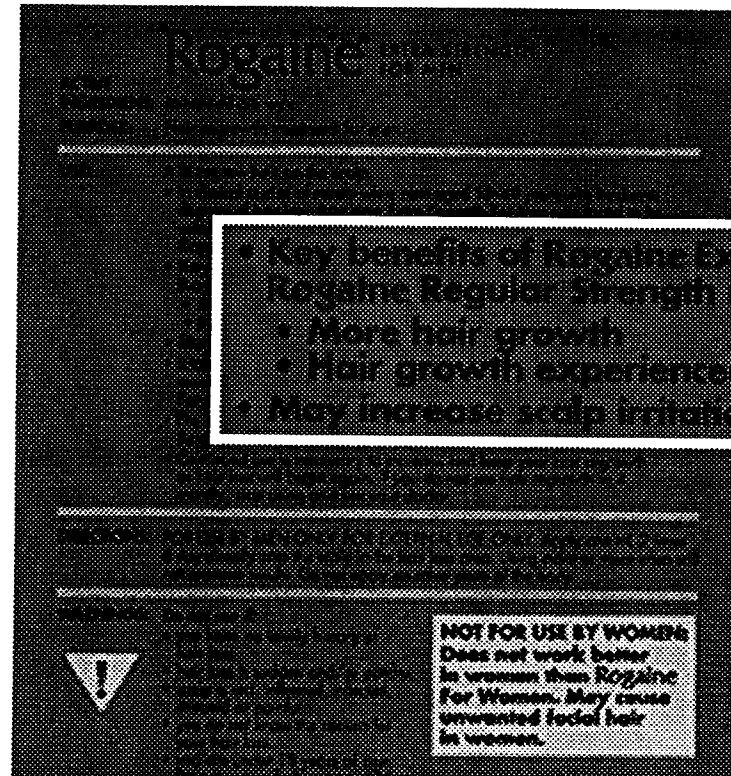
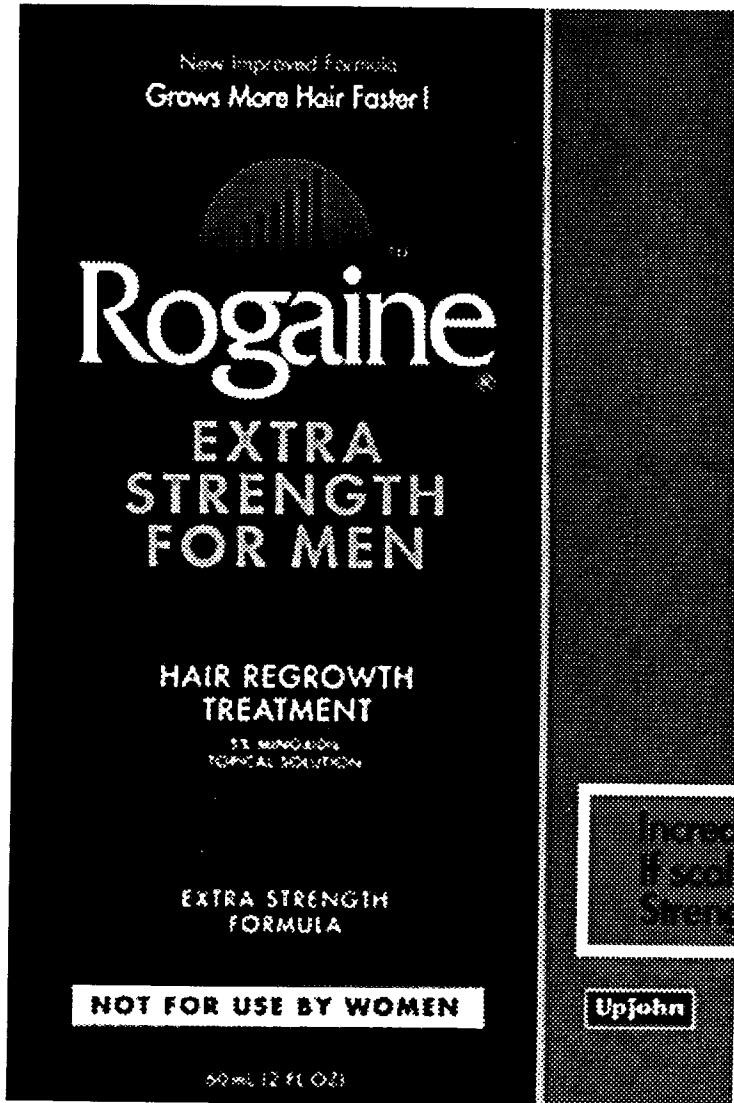
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APPEARS THIS WAY
ON ORIGINAL

Test Stimulus

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Increased scalp irritation may occur with Rogaine Extra Strength. If scalp irritation is experienced, consider switching to Rogaine Regular Strength. If scalp irritation continues, stop use and see a doctor.

APPEARS THIS WAY IN ORIGINAL

Results — Benefit Assessment

Percent Correct Response

APPEARS THIS WAY ON ORIGINAL	Non-users		ROGAINE users	
	Store read	Complete read	Store read	Complete read
	%	%	%	%
Grows more hair	74	80 [†]	77	83
Grows hair faster	72	83 [†]	76	83

†Statistically significant between store read and complete read.

Results — Risk Assessment

Percent Correct Response

	Non-users		ROGAINE users	
	Store read	Complete read	Store read	Complete read
	%	%	%	%
APPEARS THIS WAY ON ORIGINAL				
More likely to cause scalp irritation	52	68 [†]	53	71 [†]
Should switch to ROGAINE Regular Strength if scalp irritation occurs	63	67	69	74
			APPEARS THIS WAY ON ORIGINAL	

†Statistically significant between store read and complete read.

Conclusions

- Men understand the efficacy benefit after the store read level
 - Grows more hair/grows hair sooner
- Comprehension of risk assessment improves following a complete read
 - Increased chance of scalp irritation
 - Switch to ROGAINE Regular Strength if scalp irritation occurs
- Label further strengthened based on learning

Label Further Strengthened

Rogaine® EXTRA STRENGTH FOR MEN

ACTIVE INGREDIENT: Minoxidil 5% w/v
PURPOSE: Hair regrowth treatment for men

- USE:**
- To regrow hair on the scalp.
 - Clinical research in mostly white men on degrees of hair loss showed that Rogaine is safe for over-the-counter use.
 - Provides more hair regrowth.
 - Provides hair regrowth sooner.
 - May cause more scalp irritation, however, consider switching to 1) If scalp irritation worsens, stop
 - It takes time to regrow hair. With Rogaine visible results may be seen as early as 2 weeks. For some men it may take at least
 - The amount of hair regrowth is different Rogaine will not work for everyone.
 - Continued use is necessary to increase c or hair loss will begin again. If you do n stop using and see your doctor.

DIRECTIONS: FOR USE BY MEN ONLY FOR EXTERNAL USE ONLY. Apply one ml with dropper or sprayer (6 sprays) 2 times a day directly onto the scalp in the hair loss area. Using more or more often will not improve results. Using less, or less often, however will decrease results. Do not apply on other parts of the body.

- WARNINGS:** Do not use if:
- you have no family history of hair loss.
 - you are female.
 - hair loss is sudden and/or patchy.
 - scalp is red, inflamed, itched, irritated or painful.
 - you do not know the reason for your hair loss.
 - you are under 18 years of age. Do not use on babies and children.
 - you use other topical prescription products on the scalp.

Stop use and see a doctor if you get:

- chest pain, rapid heartbeat, lightheadedness, or
- sudden unexplained weight gain.
- swollen hands or feet.

Increased scalp irritation may occur with it. If scalp irritation persists, consider switching Strength. If scalp irritation worsens, stop use

Avoid contact with eyes. In case of accidents amounts of cool tap water. Keep this and oil Do not use on babies or children. In case of professional assistance or contact a Poison Control Center immediately. Before use, read all label information. Keep the carton. It contains important information.

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degrees of hair loss showed that Rogaine Extra Strength For Men is safe for over-the-counter use and differs from Regular Strength For Men products in the following ways:

- Provides more hair regrowth.
- Provides hair regrowth sooner.
- May cause more scalp irritation. If scalp irritation persists, however, consider switching to Rogaine Regular Strength. If scalp irritation worsens, stop use and see a doctor.

NOT FOR USE BY WOMEN: Does not work better in women than Rogaine For Women. May cause unwanted facial hair in women.

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Increased scalp irritation may occur with Rogaine Extra Strength. If scalp irritation persists, consider switching to Rogaine Regular Strength. If scalp irritation worsens, stop use and see a doctor.

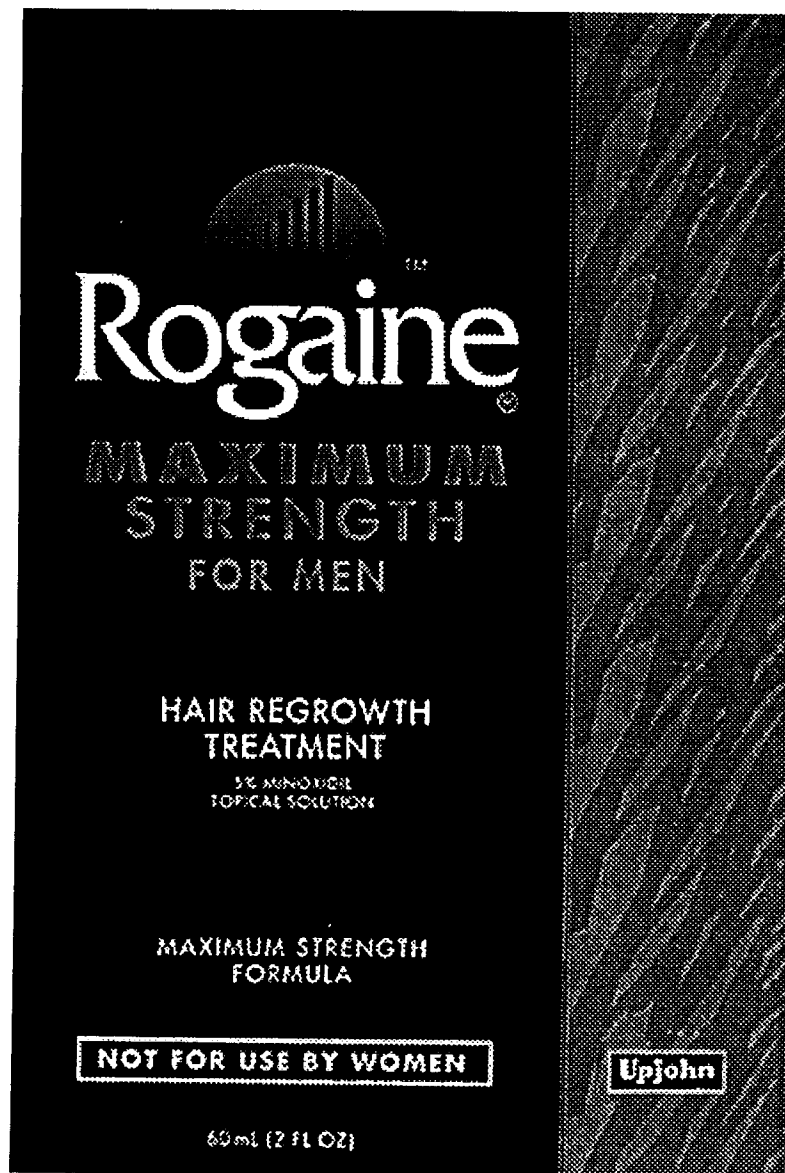
Intent to Heed Warning Among Women

APPEARS THIS WAY
ON ORIGINAL

- FDA raised question about number of women who would use product given absence of female offering
- Developed label to strongly discourage female use
- Commissioned Intent to Heed Study to address issue

APPEARS THIS WAY
ON ORIGINAL

Test Stimulus — Front Panel



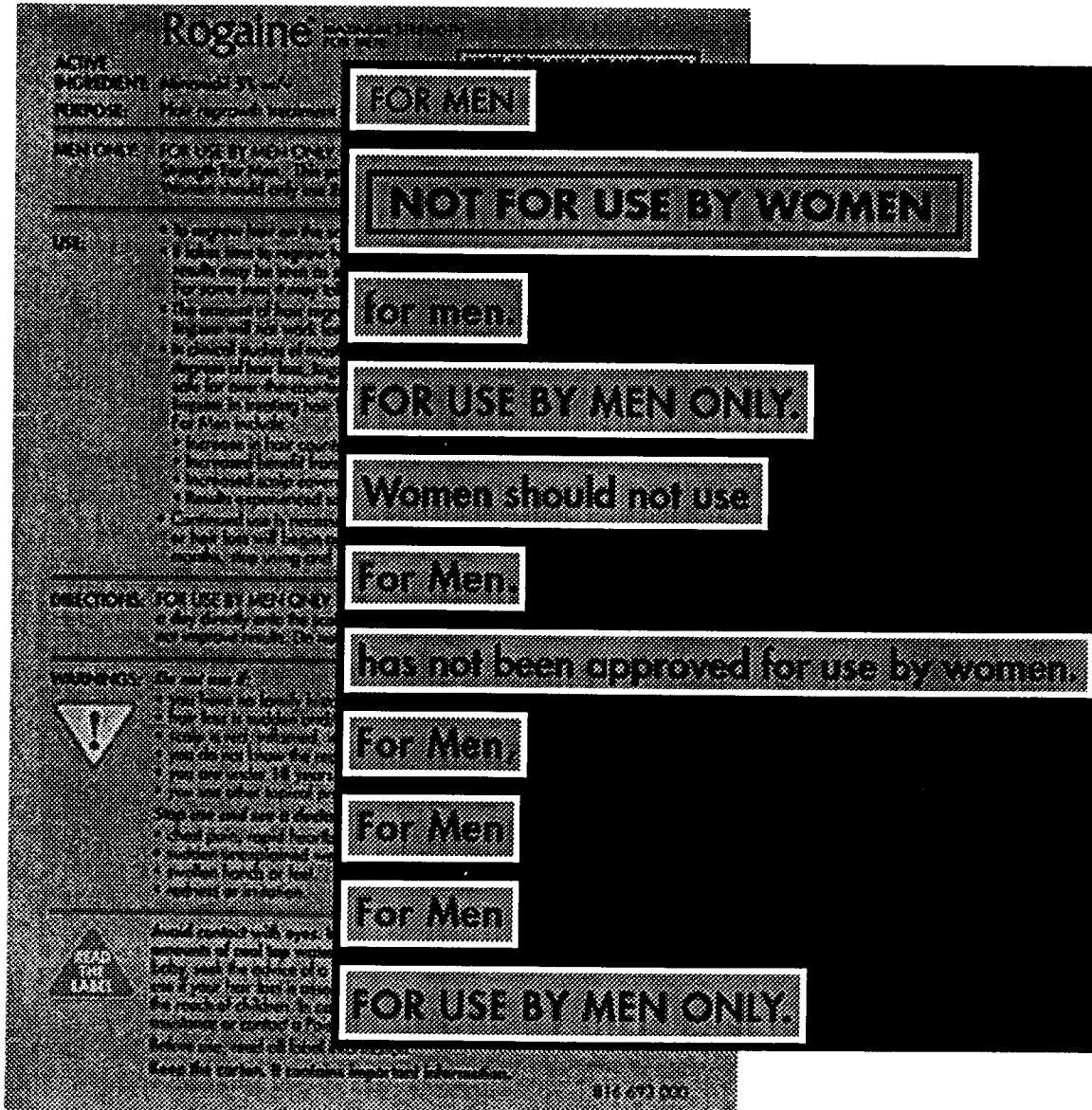
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Test Stimulus — Back Panel

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Objective: Intent to Heed Among Women

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ON ORIGINAL

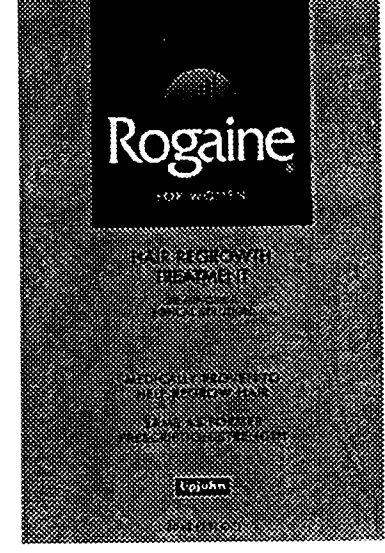
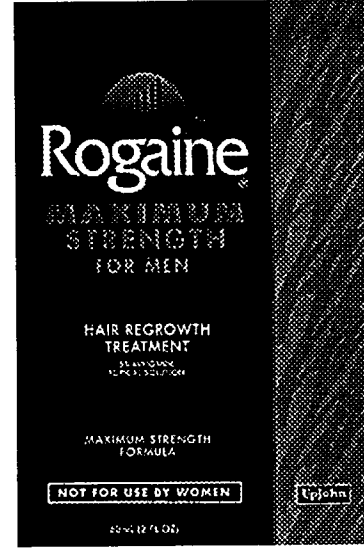
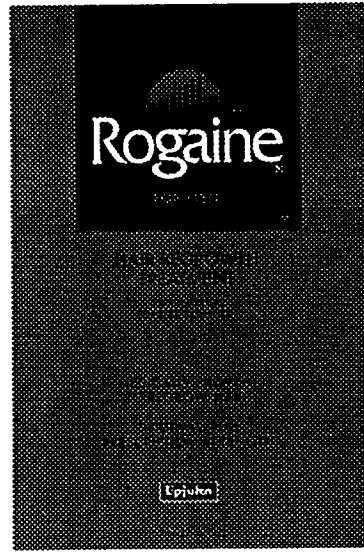
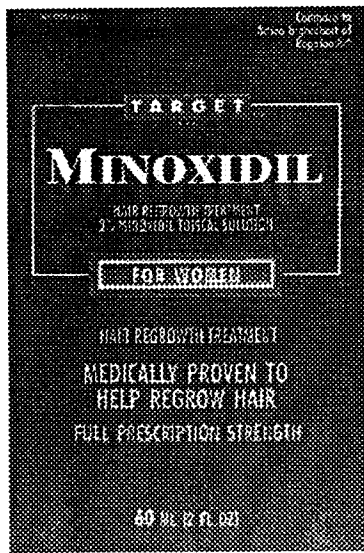
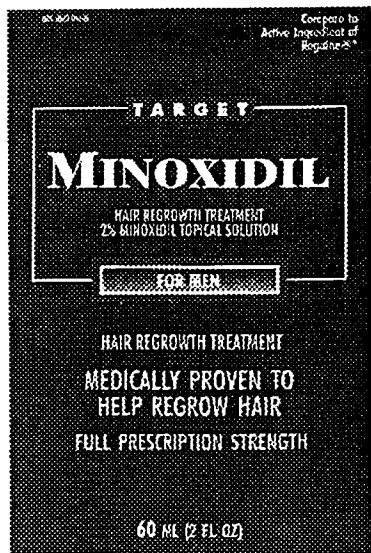
- Provide reassurance that very few women would in fact use ROGAINE Maximum Strength for Men
- Estimate proportion of women who would make incorrect choice
- May include women who choose to use despite risk of unwanted cosmetic effect

APPEARS THIS WAY
ON ORIGINAL

Test Stimulus

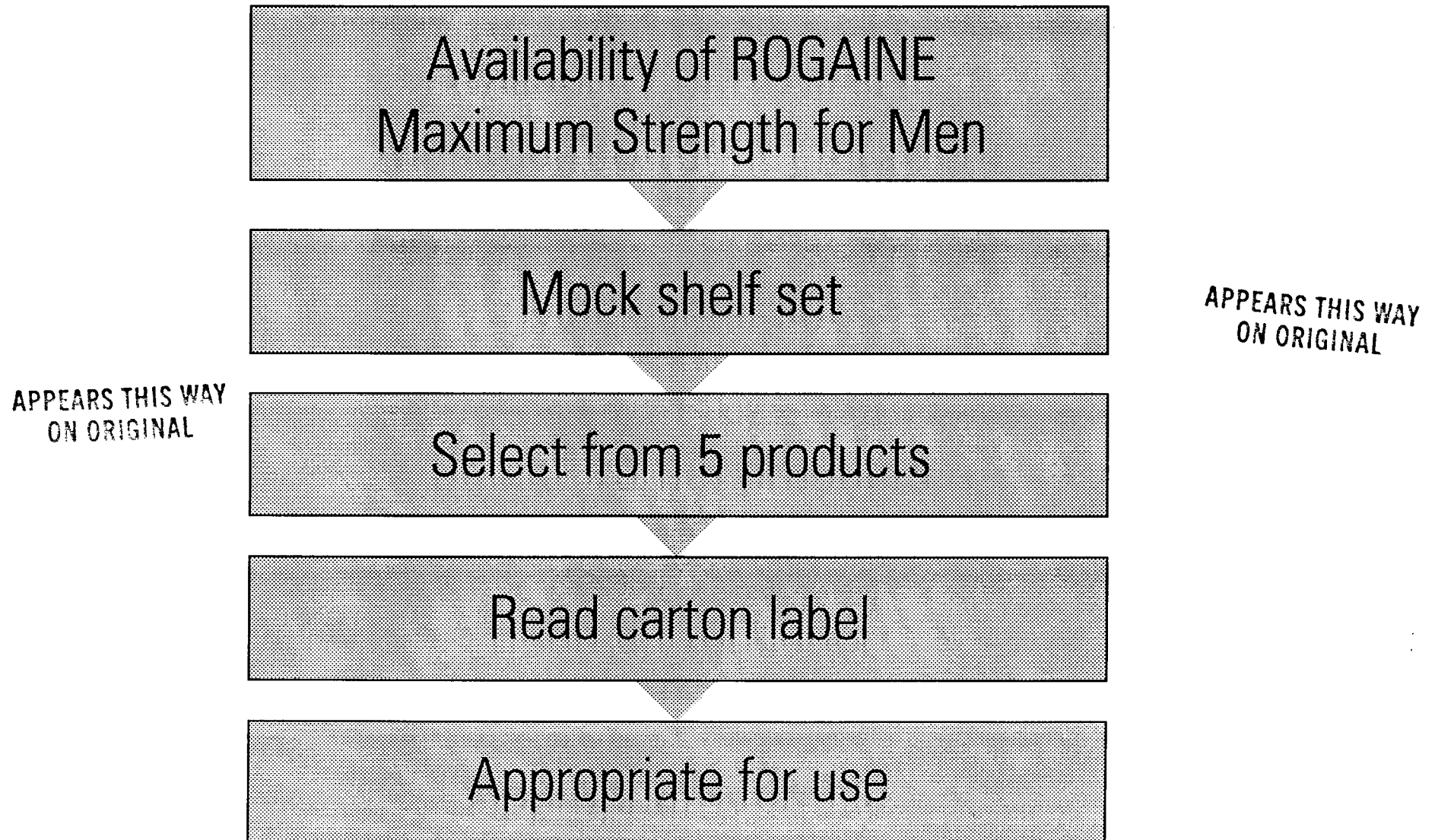
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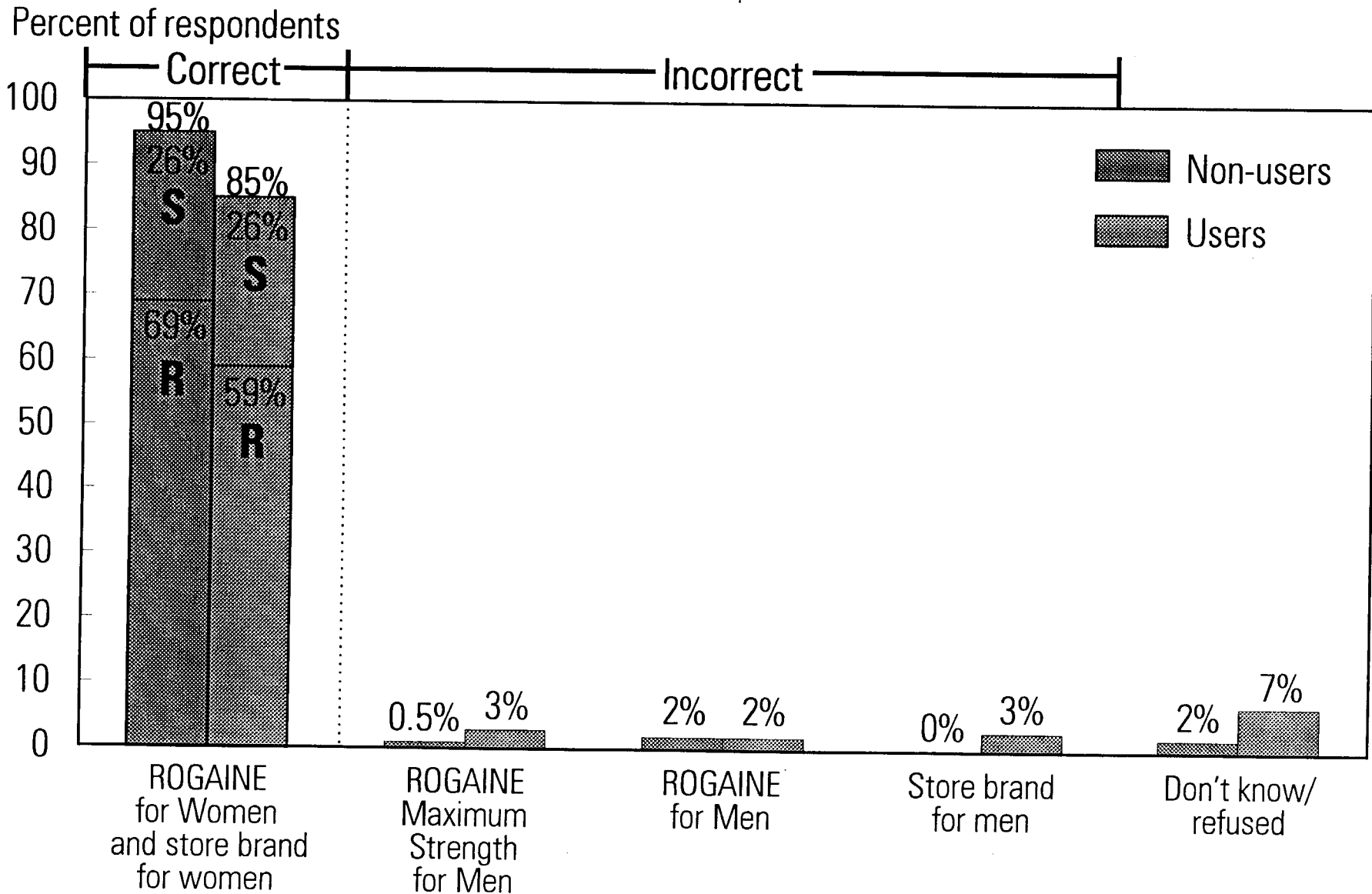


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Interview Content and Flow

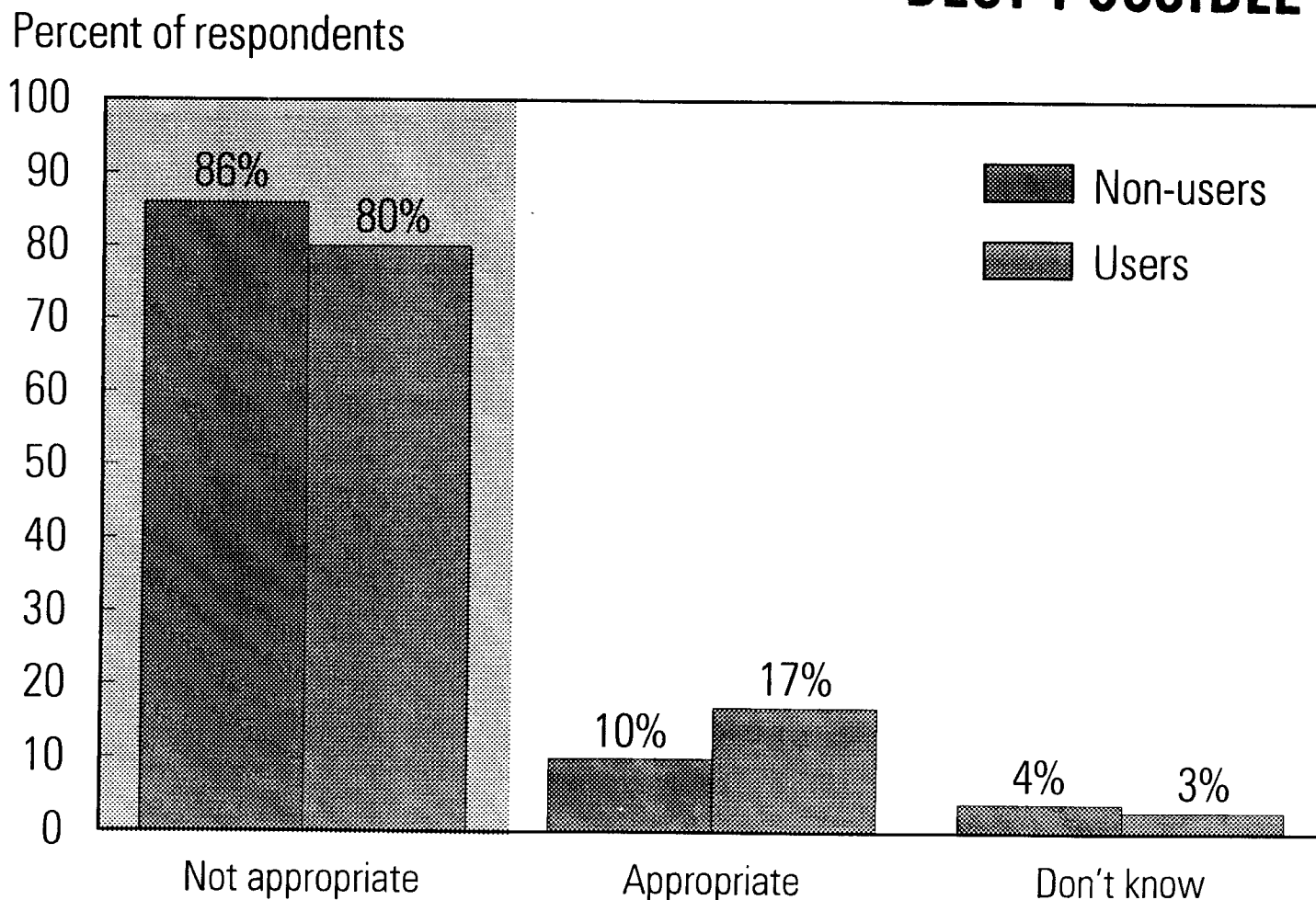


Results — Product Selection *BEST POSSIBLE COPY*



Results — Not Appropriate for Use

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Conclusions

APPEARS THIS WAY
ON ORIGINAL

- Number of women who would select ROGAINE Maximum Strength for Men is very small
- Test label adequately discourages female use

APPEARS THIS WAY
ON ORIGINAL

Outcome and Action Steps

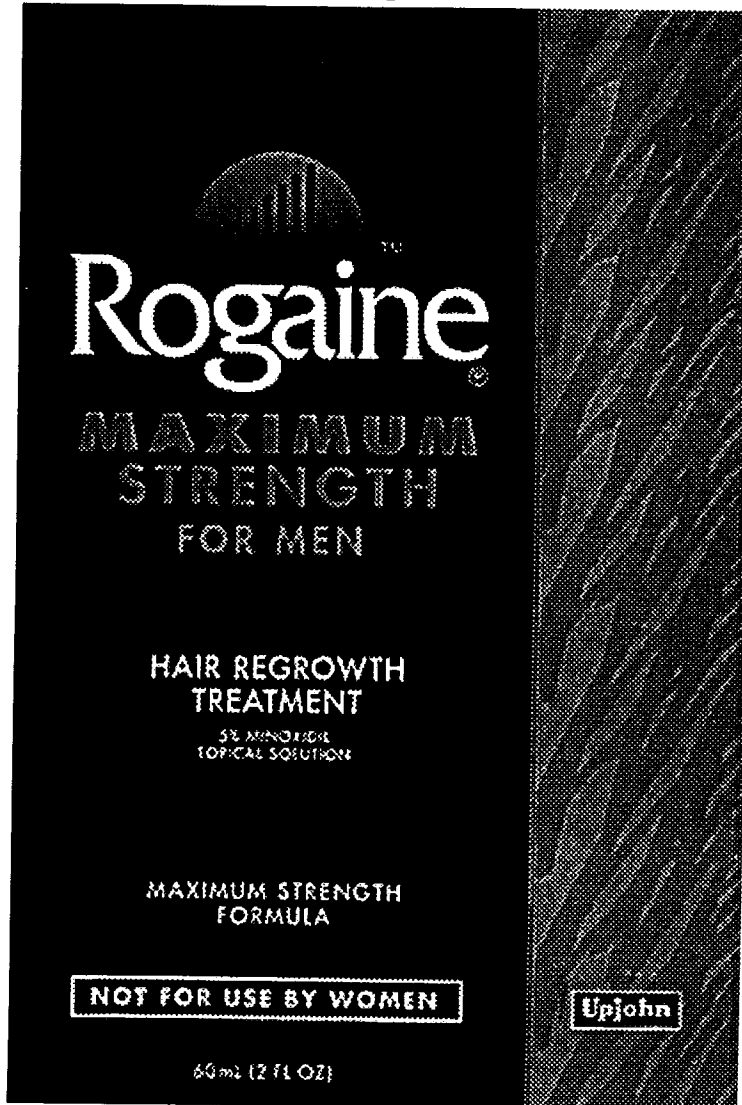
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- Stronger labeling
- Name change
- Re-test

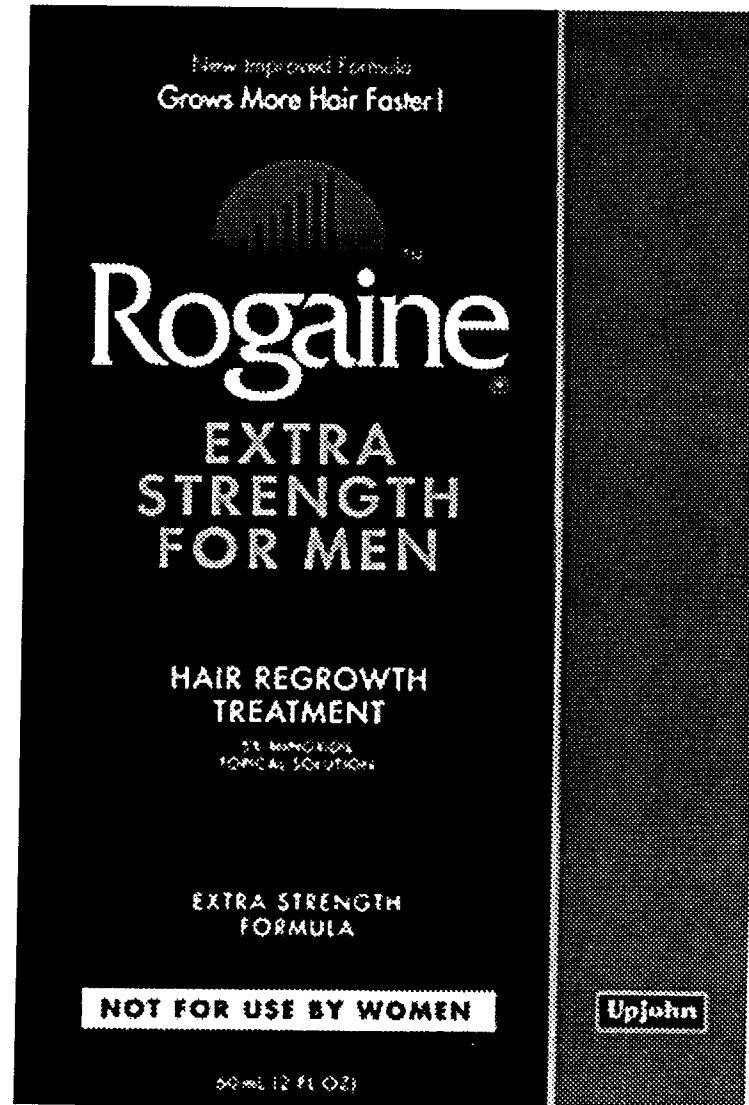
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Label Further Strengthened **BEST POSSIBLE COPY**

Original



Revised



Label Further Strengthened

Test Label

Rogaine® EXTRA STRENGTH FOR MEN

ACTIVE INGREDIENT: Minoxidil 5% w/v

PURPOSE: Hair regrowth treatment for men.

- USE:**
- To regrow hair on the scalp.
 - In clinical studies of mostly white men aged 18-49 years with moderate degrees of hair loss, Rogaine Extra Strength For Men was found to be safe for over-the-counter use and produced better results than Rogaine Regular Strength in treating hair loss.
 - Key benefits of Rogaine Extra Strength versus Rogaine Regular Strength include:
 - More hair growth
 - Hair growth experienced sooner
 - May increase scalp irritation
 - It takes time to regrow hair. With Rogaine Extra Strength For Men, results may be seen as early as 2 months with twice daily usage. For some men it may take at least 4 months for results to be seen.
 - The amount of hair regrowth is different for each person. Rogaine will not work for everyone.
 - Continued use is necessary to increase and keep your hair regrowth or hair loss will begin again. If you do not see hair regrowth in 4 months, stop using and see your doctor.

DIRECTIONS: FOR USE BY MEN ONLY. FOR EXTERNAL USE ONLY. Apply one mL 2 times a day directly onto the scalp in the hair loss area. Using more or more often will not improve results. Do not apply on other parts of the body.

WARNINGS: Do not use if:



- you have no family history of hair loss.
- hair loss is sudden and/or patchy.
- scalp is red, inflamed, infected, irritated or painful.
- you do not know the reason for your hair loss.
- you are under 18 years of age.
- Do not use on babies and children.
- you use other topical prescription products on the scalp.

Stop use and see a doctor if you get:

- chest pain, rapid heartbeat, lightheadedness, or dizziness.
- sudden unexplained weight gain.
- swollen hands or feet.

Increased scalp irritation may occur with Rogaine Extra Strength. If scalp irritation is experienced, consider switching to Rogaine Regular Strength. If scalp irritation continues, stop use and see a doctor.



Avoid contact with eyes. In case of accidental contact, rinse with large amounts of cool tap water. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Before use, read all label information. Keep the carton. It contains important information.

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FOR USE BY MEN ONLY. FOR EXTERNAL USE ONLY. Apply one mL 2 times a day directly onto the scalp in the hair loss area. Using more or more often will not improve results. Do not apply on other parts of the body.

**NOT FOR USE BY WOMEN:
Does not work better
in women than Rogaine
For Women. May cause
unwanted facial hair
in women.**

Interview Content and Flow

APPEARS THIS WAY
ON ORIGINAL

Exposure to carton label (store read)

Purchase intent

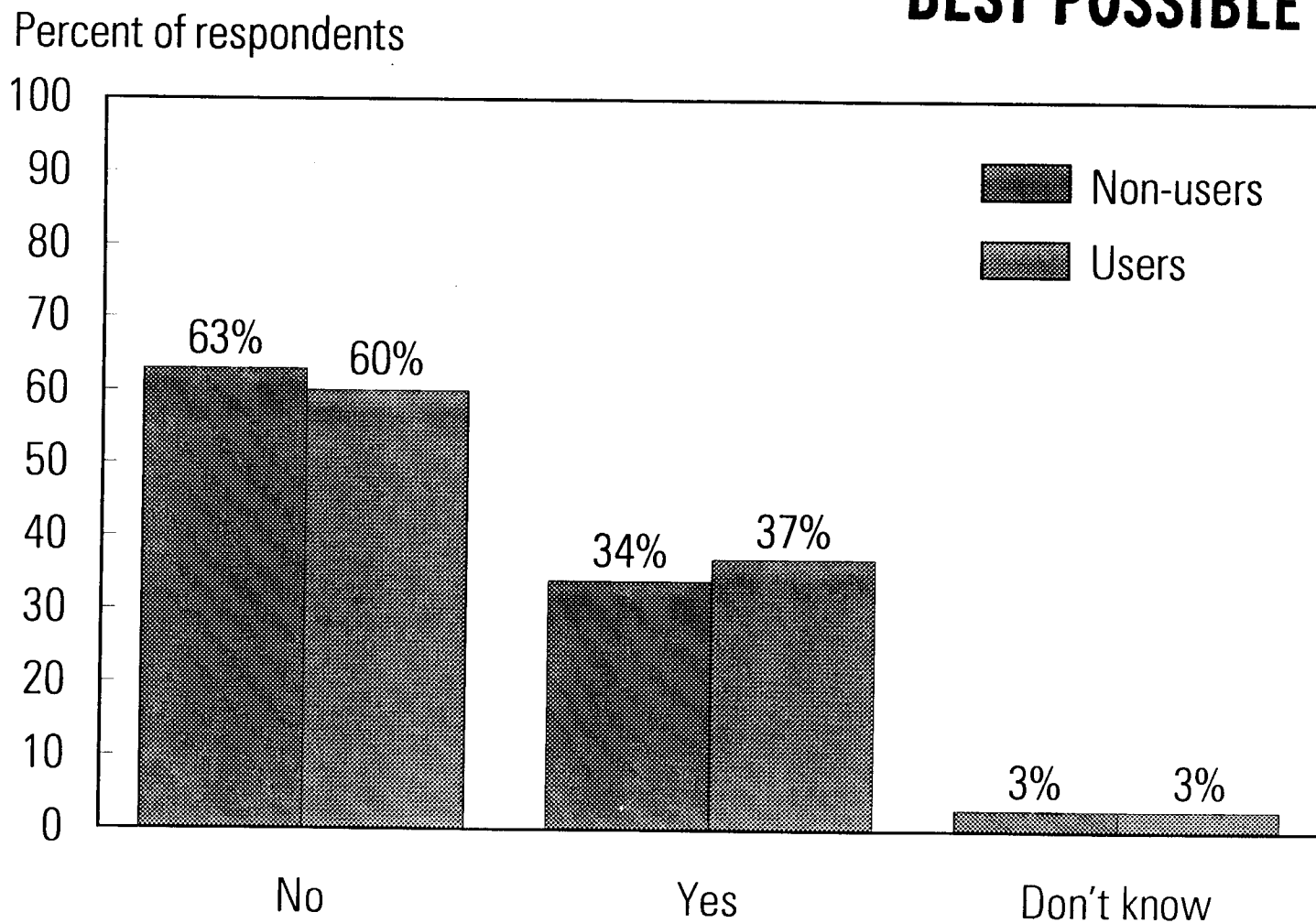
Re-exposure to carton label (complete read)

"Men only" probe

APPEARS THIS WAY
ON ORIGINAL

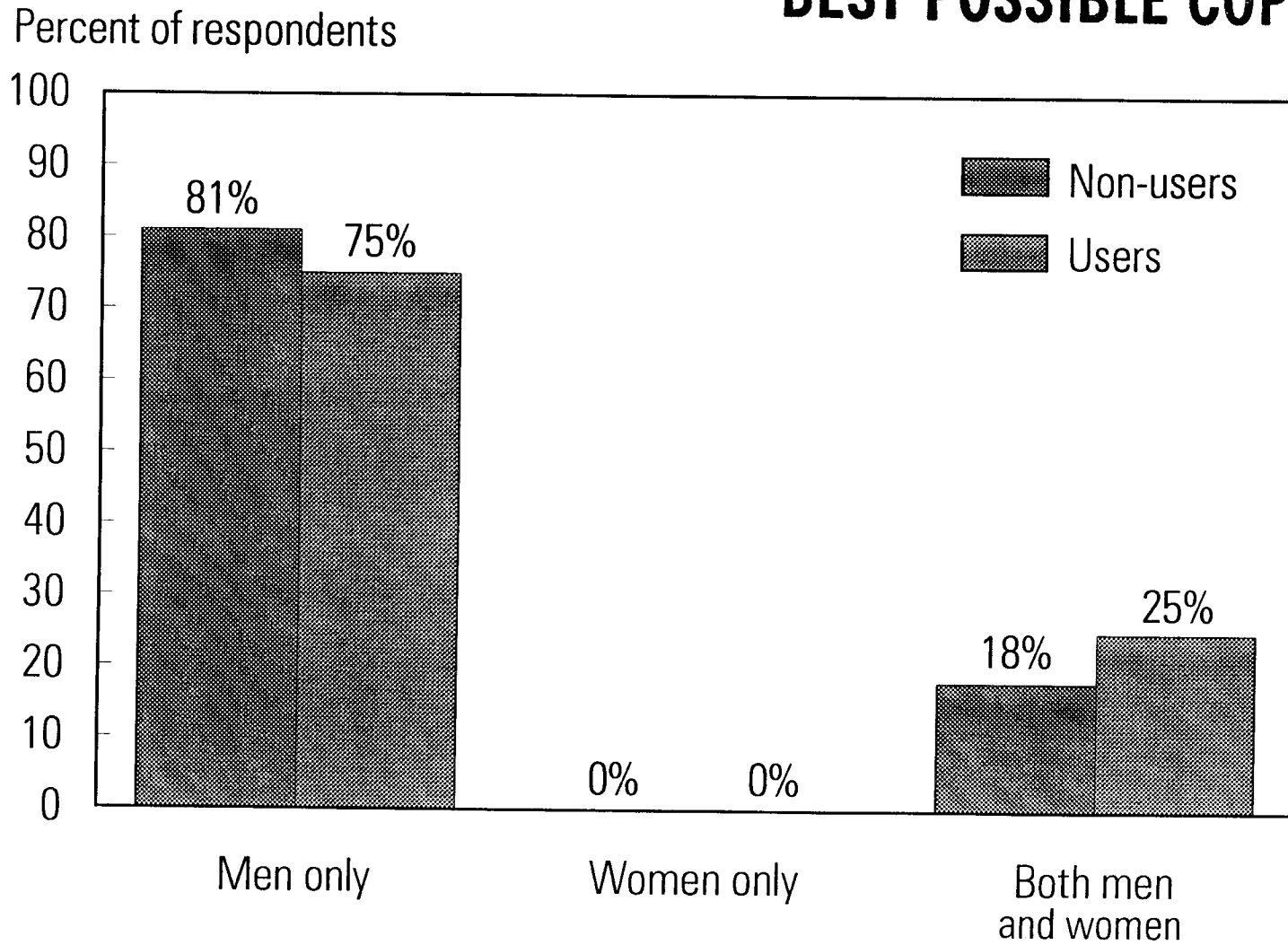
Results: Purchase Interest

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Results: Comprehension After Complete Read

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Comparison of Results

APPEARS THIS WAY
ON ORIGINAL

	Choice	No Choice
	ROGAINE Maximum Strength for Men	ROGAINE Extra Strength for Men
	"Would select"	"Would buy"
	Initial design	Second design
Non-users	0.5%	34%
Users	3%	37%

APPEARS THIS WAY
ON ORIGINAL

Outcome Due to Test Design Differences

APPEARS THIS WAY
ON ORIGINAL

- Absence of choice
 - Real world tells consumers what the choices are
- Yea-saying tendency

APPEARS THIS WAY
ON ORIGINAL

Magnitude of Outcome Is Grossly Overstated

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APPEARS THIS WAY
ON ORIGINAL

250,000* Women currently using
ROGAINE for Women*/store brand

8,000,000 Calculated number of women who
would use ROGAINE Extra
Strength for Men as indicated by
second Intent to Heed Study

- 32-fold increase in the number of users

APPEARS THIS WAY
ON ORIGINAL

*Source: A.C. Nielsen Household Panel.

Supplemental Control Arm

APPEARS THIS WAY
ON ORIGINAL

- Control arm helps put both studies in perspective
- Test design identical to second Intent to Heed Study except for stimulus
 - ROGAINE® for Men (2% MTS)
- Isolate and eliminate context bias inherent to second test design

APPEARS THIS WAY
ON ORIGINAL

Control Arm Results

APPEARS THIS WAY
ON ORIGINAL

	Choice	No choice	
	ROGAINE® Maximum Strength for Men	ROGAINE Extra Strength for Men	ROGAINE for Men
	"Would select"	"Would buy"	
	Initial design	Second design	Control arm – 2%
Non-users	0.5%	34%	46%
Users	3%	37%	60%

APPEARS THIS WAY
ON ORIGINAL

Conclusions

APPEARS THIS WAY
ON ORIGINAL

- Men will appropriately self-select between ROGAINE Extra and Regular Strength
- Women will appropriately avoid use of ROGAINE Extra Strength for Men
- Supports OTC approval of a male-only ROGAINE Extra Strength product

APPEARS THIS WAY
ON ORIGINAL

APPEARS THIS WAY
ON ORIGINAL

New Proposed Label

APPEARS THIS WAY
ON ORIGINAL

New Proposed Label

BEST POSSIBLE COPY

Rogaine® EXTRA STRENGTH FOR MEN

ACTIVE INGREDIENT: Minoxidil 5% w/v

PURPOSE: Hair regrowth treatment for men.

USE:

- To regrow hair on the scalp.
- Clinical research in mostly white men aged 18-49 years with moderate degrees of hair loss showed that Rogaine Extra Strength For Men is safe for over-the-counter use and differs from Regular Strength For Men products in the following ways:
 - Provides more hair regrowth.
 - Provides hair regrowth sooner.
 - May cause more scalp irritation. If scalp irritation persists, however, consider switching to Rogaine Regular Strength. If scalp irritation worsens, stop use and see a doctor.
- It takes time to regrow hair. With Rogaine Extra Strength For Men, visible results may be seen as early as 2 months with twice daily usage. For some men it may take at least 4 months for results to be seen.
- The amount of hair regrowth is different for each person. Rogaine will not work for everyone.
- Continued use is necessary to increase and keep your hair regrowth or hair loss will begin again. If you do not see hair regrowth in 4 months, stop using and see your doctor.

DIRECTIONS: FOR USE BY MEN ONLY. FOR EXTERNAL USE ONLY. Apply one ml with dropper or sprayer (6 sprays) 2 times a day directly onto the scalp in the hair loss area. Using more or more often will not improve results. Using less, or less often, however, will decrease results. Do not apply on other parts of the body.

WARNINGS: Do not use if:

- you have no family history of hair loss.
- you are allergic.
- hair loss is sudden and/or patchy.
- scalp is red, inflamed, infected, irritated or painful.
- you do not know the reason for your hair loss.
- you are under 18 years of age.

Do not use on babies and children.

- you use other topical prescription products on the scalp.

Stop use and see a doctor if you get:

- chest pain, rapid heartbeat, faintness, or dizziness.
- sudden unexplained weight gain.
- swollen hands or feet.

Increased scalp irritation may occur with Rogaine Extra Strength. If scalp irritation persists, consider switching to Rogaine Regular Strength. If scalp irritation worsens, stop use and see a doctor.

NOT FOR USE BY WOMEN: Does not work better in women than Rogaine For Women. May cause unwanted facial hair in women.

Avoid contact with eyes. In case of accidental contact, rinse with large amounts of cool tap water. Keep this and all drugs out of the reach of children. Do not use on babies or children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Before use, read all label information.

Keep the carton. It contains important information. 817 108 000

degrees of hair loss showed that Rogaine Extra Strength For Men is safe for over-the-counter use and differs from Regular Strength For Men products in the following ways:

- Provides more hair regrowth.
- Provides hair regrowth sooner.
- May cause more scalp irritation. If scalp irritation persists, however, consider switching to Rogaine Regular Strength. If scalp irritation worsens, stop use and see a doctor.

BEST POSSIBLE COPY

Do not use if:

- you are female.

NOT FOR USE BY WOMEN: Does not work better in women than Rogaine For Women. May cause unwanted facial hair in women.

APPROVED BY
DATE

Risk/Benefit & Conclusions

APPROVED BY
DATE

APPEARS THIS WAY
ON ORIGINAL

“The question we have to ask is not,
‘Can it be labeled so that
nobody uses it wrong?’
but ‘What happens when people
do use it wrong?’”

Dr. Randy Juhl
Former NDAC Chair

November 17, 1995

Risk/Benefit in Males

APPEARS THIS WAY
ON ORIGINAL

- Comparable safety
- Superior efficacy
 - Magnitude of response
 - Time to response
- Psychosocial considerations

Conclusions

- Labeling studies have shown
 - Women will avoid ROGAINE Extra Strength for Men
 - Men can choose between ROGAINE 5% and ROGAINE 2%
- Safety and efficacy have been established
 - Clinical trials
 - Commercial marketing experience
- ROGAINE Extra Strength for Men is an appropriate product for direct OTC approval

APPEARS THIS WAY
ON ORIGINAL