Cathy A. Groupe Center for Drug Evaluation and Research (HFD-21) Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

January 6, 2005

RE: Oral Presentation from the public: NDA 21-213

Dear Ms. Groupe:

I am writing to request the opportunity for the National Consumers League (NCL) to present consumer research findings relevant to NDA 21-213, proposing over-the-counter (OTC) use of a 20 mg statin therapy. Alison Rein, Assistant Director of Food and Health Policy, would be the presenting staff member.

About NCL:

For over 100 years, NCL has worked to achieve better health for all consumers by promoting access to safe, effective, and affordable healthcare. NCL frequently engages in consumer research efforts to better understand awareness and perceptions, and uses this information to inform its education and outreach activities.

NCL offices are located in Washington, DC at the address below: 1701 K Street NW, Suite 1200

Washington, DC 20006

About the Presentation:

In August of 2004, NCL commissioned Harris Interactive to collaborate on the design and implementation of an online survey of US adults, with either a known or potential moderate risk for cardiovascular disease. NCL commissioned this research to explore consumers' knowledge about the significance of high cholesterol, their attitudes toward the possibility of an OTC statin option, and perspectives on relevant safety and use issues. In considering this topic, NCL did not lend or withhold support to an OTC statin option.

For this presentation, NCL would like to share some of the key consumer research findings with members of the Advisory Panel. Given the nature of the information, NCL requests a time slot of no less than 5 minutes - if at all possible given the schedule of presenters. In addition, NCL would like to submit two written documents for reference use by the Advisory Panel: an annotated version of the full survey instrument, and a Power Point presentation that describes the research methodology and key findings.

Disclosure:

This research effort was funded through an unrestricted research grant from Johnson&Johnson/Merck.

CC: Hilda Scharen

HARRIS INTERACTIVE 111 Fifth Avenue New York, NY 10003

Project Manager: Jordon Peugh Email: jpeugh@harrisinteractive.com

Phone: 212-539-9706

Date: September 17, 2004

J21967

NATIONAL CONSUMERS LEAGUE: SURVEY TO EVALUATE INTEREST IN CHOLESTEROL-LOWERING OTC **MEDICATION**

SAMPLE PRELOAD AND SCREENING QUESTIONS SECTION 300:

BASE: US RESIDENTS AGED 35+

Q320 Have you ever been told by a doctor or other health professional that your cholesterol level is...?

		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
	M. Bish	-	-	-
1	Very high	13	25	-
2	Moderately high	27	53	-
3	Borderline high		18	56
4	Normal	36	2	7
5	Low	4	2	,
_	Destar a sucretic succeed my cholesterol level with me	15	2	30
6	Doctor never discussed my cholesterol level with me.	3	1	7
7	Not sure	~	_	_
9	Decline to answer	•		

BASE: US RESIDENTS AGED 35+

Q325 What is your total cholesterol level?

		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1 2 3	Under 180 180 – 199 200 – 240	22 18 20	6 35 38	39 - -
4 5 9	Over 240 Not sure Decline to answer	- 40 -	- 20 -	61 -

BASE: US RESIDENTS AGED 35+

Q330 Are you currently doing any of the following to control or lower your cholesterol? <>> Please select all that apply. </l>

[MULTIPLE RESPONSE]

į̈RΑ	NDOMIZE]	<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1	Seeing a doctor or other health care provider to monitor my cholesterol	8	13	2
2 3 4	Taking a prescription medication to lower my cholesterol Watching my diet to control or lower my cholesterol Exercising to control or lower my cholesterol	32 29 28	49 45 44	15 13 11

BASE: US RESIDENTS AGED 35+

Q335 Do any of the following statements describe you? < > Please select all that apply. </l>

[RANDOMIZE] [MULTIPLE RESPONSE]

		Total	Known <u>Risk</u>	Potential <u>Risk</u>
1	I have a family history of premature heart disease (heart attack or angina			
2	in father or brother before age 55 or in mother or sister before age 65).	15	13	17
2	smoke cigarettes.	31	17	46
3	I have high blood pressure and/or I'm currently taking high blood		.,	46
4	pressure medication.	25	24	26
4	I have HDL, or good cholesterol, lower than it should be (below 40).	9	10	20
5	None of these (E) (ANCHOR)	39		/
9	Decline to answer (E) (ANCHOR)	39	52	26
	(-) (-	1	_

BASE: RESPONDENTS THAT GAVE HEIGHT AND WEIGHT (Q340/3-8 AND Q341/0-11 AND Q345 > OR = 75) Q347 CLASSIFICATIONS BASED ON BMI (Does not appear on screen.)

(Note: N=728)			Known	5 -4 '
		<u>Total</u>	Risk	Potential <u>Risk</u>
1 Underweigh 2 Normal	Q346 GREATER THAN OR EQUAL TO	1 18	2 20	* 15
3 Overweight	18.5 AND Q346 LESS THAN 25.0 Q346 GREATER THAN OR EQUAL TO 25.0 AND Q346 LESS THAN 30.0	43	44	42
4 Obese	Q346 GREATER THAN OR EQUAL TO 30.0	38	34	42

BASE: US RESIDENTS AGED 35+ AND WHO REFUSED WEIGHT/HEIGHT

Q350 Are you at least 30 pounds over the ideal weight for your frame?

(Not	e: N=2)			
		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1 2	Yes No	100	100	1002
3	Not sure	• -	-	-
9	Decline to answer	· ·	-	-
		-	-	-

BASE: US RESIDENTS AGED 35+

Q353 How concerned are you about your cholesterol?

		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1 2 3 4 5	Not at all concerned Somewhat concerned Concerned Very concerned Extremely concerned	33 43 19 3 2	18 52 23 3 4	50 33 15 2

BASE: ALL RESPONDENTS Q355 QUOTA GROUPS

	<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1 KNOWN MODERATE RISK MALES (QUOTA 178) 2 KNOWN MODERATE RISK FEMALES (Quota 178) 3 POTENTIAL RISK MALES (Quota 178) 4 POTENTIAL RISK FEMALES (Quota 178) 5 ALL OTHERS (Not qualified, jump to Q77)	28 24 27 20 -	54 46 - -	- 57 43 -

BASE: US RESIDENTS AGED 35+
Q900 Are you of Hispanic origin, such as Latin American, Mexican, Puerto Rican, or Cuban?

		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1	Yes, of Hispanic origin	10	7	14
2	No, not of Hispanic origin	89	92	86
9	Decline to answer	*	1	*

BASE: US RESIDENTS AGED 35+ Q905 Do you consider yourself...?

		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
01 02	White Black / African American	81 13	89 8 *	71 19 1
03 04	Asian or Pacific Islander Native American or Alaskan native	1 1 2	* 1	1 2
05 06 94	Mixed racial background Other race Decline to answer	2	1 1	4 1

SECTION 400: EVALUATION OF THE IMPACT OF AN OTC STATIN

BASE: QUALIFIED RESPONDENTS

Q400 First, we would like you to carefully read the following description of a new over-the-counter (non-prescription) medication to reduce cholesterol. Please read the following description carefully, as we will be asking you to give us your opinion of this product.

<|>Please read the description carefully and then click on the NEXT button to proceed.</|>

[PROGRAMMER NOTE: INSERT PRODUCT DESCRIPTION IN BLUE IN BOX WITH OUTLINE]

Over-the-Counter Cholesterol-Lowering Medication

The U.S. FDA (Food and Drug Administration) is currently evaluating a new non-prescription, "over-the-counter" medication that can help lower cholesterol, which may prevent a first heart attack. The drug being evaluated has been available for the past eighteen years as a prescription medication and, if approved, would be the first product of its kind to be available in non-prescription form.

This product helps to lower LDL "bad cholesterol," and increase HDL "good cholesterol."

This product is appropriate only for people who meet all of the following criteria:

- "Borderline" cholesterol levels (total cholesterol 200-240)
- Male aged 45 or older or female aged 55 or older
- Has one of the following conditions that increase heart risk:
 - a. Is a smoker
 - b. Has HDL "good" cholesterol of 1-39 (too low)
 - Has a family history of premature heart disease (heart attack or angina in father or brother before age 55 or in mother or sister before age 65)
 - d. Has high blood pressure

The drug is a small tablet that is taken once a day, preferably with an evening meal.

Side effects from this product are rare and similar to those seen with sugar pill (placebo).

People who have very high cholesterol (over 240), have had a stroke, heart disease (heart attack or angina), liver disease, diabetes, or who are currently taking a prescription cholesterol-lowering medication should <u>not</u> take this product. Also, women who are pregnant or breast-feeding should not take this product.

Please consider the product you just read about when answering the following questions.

BASE: QUALIFIED RESPONDENTS

Q405 Based on what you have read about this product, which statement below best describes how likely you would be to use this product?

1 2 3 4 5	Not at all likely Somewhat likely Likely Very likely Extremely likely	Total 42 33 12 8	Known <u>Risk</u> 34 34 12	Potential Risk 50 32 16 3
4	Very [°] likely		· -	16

[PN: INSERT DEFINITION: J/US/NYC/INSERT PATH]

BASE: QUALIFIED RESPONDENTS

Q415 Based on the description you just read, what, if anything, is there about this product that you think you would like? Please be specific.

	<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
Convenience (NET) Efficacy (NET) Safety/Side-Effects (NET) Need/Criteria (NET) Product Attributes (NET) Overall Positive (NET) Price (NET) Other (NET) None/Nothing Don't Know Decline to Answer	31 24 14 12 5 3 3 8 15 1	36 28 19 9 5 3 3 14 1	26 20 9 14 5 4 4 8 17 1

BASE: QUALIFIED RESPONDENTS

Q420 Based on the description you just read, what, if anything, is there about this product that you think you would not like? Please be specific.

	<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
Need/Criteria (NET) Safety/Side-Effects (NET) Price (NET) Efficacy (NET) Dosage (NET) Other (NET) None/Nothing Don't Know Decline to Answer	17	18	15
	9	10	8
	4	5	3
	2	2	2
	1	2	1
	17	16	18
	47	46	48
	3	3	4
	2	2	3

BASE: QUALIFIED RESPONDENTS

Based on what you have read about this product, how likely would you be to discuss this product with your doctor or another health care professional?

iouiei	Health Care professional:		Known	Potential
		<u>Total</u>	<u>Risk</u>	<u>Risk</u>
1 2 3 4 5	Not at all likely Somewhat likely Likely Very likely	32 30 20 10 9	20 32 23 13 12	44 27 16 8 6
5	Extremely likely	9		12

[PN: INSERT DEFINITION: J/US/NYC/INSERT PATH]

BASE: QUALIFIED RESPONDENTS

Q435 Based on what you have read about this product, how likely would you be to seek out more information about this product?

oduct?		Known	Potential
1 Not at all likely	<u>Total</u> 33	<u>Risk</u> 24	<u>Risk</u> 43 27
2 Somewhat likely	26	26	21

3	Likely		10	04	
4	Very likely	 	10	21	15
	Extremely likely		13	18	8
•	Exaction incly		10	12	7

[PN: INSERT DEFINITION: J/US/NYC/INSERT PATH]

BASE: QUALIFIED RESPONDENTS

Q440 Based on what you have read about this product, which statement best describes how you feel about the claims made about this product?

		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1	Completely unbelievable	2	1	4
2	Somewhat unbelievable	11	10	11
3	Somewhat believable	56	49	64
4	Very believable	27	37	17
5	Completely believable	4	3	5

[PN: INSERT DEFINITION: J/US/NYC/INSERT PATH]

BASE: QUALIFIED RESPONDENTS

Q445 Based on what you have read about this product, how effective do you think this product would be at lowering your cholesterol?

		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1 2 3 4 5	Not at all effective Somewhat effective Effective Very effective Extremely effective	7 43 39 10 2	5 41 37 14 3	8 45 40 5

[PN: INSERT DEFINITION: J/US/NYC/INSERT PATH]

BASE: QUALIFIED RESPONDENTS

Q450 Based on what you have read about this product, how concerned are you about any side effects that might be caused by using this product?

		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1	Not at all concerned Somewhat concerned Concerned Very concerned Extremely concerned	29	26	33
2		32	37	26
3		19	18	21
4		10	10	9
5		10	10	11

[PN: INSERT DEFINITION: J/US/NYC/INSERT PATH]

EXPLORATION OF MOTIVATIONS SECTION 500:

BASE: QUALIFIED RESPONDENTS

4500 Here is a list of phrases for your consideration. Based on what you have read, please indicate how much you agree or disagree that each statement describes this product. <1>Please select one response for each statement.</1>

[RA	NDOMIZE]	Agree Strongly	Agree <u>Somewhat</u>	<u>Disagree</u>
1	This product is effective.		70	10
	Total	11	79 70	7
	Known Risk	13	79 78	13
	Potential Risk	9	70	13
2	This is a product I am comfortable taking on a daily basis.	40	57	25
	Total	18	57 52	24
	Known Risk	24	63	26
	Potential Risk	10	03	20
3	This product is good for preventing heart disease.	16	66	18
	Total	20	64	16
	Known Risk	20 12	68	21
	Potential Risk	12	00	_,
4	This product prevents borderline cholesterol from getting too high.	26	66	8
	Total	32	62	6
	Known Risk	20	70	10
	Potential Risk		, 0	
5	This product will help me to make lifestyle improvements (e.g., improving die	10	51	39
	Total	12	49	39
	Known Risk	8	53	39
	Potential Risk	Ü	00	
6	This product gives me control over my health.	16	62	22
	Total	20	59	21
	Known Risk	12	65	23
	Potential Risk	12	•	
7	This product is not strong enough to improve my heart health.	3	37	59
	Total	5	37	58
	Known Risk	2	38	60
	Potential Risk			
8	This product would be preferable to having to take a prescription drug to low	38	47	. 15
	Total	47	42	11
	Known Risk	28	53	19
_	Potential Risk			
9	This product is unsafe.	3	28	69
	Total	2	27	71
	Known Risk	3	30	67
	Potential Risk			
10	This product is no better than current prescription options.	8	55	38
	Total	11	55	35
	Known Risk	5	54	41
4	Potential Risk This product is no better than supplements or vitamins that are currently available.			
11		6	37	57
	Total Known Risk	6	32	62
	Potential Risk	5	42	53
	Lorential Liev			

BASE: QUALIFIED RESPONDENTS

The following is a list of statements that might or might not describe the kind of people who would be appropriate candidates for this product. Thinking about the product you just read about, please indicate how much you think that each statement describes a person who would use this product. <I>Please select a response for each

[F	RANDOMIZE]	Describes	Describes	Does Not
4	Company	Von. Woll	Somewhat	Describe At All
1	Someone who has a hard time remembering to take his or her medication	ns		December At All
	Total	8	37	54
	Known Risk	8	37	56
_	Potential Risk	9	38	53
2	Someone who relies on his or her doctor to oversee his or her health			00
	Total	18	48	34
	Known Risk	18	46	36
_	Potential Risk	18	50	33
3	Someone who is interested in preventing heart disease		00	33
	Total	48	46	6
	Known Risk	53	41	6
	Potential Risk	43	52	7
4	Someone who takes good care of himself/herself	,,	32	5
	Total	30	53	4=
	Known Risk	31	55	17
	Potential Risk	28		14
5	Someone who already takes a lot of medications	20	52	21
	Total	12	20	
	Known Risk	12	38	51
	Potential Risk	11	36	52
6	Someone who likes to take charge of his or her health	11	40	49
	Total	40		
	Known Risk	43	49	9
	Potential Risk	48	43	8
7	Someone who is in poor health	36	54	10
	Total	4.5		
	Known Risk	15	42	43
	Potential Risk	12	43	45
8	Someone with an active lifestyle	19	41	40
	Total			
	Known Risk	21	55	24
	Potential Risk	24	54	22
	· Station From	18	56	26

[RAI	NDOMIZE]	Describes Very Well	Describes Somewhat	Does Not Describe At All
9	Someone who relies on caregivers or family members to help make dec Total Known Risk Potential Risk Someone whose serious risk for heart disease requires consistent phys	7 8 7	her health 38 32 44	55 60 49
	Total Known Risk Potential Risk Someone who is trying to control his or her cholesterol with diet and except	20 16 25	36 34 38	43 50 37
11	Total Known Risk Potential Risk	42 47 36	51 45 57	8 8 7
12	Someone with health care concerns and needs much like my own (ANC Total Known Risk Potential Risk	25 33 16	48 48 48	27 20 36

[PN: INSERT DEFINITION: J/US/NYC/INSERT PATH]

SECTION 600: COMPARISON OF OTC AND RX

BASE: QUALIFIED RESPONDENTS

Q600 Now we would like you to consider both the over-the-counter product you have been evaluating and a similar low-dose cholesterol-lowering medication that is available only by prescription from a doctor.

Please tell us which product would be better in each of the following areas, or if you think both are the same.

Which product do you believe would be...?

[R	ANDOMIZE]	Over-the-	Prescription	Both Are
1	More effective at lowering cholesterol	Counter Produce	Product	the Same
	Total	5	41	54
	Known Risk	6	39	55
2	Potential Risk	4	43	54
2	A more reliable treatment Total			04
	- 	6	43	51
	Known Risk	6	41	53
3	Potential Risk More trustworthy	6	46	48
Ŭ	Total			
	Known Risk	4	36	60
	Potential Risk	7	33	60
4	Less likely to cause side effects	2	38	60
	Total			
	Known Risk	34	17	49
	Potential Risk	37	15	48
5	More natural	30	20	50
	Total	0.5		
	Known Risk	35	13	52
	Potential Risk	38	12	50
6	Safer to use	32	15	53
	Total	22	00	
	Known Risk	25 25	26	51
	Potential Risk		26	50
		20	27	53

BASE: QUALIFIED RESPONDENTS

Considering the same two products, please tell us which product would be better in each of the following areas. For each select either the over-the-counter product or the prescription product, even if you think one is only slightly better than the other.

Please tell us which product you believe would be....

Q606

[RANDO	DMIZE]	Over-the- Counter Produce	Prescription <u>Product</u>
2	Easier to keep taking every day Total Known Risk Potential Risk Easier to buy at a store where you shop	73 78 68	27 22 32
2	Total Known Risk Potential Risk	91 92 90	9 8 10
3	More suitable for someone who is in poor health Total Known Risk Potential Risk	16 14 18	84 86 82
4	More suitable for someone who takes charge of his or her health Total Known Risk Potential Risk	78 86 70	22 14 30
5	More suitable for somebody with your health care needs (ANCHOR) Total Known Risk Potential Risk	70 72 67	30 28 33

BASE: QUALIFIED RESPONDENTS

Still considering the same two products, the over-the-counter product and the prescription product, please tell us Q610 which product you would be more likely to....

[RA	ANDOMIZE]	Over-the- Counter Produce	Prescription Product
1	Discuss with your doctor Total Known Risk Potential Risk	57 60 53	43 40 47
2	Seek more information about Total Known Risk Potential Risk	75 79 72	25 21 28
3	Consider taking Total Known Risk Potential Risk	76 78 73	24 22 27
4	Recommend to a friend or family member Total Known Risk Potential Risk	76 79 73	24 21 27

SECTION 700: RESPONDENT PROFILE

BASE: ALL RESPONDENTS
Q700 The following is a list of statements that may or may not describe you. Please indicate how much you think that each statement describes you. <I>Please select one response for each statement.</I>

		Describes Me <u>Very Well</u>	Describes Me Somewhat	Does Not Describe
1	I have a hard time remembering to take my medications and vitamins.	<u> </u>	Comewhat	Me At All
	Total	7	21	72
	Known Risk	7	23	70
_	Potential Risk	7	19	74
2	I usually do what my doctor tells me to do.		.0	74
	Total	32	29	34
	Known Risk	29	61	9
_	Potential Risk	34	51	15
3	I believe that prescription medications work better than over-the-counte	r medications.	01	13
	Total	21	41	38
	Known Risk	20	40	40
	Potential Risk	23	42	36
4	I believe that over-the-counter medications are safer than prescription m	nedications	72	30
	lotal	7	38	EE
	Known Risk	8	45	55 48
	Potential Risk	7	31	48
5	I am actively involved in managing my own health care.	•	51	62
	Total	43	46	11
	Known Risk	51	41	
	Potential Risk	34	52	8
6	I see my doctor as a partner in managing my health care.	04	32	15
	Total	32	47	0.4
	Known Risk	31	47 54	21
	Potential Risk	3/	3 4 39	15
7	I often consult my pharmacist when choosing over-the-counter medication	nne	39	27
	Total	17	44	
	Known Risk	17	41	42
	Potential Risk	17	42	41
8	I am at risk for developing high cholesterol.	17	39	44
	Total	17	45	
	Known Risk	23	45 55	37
	Potential Risk	23 11	55 25	22
		11	35	54

BASE: ALL RESPONDENTS
Q705 Please rate the extent to which you agree or disagree with the following statements. <I>Please select one response for each statement.</I>

[R/	ANDOMIZE]	Agree Strongly	Agree Somewhat	<u>Disagree</u>
1	I believe over-the-counter cholesterol medication is safe to take over	long periods of t	ime.	00
	Total	11	53	36
	Known Risk	16	55	29
	Potential Risk	6	50	43
2	I believe over-the-counter cholesterol medication lowers cholesterol	more effectively t	han diet and/or e	exercise
	alone.		44	46
	Total	9	44 46	42
	Known Risk	12 7	43	51
	Potential Risk	•	43	31
3	Over-the-counter cholesterol medications have side effects that con-	cern me.	50 ⁻	34
	Total	16 17	50 51	32
	Known Risk	17	49	36
	Potential Risk		49	00
4	Prescription cholesterol medications have side effects that concern	me. 29	52	19
	Total	33	49	18
	Known Risk	33 24	54	21
	Potential Risk		- ·	
5	I would recommend over-the-counter cholesterol medication to som	eone i care abou	55	27
	Total	17	61	22
	Known Risk	17	49	32
	Potential Risk		· -	
6	High cholesterol should be treated with medication, regardless of wi	nether it is presci 35	41	24
	Total	31	43	26
	Known Risk	39	39	22
	Potential Risk			
7	The benefit of taking over-the-counter cholesterol medication is gre	16	55	29
	Total	16	56	28
	Known Risk	15	55	30
	Potential Risk			
8	I believe prescription cholesterol medication is safe to take over lon	g periods of time	51	36
	Total	13	50	37
	Known Risk	13	51	36
	Potential Risk	13	.	

BASE: ALL RESPONDENTS

Q710 Do you pay more attention to the nutrition content on food labels now than you did five years ago?

[RESULTS LABEL: PERCENTAGE OF THOSE WHO DO/DO NOT PAY MORE ATTENTION TO NUTRITIONAL CONTENTS ON FOOD LABELS]

	<u>Total</u>	own Potential isk <u>Risk</u>
1 Yes	73	33 62
2 No	27	17 38

BASE: ALL RESPONDENTS

Q715 How would you describe your health overall?

[RESULTS LABEL: PERCENT INDICATING HEALTH OVERALL]

	<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1 Poor 2 Fair 3 Good 4 Very good 5 Excellent	2	2	2
	14	9	19
	44	50	38
	32	30	34
	8	10	6

BASE: QUALIFIED RESPONDENTS

Q720 How many visits to a doctor have you made in the past 12 months? <I>If you are not sure, please enter "999".</I>

	<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
0	14	11	40
1	23	23	18
2-3	29	33	23 24
4-5 6-10	11	14	9
11 or more	11	12	10
Don't know	6	3	8
DOM CRICOV	6	4	8
MEAN number of visits	3.5	3.1	3.9

BASE: QUALIFIED RESPONDENTS

Q725 How satisfied are you with the medical care you have received in the past 12 months?

		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
Not at all satiSomewhat saSatisfiedVery satisfiedExtremely sa	atisfied d	3 16 31 30 20	3 17 33 32 15	4 13 28 28 26

BASE: ALL RESPONDENTS

Q728 Do you take any daily vitamins or supplements?

[RESULTS LABEL: PERCENTAGE OF THOSE WHO TAKE DAILY VITAMINS OR SUPPLEMENTS]

		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1 2	Yes	63	66	59
	No	37	34	41

BASE: ALL RESPONDENTS

Q730 Do you currently have health insurance?

			Known	Potential
		<u>Total</u>	<u>Risk</u>	<u>Risk</u>
_	V	84	86	81
1	Yes	16	13	19
2	No	1	1	*
9	Decline to answer	ı	•	

[PROGRAMMER NOTE: IF 730/2,9, JUMP TO Q740]

BASE: RESPONDENTS WHO HAVE HEALTH INSURANCE (Q730/1)

Q735 Does your current health insurance cover prescription medications?

		<u>Total</u>	Known <u>Risk</u>	Potential <u>Risk</u>
1 2	Yes	92	92	93
	No	8	8	7

BASE: ALL RESPONDENTS

Q740 Where do you typically get health information? <I>Please select all that apply. </I>

[RESULTS LABEL: PERCENTAGE INDICATING WHERE HEALTH INFORMATION IS TYPICALLY ACQUIRED]

[MULTIPLE RESPONSE]	<u>Total</u>	Known	Potential
[RANDOMIZE]		<u>Risk</u>	<u>Risk</u>
 Doctors or other health professionals Friends and/or family News media (newspapers, news magazines, television news, etc.) Entertainment media (television programs, popular magazines, etc.) 	76	81	70
	40	36	44
	44	49	39
	13	12	14
[ANCHOR AFTER ITEM 3] 5 Books or journals 6 The Internet/The Web 7 Other (ANCHOR) 8 None (E) (ANCHOR) 98 Not sure (E) (ANCHOR)	36	40	33
	63	72	54
	7	7	7
	2	*	3
	2	1	3

SECTION 100: DEMOGRAPHICS

BASE: ALL RESPONDENTS

Q112 [HIDDEN QUESTION - MANDATORY QUESTION SELECTION.]

[MULTIPLE RESPONSE]

[PROGRAMMER: DESÉLECT CODE 18.]

[PROGRAMMER NOTE: IF 18 OR OLDER OR AGE UNKNOWN (Q106/3-13,99) PICK CODES 3,6,7,9,10,12,13,14,15,16,17, 19,20,22,24. IF 17 OR YOUNGER (Q106/1,2) PICK CODES 3,6,7,9,10,12,13,17, 19,20,21,22,24. DESELECTION OF ANY CODES REQUIRES WRITTEN PERMISSION FROM INTERNET METHODOLOGY TEAM.]

[DO NOT SHOW CODE 21: THE SERIES OF QUESTIONS ARE SHOWN AS PART OF THE SCREENER] [PROGRAMMER NOTE: PLEASE AUOT-FILL Q112/21 WITH ANSWERS FROM SCREENER QUESTIONS Q900-Q920]

- 03 PRESENT SOLE EMAIL USER (Q199)
- 06 PRESENT COUNTRY OF RESIDENCE (Q110/Q166)
- 07 PRESENT CONFIRMATION SCREEN (Q150)
- 09 PRESENT CITIZENSHIP (Q170)
- 10 PRESENT INTERNET CONNECTION (Q190)
- 12 PRESENT INTERNET USAGE (Q194/Q195/Q196)
- 13 PRESENT EDUCATION (Q214 OR Q216)
- 14 PRESENT MULTI-EMPLOYMENT (Q210)
- 15 PRESENT RELATIVE INCOME (Q230)
- 16 PRESENT INCOME (Q232)
- 17 PRESENT STATE/TERRITORY/PROVINCE (Q172)
- 18
- 19 PRESENT ZIP CODE (Q178)
- 20 PRESENT POSTAL CODE (Q180)
- 21 PRESENT RACE (Q236-Q244)
- 22 PRESENT SURVEY EVALUATION (Q288-Q294)
- 24 PRESENT SWEEPSTAKES (Q252-Q262)

BASE: ALL RESPONDENTS

Q114 [HIDDEN QUESTION - OPTIONAL QUESTION SELECTION.]

[PROGRAMMER NOTE: GET CODE 20 AS DEFAULT. DO NOT SELECT QUESTIONS FOR PRESENTATION UNLESS INDICATED BY PROJECT RESEARCH STAFF.]

[MULTIPLE RESPONSE]

- 01 PRESENT READING COMPREHENSION (Q184)
- 02 PRESENT READING FLUENCY [CAN SELECT ONLY IF Q114/01.] (Q186)
- 04 PRESENT SURVEY LOCATION (Q200)
- 05 PRESENT MARITAL STATUS (Q202)
- 06 PRESENT ADULTS IN HOUSEHOLD (Q204)
- 07 PRESENT CHILDREN IN HOUSEHOLD (Q206)
- OB PRESENT AGE OF CHILDREN [CAN SELECT ONLY IF Q114/07.] (Q208/Q209)
- 09 PRESENT SINGLE EMPLOYMENT (Q212)
- 10 PRESENT INDUSTRY (Q226)
- 11 PRESENT PROFESSION (Q228)
- 12 PRESENT INVESTABLE ASSETS (Q234)
- 13 PRESENT SEXUAL ORIENTATION (Q246/Q248)
- 15 PRESENT SCHOOL LOCATION (Q220)
- 16 PRESENT MOTHER'S EDUCATION (Q222)
- 17 PRESENT FATHER'S EDUCATION (Q224)
- 18 PRESENT DIRECT INCENTIVE (Q264-Q275)
- 19 PRESENT OPT-IN FOR NON-HPOL (Q278-Q284)

BASE: ALL RESPONDENTS

STATUS OF RESPONDENT (DOES NOT APPEAR ON SCREEN) Q60

- 1 QUALIFIED RESPONDENTS, QUOTA OPEN (Q355/1-4, Q365/2,3,)
 3 QUALIFIED RESPONDENTS, QUOTA CLOSED (Q355/1-4, Q365/1,)
 6 NOT QUALIFIED (ALL OTHERS)

Exploration of Consumer Perceptions about and Interest in an OTC Statin Option: Survey of Moderate Risk and Potential Risk

Respondents

Conducted By Harris Interactive In Collaboration With The National Consumers League

Background and Objectives

- The National Consumers League (NCL) commissioned Harris Interactive to conduct a survey exploring attitudes about and interest in over-the-counter (OTC) cholesterol-lowering statins.
- The NCL was interested in exploring:
 - The extent to which consumers are aware of elevated cholesterol and associated risks
 - Whether or not the option of an OTC cholesterol-lowering statin would generate interest and action among people who have borderline or moderately high cholesterol (known moderate risk) or who have risk factors for having or developing high cholesterol (optional risk).
- The factors that determine:
 - Level of interest and action in the OTC product, and
 - Extent to which respondents are able to evaluate the appropriateness of this product for various types pf people;
- The factors that inform respondent receptivity to both the OTC and Rx options

Sample and Methodology

- This survey was conducted online within the United States with members of the Harris Poll Online Panel, several million people who have agreed to participate in survey research projects.
- Interviews were conducted between August 26 and September 3, 2004.
- A total of 2,777 people participated in the survey, 730 of whom were qualified to take the entire survey based on the criteria on the next two slides.
- We refer to these 730 respondents as "at-risk" respondents throughout this document.

Sample and Methodology, continued

- Qualified at-risk respondents (n=730) met the following criteria:
- US residents
- At least 35 years of age
 Do not currently or have not had any of the following:
 Diabetes

 - Liver disease
 Liver disease
 A stroke
 A heart attack
 An angioplasty
 By-pass surgery
 A stent implant
- Have not been told by a doctor that they have "very high" cholesterol
- Do not have a cholesterol level over 240
- Not currently taking prescription medications to lower their
- (Additional qualification criteria on next slide)

Sample and Methodology, continued

- Further, to be qualified, at risk respondents had to fit into one of the following risk categories:

 Known Moderate Risk Respondents (n=370): Told by a doctor that they have moderate or borderline high cholesterol or know that their cholesterol number is between 180-240.

 Potential Risk Respondents (n=360): Not explicitly told by a doctor that they have moderate, borderline, or high cholesterol and not aware that they have a cholesterol level of 180 or higher. Nust also meet at least two of the following risk criteria:

 In the state of the

Sample and Methodology, continued

- We over sampled Black and Hispanic respondents, for a total of 109 qualified Black respondents and 106 qualified Hispanic respondents.
 - Black (30% known risk and 70% potential risk)
 - Hispanic (35% known risk and 65% potential risk)
- Demographic and propensity weighting techniques were used to ensure that the data represent the national population of adults aged 35 and older.
 - Qualified and non-qualified respondents were weighted to demographic targets from the US census.
 - Data were weighted by sex, race, education, income, and
 - "Propensity score" weighting was also used to adjust for respondents' propensity to be online.

Sample and Methodology, continued

- Throughout this study, respondents were instructed to consider a low-dose prescription statin option, as this is the appropriate alternative to the OTC option.
- The results of this study are intended for public release.

Further Defining Known Moderate Risk Respondents

- Known Moderate Risk Respondents (n=370): Told by a doctor that they have moderate or borderline high cholesterol or know that their cholesterol number is between 180-240.
 - Have been told by a doctor that their cholesterol level is:
 - Moderately high (25%)
 - Borderline high (53%)
 - Normal/low (20%)
 - Known cholesterol level:
 - 200-240 (38%)
 - · 180-199 (35%)
 - · Under 180 (6%)
 - Don't know their cholesterol level (20%)

Further Defining Potential Risk Respondents

- Potential Risk Respondents (n=360). Not explicitly told by a doctor that they have moderate, borderline, or high cholesterol and not aware that they have a cholesterol level of 180 or higher. Must also meet at least two of the following risk criteria:
 - Are male age 45 or older (42%) or female age 55 or older (18%)
 - Smoke cigarettes (46%)
 - Are overweight (42%) or obese (42%)
 - Have high blood pressure or are currently taking high blood pressure medication (26%)
 - Have HDL lower than it should be (7%)
 - Have a family history of premature heart disease (17%)

OTC Product Description

Qualified respondents were asked to review the following description for the potential OTC cholesterol-lowering product:

The U.S. FDA./Food and Doug Administration) is circuitly evaluating a new uso-prescriptor, "over-the-comite" medication in the collection of the control of

- control ettigs to 10 tower LDL. "bad cholesterni" and increase HDL. "good cholesterni " robuct is uppropriate only for poole who meet all of the following criteria: "Directrinic" cholesteric levels (table cholesteric 100°-100°-100°). Make aged 35 or obler or female aged 35 or obles of the third table of the table of ta

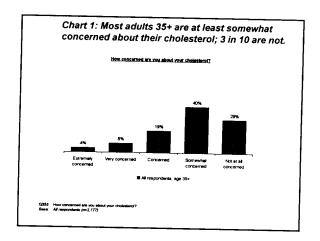
all tables that it taken once a day, preferably with an evening meal Side effects from this product are rare and similar to those seen with sugar pull (placebo)

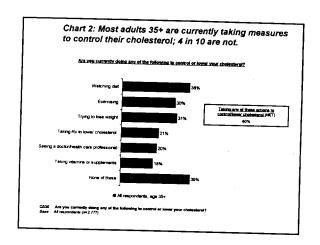
who have very high cholesterol (over 240), have had a stroke, heart disease (heart stack or nagina), liver disease, or who are currently taking a prescription cholesterol-lowering medication should not take this product. Also, who are pregnant or breast-feeding thought of the product.

Key Findings

Key Finding #1: American adults need to be educated about elevated cholesterol and its associated risks.

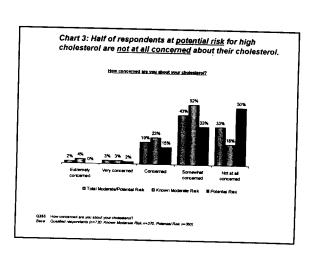
- A series of questions were asked of all respondents (both qualified and non-qualified). These respondents represent the general population of American adults aged 35 and older. Among this population, we find a real need for education about cholesterol.
 - 39% do not know their cholesterol level
 - 14% say that a doctor or other health professional has never talked to them about their cholesterol level
 - 29% are not at all concerned about their cholesterol (Chart 1)
- On a positive note, 60% of all respondents (qualified and non-qualified) say they are currently doing something to try to lower or control their cholesterol. (Chart 2)

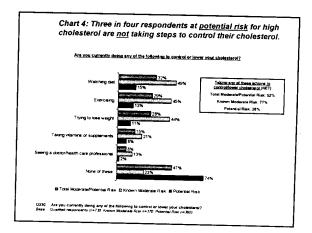




Key Finding #2: At-risk Americans need to be educated about elevated cholesterol and its associated risks.

- Looking more specifically at the two main groups of at-risk respondents, we find that potential risk respondents are much less concerned about their cholesterol and less likely to be doing something to try to manage it than are known moderate risk respondents.
 - 50% of potential risk respondents are not at all concerned about their cholesterol (vs. 18% of known moderate risk) (Chart 3)
 - 74% of potential risk respondents are not taking steps to control or lower their cholesterol (vs. 23% of known moderate risk) (Chart 4)





Key Finding #3: There is interest in an OTC option for lowering cholesterol.

- Among at-risk respondents, there is clear, though not overwhelming, interest in an OTC cholesterol-lowering medication.
 This interest is demonstrated more in the willingness to seek out more information about the product than likelihood to use it.
- Known moderate risk respondents are more likely to seek out information about the OTC product, to discuss the product with their doctor, and to use the product than are potential risk respondents. (Chart 5)
- A large majority of at-risk respondents indicate that the OTC option would be preferable to taking a prescription drug to lower cholesterol. (Chart 6)
- Further, many at-risk respondents, particularly among known moderate risk, strongly agree that this product would be very appropriate for someone with health needs much like their own (33% known moderate risk; 16% potential risk). (Chart 11)

Chart 5: Many would seek information about the OTC statin; Fewer would be likely to use it.

Likelihood to	Extremaly/Very Likely %	Likely/Somewhat Likely %	Not At All Likely
Seek out more information on the product	23	44	33
Known Moderate Risk	30	47	24
Potentski Rsik	15	42	43
Discuss this product with doctor/health care professional	19	50	32
Known Moderate Risk	24	55	20
Potential Risk	14	43	44
Use this product	13	45	42
Known Moderate Risk	20	46	34
Description Dark	5	45	50

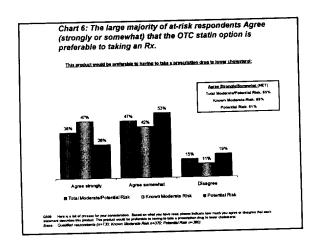
Gabb Based on what you have read about this product which bitisment below load cascables here thely you would be to use this product?

Gabb Based on what you have read about this product, how likely would you be is discuss this product with your decise or enable health care

professional?

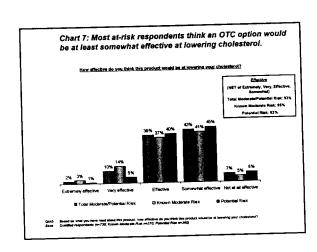
GASS Second-on what you have read about the product, here leady would you be to each sed mare information about the product?

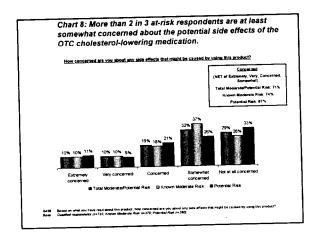
Same Custified responsional (in-726 Known Moderate Past m-476 Pastential Red (n-360)

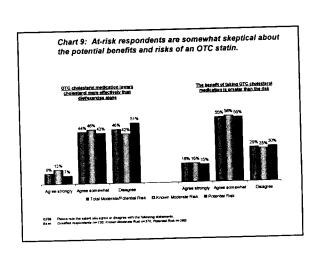


Key Finding #4: Many have concerns about the safety of OTC statin medication.

- While most believe at least somewhat in the effectiveness of the OTC statin, there are concerns about safety.
 - The large majority of at-risk respondents believe that this product would be at least somewhat effective (95% known moderate risk; 92% potential risk). (Chart 7)
 - Almost half of at-risk respondents do not think that the OTC statin would be more effective at lowering cholesterol than diet or exercise alone. (Chart 9)
 - The majority of at-risk respondents (over two-thirds) are at least somewhat concerned about the potential side effects of a cholesterol-lowering OTC. Many (20%) are very or extremely concerned. (Chart 8)
 - Almost 3 in 10 do not think that the benefit of a cholesterol-lowering OTC outweighs the risk. (Chart 9).







Key Finding #5: The OTC statin is most strongly associated with concepts of prevention and control of health...

- The OTC cholesterol-lowering medication is most strongly associated with: (Chart 10)
 - Preventing borderline cholesterol from getting too high
- Having control over one's health
- Being comfortable to take every day
- Being good for preventing heart disease
 The OTC cholesterol-lowering medication is seen as most appropriate for someone: (Chart 11)
 - Interested in preventing heart disease
 - Who takes charge of his/her health
 - Trying to control cholesterol through diet/exercise
 - Who takes good care of him/herself With an active lifestyle
- With health care concerns and needs much like my own

Key Finding #5: ...and less associated with concepts of dependence on caretakers and poor health.

- The OTC cholesterol-lowering medication is much less likely to be considered appropriate for someone who: (Chart 11)

 Relies on caregivers to help make decisions about his/her health

 - Has a hard time remembering to take medication
 - Already takes a lot of medications

 - Is in poor health
 Relies on his/her doctor to oversee his/her health
 - Has a serious risk for heart disease that needs consistent physician monitoring
- However, the number of respondents who feel that the OTC nowever, the number of respondents who feel that the OTC statin would be appropriate for someone who's heart health needs consistent physician monitoring is disturbingly large (55%). This suggests a real need for education about who should, and should not, be taking an OTC to lower their cholesterol cholesterol.

Chart 10: Association of characteristics with the OTC statin 23 10

39 39 39

Q500 Phase indicate how much you agree or designee with each statement that de see. Outsided responsents (n=730; Known Moderate Rest n=370; Potential Rest n=360)

otential Risk

Chart 10: Association of characteristics with the OTC statin, continued

The	Agree Strongly %	Agree Somewhat %	Disagrad
That product is no better then current prescription options.	8	55	38
Known Moderate Risk	21	55	
Potential Risk	5	54	35 41
This product is no better than supplements or vitamins that are currently available.	6	37	57
Known Moderate Risk Potentiel Risk	6	32	62
	5	42	53
This product is not strong enough to improve my heart health	3	37	59
Known Moderate Rask	5	37	58
Potential Risk	2	36	60
his product is uneale.	3	28	69
Known Moderate Risk	7 -	27	
Potential Risk	j 3	30	71 67

Q500 Please indicate how much you agree or disagree with each statement that desc Rees Ouelited responsions (in-730, Known Moderate Reit in-370; Polested Reit in-350)

for OTC statin, continued

Chart 11: Most appropriate types of people for OTC statin

	Describes Very Well	Describes Som swhat	Describe At A
Someone who is interested in preventing heart disease	48	46	
Known Moderate Risk Potential Risk	53	41	
	43	52	1 4
Someone who likes to take charge of his/her health	43	49	
Known Moderate Risk	48	43	
Potential Risk	36	54	1 10
Someone who is frying to control his her cholesterol with diel and exercise	42	- 51	
Known Moderate Risk	47	46	
Potential Rask	36	57	
someone who takes good care of him/herself	30	53	,
Known Moderate Rrak	31	55	
Potential Risk	28	52	14
omeone with health care concerns and needs much like my own	25		21
Known Moderate Risk	33	48	27
Potential Risk		48	20
omeone with an active identitie	16	48	36
Known Moderate Risk	21	55	24
Potential Risk	24	54	22
	18	56	26

Someone who raise on caregivers or family members to help make decisions about his har health.	Describes Very Well	Describes Somewhat %	Does Not Describe At A %
	7	38	55
Known Moderate Risk			L 55
Potential Risk	8	32	50
2	7	44	49
Someone who has a hard time remembering to take his/her medications Known Moderate Risk	8	37	54
Potential Risk	8	37	56
	9	38	53
comeone who already takes a lot of medications	12		
Known Moderate Risk		36	51
Potential Risk	12	36	52
	11	40	49
Omegne who at in poor health	15	42	
Known Moderate Risk	12		43
Potential Risk	.~	43	45
Organia who colors as I also as I al	19	41	40
omeone who relies on his/her doctor to oversee his/her health	18	48	34
Known Moderate Risk	-18		
Potential Data	10	46	36

Chart 11: Less appropriate types of people

Q506 Please indicate how much you think that each statement describes a piecon who would use this product seam. Qualified respondence (mr./30, rispen Moderate than ms./30, Postman from ns./30).

Key Finding #6: Compared to an Rx, the OTC statin is seen as more convenient, more natural, less likely to cause side effects, and more appropriate for "someone with my health care needs."

- Specifically comparing the OTC option to a similar medication available by prescription, certain characteristics strongly emerge as associated with each product. (Charts 12, 13, 14, & 15)
 - Rx is generally seen as:
 - More effective

 - More reliable
 More trustworthy
 More suitable for someone in poor health

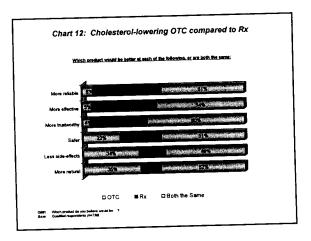
 - More suitable for solliedite in post the
 OTC is generally seen as:
 Easier to buy at a store where I shop
 Easier to keep taking every day

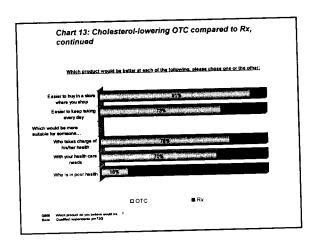
 - More natural
- More natural
 Less likely coases side effects
 More suitable for someone who takes charge of his/her health
 More suitable for someone with my health care needs
 At-risk respondents were divided on which product is safer, 51%

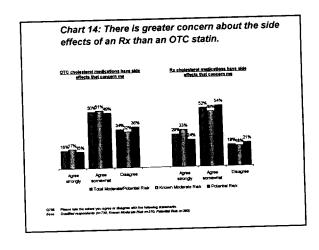
 At-risk respondents were divided on which product is safer, 51%

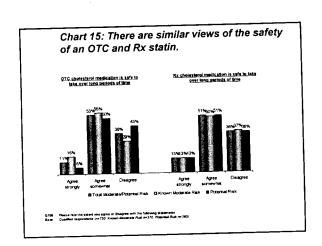
 At-risk respondents were divided on which product is safer, 51%

 At-risk respondents were divided on which product is safer. think they are both the same while 22% think the OTC is safer and 26% think the prescription medication is safer.



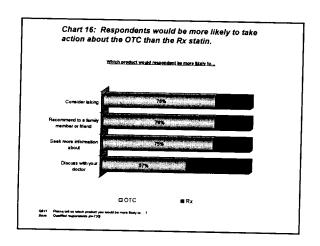


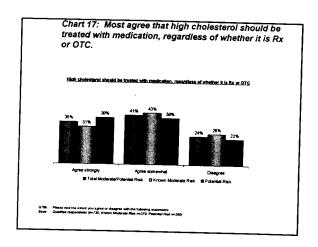


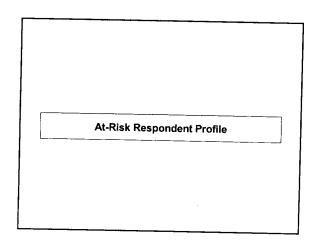


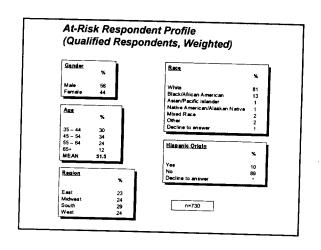
Key Finding #7: Respondents are more likely to consider taking, recommend to a friend/family member, and seek more information about an OTC than an Rx statin.

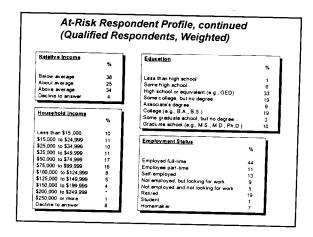
- At-risk respondents are much more likely to consider taking, seek more information about, and recommend to a friend or family member the OTC option over the prescription option. (Chart 16)
- At-risk respondents are fairly split on which statin option they would be more likely to discuss with their doctor.
- Overall, 2 in 3 at-risk respondents think that high cholesterol should be treated with medication, regardless of whether it is an OTC or prescription medication. (Chart 17)
 - This finding points to the broader question of whether or not these at-risk respondents understand their own risk for high cholesterol and the steps they should be taking to keep it under control.











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