SCREENER AND INTRODUCTION

Hello, my name is ______ calling on behalf of the U.S. Food and Drug Administration, also known as the FDA. I am calling because the FDA is conducting an important study on people's opinions of medical products. Your opinions, and the opinions of people like you, are very important to the FDA.

- 1. [PHONE ONLY] Before I tell you more about the survey, let me ask—am I reaching you on a cell phone?
 - Yes [DO NOT READ]
 - 🗙 No [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]
- 2. [PHONE ONLY; Ask if Q1 = "Yes"] Are you driving a vehicle at this moment?
 - 🔀 Yes [DO NOT READ]
 - No [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]
- 3. [PHONE ONLY; Ask if Q2 = "Yes"] When would be a better time to call you?

Set Callback Date/Time

[If respondent indicates that they are willing to talk now: "I'm sorry, but for your safety we are not able to do the interview while you're driving. When would be a better time to call you?"]

Refused [DO NOT READ]

This study is sponsored by the FDA but is being conducted by RTI, a not-for-profit research organization, and Precision Opinion research. Your participation is voluntary and the survey will only take 15 minutes. I'm now going to give you contact information for the study supervisor and the ethics committee that approved the study. You may want to write it down in case you have questions later about the study or your rights as a participant. You can contact the study supervisor toll-free at 1-XXX-XXX-XXXX. And if you have questions about your rights as a study participant, you can call 1-866-214-2043.

Remember, all of your answers will be kept private and only the overall study data will be reported. By participating in the survey, you will help the FDA design better programs to improve the Nation's health.

4. [PHONE ONLY] Do you live in zip code <INSERT ZIP FROM ADDRESS>?

- Yes [DO NOT READ]
- No [Thank you, but we need to speak to someone in that area. I appreciate your time. Have a good day. CODE CASE AND TERMINATE]

Refused [PHONE ONLY; DO NOT READ]

5. [PHONE ONLY] Am I speaking to a member of this household who is at least 18 years old?

🗙 Yes

- No [Thank you, but we need to speak to someone 18 or older. Is there anyone at home 18 or older with whom we can speak?]
- 6. [PHONE ONLY; Ask if Q5 = "Yes"] How many adults age 18 and older currently live in this household? *Please do not include students living away at school.*

Adults

X

[The computer will randomly choose an adult in your household for this survey. To help the computer choose this person, which adult had the most recent birthday?] IDENTIFY RESPONDENT Refused [DO NOT READ]

In this survey, the phrase "medical products" includes many things. It includes:

- Things that might be used at a visit to your doctor or dentist like vaccinations or shots, lasers for eye surgery, or dental fillings;
- Things you might get during a hospital visit like an x-ray, blood transfusion, implant, or pacemaker;
- Things you might buy off the shelf like over-the-counter drugs, vitamins, stop-smoking patches, thermometers, hearing aids, pregnancy tests, and blood sugar testing kits; and
- Things you need a prescription for like contact lenses and prescription drugs.
- 7. So, have you (or a family member you make health decisions for) used or received treatment with any medical products in the <u>past 3 months</u>?
 - Yes [DO NOT READ]
 - 🔀 No [DO NOT READ]
 - 🔀 Not sure [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]

IF Q7 = "No," "Not sure," or Refused \rightarrow SAY: Thank you. At this time, we are only speaking with adults age 18 or older who have recent experience with a medical product. I appreciate your time. Have a good day. CODE CASE AND TERMINATE

IF Q7 = "Yes" \rightarrow SAY: The phrase "medical products" will be used often in this survey. Let me know if you would like me to repeat the list of examples at any time.

ATTITUDES & OPINIONS

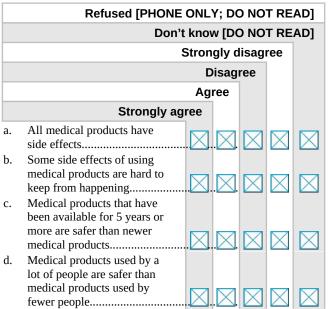
8. For this next set of questions, please think about what it means to you when the FDA approves a medical product as being "safe and effective."

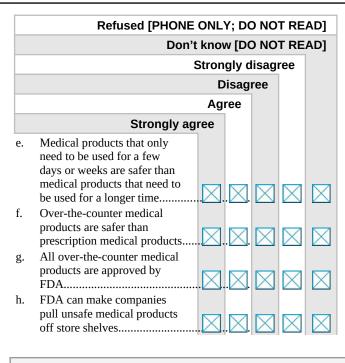
An approved medical product [INSERT RANDOMIZED]. Would you say that you strongly agree, agree, disagree, or strongly disagree?

	Refused [PHONE ONLY; DO NOT READ]				
	Don't know [DO NOT READ]				
	Strongly disagree				
	Disagree				
	Agree				
	Strongly agree				
a.	Has no life-threatening risks	\boxtimes	\times	\square	
b.	Can have minor risks, such as slightly irritating side effects.	\boxtimes	\boxtimes		
c.	Only has risks that are unlikely to happen	\boxtimes	\boxtimes	\boxtimes	
d.	Offers benefits that are greater than the risks		\boxtimes		
e.	Is safe for anyone to use	\boxtimes	\times	\boxtimes	
f.	Will help everyone who uses it	\boxtimes	\boxtimes	\boxtimes	
g.	Was approved because FDA had enough scientific information about it		\boxtimes		

9. How much do you agree or disagree with the following statements?

The first statement is [INSERT RANDOMIZED]. Would you say that you strongly agree, agree, disagree, or strongly disagree?





DRUGS

The next questions are about over-the-counter drugs that you can buy off the shelf without a prescription.

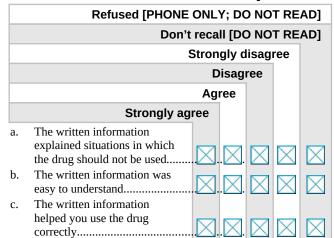
- 10. Have you ever taken more of an over-the-counter drug than the amount the label says you can take during a 24-hour period of time?
 - 🗙 Yes [DO NOT READ]
 - 🗙 No [DO NOT READ]
 - X Not sure [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]
- 11. [Ask if Q10 = "Yes"] Why did you take more than the label said you can take?
- [CODE ALL RESPONSES; DO NOT READ CODES]
- 01 It was an accident
- 02 Didn't read the label
- 03 Thought taking more of the drug would treat my symptoms better
- 04 Did not think my health would suffer if I took more of the drug
- 05 Previously had taken the prescription version
- 06 Over-the-counter drugs are safer than prescription drugs
- 07 Over-the-counter drugs are weaker than prescription drugs
- 08 My physician told me to take more
- 09 Did not get better taking the recommended amount
- 10 Other (please specify)
- 11 Not sure
- 99 Refused

- 12. Have you ever seen a label on an over-the-counter drug that includes directions and warnings?
 - 🔀 Yes [DO NOT READ]
 - 🔀 No [DO NOT READ]
 - 🔀 Not sure [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]
- 13. [Ask if Q12 = "Yes"] Before you use an over-thecounter drug for the first time, how often do you read the label? Would you say...
 - 🗙 Always
 - X Often
 - X Sometimes
 - 🗙 Rarely
 - X Never
 - Don't know [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]
- 14. [Ask if Q13 = "Always", "Often", "Sometimes", or "Rarely"] Before you use an over-the-counter drug for the first time, how often do you check the ingredients? Would you say...
 - 🔀 Always
 - X Often
 - X Sometimes
 - X Rarely
 - X Never
 - 🔀 Don't know [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]
- 15. [Ask if Q12 = "Yes"] How easy or difficult is it to <u>understand</u> the label on over-the-counter drugs? Would you say...
 - 🔀 Very easy
 - 🗙 Easy
 - Difficult
 - 🗙 Very difficult
 - 🗙 Don't know [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]

16. In the past 3 months, have you...

	Refused [PHONE ONLY; DO NOT READ]
	Not sure [DO NOT READ]
	No [DO NOT READ]
	Yes [DO NOT READ]
a.	Refilled a prescription for a drug you were already taking?
b.	Filled a new prescription for a drug you were <i>not</i> already taking?
c.	Taken more than the prescribed daily amount of a drug to make it work better?
d.	Taken less than the prescribed daily amount of a drug to make it last longer?
e.	Taken less than the prescribed daily amount of a drug to avoid side effects?

- 17. [Ask if Q16b = "Yes"] Think about the new prescription you filled most recently. Did you read any of the written information you got with it?
 - Yes [DO NOT READ]
 - No [DO NOT READ]
 - 🔀 Not sure [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]
- [Ask if Q17 = "Yes"] I am going to read some statements about the written information you got with your prescription. The first statement is [INSERT RANDOMIZED]. Would you say that you strongly agree, agree, disagree, or strongly disagree? The next statement is [INSERT RANDOMIZED]...[REPEAT RESPONSE OPTIONS AS NECESSARY]



- [RANDOMIZE WITH Q25] How well or poorly would you say a cholesterol-lowering drug works if it helps 75% (or 3 out of every 4) people who use it? Would you say...
 Very well
 - 🗙 Well

 - X Poorly
 - 🔀 Very poorly
 - Don't know [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]

For the next two questions, imagine you are taking a prescription drug. Initial reports from 10 patients across the country suggest the drug is causing a rare side effect. FDA is going to investigate. [RANDOMIZE Q20 AND Q21]

- 20. If the drug could cause you to be <u>hospitalized</u>, how soon would you want this information? Would you say... [RANDOMIZE ORDER OF "BEFORE" AND "AFTER"]
 - Before the investigation even starts
 - During the investigation, as soon as early results are available
 - After the investigation can provide firm advice on what to do
 - 🔀 Don't know [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]
- 21. If the drug could cause a <u>relatively minor problem,</u> <u>such as a slight skin rash</u>, how soon would you want this information? Would you say... [RANDOMIZE ORDER OF "BEFORE" AND "AFTER"]
 - Before the investigation even starts
 - During the investigation, as soon as early results are available
 - After the investigation can provide firm advice on what to do
 - 🔀 Don't know [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]
- 22. Suppose you are taking a prescription drug for a long-lasting health condition. You think you may need to stop taking the drug because you heard about a new and serious side effect. How much do you agree or disagree that the Internet and media can provide you with enough information to make this decision without checking with your doctor? Would you say...
 - 🗙 Strongly agree
 - X Agree
 - 🗙 Disagree
 - X Strongly disagree

- Don't know [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]
- 23. Suppose you become really dizzy after taking a prescription drug and the label does not list dizziness as a side effect. I am going to list some authorities you might inform of this side effect. For each, please tell me if you would be very likely, likely, unlikely, or very unlikely to inform this authority. [INSERT RANDOMIZED]. Would you say that you are very likely, likely, unlikely, or very unlikely to inform this authority?

Refused [PHONE ONLY; DO NOT READ]					
	Don't know [DO NOT READ]				
	Very	unlik	ely		
	Unlik	ely			
	Likely				
	Very likely				
a.	Your doctor	\square	\times	\square	
b.	Your pharmacist		\times	\square	
c.	The Food and Drug Administration (or FDA)		\boxtimes	\boxtimes	
d.	The Centers for Disease				
	Control and Prevention (or CDC)	\square	\boxtimes	\square	
e.	The company that made the drug	\square	\boxtimes	\square	

- 24. Before today, did you know that you can report medical product problems or side effects directly to the FDA by telephone?
 - X Yes [DO NOT READ]
 - No [DO NOT READ]
 - 🗙 Not sure [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]

[Read] For your information, the telephone number to report problems or side effects is 1-800-FDA-1088.

- 25. [RANDOMIZE WITH Q19] How safe or unsafe would you say a cholesterol-lowering drug is if it causes a minor skin rash in 25% (or 1 out of every 4) people who use it? Would you say...
 - 🗙 Very safe
 - 🗙 Safe
 - 🟹 Unsafe
 - 🗙 Very unsafe
 - 🔀 Don't know [DO NOT READ]

26.	How often do you need to have someone help you material from your doctor or pharmacy? Would you say Always Often Sometimes Rarely Never Don't know [DO NOT READ]	30.	[Ask if Q28 = "Yes"] How did you obtain the infant sleep positioner for your youngest child?
	Refused [PHONE ONLY; DO NOT READ]		
	MEDICAL DEVICES	31.	
27.	Are you the parent or caregiver of a child <u>under 3</u> years old?		Yes [DO NOT READ]
	Yes [DO NOT READ]		Refused [PHONE ONLY; DO NOT READ]
	No [DO NOT READ] Refused [PHONE ONLY; DO NOT READ]	32.	[Ask if Q31 = "Yes"] Have you ever read the instructions for contact lens solution?
28.	[Ask if Q27 = "Yes"] An infant sleep positioner is a product intended to keep a baby in a desired position (such as on their back, side, or stomach) while sleeping. Thinking of your youngest child, have you used an infant sleep positioner?		No [DO NOT READ] Not sure [DO NOT READ] Refused [PHONE ONLY; DO NOT READ]
	Yes [DO NOT READ]	33.	[Ask if Q32 = "Yes"] How easy or difficult was it to <u>understand</u> those instructions? Would you say
	Not sure [DO NOT READ]		🔀 Very easy
	Refused [PHONE ONLY; DO NOT READ]		🔀 Easy
29.	[Ask if Q28 = "Yes"] Did you use the infant sleep positioner for any of the following reasons?		Difficult Very difficult
	Refused [PHONE ONLY; DO NOT READ]		Don't recall [DO NOT READ]
	Not sure [DO NOT READ]		Refused [PHONE ONLY; DO NOT READ]

	Not sure [DO NOT READ]	
	No [DO NOT READ]	
	Yes [DO NOT READ]	
a.	To prevent the chance of Sudden Infant Death Syndrome (SIDS),	\times
b.	To keep your baby from getting a flat head	\times
c.	To prevent or treat reflux	X
d.	To follow the advice of your baby's doctor	\times
e.	To follow the advice of your family or friends	\times
f.	Some other reason (<i>please</i> specify)	\times

Γ

FDA COMMUNICATIONS

34. I am going to read some statements about how new risks of medical products are communicated to the public. For each, please tell me if you strongly agree, agree, disagree, or strongly disagree.

Refused [PHONE ONLY; DO NOT READ]					
Don't know [DO NOT READ]					
	Strongly disagree				
	Disagree				
	Agree				
	Strongly agree				
a.	Communications about new risks are made available as soon as possible				
b.	Communications about new risks are understandable to you				
c.	Communications about new risks are useful to you	\leq			

35. How much do you agree or disagree with the following statements? The FDA gives the public enough information about how it makes its decisions. Would you say you...

- 🔀 Strongly agree
- 🗙 Agree
- 🗙 Disagree
- X Strongly disagree
- 🗙 Don't know [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]
- 36. The FDA is a trustworthy source of information about medical products. Would you say you...
 - 🔀 Strongly agree
 - X Agree
 - 🗙 Disagree
 - 🔀 Strongly disagree
 - 🔀 Don't know [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]

37. How much do you trust each of the following sources to give you correct information about medical products? The first source is [INSERT RANDOMIZED]. Would you say that you trust this source a lot, a little, or not at all? The next source is [INSERT RANDOMIZED]...[REPEAT RESPONSE OPTIONS AS NECESSARY]

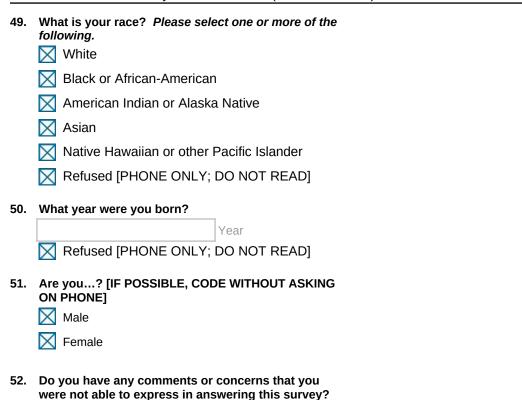
	Refused [PHONE ONLY; DO NOT READ]				
	Don't know [DO NOT READ]				
	Not a	t all			
	A little				
	A lot				
a.	Your doctor		\times		
b.	Your pharmacist		\times		
c.	Information in books, newspapers, or magazines				
	(not including advertisements)	. 🖂 [\times		
d.	TV or radio news	$ $ \square	\times		
e.	The Food and Drug Administration (or FDA)		\times		
f.	The company that made the medical product		\times		
g.	Your health insurance company		\times		

- Overall, how satisfied are you with how FDA communicates health-related information to the public? Would you say...
 - 🔀 Very satisfied
 - X Satisfied
 - Dissatisfied
 - Very dissatisfied
 - 🔀 Don't know [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]

FDA WEBSITE

- 39. In the <u>past 6 months</u>, have you visited the Food and Drug Administration's website (www.fda.gov)?
 - Yes [DO NOT READ]
 - No [DO NOT READ]
 - 🔀 Not sure [DO NOT READ]
 - Refused [PHONE ONLY; DO NOT READ]

40.	[Ask if Q39 = "Yes"] Thinking of the most recent time you visited FDA's website, what type of information were you most interested in finding?		Refused [PHONE ONLY; DO NOT READ]
	General information about FDA		BACKGROUND INFORMATION
	A product label (which includes reasons to use the product, directions, side effects to know about, and more)	44.	In general, would you say your health is
	Recalls or Public Health Notifications		Excellent
	Information on how to report a problem		Very good
	Some other type of product information (please		Good
	specify)		Fair
	Don't recall [DO NOT READ]		Poor
			Don't know [DO NOT READ]
	Refused [PHONE ONLY; DO NOT READ]		Refused [PHONE ONLY; DO NOT READ]
41.	[Ask if Q40 = any except "General information about FDA" or "Don't recall"] What type of product was this information for?	45.	Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, or government plans such as Medicare?
	Food		Yes [DO NOT READ]
	Drug		🔀 No [DO NOT READ]
	Medical device		Don't know [DO NOT READ]
	Vaccine, blood, or biologic		Refused [PHONE ONLY; DO NOT READ]
	Other (please specify)	46.	[Ask if Q45 = "Yes"] Does your current health
		-0.	coverage help pay for prescription drugs?
	Don't recall [DO NOT READ]		Yes [DO NOT READ]
	Refused [PHONE ONLY; DO NOT READ]		No [DO NOT READ]
42.			Don't know [DO NOT READ]
	was it to <u>find</u> the information you were looking for? Would you say		Refused [PHONE ONLY; DO NOT READ]
	Very easy	47.	What is the highest degree or level of school that
	Easy		you have completed? Would you say
	Difficult		Less than high school
	Very difficult		High school graduate or GED
	I could not find the information		Technical or vocational school
	Don't recall [DO NOT READ]		Some college
	Refused [PHONE ONLY; DO NOT READ]		Bachelor's degree
			Master's, doctoral, or professional school degree
43.	"Very difficult"] In general, how easy or difficult was it to <u>understand</u> the information after you found it?		Refused [PHONE ONLY; DO NOT READ]
	Would you say	48.	Are you of Hispanic, Latino, or Spanish origin?
	Very easy		Yes [DO NOT READ]
	Easy		No [DO NOT READ]
	Difficult		Refused [PHONE ONLY; DO NOT READ]
	Very difficult		
	🔀 Don't recall [DO NOT READ]		



[Read if Q27 = "Yes"] You indicated in the survey that you are a parent or caregiver. Many people are not aware that the Food and Drug Administration and the Consumer Product Safety Commission are currently urging caregivers to stop using infant sleep positioners because information suggests the risk of suffocation associated with their use. To learn more, please visit www.fda.gov or call 1-800-638-2041.

Thank you for taking time to complete and submit this survey.

If you have questions related to your rights as a survey respondent, you may call RTI's Office of Research Protections toll-free at 1-866-214-2043. If you have further questions about the study, you may contact a study team member toll-free at 1-XXX-XXX-XXXX.