

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

[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 past 3 months?

- 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 → 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" → 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.....	<input checked="" type="checkbox"/>				
b. Can have minor risks, such as slightly irritating side effects.....	<input checked="" type="checkbox"/>				
c. Only has risks that are unlikely to happen.....	<input checked="" type="checkbox"/>				
d. Offers benefits that are greater than the risks.....	<input checked="" type="checkbox"/>				
e. Is safe for anyone to use.....	<input checked="" type="checkbox"/>				
f. Will help everyone who uses it.....	<input checked="" type="checkbox"/>				
g. Was approved because FDA had enough scientific information about it.....	<input checked="" type="checkbox"/>				

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?

	Refused [PHONE ONLY; DO NOT READ]				
	Don't know [DO NOT READ]				
	Strongly disagree				
	Disagree				
	Agree				
	Strongly agree				
a. All medical products have side effects.....	<input checked="" type="checkbox"/>				
b. Some side effects of using medical products are hard to keep from happening.....	<input checked="" type="checkbox"/>				
c. Medical products that have been available for 5 years or more are safer than newer medical products.....	<input checked="" type="checkbox"/>				
d. Medical products used by a lot of people are safer than medical products used by fewer people.....	<input checked="" type="checkbox"/>				

Refused [PHONE ONLY; DO NOT READ]

Don't know [DO NOT READ]

Strongly disagree

Disagree

Agree

Strongly agree

e. Medical products that only need to be used for a few days or weeks are safer than medical products that need to be used for a longer time.....	<input checked="" type="checkbox"/>				
f. Over-the-counter medical products are safer than prescription medical products.....	<input checked="" type="checkbox"/>				
g. All over-the-counter medical products are approved by FDA.....	<input checked="" type="checkbox"/>				
h. FDA can make companies pull unsafe medical products off store shelves.....	<input checked="" type="checkbox"/>				

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]
- 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-the-counter drug for the first time, how often do you read the label? Would you say...

- Always
- Often
- Sometimes
- Rarely
- 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
- Often
- Sometimes
- Rarely
- 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 understand 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?.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
b. Filled a new prescription for a drug you were <i>not</i> already taking?.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
c. Taken more than the prescribed daily amount of a drug to make it work better?.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
d. Taken less than the prescribed daily amount of a drug to make it last longer?.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
e. Taken less than the prescribed daily amount of a drug to avoid side effects?.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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]

18. [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]

	Refused [PHONE ONLY; DO NOT READ]				
	Don't recall [DO NOT READ]				
	Strongly disagree				
	Disagree				
	Agree				
	Strongly agree				
a. The written information explained situations in which the drug should not be used.....	<input checked="" type="checkbox"/>				
b. The written information was easy to understand.....	<input checked="" type="checkbox"/>				
c. The written information helped you use the drug correctly.....	<input checked="" type="checkbox"/>				

19. [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
- 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 hospitalized, 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 relatively minor problem, such as a slight skin rash, 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
- Agree
- Disagree
- 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?

	Very likely	Likely	Unlikely	Very unlikely	Don't know [DO NOT READ]	Refused [PHONE ONLY; DO NOT READ]
a. Your doctor.....	<input checked="" type="checkbox"/>					
b. Your pharmacist.....	<input checked="" type="checkbox"/>					
c. The Food and Drug Administration (or FDA).....	<input checked="" type="checkbox"/>					
d. The Centers for Disease Control and Prevention (or CDC).....	<input checked="" type="checkbox"/>					
e. The company that made the drug.....	<input checked="" type="checkbox"/>					

24. Before today, did you know that you can report medical product problems or side effects directly to the FDA by telephone?

- 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 understand instructions, pamphlets, or other written material from your doctor or pharmacy? Would you say...

- Always
- Often
- Sometimes
- Rarely
- Never
- Don't know [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

30. [Ask if Q28 = "Yes"] How did you obtain the infant sleep positioner for your youngest child?

- Bought it new [DO NOT READ]
- Bought it used [DO NOT READ]
- Received it as a gift [DO NOT READ]
- Hand-me-down from an older child in the family [DO NOT READ]
- Hand-me-down from another family [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]
- Other (please specify) [DO NOT READ]

MEDICAL DEVICES

27. Are you the parent or caregiver of a child under 3 years old?

- Yes [DO NOT READ]
- No [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

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?

- Yes [DO NOT READ]
- No [DO NOT READ]
- Not sure [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

29. [Ask if Q28 = "Yes"] Did you use the infant sleep positioner for any of the following reasons?

	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).....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
b. To keep your baby from getting a flat head.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
c. To prevent or treat reflux.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
d. To follow the advice of your baby's doctor.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
e. To follow the advice of your family or friends.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
f. Some other reason (please specify).....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

31. Do you wear contact lenses?

- Yes [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?

- Yes [DO NOT READ]
- No [DO NOT READ]
- Not sure [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

33. [Ask if Q32 = "Yes"] How easy or difficult was it to understand those instructions? Would you say...

- Very easy
- Easy
- Difficult
- Very difficult
- Don't recall [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

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.....			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
b. Communications about new risks are understandable to you.....			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
c. Communications about new risks are useful to you.....			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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
- 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
- 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 at all	A little	A lot
a. Your doctor.....			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
b. Your pharmacist.....			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
c. Information in books, newspapers, or magazines (not including advertisements).....			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
d. TV or radio news.....			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
e. The Food and Drug Administration (or FDA).....			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
f. The company that made the medical product.....			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
g. Your health insurance company.....			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

38. Overall, how satisfied are you with how FDA communicates health-related information to the public? Would you say...

- Very satisfied
- Satisfied
- Dissatisfied
- Very dissatisfied
- Don't know [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

FDA WEBSITE

39. In the past 6 months, 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?

- General information about FDA
- A product label (which includes reasons to use the product, directions, side effects to know about, and more)
- Recalls or Public Health Notifications
- Information on how to report a problem
- Some other type of product information (*please specify*)

- Don't recall [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?

- Food
- Drug
- Medical device
- Vaccine, blood, or biologic
- Other (*please specify*)

- Don't recall [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

42. [Ask if Q39 = Yes] In general, how easy or difficult was it to find the information you were looking for? Would you say...

- Very easy
- Easy
- Difficult
- Very difficult
- I could not find the information
- Don't recall [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

43. [Ask if Q42 = "Very easy", "Easy", "Difficult", or "Very difficult"] In general, how easy or difficult was it to understand the information after you found it? Would you say...

- Very easy
- Easy
- Difficult
- Very difficult
- Don't recall [DO NOT READ]

- Refused [PHONE ONLY; DO NOT READ]

BACKGROUND INFORMATION

44. In general, would you say your health is...

- Excellent
- Very good
- Good
- Fair
- Poor
- Don't know [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

45. Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, or government plans such as Medicare?

- Yes [DO NOT READ]
- No [DO NOT READ]
- Don't know [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

46. [Ask if Q45 = "Yes"] Does your current health coverage help pay for prescription drugs?

- Yes [DO NOT READ]
- No [DO NOT READ]
- Don't know [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

47. What is the highest degree or level of school that you have completed? Would you say...

- Less than high school
- High school graduate or GED
- Technical or vocational school
- Some college
- Bachelor's degree
- Master's, doctoral, or professional school degree
- Refused [PHONE ONLY; DO NOT READ]

48. Are you of Hispanic, Latino, or Spanish origin?

- Yes [DO NOT READ]
- No [DO NOT READ]
- Refused [PHONE ONLY; DO NOT READ]

49. **What is your race? Please select one or more of the following.**

- White
- Black or African-American
- American Indian or Alaska Native
- Asian
- Native Hawaiian or other Pacific Islander
- Refused [PHONE ONLY; DO NOT READ]

50. **What year were you born?**

 Year

- Refused [PHONE ONLY; DO NOT READ]

51. **Are you...? [IF POSSIBLE, CODE WITHOUT ASKING ON PHONE]**

- Male
- Female

52. **Do you have any comments or concerns that you were not able to express in answering this survey?**

[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.