

SCREENER AND INTRODUCTION

The U.S. Food and Drug Administration, also known as 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.

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. If you have questions about the study, you can contact the study supervisor toll-free at 1-XXX-XXX-XXXX. If you have questions about your rights as a study participant, you can call 1-866-214-2043.

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.

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.

1. Based on this list of examples, 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
 No
 Not sure

IF Q1 = "No," "Not sure," or missing → DISPLAY: Thank you. At this time, we are only surveying adults age 18 or older who have recent experience with a medical product. We appreciate your time. Have a good day. CODE CASE AND TERMINATE

IF Q1 = "Yes" → DISPLAY: The phrase "medical products" will be used often in this survey. Click on "medical products" at any time during this survey to see the list of examples repeated.

ATTITUDES & OPINIONS

2. How much do you agree or disagree that when FDA approves a medical product as being "safe and effective," it means...? [RANDOMIZE]

	Don't know				
	Strongly disagree				
	Disagree				
	Agree				
	Strongly agree				
a. The medical product has no life-threatening risks.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
b. The medical product can have minor risks, such as slightly irritating side effects.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
c. The medical product only has risks that are unlikely to happen.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
d. The medical product offers benefits that are greater than the risks.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
e. The medical product is safe for anyone to use.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
f. The medical product will help everyone who uses it.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
g. The medical product was approved because FDA had enough scientific information about it.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

3. How much do you agree or disagree with the following statements? [RANDOMIZE]

	Don't know				
	Strongly disagree				
	Disagree				
	Agree				
	Strongly agree				
a. All medical products have side effects.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
b. Some side effects of using medical products are hard to keep from happening.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<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"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<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"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
f. Over-the-counter medical products are safer than prescription medical products.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

	Strongly disagree	Disagree	Agree	Strongly agree	Don't know
g. All over-the-counter medical products are approved by FDA.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
h. FDA can make companies pull unsafe medical products off store shelves.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

7. [Ask if Q6 = "Yes"] Before you use an over-the-counter drug for the first time, how often do you read the label?

- Always
- Often
- Sometimes
- Rarely
- Never
- Don't know

8. [Ask if Q7 = "Always", "Often", "Sometimes", or "Rarely"] Before you use an over-the-counter drug for the first time, how often do you check the ingredients?

- Always
- Often
- Sometimes
- Rarely
- Never
- Don't know

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

4. 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
- No
- Not sure

5. [Ask if Q4 = "Yes"] Why did you take more than the label said you can take?

[CODE ALL RESPONSES]

- 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

6. Have you ever seen a label on an over-the-counter drug that includes directions and warnings?

- Yes
- No
- Not sure

9. [Ask if Q6 = "Yes"] How easy or difficult is it to understand the label on over-the-counter drugs?

- Very easy
- Easy
- Difficult
- Very difficult
- Don't know

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

	Yes	No	Not sure
a. Refilled a prescription for a drug you were already taking?.....	<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"/>
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"/>
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"/>
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"/>

11. [Ask if Q10b = "Yes"] Think about the new prescription you filled most recently. Did you read any of the written information you got with it?

- Yes
- No
- Not sure

12. [Ask if any Q11 = "Yes"] How much do you agree or disagree that the written information you got with your prescription...

	Strongly agree	Agree	Disagree	Strongly disagree	Don't recall
a. Explained situations in which the drug should not be used?.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
b. Was easy to understand?.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
c. Helped you use the drug correctly?.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

13. [RANDOMIZE WITH Q19] 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?

- Very well
- Well
- Poorly
- Very poorly
- Don't know

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 Q14 AND Q15]

14. If the drug could cause you to be hospitalized, how soon would you want this information? [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

15. If the drug could cause a relatively minor problem, such as a slight skin rash, how soon would you want this information? [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

16. 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?

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

17. Suppose you become really dizzy after taking a prescription drug and the label does not list dizziness as a side effect. How likely or unlikely are you to inform the following authorities of this side effect? [RANDOMIZE]

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

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

- Yes
- No
- Not sure

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

19. [RANDOMIZE WITH Q13] 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?

- Very safe
- Safe
- Unsafe
- Very unsafe
- Don't know

20. How often do you need to have someone help you understand instructions, pamphlets, or other written material from your doctor or pharmacy?

- Always
- Often
- Sometimes
- Rarely
- Never
- Don't know

	Not sure		
	No		
	Yes		
e. To follow the advice of your family or friends.....	<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"/>

24. [Ask if Q22 = "Yes"] How did you obtain the infant sleep positioner for your youngest child?

- Bought it new
- Bought it used
- Received it as a gift
- Hand-me-down from an older child in the family
- Hand-me-down from another family
- Other (please specify)

25. Do you wear contact lenses?

- Yes
- No

26. [Ask if Q25 = "Yes"] Have you ever read the instructions for contact lens solution?

- Yes
- No
- Not sure

27. [Ask if Q26 = "Yes"] How easy or difficult was it to understand those instructions?

- Very easy
- Easy
- Difficult
- Very difficult
- Don't recall

MEDICAL DEVICES

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

- Yes
- No

22. [Ask if Q21 = "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
- No
- Not sure

23. [Ask if Q22 = "Yes"] Did you use the infant sleep positioner for any of the following reasons?

	Not sure		
	No		
	Yes		
a. To prevent the chance of Sudden Infant Death Syndrome (SIDS).....	<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"/>
c. To prevent or treat reflux.....	<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"/>

FDA COMMUNICATIONS

28. How much do you agree or disagree with the following statements about how new risks of medical products are communicated to the public?

	Don't know				
	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"/>	<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"/>	<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"/>	<input checked="" type="checkbox"/>

29. How much do you agree or disagree that the FDA gives the public enough information about how it makes its decisions?

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

30. How much do you agree or disagree that the FDA is a trustworthy source of information about medical products?

- Strongly agree
- Agree
- Disagree
- Strongly disagree
- Don't know

31. How much do you trust each of the following sources to give you correct information about medical products? [RANDOMIZE]

	Don't know			
	Not at all			
	A little			
	A lot			
a. Your doctor.....	<input checked="" type="checkbox"/>	<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"/>	<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"/>	<input checked="" type="checkbox"/>
d. TV or radio news.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

	Don't know			
	Not at all			
	A little			
	A lot			
e. The Food and Drug Administration (or FDA).....	<input checked="" type="checkbox"/>	<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"/>	<input checked="" type="checkbox"/>
g. Your health insurance company.....	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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

- Very satisfied
- Satisfied
- Dissatisfied
- Very dissatisfied
- Don't know

FDA WEBSITE

33. In the past 6 months, have you visited the Food and Drug Administration's website (www.fda.gov)?

- Yes
- No
- Not sure

34. [Ask if Q33 = "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

35. [Ask if Q34 = 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

36. [Ask if Q33 = Yes] In general, how easy or difficult was it to **find** the information you were looking for?

Very easy

Easy

Difficult

Very difficult

I could not find the information

Don't recall

37. [Ask if Q36 = "Very easy", "Easy", "Difficult", or "Very difficult"] In general, how easy or difficult was it to **understand** the information after you found it?

Very easy

Easy

Difficult

Very difficult

Don't recall

BACKGROUND INFORMATION

38. In general, would you say your health is...?

Excellent

Very good

Good

Fair

Poor

Don't know

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

Yes

No

Don't know

40. [Ask if Q39 = "Yes"] Does your current health coverage help pay for prescription drugs?

Yes

No

Don't know

41. What is the highest degree or level of school that you have completed?

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

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

Yes

No

43. What is your race? Please select one or more.

White

Black or African-American

American Indian or Alaska Native

Asian

Native Hawaiian or other Pacific Islander

44. What year were you born?

 Year

45. Are you...?

Male

Female

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

[Show if Q21 = "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.