



HEADER / TITLE: FDA Terms and Phrases Study

OMB No. 0910-0895: Approval Expires 03/31/2024

FOOTER: If you have questions about the study, please contact the toll-free project hotline at 1-866-860-7853

Screener

INTRO. Hello, we are recruiting people for a research study sponsored by the Food and Drug Administration. The purpose of the study is to find out how people understand words and phrases that are commonly used in prescription drug advertising.

RTI International, an independent, nonprofit research institute, will be conducting the survey with consumers nationwide. The survey will take approximately 20 minutes. If you participate, you will receive \$20 in appreciation for your time. To see if you are eligible, please complete the brief survey linked below.

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S1. How old were you on your last birthday?

_____	Over Age 18 → CONTINUE Under Age 18 → TERMINATE
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S2. Are you a medical or health professional?

Yes	→ TERMINATE
No	→ CONTINUE

S3. Have you ever worked for...?

Department of Health and Human Services	→ TERMINATE
U.S. Food and Drug Administration	→ TERMINATE
Market research firm	→ TERMINATE
Pharmaceutical company	→ TERMINATE
Itracks	→ TERMINATE
RTI International	→ TERMINATE

Burden Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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**[IF NOT ELIGIBLE:
Thank and Terminate]**

TERMINATE. We're sorry, but you are not eligible for this study. There are many possible reasons people are not eligible for this study. These reasons were decided earlier by the researchers. However, thank you for your interest in this study and for taking the time to answer our questions today.

[END SURVEY – CODE INELIG.]

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[IF ELIGIBLE]

CONSENT.

Introduction and Purpose

You have been invited to take part in a research study. The purpose of the study is to find out how people understand words and phrases that are commonly used in prescription drug advertising. RTI International, a nonprofit research organization in North Carolina, is conducting this study sponsored by the U.S. Food and Drug Administration (FDA).

Procedures

You are one of about 1,000 people from around the United States being asked to participate in this study. If you agree to participate, you will take part in a web-based survey. The survey should take about **20 minutes**.

Benefits

There is no direct benefit to you for participating. Your responses are very important because they will help researchers find out how people understand information included in prescription drug advertising.

Risks

There are no known risks to participating in this study. We will not ask you any personal health questions, but if any questions make you uncomfortable, you can refuse to answer. There is also a potential risk of loss of confidentiality. Every effort will be made to protect your information, but this cannot be guaranteed.

Confidentiality

The privacy and confidentiality of your information is of the highest importance, and we are committed to maintaining a secure environment in which you can participate. All information you share in this study will be kept confidential to the extent provided by law. The study team will not reveal your name or any of your responses, and your personal information (name, address, phone number) will not be

linked to any of your responses. The information you share with us will be combined into a summary report so that details of individual surveys cannot be linked to a specific participant. You will not be recontacted about this research study in the future. However, once de-identified, your data may be shared with other researchers or used by RTI/FDA for future research purposes.

Reimbursement

After the interview has been completed, you will receive a check by mail for \$20 within 4 to 6 weeks in appreciation for your time.

Right to Refuse or Withdraw

Your participation in this study is completely voluntary, and you can withdraw from the study for any reason at any time without penalty.

Persons to Contact

If you have questions about the study, you can call the project director, Dr. Bridget Kelly, at 1-800-334-8571, ext. 22098. She can be reached between 9:00 a.m. and 5:00 p.m. Eastern Time Monday to Friday. If you have questions about your rights as a participant, you can call RTI's Office of Research Protection toll-free at 1-866-214-2043.

[CONSENT1.] If you have read this screen and agree to participate, please click the Yes button. If not, click the No button.

1. Yes, I agree to participate. [Continue to SURVEY_INTRO]
2. No, I do not agree to participate. [Go on to CONSENT2]

[IF CONSENT1=NO OR SKIP]

[CONSENT2.] Are you sure you don't want to participate? Your opinions are important to us. Please select the Yes button if you'd like to proceed to the survey. Select the No button to exit.

1. Yes, I agree to participate. [Continue to SURVEY_INTRO]
2. No, I do not agree to participate. [GO TO NOCONSENT]

{page break}

NOCONSENT: Thank you for your time.

[END SURVEY – CODE INELIG.]

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SURVEY_INTRO.

This survey focuses on words and phrases that are commonly used in prescription drug advertising. Some questions include one or more example statements featuring the word or phrase we are asking about. This survey will take about 20 minutes to complete. We ask you to complete the study in one sitting (without taking any breaks) in order to avoid distractions.

Please answer the questions to the best of your ability.

Q1. When you read each statement, which of the following come to mind about the drugs listed?

PLEASE CHECK ALL THAT APPLY.

	It will be easy to take the medication as intended by my doctor.	The drug is a pill (not a shot).	The drug does not involve measurement or cutting pills in half.	The instructions are clear.	The drug does not have to be taken at a specific time of day.	The drug does not have to be taken with food.	The drug does not require trips to the doctor for blood testing.	Other
This drug is " <u>convenient.</u> "								
This drug is " <u>straight forward to use.</u> "								
This drug is " <u>simple to use.</u> "								
This drug is " <u>easy to use.</u> "								

[IF Q1_A1=8] You selected "Other" for the statement: The drug is "convenient"

Please specify: [OPEN RESPONSE]

[IF Q1_A2=8] You selected "Other" for the statement: The drug is "straightforward to use"

Please specify: [OPEN RESPONSE]

[IF Q1_A3=8] You selected "Other" for the statement: The drug is "simple to use"

Please specify: [OPEN RESPONSE]

[IF Q1_A4=8] You selected "Other" for the statement: The drug is "easy to use"

Please specify: [OPEN RESPONSE]

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Q2. How safe do you think each of the following drugs is compared to other drugs for the same condition?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	Much less safe	Somewhat less safe	Equally as safe	Somewhat safer	Much safer	Safety cannot be compared to other drugs
This drug is " <u>convenient.</u> "						
This drug is " <u>straightforward to use.</u> "						
This drug is " <u>simple to use.</u> "						
This drug is " <u>easy to use.</u> "						

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Q3. How effective do you think each of the following drugs is compared to other drugs for the same condition?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	1 Much less effective	2 Somewhat less effective	3 Equally as effective	4 Somewhat more effective	5 Much more effective	6 Effectiveness cannot be compared to other drugs
This drug is " <u>convenient.</u> "						
This drug is " <u>straightforward to use.</u> "						
This drug is " <u>simple to use.</u> "						
This drug is " <u>easy to use.</u> "						

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Q4. When you read each statement, how likely do you think it is that a patient taking each drug would experience a severe asthma attack?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	Not at all likely	Somewhat likely	Neither likely nor unlikely	Somewhat likely	Extremely likely
This drug is shown to <u>“prevent”</u> severe asthma attacks.					
This drug is shown to <u>“help prevent”</u> severe asthma attacks.					
This drug is shown to <u>“reduce the risk”</u> of severe asthma attacks.					
This drug is <u>“proven to help”</u> prevent severe asthma attacks.					
This drug is <u>“proven effective”</u> at preventing severe asthma attacks.					

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Q5. When you read each statement, which of the following come to mind about the drugs listed?

PLEASE CHECK ALL THAT APPLY

	There have been studies to show the drug works as it is supposed to.	The drug would need to be taken with other drugs in order to work.	The drug is guaranteed to be effective at preventing severe asthma attacks.	Other
This drug is <u>“proven to help”</u> prevent severe asthma attacks.				
This drug is <u>“proven effective”</u> at preventing severe asthma attacks.				

[IF Q5_A1=4] You selected “Other” for the statement: This drug is “proven to help” prevent severe asthma attacks.

Please specify: [OPEN RESPONSE]

[IF Q5_A2=4] You selected “Other” for the statement: This drug is “proven effective” at preventing severe asthma attacks.

Please specify: [OPEN RESPONSE]

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Q6. When you read each statement, what comes to mind about the following drugs?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	The drug works only on a <u>specific cause</u> of the migraine and does not affect any other parts of the body.	The drug works on a <u>specific cause</u> of the migraine, but may also affect other parts of the body.	The drug works only at <u>the site or location</u> of the migraine and does not affect any other parts of the body.	The drug works at <u>the site or location</u> of the migraine but may also affect other parts of the body.	The drug is applied topically (to the skin).	I don't know	Other
This drug acts by “ <u>targeting</u> ” calcitonin gene related peptide (CGRP) receptors to help address migraines.							

This drug “ acts locally ” to help address migraines.							
This drug has a “ targeted mechanism of action ” to help address migraines.							

[IF Q6_A1=7] You selected “Other” for the statement: This drug acts by “**targeting**” calcitonin gene related peptide (CGRP) receptors to help address migraines.

Please specify: [OPEN RESPONSE]

[IF Q6_A2=7] You selected “Other” for the statement: This drug “**acts locally**” to help address migraines.

Please specify: [OPEN RESPONSE]

[IF Q6_A3=7] You selected “Other” for the statement: This drug has a “**targeted mechanism of action**” to help address migraines.

Please specify: [OPEN RESPONSE]

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Q7. When you read each statement, which of the following come to mind about the drugs listed?

PLEASE SELECT ALL THAT APPLY.

	It is strong.	It works better than other drugs.	It has long-lasting benefits.	It works quickly.	It might have more side effects than other drugs.	It could be addictive.	It might be effective on its own (not require another drug to be taken with it).	Other
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This drug is " powerful. "								
This drug is " potent. "								

[IF Q7_A1=8] You selected "Other" for the statement: This drug is "**powerful.**"

Please specify: [OPEN RESPONSE]

[IF Q7_A2=8] You selected "Other" for the statement: This drug is "**potent.**"

Please specify: [OPEN RESPONSE]

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Q8. How safe do you think each of the following drugs is compared to other drugs for the same condition?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	1 Much less safe	2 Somewhat less safe	3 Equally as safe	4 Somewhat safer	5 Much safer	6 Safety cannot be compared to other drugs
This drug is shown to " prevent " ...						
This drug is shown to " help prevent " ...						
This drug is shown to " reduce the risk " of...						
This drug is " proven to help " ...						
This drug is " proven effective " ...						
This drug is made from a " natural " ingredient.						

This drug works by " <u>targeting</u> "...						
This drug " <u>acts locally.</u> "						
This drug has a " <u>targeted mechanism of action.</u> "						
This drug is " <u>powerful.</u> "						
This drug is " <u>potent.</u> "						

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Q9. How effective do you think each of the following drugs is compared to other drugs for the same condition?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	1 Much less effective	2 Somewhat less effective	3 Equally as effective	4 Somewhat more effective	5 Much more effective	6 Effectiveness cannot be compared to other drugs
This drug is shown to " <u>prevent</u> " ...						
This drug is shown to " <u>help prevent</u> " ...						
This drug is shown to " <u>reduce the risk</u> " of...						
This drug is " <u>proven to help</u> " ...						
This drug is " <u>proven effective</u> " ...						
This drug is made from a " <u>natural</u> " ingredient.						
This drug works by " <u>targeting</u> " ...						
This drug " <u>acts locally.</u> "						
This drug has a " <u>targeted mechanism of action.</u> "						
This drug is " <u>powerful.</u> "						
This drug is " <u>potent.</u> "						

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Q10. How would knowing that a drug is the “#1 prescribed” drug affect *your intention* to ask your doctor about it?

PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.

Would it make you:

- A lot less likely to ask my doctor
- A little less likely to ask my doctor
- Neither more nor less likely to ask my doctor
- A little more likely to ask my doctor
- A lot more likely to ask my doctor

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Q11. How would knowing that a drug is the “#1 prescribed” drug affect *other people’s intentions* to ask their doctors about it?

PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.

Would it make them:

- A lot less likely to ask their doctor
- A little less likely to ask their doctor
- Neither more nor less likely to ask their doctor
- A little more likely to ask their doctor
- A lot more likely to ask their doctor

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Q12. What do you think about a drug when you read that it is the #1 prescribed” drug?

PLEASE CHECK ALL THAT APPLY.

- It is the best available option.
- It is safer than other drugs.
- It is less expensive than other drugs.
- It is more expensive than other drugs.
- It is more likely to be covered by insurance than other drugs.

- It is the most commonly prescribed.
- It is more effective than other drugs.
- It is more readily available than other drugs.
- Other (please specify): _____

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Q13. How safe do you think each of the following drugs is compared to other drugs for the same condition?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	Much less safe	Some what less safe	Equally as safe	Some what safer	Much safer	Safety cannot be compared to other drugs
This drug is " <u>new</u> ."						
This drug " <u>works differently</u> ."						
This drug is the " <u>first and only</u> " drug to...						
This drug uses a " <u>novel mechanism of action</u> ."						

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Q14. How effective do you think each of the following drugs is compared to other drugs for the same condition?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	Much less effective	Somewhat less effective	Equally as effective	Somewhat more effective	Much more effective	Effectiveness cannot be compared to other brands
This drug is " <u>new</u> ."						
This drug " <u>works differently</u> ."						
This drug is the " <u>first and only</u> " drug to...						
This drug uses a " <u>novel mechanism of action</u> ."						

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Q15. Which of the following come to mind when you read that a drug has been "FDA approved"?

PLEASE CHECK ALL THAT APPLY.

- The drug must not have any serious side effects.
- The drug has been evaluated for safety and effectiveness.
- The drug offers benefits that are greater than the risks.
- The drug is safer than other drugs.
- The drug is as safe as other drugs.
- Other (please specify): _____

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Q16. Which of the following come to mind when you read that a prescription drug is used “off-label”?

PLEASE CHECK ALL THAT APPLY.

- It does NOT have FDA approval for the specific medical condition for which it is being used.
- It does NOT have FDA approval for *any* use.
- It is used for an unapproved age group or dose.
- It is used illegally.
- It is a generic drug (not the brand name drug).
- It is available over the counter.
- Other (please specify): _____

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Q17. When you read that a drug “reverses” bone loss, what does that mean to you?

PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.

- It will return bone density to normal.
- It will build back bone that was lost.
- It will stop bone density loss.
- It will slow bone density loss.
- Other (please specify): _____

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Q18. Which of the following come to mind when you read, “individual results may vary” in a statement about a drug?

PLEASE SELECT ALL THAT APPLY.

- The benefits will generally be the same for everyone.
- The benefits will vary from person to person.
- It will work for few people.
- There is no guarantee it will work for you.
- Other (please specify): _____

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Q19. What do you think about a drug when you read that the difference in effectiveness between it and a placebo was “not statistically significant”?

PLEASE DESCRIBE IN YOUR OWN WORDS:

[OPEN-ENDED]

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Q20.

Please read the following four statements:

Statement 1: “This drug offers a manageable safety profile.”

Statement 2: “This drug offers an established safety profile.”

Statement 3: “This drug offers a well-studied safety profile.”

Statement 4: “This drug is well-tolerated.”

Do these four statements mean the same thing or do some of them mean something different to you?

- They all mean the same thing.
- They mean something different. Please specify the difference: _____

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Q21. When you read each statement, what comes to mind about the following drugs?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	The drug’s risks and side effects are well understood.	The drug has fewer risks and side effects than other drugs for the same condition.	Health care providers know how to manage the risks and side effects.	Other
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This drug offers a " <u>manageable safety profile.</u> "				
This drug offers an " <u>established safety profile.</u> "				
This drug offers a " <u>well-studied safety profile.</u> "				
This drug is " <u>well-tolerated.</u> "				

[IF Q21_A1=4] You selected "Other" for the statement: This drug offers a "manageable safety profile."

Please specify: [OPEN RESPONSE]

[IF Q21_A2=4] You selected "Other" for the statement: This drug offers an "established safety profile."

Please specify: [OPEN RESPONSE]

[IF Q21_A3=4] You selected "Other" for the statement: This drug offers a "well-studied safety profile."

Please specify: [OPEN RESPONSE]

[IF Q21_A4=4] You selected "Other" for the statement: This drug is "well-tolerated."

Please specify: [OPEN RESPONSE]

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Q22. When you read each statement, what comes to mind about the following drugs?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	It will return vaginal tissue to its original condition.	It will create tissue that is stronger or better than the original tissue.	It will relieve symptoms.	It involves building new tissue, but may not return tissue to its original state.	Other
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This drug “ <u>restores</u> ” vaginal tissue.					
This drug “ <u>rebuilds</u> ” vaginal tissue.					

[IF Q22_A1=5] You selected “Other” for the statement: This drug “restores” vaginal tissue.

Please specify: [OPEN RESPONSE]

[IF Q22_A2=5] You selected “Other” for the statement: This drug “rebuilds” vaginal tissue.

Please specify: [OPEN RESPONSE]

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Q23. How safe do you think each of the following drugs is compared to other drugs for the same condition?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	Much less safe	Somewhat less safe	Equally as safe	Somewhat safer	Much safer	Safety cannot be compared to other drugs
This drug is the “ <u>#1 prescribed</u> ” drug.						
This drug is “ <u>FDA approved</u> .”						
This drug is used “ <u>off label</u> .”						
This drug “ <u>reverses</u> ”...						

For this drug, " <u>individual results may vary.</u> "						
This drug " <u>restores</u> " ...						
This drug " <u>rebuilds</u> " ...						

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Q24. How effective do you think each of the following drugs is compared to other drugs for the same condition?

PLEASE SELECT THE RESPONSE FOR EACH UNDERLINED TERM THAT COMES CLOSEST TO YOUR BELIEFS.

	Much less effective	Somewhat less effective	Equally as effective	Somewhat more effective	Much more effective	Effectiveness cannot be compared to other drugs
This drug is the " <u>#1 prescribed</u> " drug.						
This drug is " <u>FDA approved.</u> "						
This drug is used " <u>off label.</u> "						
This drug " <u>reverses</u> " ...						
For this drug, " <u>individual results may vary.</u> "						
The difference in effectiveness between this drug and a placebo was " <u>not statistically significant.</u> "						
This drug " <u>restores</u> " ...						
This drug " <u>rebuilds</u> " ...						

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Q25. How many people out of 100 do you think of when you see each of the following? If you are thinking of a range, please enter the midpoint of that range.

Many	_____ (enter a number from 0–100)
A few	_____ (enter a number from 0–100)
Some	_____ (enter a number from 0–100)
The majority	_____ (enter a number from 0–100)
Most	_____ (enter a number from 0–100)

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Please read the following two statements:

“Pharmaceutical companies engage in prescription drug promotion to market their products.”

“Pharmaceutical companies engage in prescription drug advertising to market their products.”

Q26. Do these statements mean the same thing to you or do they mean different things?

- They mean the same thing to me.
- They mean different things to me. Please specify the difference: _____

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Q27. Which of the following do you think about when you read “prescription drug promotion” and “prescription drug advertising”?

PLEASE CHECK ALL THAT APPLY.

	Prescription drug promotion	Prescription drug advertising
Pharmaceutical representatives’ visits to doctors’ offices to discuss prescription drugs	<input type="checkbox"/>	<input type="checkbox"/>
Drug information provided to doctors at medical conferences	<input type="checkbox"/>	<input type="checkbox"/>
Print or web materials (e.g., ads in medical journals) developed specifically for health care providers about a prescription drug	<input type="checkbox"/>	<input type="checkbox"/>
Television or radio ads about the drug directed at consumers	<input type="checkbox"/>	<input type="checkbox"/>
Print ads in magazines or journals directed at consumers	<input type="checkbox"/>	<input type="checkbox"/>
Website, web, or social media ads about the drug directed at consumers	<input type="checkbox"/>	<input type="checkbox"/>
A coupon, discount, or special offer	<input type="checkbox"/>	<input type="checkbox"/>
Other (please specify): _____	<input type="checkbox"/>	<input type="checkbox"/>

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Q28. How safe do you think each of the following drugs is compared to other drugs for the same condition?

	Much less safe	Somewhat less safe	Equally as safe	Somewhat safer	Much safer	Safety cannot be compared to other drugs
This drug can cause “ <u>reactions.</u> ”						
This drug can cause “ <u>serious reactions</u> ”						
This drug can cause “ <u>severe, life-threatening reactions.</u> ”						

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Q29. How effective do you think each of the following drugs is compared to other drugs for the same condition?

	Much less effective	Somewhat less effective	Equally as effective	Somewhat more effective	Much more effective	Effectiveness cannot be compared to other drugs
This drug can cause " <u>reactions.</u> "						
This drug can cause " <u>serious reactions.</u> "						
This drug can cause " <u>severe, life-threatening reactions.</u> "						

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Q30. Please read the following statement: This drug's effectiveness was based on clinical trial endpoints.

In this statement, what does "endpoint" mean to you?

[Open-ended]

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Q31. When you read each statement, which of the following come to mind about the following drugs?

PLEASE CHECK ALL THAT APPLY.

	It is all natural.	The ingredients are undiluted or unadulterated.	It does not include any artificial ingredients.	It is environmentally friendly.	It is regulated to ensure its purity.	Other
This drug is a " <u>pure</u> " solution.						
This drug follows strict " <u>purity</u> " standards.						

[IF Q31_A1=6] You selected “Other” for the statement: This drug is a “pure” solution.

Please specify: [OPEN RESPONSE]

[IF Q31_A2=6] You selected “Other” for the statement: This drug follows strict “purity” standards.

Please specify: [OPEN RESPONSE]

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DEMO_INTRO: Thank you for answering those questions. Now, we have just a few more questions about you.

Q32. What is your gender?

- Male
- Female
- Prefer not to answer

Q33. Are you Hispanic or Latino?

- Yes
- No

Q34. What is your race? You may select one or more races.

- American Indian or Alaskan Native
- Asian
- Black or African American
- Native Hawaiian or other Pacific Islander
- White
- Prefer not to answer

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Q35. What is the highest level of education you have attained?

- Less than high school
- High school graduate (or GED)
- Some college or technical school (no degree)
- College graduate (2- or 4-year degree)
- Some graduate school
- Graduate school degree

Q36. Was your total household income in 2021?

- Less than \$20,000
- \$20,000–\$34,999
- \$35,000–\$49,999
- \$50,000–\$74,999
- \$75,000–\$99,999
- \$100,000–\$149,999
- \$150,000 or more
- Prefer not to answer

Q37. How confident are you filling out medical forms by yourself?

- Not at all confident
- A little bit confident
- Somewhat confident
- Quite a bit confident
- Extremely confident

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END. That concludes the survey. Thank you for your time. Your responses will help make prescription drug information clearer. You will receive a check by mail for \$20 within 4 to 6 weeks in appreciation for your time.

Please click [SUBMIT] to submit your responses.

For any questions related to prescription drugs that might be relevant for you, please consult your doctor.

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