

<b>List of Terms and Phrases for Consumers</b>	
1. Convenient	17. Restores; rebuilds
2. Straightforward/simple/easy to use	18. Many/most/some/few; majority
3. Prevent; vs. help prevent; vs. reduce the incidence	19. Prescription drug promotion versus prescription drug advertising
4. Proven to help; proven effective	20. reaction; serious reaction; severe life-threatening reaction
5. Natural	21. Endpoint
6. Targeted; acts locally, targeted mechanism of action	22. Pure; purity
7. Powerful; potent	
8. #1 prescribed	
9. New (as in new product)	
10. Novel/unique; first and only; works differently	
11. FDA-approved	
12. Off-label	
13. Reverses	
14. Individual results may vary	
15. Significant (as in statistically significant)	
16. Manageable safety profile; established safety profile; well-studied safety profile; well-tolerated	

## Screener

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 a \$20 check in appreciation for your time. To see if you are eligible, please complete the brief survey linked below.

### 1. How old were you on your last birthday?

_____	Over Age 18 → CONTINUE Under Age 18 → TERMINATE
-------	--

### 2. Are you a medical or health professional?

Yes	→ TERMINATE
No	→ CONTINUE

### 3. 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
None of the above	→ CONTINUE

**[IF NOT ELIGIBLE:**

**Thank and 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.

## **[IF ELIGIBLE]**

### **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 US 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 phase of the study. If you agree to participate, you will take part in a web-based survey. The survey should take about **20 minutes**. All aspects of the study may not be revealed until the end.

### **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. Although the questions we ask are not related to your personal health, there is always a chance that you may feel uncomfortable with some of the questions. You do not have to answer any question that you don't want to answer. Although we have taken steps to ensure your confidentiality, there is still a small risk that your privacy could be broken.

### **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.

### **Reimbursement**

After the interview has been completed, you will receive a check by mail for \$20 within 4-6 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 AM and 5:00 PM 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 the previous screens and agree to participate, please click the Yes button. If not, click the No button.

1. Yes, I agree to participate. [Continue to 1<sup>st</sup> survey screen]
2. No, I do not agree to participate. [Go on to next question]

[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 1<sup>st</sup> survey screen]
2. No, I do not agree to participate. [Exit]

This survey focuses on words and phrases that are commonly used in prescription drug advertising. Each question includes 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.

“Taking one dose a day of drug A is **convenient**.”

**Q1. What do you think about drug A when you read that it is “convenient”? PLEASE CHECK ALL THAT APPLY.**

- It requires fewer doses than other drugs.
- I can take it at a time that works best for me.
- It fits into my lifestyle.
- I don't have to stop what I'm doing to take medication multiple times per day.
- It does not require as many trips to the doctor or pharmacy.
- [Additional answer options to be developed based on Phase 1 interviews]
- Other (please specify): \_\_\_\_\_

**Q2. When you read the statement in the column to the left, what comes to mind about the following drugs? PLEASE CHECK ALL THAT APPLY.**

	The drug will not be difficult to take.	The pill is small and not difficult to swallow.	The dose does not involve measurement.	The dose does not involve cutting pills in half.	[Additional answer options to be developed based on Phase 1 interviews.]	Other (please specify):
Drug B is <b>“straightforward to use”</b> .						
Drug C is <b>“simple to use”</b> .						
Drug D is <b>“easy to use.”</b>						

**Q3. How safe do you think each of the following drugs is compared to other drugs for the same condition? CHECK THE BOX IN THE COLUMN THAT COMES CLOSEST TO YOUR BELIEFS.**

	1 Much less safe	2 A little bit less safe	3 Equally as safe	4 A little bit more safe	5 Much safer
Drug A is <b>"convenient."</b>					
Drug B is <b>"straightforward to use".</b>					
Drug C is <b>"simple to use".</b>					
Drug D is <b>"easy to use."</b>					

**Q4. How effective do you think each of the following drugs is compared to other drugs for the same condition? CHECK THE BOX IN THE COLUMN THAT COMES CLOSEST TO YOUR BELIEFS.**

	1 Much less effective	2 A little bit less effective	3 Equally as effective	4 A little bit more effective	5 Much more effective
Drug A is <b>"convenient".</b>					
Drug B is <b>"straightforward to use".</b>					
Drug C is <b>"simple to use".</b>					
Drug D is <b>"easy to use."</b>					

**Q5. When you read the statement in the column to the left, what comes to mind about the following drugs? PLEASE CHECK THE BOX IN THE COLUMN THAT COMES CLOSEST TO YOUR BELIEFS.**

	The drug will eliminate severe asthma attacks.	The drug will make severe asthma attacks less likely.	[Alternate wording: The drug will reduce the likelihood of a severe asthma attack.]	[Additional answer options to be developed based on Phase 1 interviews.]	Other (please specify):
Drug E is shown to <b>"prevent"</b> severe asthma attacks.					
Drug F is shown to <b>"help prevent"</b> severe asthma attacks.					

Drug G is shown to <b>“reduce the incidence”</b> of severe asthma attacks.					
Drug H is <b>“proven to help”</b> reduce the risk of severe asthma attacks.					
Drug I is <b>“proven effective”</b> at reducing the risk of severe asthma attacks.					

“Drug J is a prescription medication that’s made from a **natural** ingredient: omega-3 fish oil.”

**Q6. What do you think about drug J when you read that it is made from a “natural” ingredient?**

**PLEASE CHECK ALL THAT APPLY.**

- It is made only from ingredients occurring in nature.
- It does not include any synthetic ingredients.
- It is environmentally friendly.
- It is less effective.
- It is more expensive.
- [Additional answer options to be developed based on Phase 1 interviews]
- Other (please specify): \_\_\_\_\_

“Drug K addresses migraines by **“targeting”** and blocking calcitonin gene related peptide (CGRP) receptors.”

**Q7. When you read the statement above, what comes to mind about drug K? PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.**

- It works at the site of the headache but may also travel to other parts of the body.
- It affects only the CGRP receptors and not other cells in the body.
- [Additional answer options to be developed based on Phase 1 interviews]
- Other (please specify): \_\_\_\_\_

**Q8. When you read the statement in the column to the left, what comes to mind about the following drugs? CHECK THE BOX IN THE COLUMN THAT COMES CLOSEST TO YOUR BELIEFS.**

	It works only at the site of the headache and does not travel to	It works at the site of the headache but may also travel	[Additional answer options to be developed based on Phase 1 interviews.]	Other (please specify):
--	--	--	--	-------------------------

	other parts of the body.	to other parts of the body.		
Drug L <b>“acts locally”</b> to help address migraines.				
Drug M has a <b>“targeted mechanism of action”</b> to help address migraines.				

**Q9. When you read the statement in the column to the left, what comes to mind about the following drugs? CHECK THE BOX IN THE COLUMN THAT COMES CLOSEST TO YOUR BELIEFS.**

	It is strong .	It works better than other drugs .	It has long-lasting benefits .	It works quickly .	It has many side effects .	It could be addictive.	[Additional answer options to be developed based on Phase 1 interviews.]	Other (please specify) :
Drug N is a <b>“powerful”</b> single-tablet regimen with a high barrier to resistance. "								
Drug O is a <b>“potent”</b> single-tablet regimen with a high barrier to resistance. "								



**Q10. How safe do you think each of the following drugs is compared to other drugs for the same condition? CHECK THE BOX IN THE COLUMN THAT COMES CLOSEST TO YOUR BELIEFS.**

	1 Much less safe	2 A little bit less safe	3 Equally as safe	4 A little bit more safe	5 Much safer
Drug E is shown to <b>“prevent”</b> ...					
Drug F is shown to <b>“help prevent”</b> ...					
Drug G show to <b>“reduce the incidence”</b> of...					
Drug H is <b>“proven to help”</b> ...					
Drug I is <b>“proven effective...”</b>					
Drug J is made from a <b>“natural”</b> ingredient.					
Drug K works by <b>“targeting”</b> ...					
Drug L <b>“acts locally...”</b>					
Drug M has a <b>“targeted mechanism of action.”</b>					
Drug N is <b>“powerful...”</b>					
Drug O is <b>“potent.”</b>					

**Q11. How effective do you think each of the following drugs is compared to other drugs for the same condition? CHECK THE BOX IN THE COLUMN THAT COMES CLOSEST TO YOUR BELIEFS.**

	1 Much less effective	2 A little bit less effective	3 Equally as effective	4 A little bit more effective	5 Much more effective
Drug E is shown to <b>“prevent”</b> ...					
Drug F is shown to <b>“help prevent”</b> ...					
Drug G is shown to <b>“reduce the incidence”</b> of...					
Drug H is <b>“proven to help”</b> ...					
Drug I is <b>“proven effective.”</b>					
Drug J is made from a <b>“natural”</b> ingredient.					
Drug K works by <b>“targeting”</b> ...					
Drug L <b>“acts locally.”</b>					

Drug M has a <b>“targeted mechanism of action.”</b>					
Drug N is <b>“powerful.”</b>					
Drug O is <b>“potent.”</b>					

“Drug P is the #1 prescribed weight loss brand.”

**Q12. How would knowing that a drug is the “#1 prescribed” brand affect *your intention* to ask your doctor about it? PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS. Would it make you:**

1 A lot less likely to ask about it	2 A little less likely to ask about it	3 Neither more nor less likely to ask about it	4 A little more likely to ask about it	5 A lot more likely to ask about it
--	---	---	---	--

**Q13. How would knowing that a drug is the “#1 prescribed” brand 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:**

1 A lot less likely to ask about it	2 A little less likely to ask about it	3 Neither more nor less likely to ask about it	4 A little more likely to ask about it	5 A lot more likely to ask about it
--	---	---	---	--

**Q14. What do you think about drug L when you read that it is the #1 prescribed” brand? PLEASE CHECK ALL THAT APPLY.**

- It is the most popular brand (most commonly prescribed).
- It is favored by doctors.
- It is a higher quality drug.
- It is more readily accessible.
- It is less expensive than other brands.
- It is more expensive than other brands.
- It is more likely to be covered by insurance than other brands.
- It is less likely to be covered by insurance than other brands.
- [Additional answer options to be developed based on Phase 1 interviews]
- Other (please specify): \_\_\_\_\_

**Q15. What do you think of the drugs below when you read each of the statements in the left-hand column? PLEASE CHECK ALL THAT APPLY:**

	It uses a different mechanism of action	It may be expensive	It has not been studied for very long	It is first in its class	It is possible there are side effects that have not yet been identified	It is likely to be cutting edge	Other (please specify):
--	---	---------------------	---------------------------------------	--------------------------	---	---------------------------------	-------------------------

Drug Q is "new."							
Drug R "works differently."							
Drug S is the "first and only" drug to...							
Drug T uses a "novel mechanism of action."							

"Drug U is a prescription drug available for the treatment of plaque psoriasis. Drug U is **FDA approved**."

**Q16. What do you think about drug U when you read that it has been "FDA approved"? PLEASE CHECK ALL THAT APPLY.**

- It 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.
- [Additional answer options to be developed based on Phase 1 interviews.]
- Other (please specify): \_\_\_\_\_

"Drug V is used **off-label**."

**Q17. What do you think when you read that a prescription drug is used "off-label"? PLEASE CHECK ALL THAT APPLY.**

- It does NOT have FDA approval for this use.
- It is used for an unapproved medical condition, age group, dose, etc.
- It is used illegally.
- It is not approved to be prescribed to patients.
- [Additional answer options to be developed based on Phase 1 interviews.]
- Other (please specify): \_\_\_\_\_

"Drug W **reverses** bone loss."

**Q18. What does "reverses" mean in the statement above? PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.**

- It will improve bone density.
- It will return bone density to normal.
- It will stop bone density loss.
- It will slow bone density loss.
- It will have no effect on bone density.
- [Additional answer options to be developed based on Phase 1 interviews.]
- Other (please specify): \_\_\_\_\_

"Cure means no virus found in the blood 3 months after treatment ends. **Individual results may vary**."

**Q19. What do you think of when you read, “Individual results may vary”? PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.**

- The benefits will generally be the same for everyone.
- The benefits will differ depending on the person.
- It will work for few people.
- It does not work.
- [Additional answer options to be developed based on Phase 1 interviews.]
- Other (please specify): \_\_\_\_\_

Statement 1 (*control – no term assessed*): “Compared with placebo, people taking drug X saw a slight decrease in respiratory symptoms. It is not certain if drug X was responsible for this decrease.” **[NOTE for team: This is a fictitious example]**

**Now please read this statement:**

Statement 2: “Compared with placebo, people taking drug X saw a slight decrease in respiratory symptoms. This change was not **statistically significant.**”

**Q20. Compared to the initial statement, has this statement changed your opinion about drug X’s effectiveness?**

- Yes
- No

**Q21. What do you think about drug X when you read that the difference between it and a placebo was not “statistically significant”? PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.**

- There was no difference.
- There was no detectable difference.
- There may have been a difference, but it was not large enough to meet a specific statistical threshold.
- [Alternate answer options to be developed based on Phase 1 interviews.]
- Other (please specify): \_\_\_\_\_

**Q22. When you read the statement in the column to the left, what comes to mind about the following drugs? PLEASE CHECK THE BOX IN THE COLUMN THAT COMES CLOSEST TO YOUR BELIEFS.**

	The risks are well understood.	The drug has only minimal risks.	There are specific options for addressing the risks or side effects.	[Alternate answer options to be developed based on Phase 1 interviews.]	Other (please specify):
Drug Y offers a “manageable safety profile.”					

Drug Z offers an <b>“established safety profile.”</b>					
Drug AA offers a <b>“well-studied safety profile.”</b>					
Drug BB is <b>“well tolerated.”</b>					

Statement 1: “Drug Y offers a **manageable safety profile.**”

Statement 2: “Drug Z offers an **established safety profile.**”

Statement 3: “Drug AA offers a **well-studied safety profile.**”

Statement 4: “Drug BB is **well-tolerated.**”

**Q23. 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: \_\_\_\_\_

**Q24. When you read the statement in the column to the left, what comes to mind about the following drugs? PLEASE CHECK THE BOX IN THE COLUMN THAT COMES CLOSEST TO YOUR BELIEFS.**

	It improves the condition of vaginal tissue only slightly	It will return vaginal tissue to its original condition.	It will relieve symptoms.	[Additional answer options to be developed based on Phase 1 interviews]	Other (please specify):
Drug CC <b>“restores”</b> vaginal tissue.					
Drug DD <b>“rebuilds”</b> vaginal tissue.					

**Q21. Do these statements mean the same thing to you or do they mean different things?**

- They mean the same thing.
- They mean different things. Please specify the difference: \_\_\_\_\_

**Q25. How safe do you think each of the following drugs is compared to other drugs for the same condition? PLEASE CHECK THE BOX IN THE COLUMN THAT COMES CLOSEST TO YOUR BELIEFS.**

	1 Much less safe	2 A little bit less safe	3 Equally as safe	4 A little bit more safe	5 Much safer
Drug P is the <b>"#1 prescribed"</b> brand.					
Drug Q is <b>"new."</b>					
Drug R <b>"works differently."</b>					
Drug S is the <b>"first and only"</b> drug to...					
Drug T uses a <b>"novel mechanism of action."</b>					
Drug U is <b>"FDA approved."</b>					
Drug V is used <b>"off label."</b>					
Drug W <b>"reverses"...</b>					
<b>"Individual results may vary."</b>					
The difference between drug X and a placebo was not <b>"statistically significant."</b>					
Drug CC <b>"restores"...</b>					
Drug DD <b>"rebuilds"...</b>					

**Q26. How effective do you think each of the following drugs is compared to other drugs for the same condition? PLEASE CHECK THE BOX IN THE COLUMN THAT COMES CLOSEST TO YOUR BELIEFS.**

	1 Much less effective	2 A little bit less effective	3 Equally as effective	4 A little bit more effective	5 Much more effective
Drug P is the <b>"#1 prescribed"</b> brand.					
Drug Q is <b>"new."</b>					
Drug R <b>"works differently."</b>					
Drug S is the <b>"first and only"...</b>					
Drug T uses a <b>"novel mechanism of action."</b>					
Drug U is <b>"FDA approved."</b>					
Drug V is used <b>"off label."</b>					

Drug W “reverses”...					
“Individual results may vary.”					
The difference between drug Y and a placebo was not “statistically significant.”					
Drug CC “restores”...					
Drug DD “rebuilds”...					

“For [many/a few/some/the majority/most] drug EE cuts the number of monthly migraine days in half...or more....with some people being migraine free.”

**Q27. How many people out of 100 do you think of when you see each of the following?**

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)

Statement 1: “Pharmaceutical companies engage in **prescription drug promotion** to market their products.”

Statement 2: “Pharmaceutical companies engage in **prescription drug advertising** to market their products.”

**Q28. 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: \_\_\_\_\_

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

“Pharmaceutical companies develop **prescription drug advertising** to market their products.”

**Q29. 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 developed specifically for healthcare 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"/>
Websites, web or social media ads about the drug directed at consumers	<input type="checkbox"/>	<input type="checkbox"/>
[Additional answer options to be developed based on Phase 1 interviews]	<input type="checkbox"/>	<input type="checkbox"/>
Other (please specify): _____	<input type="checkbox"/>	<input type="checkbox"/>

[Note to team: Term 28 includes, "reactions;" "serious reactions;" "severe, life-threatening reactions,"]

Statement 1: Drug FF can cause **reactions**.

Statement 2: Drug GG can cause **serious reactions**.

Statement 3: Drug HH can cause severe, **life-threatening reactions**.

**Q30. How safe do you think each of the following drugs is compared to other drugs for the same condition?**

	1 Much less safe	2 A little bit less safe	3 Equally as safe	4 A little bit more safe	5 Much safer
Drug FF can cause <b>reactions</b>					
Drug GG can cause <b>serious reactions</b>					
Drug HH can cause <b>severe, life-threatening reactions</b>					

**Q31. How effective do you think each of the following drugs is compared to other drugs for the same condition?**

	1 Much less effective	2 A little bit less effective	3 Equally as effective	4 A little bit more effective	5 Much more effective
Drug FF can cause <b>reactions</b>					
Drug GG can cause <b>serious reactions</b>					
Drug HH can cause <b>life-threatening reactions</b>					



Drug II's effectiveness was based on clinical trial **endpoints**.

**Q32. Within this context, what does "endpoint" mean to you?**

[Open-ended]

**Q33. When you read the statement in the column to the left, what comes 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.	[Additional answer options to be developed based on Phase 1 interviews].	Other (please specify):
Drug JJ is a "pure" solution.						
Drug KK follows strict... "purity" standards.						

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

**Q34. What is your gender?**

- Male
- Female
- Other

**Q35. Are you Hispanic or Latino?**

- Yes
- No

**Q36. 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

**Q37. 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

**Q38. Was your total household income in [YEAR]...?**

- 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

**Q39. 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

That concludes the survey. Thank you for your time.

To obtain the most objective responses, the drug names used as examples in this survey are not for real drugs. For any questions related to prescription drugs that might be relevant for you, please consult your doctor.