FDA Terms and Phrases Study
U.S. Food and Drug Administration

FDA **U.S. FOOD & DRUG**
ADMINISTRATION

Acting as data collection agent: RTI International

Hello, we are recruiting health care providers 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 health care providers nationwide. The survey will take approximately 20 minutes.

To see if you are eligible to participate, please answer the questions below.

Please place a check mark next to the best answer.

E1.   What percentage of your time do you spend providing direct patient care?

○   50% or more ➡ *Continue to Question E2*
○   Less than 50% ➡ *Please return blank survey in the envelope provided*

E2.   How many hours a week do you practice medicine?

○   At least 32 hours ➡ *Continue to Question E3*
○   Less than 32 hours ➡ *Please return blank survey in the envelope provided*

E3.   Have you ever worked for any of the following?

☐   Department of Health and Human Services
☐   U.S. Food and Drug Administration
☐   Market research firm   *Please return blank survey in the*
☐   Pharmaceutical company   *envelope provided*
☐   RTI International

○   None of the above ➡ **Continue to next page**

Introduction and Purpose

You have been invited to take part in a research study. The purpose of the study is to find out how health care providers 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 on behalf of, and sponsored by, the U.S. Food and Drug Administration (FDA).

Procedures

You are one of about 1,000 health care providers being asked to participate in this study. If you agree to participate, the survey should take approximately **20 minutes** to complete.

Benefits

There is no direct benefit to you for participating. Your responses are very important because they will help FDA better understand how to communicate prescription drug information to healthcare providers.

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

To thank you in advance for your time and participation in the study, we have enclosed a $50 check.

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. Do you agree to participate?

- ◯ Yes, I consent to participate ➡ *Continue to Question 1*
- ◯ No, I do not consent to participate ➡ *Please return blank survey in the envelope provided*

Q1. When you read the statement in the column to the left, which of the following come to mind about the drugs listed? PLEASE CHECK ALL THAT APPLY.

	It will increase compliance.	The drug is taken orally, not through injection or infusion.	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 monitoring of the patient.	Other (please specify)
This drug is "**convenient**."	☐	☐	☐	☐	☐	☐	☐	☐
This drug is "**straightforward to use**."	☐	☐	☐	☐	☐	☐	☐	☐
This drug is "**simple to use**."	☐	☐	☐	☐	☐	☐	☐	☐
This drug is "**easy to use**."	☐	☐	☐	☐	☐	☐	☐	☐

Q2. How <u>safe</u> 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 "**convenient**."	○	○	○	○	○	○
This drug is "**straightforward to use**."	○	○	○	○	○	○
This drug is "**simple to use**."	○	○	○	○	○	○
This drug is "**easy to use**."	○	○	○	○	○	○

Q3. How <u>effective</u> 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 "**convenient**."	○	○	○	○	○	○
This drug is "**straightforward to use**."	○	○	○	○	○	○
This drug is "**simple to use**."	○	○	○	○	○	○
This drug is "**easy to use**."	○	○	○	○	○	○

Q4. When you read the statement in the column to the left, 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.**

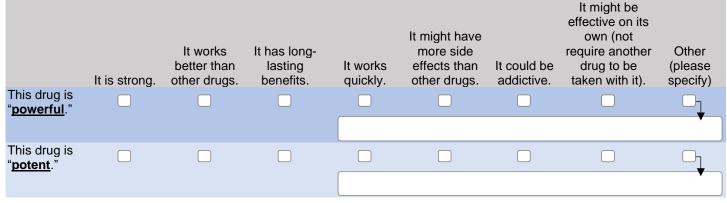|	Not at all likely	Somewhat unlikely	Neither likely nor unlikely	Somewhat likely	Extremely likely
This drug is shown to "**prevent**" severe asthma attacks.	○	○	○	○	○
This drug is shown to "**help prevent**" severe asthma attacks.	○	○	○	○	○
This drug is shown to "**reduce the incidence**" of severe asthma attacks.	○	○	○	○	○
This drug is "**proven to help**" prevent severe asthma attacks.	○	○	○	○	○
This drug is **"proven effective"** at preventing severe asthma attacks.	○	○	○	○	○

Q5. When you read the statement in the column to the left, which of the following come to mind about the drugs listed? **PLEASE CHECK ALL THAT APPLY.**

	There is data to suggest the drug works as intended.	The drug would need to be prescribed in combination with other drugs for this indication.	The drug is guaranteed to be effective at preventing asthma attacks.	Other (please specify):
This drug is **"proven to help"** prevent severe asthma attacks.	☐	☐	☐	☐
This drug is "**proven effective**" at preventing severe asthma attacks.	☐	☐	☐	☐

Q6. When you read the statement in the column to the left, 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 specific cause** of the migraine and does not affect any other parts of the body	The drug works on **a specific cause** of the migraine but may also affect other parts of the body	The drug works only at **the site or location** of the migraine and does not affect any other parts of the body	The drug works only at **the site or location** of the migraine but may also affect other parts of the body	I don't know	Other (please specify)
This drug acts by "**targeting**" 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.	○	○	○	○	○	○

Q7. When you read the statement in the column to the left, which of the following come to mind about the drugs listed? PLEASE CHECK 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 (please specify)
This drug is "**powerful**."	☐	☐	☐	☐	☐	☐	☐	☐
This drug is "**potent**."	☐	☐	☐	☐	☐	☐	☐	☐

Q8. How <u>safe</u> 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 shown to "**prevent**"…	○	○	○	○	○	○
This drug is shown to "**help prevent**"…	○	○	○	○	○	○
This drug is shown to "**reduce the incidence**" of…	○	○	○	○	○	○
This drug is "**proven to help**"…	○	○	○	○	○	○
This drug is "**proven effective**"…	○	○	○	○	○	○
This drug is made from a "**natural**" ingredient.	○	○	○	○	○	○
This drug works by "**targeting**"…	○	○	○	○	○	○
This drug "**acts locally**."	○	○	○	○	○	○
This drug has a "**targeted mechanism of action**."	○	○	○	○	○	○
This drug is "**powerful**."	○	○	○	○	○	○
This drug is "**potent**."	○	○	○	○	○	○

Q9. How <u>effective</u> 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 shown to "**prevent**"…	○	○	○	○	○	○
This drug is shown to "**help prevent**"…	○	○	○	○	○	○
This drug is shown to "**reduce the incidence**" of…	○	○	○	○	○	○
This drug is "**proven to help**"…	○	○	○	○	○	○
This drug is "**proven effective**"…	○	○	○	○	○	○
This drug is made from a "**natural**" ingredient.	○	○	○	○	○	○
This drug works by "**targeting**"…	○	○	○	○	○	○
This drug "**acts locally**."	○	○	○	○	○	○
This drug has a "**targeted mechanism of action**."	○	○	○	○	○	○
This drug is "**powerful**."	○	○	○	○	○	○
This drug is "**potent**."	○	○	○	○	○	○

Q10. How would knowing that a drug is the "#1 prescribed" drug affect *your intention* to prescribe the drug? PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.
Would it make you:

- ◯ A lot less likely to prescribe it
- ◯ A little less likely to prescribe it
- ◯ Neither more nor less likely to prescribe it
- ◯ A little more likely to prescribe it
- ◯ A lot more likely to prescribe it

Q11. How would knowing that a drug is the "#1 prescribed" drug affect *other providers' intentions* to prescribe the drug? PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.
Would it make them:

- ◯ A lot less likely to prescribe it
- ◯ A little less likely to prescribe it
- ◯ Neither more nor less likely to prescribe it
- ◯ A little more likely to prescribe it
- ◯ A lot more likely to prescribe it

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):

[   ]

Q13. How <u>safe</u> 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 "**new**."	◯	◯	◯	◯	◯	◯
This drug "**works differently**."	◯	◯	◯	◯	◯	◯
This drug is the "**first and only**" drug to…	◯	◯	◯	◯	◯	◯
This drug is the "**first in class**."	◯	◯	◯	◯	◯	◯
This drug uses a "**novel mechanism of action**."	◯	◯	◯	◯	◯	◯

Q14. How <u>effective</u> 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 "**new**."	○	○	○	○	○	○
This drug "**works differently**."	○	○	○	○	○	○
This drug is the "**first and only**" drug to…	○	○	○	○	○	○
This drug is the "**first in class**."	○	○	○	○	○	○
This drug uses a "**novel mechanism of action**."	○	○	○	○	○	○

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):

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 indication for which it is being used.
- ☐ It does NOT have FDA approval for any use.
- ☐ It is used for an unapproved age group, dosage, or route of administration.
- ☐ It is used illegally.
- ☐ Other (please specify):

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):

Q18. Which of the following come to mind when you read, "individual results may vary" in a statement about a drug? PLEASE CHECK 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 your patient.
- ☐ Other (please specify):

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:

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**."

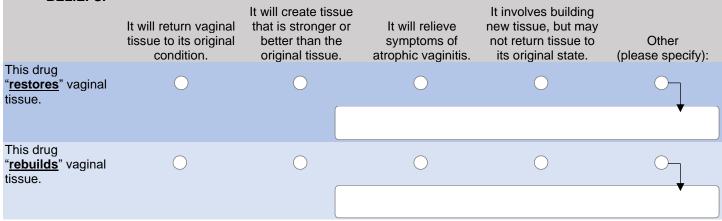**Do these four statements mean the same thing or do some of them mean something different to you?**

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

Q21. When you read the statement in the column to the left, 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 (please specify):
This drug offers a "**manageable safety profile**."	◯	◯	◯	◯
This drug offers an "**established safety profile**."	◯	◯	◯	◯
This drug offers a "**well-studied safety profile**."	◯	◯	◯	◯
This drug is "**well-tolerated**."	◯	◯	◯	◯

Q22. When you read the statement in the column to the left, 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 of atrophic vaginitis.	It involves building new tissue, but may not return tissue to its original state.	Other (please specify):
This drug "**restores**" vaginal tissue.	○	○	○	○	○
This drug "**rebuilds**" vaginal tissue.	○	○	○	○	○

Q23. How <u>safe</u> 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 "**#1 prescribed**" drug.	○	○	○	○	○	○
This drug is "**FDA approved**."	○	○	○	○	○	○
This drug is used "**off label**."	○	○	○	○	○	○
This drug "**reverses**"…	○	○	○	○	○	○
For this drug, "**individual results may vary**."	○	○	○	○	○	○
This drug "**restores**"…	○	○	○	○	○	○
This drug "**rebuilds**"…	○	○	○	○	○	○

Q24. How <u>effective</u> 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 "**#1 prescribed**" drug.	○	○	○	○	○	○
This drug is "**FDA approved**."	○	○	○	○	○	○
This drug is used "**off label**."	○	○	○	○	○	○
This drug "**reverses**"…	○	○	○	○	○	○
For this drug, "**individual results may vary**."	○	○	○	○	○	○
The difference in effectiveness between this drug and a placebo was "**not statistically significant**."	○	○	○	○	○	○
This drug "**restores**"…	○	○	○	○	○	○
This drug "**rebuilds**"…	○	○	○	○	○	○

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.)

Q26. **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."

Do these statements mean the same thing or do they mean different things?

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

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 detailing visits	☐	☐
Drug information disseminated during medical conferences	☐	☐
Print or web materials (e.g., ads in medical journals) developed specifically for health care providers about a prescription drug	☐	☐
Television or radio ads about the drug directed at consumers	☐	☐
Print ads in magazines or journals directed at consumers	☐	☐
Website, web, or social media ads about the drug directed at consumers	☐	☐
A coupon, discount, or special offer	☐	☐
Other (please specify):	☐	☐

Q28. **Have you ever heard the term "scientific exchange"?**

◯ No → *Skip to Q30*
◯ Yes

Q29. **In your own words, what does "scientific exchange" mean to you?**

For the following few questions, we would like you to choose the ONE best answer. Please do not guess. If you are unsure, please select "I am not familiar with this term."

Q30. **What does "overall response rate" mean to you in the context of cancer care?**
PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.
- ◯ I am not familiar with this term.

- ◯ The number of patients who started or "responded to" the study.
- ◯ The percentage of patients whose cancer shrinks or disappears after treatment
- ◯ How well the drug works.
- ◯ The percentage of people who are still alive after 5 years or at the conclusion of the study.
- ◯ Other (please specify):

Q31. **What does "response duration" mean to you?**
PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.
- ◯ I am not familiar with this term.

- ◯ The amount of time it takes for the medication to start working.
- ◯ Once a medication starts working, the amount of time the medication works before disease progression or relapse.
- ◯ The amount of time it takes for the medication to start working and the amount of time it works before disease progression or relapse.
- ◯ Other (please specify):

Q32. **What does "randomized controlled trial" mean to you?**
PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.
- ◯ I am not familiar with this term.

- ◯ A study in which patients are randomly selected to participate.
- ◯ A study that involves randomly assigning patients to receive the treatment under investigation or a control (placebo or standard treatment).
- ◯ A study in which patients receiving the treatment under investigation are matched with a control group that has similar demographic characteristics.
- ◯ Other (please specify):

Q33. **What does "non-inferiority randomized controlled trial" mean to you?**
PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.
- ◯ I am not familiar with this term.

- ◯ A trial that aims to demonstrate that a treatment is better than another treatment by more than a small amount.
- ◯ A trial that aims to demonstrate that a treatment is equivalent to another treatment.
- ◯ A trial that aims to demonstrate that a treatment is not worse than another treatment by more than a small amount.
- ◯ Other (please specify):

Q34. What does "intent-to-treat analysis" mean to you?
PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.

○ I am not familiar with this term.

○ Results are based on the participants' original random assignment, regardless of whether they completed the protocol or actually received the treatment.

○ Results are based on the final treatment received, regardless of which group patients were originally assigned to.

○ Analyses include only those participants who completed the study.

○ Analyses include those populations you most want to treat for a specific condition.

○ Analysis includes all available treatments providers intend to use for a medical condition.

○ Other (please specify):

Q35. What does "per-protocol analysis" mean to you?
PLEASE CHOOSE THE ANSWER THAT COMES CLOSEST TO YOUR BELIEFS.

○ I am not familiar with this term.

○ Results are based on the final treatment received, regardless of which group patients were originally assigned to.

○ Analyses include only those participants who completed the study.

○ Analysis of whether the study is being conducted according to the protocol identified at the start

○ Results are based on the participants' original random assignment, regardless of whether they completed the protocol or actually received the treatment.

○ Other (please specify):

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

Q36. Are you Hispanic or Latino?

○ Yes
○ No

Q37. What is your race? You may select one or more races.

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

Q38. In what states are you currently practicing?

That concludes the survey.

Thank you for your time. Your responses will help make prescription drug information clearer. Please place the completed survey in the provided envelope and return it at your earliest convenience.