FDA Terms and Phrases Study U.S. Food and 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 Pharmaceutical company RTI International None of the above → Continue to next page 						

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.

Consent Form

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	particii	oate?
CONCENT I.	Do you	agree to	partion	outo:

\bigcirc	Yes, I consent to participate → Continue to Question 1
\bigcirc	No, I do not consent to participate -> Please return blank survey in the envelope provided

Q1. When you listed? PL	read the state EASE CHECK			e left, which	of the followin	g come to m	ind about the	e drugs
	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> d PLEASE SI BELIEFS.					ed to other drug TERM THAT CO		EST TO YOU	R
	Much less		what less afe Equ	ally as safe	Somewhat safer	Much saf		annot be ared to drugs
This drug is "convenient."	0	(0	0	0	0		
This drug is "straightforward to use."	\bigcirc	(\bigcirc	0	\bigcirc	\bigcirc		
This drug is " <u>simple to use</u> ."	0	(0	0	0	0		
This drug is "easy to use."		(\circ		\circ	0		
Q3. How effect					npared to other			
BELIEFS.		20. 0.102 .				, <u>20 0200</u> 1	Effectiv	
	Much les			qually as effective	Somewhat more effective	Much mor		red to
This drug is "convenient."	0	(0	0	0	0		
This drug is " <u>straightforward</u> <u>to use</u> ."	0	(\circ	0			
This drug is "simple to use."	0	(\circ	0	0	0		
This drug is "easy to use."		(

Q4. When you read the st each drug would expo UNDERLINED TERM	erience a severe	asthma at	tack? PLEA	SE SELECT TH		
	Not at all		Somewhat unlikely	Neither likely no unlikely	r Somewhat likely	Extremely likely
This drug is shown to "prever severe asthma attacks.		iiitory				
This drug is shown to "help prevent" severe asthma attac	cks.		\bigcirc	\bigcirc		0
This drug is shown to "reduce incidence" of severe asthma attacks.	e the		0	0	0	0
This drug is "proven to help" prevent severe asthma attack					\bigcirc	
This drug is "proven effective preventing severe asthma atta					\circ	
Q5. When you read the st drugs listed? PLEAS	There is data suggest the drug	The to two two to two to two two two two tw	drug would ne be prescribed abination with	eed to The drug i in to be e other preventi	s guaranteed ffective at ng asthma	
This drug is "proven to help" prevent severe asthma attacks.	as intended	. arug	s for this indic	ation. att	acks. Othe	er (please specify):
This drug is " <u>proven</u> <u>effective</u> " at preventing severe asthma attacks.						
						·
Q6. When you read the st PLEASE SELECT THE BELIEFS.	E RESPONSE FO	R EACH U	JNDERLINED	TERM THAT C	OMES CLOSEST	
	The drug works only on <u>a</u> <u>specific cause</u> of the migraine and does not affect any other parts of the body	on a spec	the or locate but migra affect does respond to the control of the	the site only a sition of the or low ine and the minot affect may a ser parts of other	t the site	Other (please know specify)
This drug acts by "targeting" calcitonin gene related peptide (CGRP) receptors to help address migraines.	•	0	(O	•	
This drug "acts locally" to				\sim	\cap	
help address migraines.						
This drug has a " <u>targeted</u> mechanism of action" to help address migraines.	0	0)	0 0	$\bigcirc \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \!$

Q7. When you read the sta				hich of the fo	ollowing come	e to mind ab	out the
	It works petter than	It has long lasting	- It works	It might hav more side effects than	n It could be	It might be effective on own (not require another drug to be	its her Other (please
It is strong. o	ther drugs.	benefits.	quickly.	other drugs	. addictive.	taken with i	t). specify)
"powerful."							
							•
This drug is							
"potent."							
							•
)
Q8. How <u>safe</u> do you think PLEASE SELECT THE BELIEFS.							
	_						Safety cannot
	N	/luch less safe	Somewhat less safe	Equally as safe	Somewhat safer	Much safer	be compared to other drugs
This drug is shown to "preven	t"	Sale	less sale	Sale	Salei	Wideli Salei	to other drugs
This drug is shown to "help	<u>.</u>						
prevent"							
This drug is shown to "reduce	the						
<u>incidence</u> " of This drug is " <u>proven to help</u> ".							
This drug is "proven effective		$\overline{}$		$\overline{}$	$\overline{}$		$\overline{}$
This drug is made from a "natu							
ingredient.				0			
This drug works by "targeting	"	\bigcirc					
This drug "acts locally."							
This drug has a "targeted mechanism of action."							
This drug is "powerful."							
This drug is "potent."							
Q9. How effective do you PLEASE SELECT THE BELIEFS.							O YOUR
							Effectiveness
		Auch less effective	Somewhat less effective	Equally as effective	Somewhat more effective	Much more effective	cannot be compared to other drugs
This drug is shown to "preven	<u>t</u> "		\bigcirc	O	O	\bigcirc	\bigcirc
This drug is shown to "help prevent"	dh a	<u> </u>	0	0	0		0
This drug is shown to "reduce incidence" of		0	0		0	0	
This drug is "proven to help". This drug is "proven effective							
This drug is made from a "nate							
ingredient.							
This drug works by "targeting		0				O	
This drug "acts locally."			\circ	\circ	O		O
This drug has a "targeted							
mechanism of action." This drug is "powerful."							
This drug is "potent."		Ŏ	Ŏ	Ŏ	Ŏ	Ŏ	Ŏ

Q10.	How would knowing PLEASE CHOOSE TH Would it make you: A lot less likely to p A little less likely to Neither more nor le A little more likely to A lot more likely to	rescribe it prescribe it ess likely to prescribe o prescribe it	COMES CLOS			o prescribe t	he drug?
Q11.	the drug? PLEASE Would it make them A lot less likely to A little less likely to	CHOOSE THE AND ITEM ITEM ITEM ITEM ITEM ITEM ITEM ITEM	SWER THAT C				to prescribe
Q12.	### 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 thir PLEASE SELECT TH BELIEFS.						O YOUR
 1 ·		Much less safe	Somewhat less safe	Equally as safe	Somewhat safer	Much safer	Safety cannot be compared to other drugs
	drug is " <u>new</u> ."	U					O
	drug " <u>works</u> <u>ently</u> ."			\bigcirc	\bigcirc		\bigcirc
This o	drug is the " <u>first and</u> drug to…		0		0	\circ	0
	lrug is the " <u>first in</u>	0	0	\circ	\circ	\circ	\circ
	drug uses a " <u>novel</u> anism of action."	0	0	0	0	0	0

	How <u>effective</u> do you think each PLEASE SELECT THE RESPON BELIEFS.						
							Effectiveness
		Much less effective	Somewhat less effective	Equally as effective	Somewhat more effective	Much more effective	cannot be compared to other drugs
This d	rug is " <u>new</u> ."	0	0	0		0	
	rug " <u>works differently</u> ."						
to	rug is the " <u>first and only</u> " drug	0	0	0	0	0	0
	rug is the "first in class."						
action	rug uses a " novel mechanism of ."	0	0		0		0
Q15.	Which of the following come to PLEASE CHECK ALL THAT AF		n you read that	a drug has	been "FDA ap	proved"?	
	☐ The drug must not have any se						
	The drug has been evaluated						
	The drug offers benefits that a		an the risks.				
	The drug is safer than other drug is as safe as other drug.						
	Other (please specify):	rugs.					
	(різаво вросіі)						
Q16.	Which of the following come to PLEASE CHECK ALL THAT AR It does NOT have FDA approved It does NOT have FDA approved It is used for an unapproved at It is used illegally. Other (please specify):	PPLY. val for the sperval for any use	ecific indication foe	or which it is b	eing used.	ed "off-label	"?
Q17.	When you read that a drug "re PLEASE CHOOSE THE ANSW It will return bone density to not lit will build back bone that was lit will stop bone density loss. It will slow bone density loss.	ER THAT Co ormal.					
	Other (please specify):						
	Other (piease specify).						
Q18.	Which of the following come to drug? PLEASE CHECK ALL TI			dividual res	ults may vary"	in a statem	ent about a
	☐ The benefits will generally be t	the same for	everyone.				
	The benefits will vary from per	son to persor	٦.				
	It will work for few people.						
	There is no guarantee it will we	ork for your p	atient.				
	Other (please specify):						

Q19.				ence in effectiveness be BE IN YOUR OWN WOR	
Q20.	Please read the f	ollowing four stateme	nts:		
	Statement 2 Statement 3	2: "This drug offers an <u>e</u>	anageable safety profile stablished safety profile ell-studied safety profile	<u>le</u> ."	
		<u> </u>		them mean something	different to you?
	They all mean	the same thing. mething different. Please	_	them mean something	different to you.
		y and one of the state of the s	s openity the uniteraction.	•	
Q21.	When you read th	e statement in the col	umn to the left, what co	omes to mind about the	following drugs?
Q2 1.				ERM THAT COMES CLO	
		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):
	rug offers a geable safety ."	0	0	0	
					•
	rug offers an <u>lished safety</u> e."	0	0	0	0
					•
	rug offers a " <u>well-</u> d safety profile."	0	0	0	0
This dr	rug is " <u>well-</u> t <u>ed</u> ."	0	0	0	
					•

Q22.		ead the statement LECT THE RESPO							
		It will create tissue It involves building							
		It will return vagina	al that is st	ronger or	It will relieve	new tissue,			
		tissue to its origina		han the	symptoms of	not return t		Other	
		condition.		l tissue.	atrophic vaginitis.	its origina	l state. (pl	ease specify):	
This d	lrug		J		, ,	J	,,	, ,,	
"resto	res" vaginal							\bigcirc	
tissue.								1	
								V	
This d	lrua								
	i lds " vaginal								
tissue.						\cup			
	•							▼	
Q23	How safe do	you think each of	the followi	ina druas is	compared to of	ther drugs fo	r the same co	ondition?	
		ECT THE RESPO							
								Safety canno	ot
			Much less	Somewhat	Equally as	Somewhat		be compare	
			safe	less safe	safe	safer	Much safer	to other drug	JS
This d	lrug is the "#1	prescribed"							
drug.									
This d	rug is " FDA ap	proved."							
This d	rug is used "of	f label."							
	rug " <u>reverses</u> "								
	is drug, "indivi								
may v		addi 100dilo			\bigcirc				
	rug " <u>restores</u> "								
	rug " <u>rebuilds</u> ".								
	g <u></u>	•••							
	condition? P	e do you think eac LEASE SELECT 1							
	TO YOUR BE	LIEFS.							
								Effectiveness	
						Somewhat		cannot be	
			Much less	Somewhat	1 7	more	Much more	compared to	
T.			effective	less effective	e effective	effective	effective	other drugs	
drug.	rug is the " <u>#1 r</u>		0	0	0	0	0	0	
This d	rug is " FDA ap	proved."	\bigcirc	\bigcirc			\bigcirc	\bigcirc	
This d	rug is used " <u>of</u>	f label."							
This d	rug " <u>reverses</u> "								
	is drug, " <u>indivi</u>								
may v									
	ifference in effe								
		id a placebo was							
"not s	tatistically sig	<u>ınificant</u> ."							
This d	rug " <u>restores</u> "		O						
This d	rua " rebuilds ".								

Q25.			100 do you think of when you see each of the iidpoint of that range.	e following? If you a	re thinking of a
	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.)		
000	Disease wood the f	allawina	thus statements.		
Q26.	"Pharmace "Pharmace	utical con utical con	two statements: mpanies engage in prescription drug promotion mpanies engage in prescription drug advertisi an the same thing or do they mean different the	ng to market their pro	
	They mean th		ning to me. ngs to me. Please specify the difference:		
Q27.			you think about when you read " <u>prescriptio</u> SE CHECK ALL THAT APPLY.		
				Prescription drug promotion	Prescription drug advertising
Pharm	naceutical detailing v	risits			
			ng medical conferences		
	or web materials (e.g providers about a pre		nedical journals) developed specifically for health drug		
•	•		ug directed at consumers		
Print a	ads in magazines or	journals o	lirected at consumers		
Websi	ite, web, or social me	edia ads a	about the drug directed at consumers		
A coup	pon, discount, or spe	ecial offer			
Other	(please specify):				
Q28.	O No → Skip to Yes	Q30	term "scientific exchange"? s, what does "scientific exchange" mean to y	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.	
	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):
	Other (please specify).
Q32.	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?
QUU.	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?
Q 00.	O 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.