Revised Final Questionnaires

Physician Survey of Research Data about Prescription Drugs

Informed Consent

NOTE: DO NOT DISPLAY HEADINGS IN ALL CAPS.

The Food and Drug Administration is conducting this study to better understand physicians' opinions and preferences about the type of information that is provided about prescription drugs. Your responses, and those of your colleagues nationwide, will provide valuable insight into matters affecting the medical community. Please answer honestly and give us your best guess on answers you do not know. This survey will take 15-20 minutes to complete and your responses will be kept confidential.

This research is authorized by Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a) (4)). Confidentiality is protected by 5 U.S.C. 552(a) and (b) and 21 CFR part 20.

OMB Control #0910-0900. Expires 8/24/2024.

This survey is being conducted by Westat, an independent social science research firm, on behalf of the U.S. Department of Health and Human Services. Westat is working with SERMO to conduct this survey but is not affiliated with SERMO in any way. If you have questions about this survey, please contact the project director, Dr. Simani Price, at 301-610-5536. She can be reached between 9 AM and 5 PM Eastern Time Monday to Friday.

Privacy and Confidentiality

This survey will not collect any personal information, such as your name. Your identity will not be linked to your responses. We will be very careful to only let people working on the study see your responses, which will not be linked back to any personal information that might be used to identify you. Your information will be kept secure to the extent allowed by law. Study information will be kept in password protected files on secure servers at Westat and FDA locations. The data collected in this study will be destroyed no later than three years after the project is completed.

Possible Risks or Discomforts

There are no anticipated risks to participating in the survey. However, you can skip any questions you do not wish to answer and continue with the survey. While we will be very careful to let only members of the research team see your information, there is a small risk that others might find out what you say, despite all our best efforts. In the case of a breach of confidentiality, appropriate steps will be taken to notify participants.

Benefits

Your responses are very important because they will help researchers understand how people make decisions about medications. There is no direct benefit to you for your participation.

Incentive

In appreciation for your time, you will receive **\$[46/62]** for completing this survey.

Rights as a Participant

This study is voluntary. You do not have to answer any questions that you do not want to and can withdraw from the study at any time. The Institutional Review Board (IRB) at Westat has reviewed this research study. If you have questions about your rights and welfare as a research participant, please call the Westat Human Subjects Protections office at 1-888-920-7631. Please leave a message with your first name, the name of the research study that you are calling about (FDA Communication about Data), and a phone number beginning with the area code. Someone will return your call as soon as possible.

Documentation of Informed Consent

INFORMEDCONSENT

If you have read the previous screens and <u>agree</u> to participate, please click the <u>Yes</u> button. If not, click the <u>No</u> button.

- Image: Yes, I agree to participate.
- I No, I do not agree to participate

Introduction

Thank you for participating in this survey. On the next screen, you will be shown some informational material about a prescription drug.

Please read the material. After you finish, you will be asked some questions about it.

Pharmaceutical Information Material

NOTE: THE FOLLOWING TERMINOLOGY WILL BE USED TO DISTINGUISH BETWEEN THE DIFFERENT VERSIONS OF THE STIMULI. PLEASE NOTE THAT RESPONDENTS WILL ALWAYS SEE THE FULL STIMULI BEFORE BEING SHOWN A BLURRED VERSION.

Condition	Stimuli term	Stimuli description
	STIM1	Full stimuli (2 pages)
1	STIM1_A	Disclosure box at top of page 1; all else blurred
	STIM1_B	Page 2 of stimuli
2	STIM2	Full stimuli
2	STIM2_A	Disclosure box at top of page; all else blurred
3	STIM3	Full stimuli
5	STIM3_A	Disclosure box at top of page; all else blurred
4	STIM4	Full stimuli
4	STIM4_A	Disclosure box at top of page; all else blurred
5	STIM5	Full stimuli

Please scroll down to read all the material. {DISPLAY FOR CONDITION1: It is two pages long.} When you have finished reading it, please click on "Next."

DISPLAY STIM1, STIM2, STIM3, STIM4, STIM5, BASED ON EXPERIMENT ASSIGNMENT

Q1_DISCLOSURE STATEMENT_CONFIRM VIEW

NOTE: This item is intended to confirm the respondent was able to see the material.

1. Were you able to view the material?

- 1 Yes
- □ No → END

Q2_DISCLOSURESTATEMENT_RECALL_A Q2_DISCLOSURESTATEMENT_RECALL_B Q2_DISCLOSURESTATEMENT_RECALL_C Q2_DISCLOSURESTATEMENT_RECALL_D Q2_DISCLOSURESTATEMENT_RECALL_F Q2_DISCLOSURESTATEMENT_RECALL_G

NOTE: Respondents will not be able to go back to material to answer questions. Each item will be presented individually on the screen.

FILL FOR [DRUG] FOR CANCER = imiquimod

FILL FOR [DRUG] FOR INSOMNIA = trazodone

FILL FOR [DISEASE] FOR CANCER CONDITION = lentigo maligna

FILL FOR [DISEASE] FOR INSOMNIA CONDITION = insomnia

PROGRAMMING: RANDOMIZE ORDERING OF ITEMS A-G.

2. Please indicate whether any of the following were mentioned in the materials you reviewed.

	Yes	No	l'm not sure
SHOW FOR ALL CONDITIONS:			
a. A brief report on a study that supports use of [DRUG] for [DISEASE]			
SHOW FOR ALL CONDITIONS:			
b. A discussion of the limitations of a study that supports use of [DRUG] for [DISEASE]			
SHOW FOR ALL CONDITIONS:	П		П
c. Outcomes for a placebo group			U
SHOW FOR CONDITONS 1-4 ONLY:			
d. The use of [DRUG] for [DISEASE] has been approved by the FDA.			
SHOW FOR CONDITIONS 1-3 ONLY:			
e. The materials describe other data which does not support the use of [DRUG] for [DISEASE]			
SHOW FOR CONDITIONS 2-3 ONLY:			
 f. The materials gave a citation for a study whose result does not support use of [DRUG] for [DISEASE] 	•	D	0
SHOW FOR ALL CONDITIONS:			
 g. Information about whether the described use of [DRUG] was off-label 			

Q3_CONTRARY DATA_VALIDITY

- 3. How confident are you in the validity of the conclusion that the authors draw about the use of [DRUG] for [DISEASE]?
 - Not at all confident
 - A little confident
 - Somewhat confident
 - Very confident
 - **Extremely confident**

Meaning, Influence, and Opinion Items

DISPLAY FOR CONDITION 1:

The next question asks specifically about the box at the top of the first page. This is the same material you viewed earlier.

[DISPLAY STIM1_A blurred except for disclosure box on top of page 1]

DISPLAY FOR CONDITIONS 2-4:

The next questions ask specifically about the information in the box at the top of the page. This is the same material you viewed earlier.

NOTE: WE WILL NOT REFER TO THE TEXT AS A "DISCLOSURE STATEMENT," BUT WILL REFERENCE IT DESCRIPTIVELY (I.E., "THE INFORMATION IN THE BOX").

[DISPLAY STIM2_A, STIM3_A, STIM4_A blurred except for disclosure box]

NOTE: THE BLURRED STIMULI WILL BE DISPLAYED FOR THE REMAINDER OF THE ITEMS IN THIS SECTION FOR CONDITIONS 2-4.

DISPLAY FOR CONDITION 5:

The next questions ask about the same material you viewed earlier.

[DISPLAY STIM5 entire stimuli]

NOTE: THE STIMULI WILL BE DISPLAYED FOR THE REMAINDER OF THE ITEMS IN THIS SECTION FOR CONDITION 5.

ONLY ASK ITEM 4 FOR CONDITIONS 1-4:

Q4_DISCLOSURE STATEMENT_MEANING NOTE: ASKED ONLY OF CONDITIONS 1-4

DISPLAY STIM1_A, STIM2_A, STIM3_A, STIM4_A PROGRAMMING: STIMULI AND ITEM WILL BE DISPLAYED ON THE SAME SCREEN PROGRAMMING: OPEN-ENDED TEXT BOX

4. In your own words, how would you explain the information in the box to a colleague?

ASK Q5 FOR ALL CONDITIONS:

Q5_DISCLOSURE STATEMENT_LIKELY

DISPLAY STIM1_A, STIM2_A, STIM3_A, STIM4_A, STIM5 PROGRAMMING: STIMULI AND ITEM WILL BE DISPLAYED ON THE SAME SCREEN PROGRAMMING: FILL FOR CONDITIONS 1-4 = "BOX"; CONDITION 5 = "MATERIAL"

- 5. If you were considering prescribing [DRUG] to a patient with [DISEASE], how important would the information in the [DISPLAY FILL] be in your decision-making?
 - I Not at all important
 - Image: A little important
 - ISomewhat important
 - 0 Very important
 - Image: Extremely important

DISPLAY INTRODUCTION AND Q5 FOR CONDITION 1 ONLY:

The next question asks specifically about the second page of the material. This is the same material you viewed earlier.

[DISPLAY STIM1_B]

NOTE: PAGE 2 OF THE STIMULI WILL BE DISPLAYED FOR THE REMAINDER OF THE ITEMS IN THIS SECTION FOR CONDITION 1.

Q6_DISCLOSURE STATEMENT_LIKELY 2ND PAGE

NOTE: ASKED ONLY OF CONDITION 1

DISPLAY STIM1_B PROGRAMMING: STIMULI AND ITEM WILL BE DISPLAYED ON THE SAME SCREEN

- 6. If you were considering prescribing [DRUG] to a patient with [DISEASE], how important would the information in the second brief report be in your decision-making?
 - 1 Not at all important
 - A little important
 - ISomewhat important
 - U Very important
 - Image: Extremely important

DISPLAY Q7-9 FOR ALL CONDITIONS

Q7_DISCLOSURE STATEMENT_USEFUL

DISPLAY STIM1_B, STIM2_A, STIM3_A, STIM4_A, STIM5 PROGRAMMING: STIMULI AND ITEM WILL BE DISPLAYED ON THE SAME SCREEN PROGRAMMING: FILL FOR CONDITION 1 = "ON PAGE 2"; CONDITIONS 2-4 = "IN THE BOX"; CONDITION 5 = "IN THE MATERIAL"

7. If you were considering prescribing [DRUG] for [DISEASE], how useful would the information [DISPLAY FILL] be?

- I Not at all useful
- A little useful
- Somewhat useful
- Very useful
- Extremely useful

Q8_DISCLOSURE STATEMENT_CLEAR

DISPLAY STIM1_B, STIM2_A, STIM3_A, STIM4_A, STIM5 PROGRAMMING: STIMULI AND ITEM WILL BE DISPLAYED ON THE SAME SCREEN PROGRAMMING: FILL FOR CONDITION 1 = "ON PAGE 2"; CONDITIONS 2-4 = "IN THE BOX"; CONDITION 5 = "IN THE MATERIAL"

8. How clearly is the information presented [DISPLAY FILL]?

- Not at all clear
- □ A little clear
- Somewhat clear
- U Very clear
- Extremely clear

Q9_DISCLOSURE STATEMENT_CREDIBLE

DISPLAY STIM1_B, STIM2_A, STIM3_A, STIM4_A, STIM5 PROGRAMMING: STIMULI AND ITEM WILL BE DISPLAYED ON THE SAME SCREEN PROGRAMMING: FILL FOR CONDITION 1 = "ON PAGE 2"; CONDITIONS 2-4 = "IN THE BOX"; CONDITION 5 = "IN THE MATERIAL"

9. How credible is the information presented [DISPLAY FILL]?

- I Not at all credible
- A little credible
- Somewhat credible
- □ Very credible
- Extremely credible

Q10_DISCLOSURE STATEMENT_MORE INFO

DISPLAY STIM1_B, STIM2_A, STIM3_A, STIM4_A, STIM5 PROGRAMMING: STIMULI AND ITEM WILL BE DISPLAYED ON THE SAME SCREEN PROGRAMMING: FILL FOR CONDITION 1 = "ON PAGE 2"; CONDITIONS 2-4 = "IN THE BOX"; CONDITION 5 = "IN THE MATERIAL"

- 10. After reviewing the information [DISPLAY FILL], how likely are you to search for additional information about use of [DRUG] for [DISEASE]?
 - I Not at all likely
 - A little likely
 - Somewhat likely
 - Very likely

Extremely likely

Q11_PRESCRIBING_DRUGS

- 11. Have you ever prescribed [DRUG] for [DISEASE]?
 - 1 Yes
 - 0 No

Prescribing Decisions

The next questions ask about how you decide to prescribe an approved drug for an indication that has not yet been approved by FDA, often called "off-label use."

Q12_OFF-LABEL USE: FREQ OFFLABEL

- 12. How often do you prescribe a drug for an off-label use?
 - One or more times a day
 - 1-6 times a week
 - 1-3 times a month
 - 1-11 times a year
 - Less than once a year
 - I have never prescribed a drug for an off-label use

Q13_OFF-LABEL USE: PRACTICE_FREQ

PROGRAMMING: ASK ONLY TO PARTICIPANTS WHO INDICATED PRESCRIBING OFF-LABEL IN Q12

13. Compared to you, how often do others in your practice prescribe a drug for off-label use?

- I More often
- Less often
- About the same
- **I** No other HCPs with prescribing authority in practice

Q14_OFF-LABEL USE: PRACTICE_YES/NO

PROGRAMMING: ASK ONLY OF THOSE WHO INDICATED NEVER PRESCRIBING OFF-LABEL IN Q12

14. Do others in your practice prescribe drugs for off-label use?

- 1 Yes
- 0 No
- I don't know
- □ No other HCPs with prescribing authority in practice

Q15_OFF-LABEL USE: INFO SOURCES

PROGRAMMING: ASK ONLY TO PARTICIPANTS WHO INDICATED PRESCRIBING OFF-LABEL IN Q12

PROGRAMMING: RANDOMIZE ORDERING OF RESPONSE OPTIONS, LEAVING "OTHER SPECIFY" LAST

15. Where do you typically first hear or learn about an off-label use for a prescription drug? (Select your top two sources.)

- Colleagues
- I Medical journals
- **Google or other online search engines**
- I Medical reference websites such as UpToDate or Epocrates
- DISPLAY ONLY FOR ONCOLOGISTS: National Comprehensive Cancer Network Guidelines
- Professional medical association conferences and communications
- **FDA**
- **D** Pharmaceutical companies
- Online communities of physicians
- Key opinion leaders or thought leaders in the field
- Other, please specify:

Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_COLL Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_JOURNAL Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_GOOGLE Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_REFWEB Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_NCCNG Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_PROFMEDASSN Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_FDA Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_PHARMA Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_ONLINECOMMUNITY Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_ONLINECOMMUNITY Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_OPINIONLEADER Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_OPINIONLEADER Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_OTHER Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_OTHER Q16_OFFLABELUSE_INFOSOURCES_FREQUSE_OTHER

PROGRAMMING: ASK ONLY TO PARTICIPANTS WHO INDICATED PRESCRIBING OFF-LABEL IN Q12

PROGRAMMING: RANDOMIZE ORDERING OF ITEMS A-I, LEAVING "OTHER SPECIFY" (K) LAST

	Nev er	Rare ly	Sometim es	Ofte n	Very Often
a. Colleagues					
b. Medical journals		0			
c. Google or other online search engines	0	0	0	0	۵
d. Medical reference websites such as UpToDate or Epocrates	0	0	۵	0	0
ASK ONLY TO ONCOLOGISTS e. National Comprehensive Cancer Network Guidelines	0		0	0	
f. Professional medical association conferences and communications	0	0	۵	0	۵
g. FDA					
h. Pharmaceutical companies					
i. Online communities of physicians					
j. Key opinion leaders or thought leaders in the field			0		
k. Other, please specify	0		0		

16. How often do you use the following sources to learn about off-label uses for a drug?

Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_COLL Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_JOURNAL Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_GOOGLE Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_REFWEB Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_NCCNG Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_PROFMEDASSN Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_FDA Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_PHARMA Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_ONLINECOMMUNITY Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_ONLINECOMMUNITY Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_OPINIONLEADER Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_OTHER Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_OTHER Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_OTHER Q17_OFFLABELUSE_INFOSOURCES_LIKELYUSE_OTHER

PROGRAMMING: ASK ONLY TO PARTICIPANTS WHO INDICATED PRESCRIBING OFF-LABEL IN Q12

PROGRAMMING: RANDOMIZE ORDERING OF ITEMS A-G, LEAVING "OTHER SPECIFY" (K) LAST

17. How likely are you to use the following sources to learn about off-label uses for a drug?

	Not at all likely	A little likely	Somewhat likely	Very likely	Extremel y likely
a. Colleagues				0	
b. Medical journals					
c. Google or other online search engines		0	0	۵	
d. Medical reference websites such as UpToDate or Epocrates	5	0	D	0	0
ASK ONLY TO ONCOLOGISTS e. National Comprehensiv Cancer Network Guidelines	ve		0		0
f. Professional medical association conference and communication	s D	0	0	0	0
g. FDA					
h. Pharmaceutical companies	D	0	۵	0	
i. Online communities of physicians		0	0	0	
j. Key opinion leaders or thought leaders in the field	0	0	0	۵	0
k. Other, please specify					



Q18_CONTRARY DATA_SEENSUPPPORT

- 18. Thinking of the studies you have seen in the past, how often have you seen study findings that support an off-label use of a drug?
 - Image: Never
 - **Rarely**
 - Sometimes
 - 0 Often
 - Very often

Q19_CONTRARY DATA_SEENINCONCLUSIVE

- 19. Thinking of the studies you have seen in the past, how often have you seen study findings that contradict or are inconclusive about an off-label use of a drug?
 - INever
 - **Rarely**
 - Sometimes
 - 0 Often
 - Very often

Contrary data

Q20_CONTRARYDATA_STUDYASPECTS_STUDYPOP Q20_CONTRARYDATA_STUDYASPECTS_STUDYDESIGN Q20_CONTRARYDATA_STUDYASPECTS_SAMPLE Q20_CONTRARYDATA_STUDYASPECTS_FINDSAFETY Q20_CONTRARYDATA_STUDYASPECTS_FINDSIDEEFFECT Q20_CONTRARYDATA_STUDYASPECTS_NUMBER Q20_CONTRARYDATA_STUDYASPECTS_FINDEFFECTIVE Q20_CONTRARYDATA_STUDYASPECTS_OTHER Q20_CONTRARYDATA_STUDYASPECTS_OTHER Q20_CONTRARYDATA_STUDYASPECTS_OTHER

PROGRAMMING: RANDOMIZE ORDERING OF ITEMS A-H, LEAVING "OTHER SPECIFY" (I) LAST

20. How important is it to you to know about the following aspects of a study about an off-label use of a drug?

		Not at all important	A little important	Somewhat important	Very important	Extremely important
a.	Study population	0	0	0	0	
b.	Study design, e.g., randomized controlled study, observational study, study duration	0	0	0	0	D
с.	Sample size		0	0		
d.	Findings related to safety of the off-label use	0	0	0	0	0
e.	Findings related to side effects of the off-label use	0	0	0	0	0
f.	Study sponsor					
g.	Number of studies that contradict or are inconclusive about an off- label use of a drug	0	0	0	0	0
h.	Findings related to effectiveness of the off- label use	0	0	0	0	0
i.	Other, please specify:					



Q21_CONTRARY DATA_CIRCUMSTANCES

PROGRAMMING: RANDOMIZE ORDERING OF EACH RESPONSE OPTION, LEAVING THE "OTHER SPECIFY" OPTION LAST

21. Please rank the top three circumstances where you feel it would be most important for you to know about studies that contradict or are inconclusive about an off-label use of a drug.

Please write 1, 2, or 3 in the boxes below to rank your top three choices.

- 1 There are safety concerns associated with the off-label use
- 1 The patient being treated is part of a unique population (e.g., young, critically ill, etc.)
- 1 Efficacy of the off-label use is not clearly established
- 1 There is uncertainty about whether to prescribe the drug for the off-label use
- IContradictory studies have stronger study designs than studies supporting the off-label use
- 1 The off-label use is common
- 1 The off-label use, or the drug itself, is new
- 1 There are concerns about drug interactions
- 1 Other, please specify:

Q22_CONTRARYDATA_CONTRARYSOURCES_COLLQ22_CONTRARYDATA_CONTRARYSOURCES_JOURNALQ22_CONTRARYDATA_CONTRARYSOURCES_GOOGLEQ22_CONTRARYDATA_CONTRARYSOURCES_REFWEBQ22_CONTRARYDATA_CONTRARYSOURCES_NCCNGQ22_CONTRARYDATA_CONTRARYSOURCES_PROFMEDASSNQ22_CONTRARYDATA_CONTRARYSOURCES_FDAQ22_CONTRARYDATA_CONTRARYSOURCES_PHARMAQ22_CONTRARYDATA_CONTRARYSOURCES_PHARMAQ22_CONTRARYDATA_CONTRARYSOURCES_ONLINECOMMUNITYQ22_CONTRARYDATA_CONTRARYSOURCES_OPINIONLEADERQ22_CONTRARYDATA_CONTRARYSOURCES_OTHERQ22_CONTRARYDATA_CONTRARYSOURCES_OTHERQ22_CONTRARYDATA_CONTRARYSOURCES_OTHERQ22_CONTRARYDATA_CONTRARYSOURCES_OTHER

PROGRAMMING: RANDOMIZE ORDERING OF EACH RESPONSE OPTION, LEAVING THE "OTHER SPECIFY" OPTION LAST

22. Of the following sources, please rank the top three which you would most likely use to learn about studies that contradict or are inconclusive about an off-label use of a prescription drug.

Please write 1, 2, or 3 in the boxes below to rank your top three choices.

- Colleagues
- I Medical journals
- **Google or other online search engines**
- I Medical reference websites such as UpToDate or Epocrates
- DISPLAY ONLY FOR ONCOLOGISTS: National Comprehensive Cancer Network Guidelines
- Professional medical association conferences and communications
- FDA
- Pharmaceutical companies
- Online communities of physicians
- I Key opinion leaders or thought leaders in the field
- Other, please specify:

Debrief

Thank you for taking part in this survey.

While the information presented is accurate, the information provided about {DRUG} and its off-label use for {CONDITION} is a combination of several different studies.

The Brief Report was created specifically for this survey and is not a real publication.