

Physician Questionnaire

Sample: Primary care physicians

N = 500

- Half will see the treatment claim; half will see the prevention claim (random assignment)
- Half will see a small difference between drug and placebo rate; half will see a large difference between drug and placebo rate (random assignment)

		Type of Claim	
		Treatment Claim	Prevention Claim
Difference between Drug and Placebo	Small Difference	n = 125	n = 125
	Large Difference	n = 125	n = 125

Total N = 500

Administer informed consent procedures

Physician Questionnaire:

[PROGRAMMER: Record time in milliseconds spent on each screen (including questions) throughout protocol.]

[PROGRAMMER: Randomly assign participants to conditions as described above.]

Introductory language on at least three screens (to obtain baseline reading speeds).

Thank you for taking time from your busy schedule to contribute to this research. Your answers will remain confidential.

This study is about alternative methods of presenting prescription drug information. You will review information on a new (fictitious) product and make prescribing decisions as well as answer questions about the information you saw.

[PROGRAMMER: New screen]

On the next screen you will see the highlights section of the prescribing information for a fictitious new prescription drug, Milarix (lexisalicyclic acid and milaristatin calcium). The document contains hyperlinks. This means you will be able to read the important information in

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the highlights section and explore each section in further detail by clicking on the section that interests you.

[PROGRAMMER: New screen]

Please read through this prescribing information as you would if you were learning about any new prescription-only product for the first time.

[PROGRAMMER: Display highlights section that will have hyperlinks to further information about each section. Record time spent on highlights section, time spent on each section, and order of sections chosen.]

(Perceived Benefit)

[PROGRAMMER: Randomize the order of Q1 and Q2]

Q1. If this were a real drug, how likely would you be to prescribe this drug to your patients?

- Very likely
- Somewhat likely
- Somewhat unlikely
- Very unlikely

Q1a. What about the drug caused you to select that answer? (open-ended)

Possible codes:

- Efficacy*
- Safety*
- Convenience*
- Too new*
- Other*

Q2. Based on the prescribing information you read, how effective would Milarix (lexisaliclylic acid and milaristatin calcium) be for your patients?

- | | | | | | | |
|----------------------|---|---|----------------------|---|---|----------------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| Not at all effective | | | Moderately effective | | | Very effective |

Q3. Based on the prescribing information you read, how well would Milarix (lexisaliclylic acid and milaristatin calcium) work for your patients?

- | | | | | | | |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|

Not at all
well

Moderately
well

Very
well

Q4. (open-ended) Please explain why you rated the effectiveness of Milarix (lexisaliclyic acid and milaristatin calcium) as you did.

Possible codes:

Efficacy

Safety

Convenience

Too new

Other

(Perceived Safety)

[PROGRAMMER: Randomize the order of Q5 and Q6]

Q5. Based on the prescribing information you read, how safe would Milarix (lexisaliclyic acid and milaristatin calcium) be for your patients?

1	2	3	4	5	6	7
Not at all Safe			Moderately safe			Very safe

Q6. Based on the prescribing information you read, how risky would Milarix (lexisaliclyic acid and milaristatin calcium) be for your patients?

1	2	3	4	5	6	7
Not at all risky			Moderately risky			Very risky

(Perceived Comparative Benefit)

[PROGRAMMER: Randomize the order of Q7 and Q8]

Q7a. Compared with other drugs that treat *chronic pain*, how effective do you think Milarix (lexisaliclyic acid and milaristatin calcium) is?

1	2	3	4	5	6	7
Not at all effective			Moderately effective			Very effective

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Q7b. Compared with other drugs that *reduce the risk of heart attack*, how effective do you think Milarix (lexisalicyclic acid and milaristatin calcium) is?

1	2	3	4	5	6	7
Not at all effective			Moderately effective			Very effective

(Perceived Comparative Safety)

Q8a. Compared with other drugs that treat *chronic pain*, how safe do you think Milarix (lexisalicyclic acid and milaristatin calcium) is?

1	2	3	4	5	6	7
Not at all Safe			Moderately safe			Very safe

Q8b. Compared with other drugs that *reduce the risk of heart attack*, how safe do you think Milarix (lexisalicyclic acid and milaristatin calcium) is?

1	2	3	4	5	6	7
Not at all effective			Moderately effective			Very effective

[PROGRAMMER: New screen]

Now you will see the same prescribing information that you saw earlier. Please refer to this prescribing information again, this time focusing specifically on how **effective** this drug is.

[PROGRAMMER: Display highlights section that will have hyperlinks to further information about each section. Record time spent on highlights section, time spent on each section, and order of sections chosen.]

Please answer the following specific questions based on what you learned from the Milarix (lexisalicyclic acid and milaristatin calcium) prescribing information.

[PROGRAMMER: Participants who see treatment version will see Q9; participants who see prevention version will see Q10]

Q9. Based on the prescribing information you read, what is your sense of how much this product will reduce pain symptoms on average?

1	2	3	4	5	6	7
Not much at all			Moderately			A great deal

Q10. Based on the prescribing information you read, what is your sense of what amount of reduction in heart attack risk can be expected with this drug?

1	2	3	4	5	6	7
Not much reduction reduction			A moderate amount	of reduction		A great deal of

[PROGRAMMER: All participants see Q11]

Q11. What about the information caused you to respond as you did in the last question? (open-ended)

Possible codes:

Efficacy
Safety
Convenience
Too new
Other

(Specific Benefit Accuracy)

[PROGRAMMER: For Questions 12-13, participants in the treatment study will see only questions 12T-13T. Participants in the prevention study will see only questions 12P-13P. In both cases, randomize the order of Q12-Q13]

Q12T. According to the information you just read, if 100 people take **Milarix** (lexisalicyclic acid and milaristatin calcium), how many will experience less pain?

_____ people (fill in the blank. PROGRAMMER: set acceptable range from 0 to 100)

Q13T. According to the information you just read, if 100 people take **no treatment**, how many will experience less pain?

_____ people (fill in the blank. PROGRAMMER: set acceptable range from 0 to 100)

Q12P. According to the information you just read, if 100 people take **Milarix** (lexisalicyclic acid and milaristatin calcium), how many will have a heart attack?

_____ people (fill in the blank. PROGRAMMER: set acceptable range from 0 to 100)

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Q13P. According to the information you just read, if 100 people take **no treatment**, how many will have a heart attack?

_____ people (fill in the blank. PROGRAMMER: set acceptable range from 0 to 100)

[PROGRAMMER: New screen]

Now you will see four different versions of a magazine ad directed at patients. The ad is for another drug, a fictitious drug for high cholesterol, Votrea (trevastatin calcium). These four different versions represent different ways to present the data from the prescribing information to patients.

[PROGRAMMER: New screen]

Q14. There are many ways to present scientific data. Some are better than others. After looking at each of the four versions, please rank them from best to worst in terms of how well the ad represents the scientific information. In other words, your first selection will be the one you believe best represents the data, your second choice will be the one you believe is the second-best, and so forth.

To view each version in more detail, please click on the page and it will enlarge. You will be able to zoom in and out for your ease of viewing.

[PROGRAMMER:

1. Display all four versions of Votrea ad on screen. As participants click on a version, bring that version to a full screen view. Maintain some sort of zoom capacity so that participants can enlarge sections for ease of reading. Please adjust instructions to participants as appropriate, depending on the procedure you put in place.

2. Please arrange a format whereby participants can then select each version in their chosen order.

3. A randomly selected half of the participants will see treatment claim versions of the ad:

Version name 1

Version name 2

Version name 3

Version name 4

A randomly selected half of participants will see prevention claim versions of the ad:

Version name 5

Version name 6

Version name 7

Version name 8

]

Q14a. (open-ended) What about the different versions caused you to rank them this way?

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Possible codes:

Format

Layout

Numbers

Text

Other

Q15. Now, looking at the same four versions, please rank these in order of **ease of understanding for the typical patient**. In other words, your first selection will be the version you think the typical patient will most readily understand, your second selection will be the second-most understandable version, and so forth.

[PROGRAMMER: Execute the same procedure as above. Participants will see the same versions in Q16 and Q17.]

Q15a. (open-ended) What about the different versions caused you to rank them this way?

Possible codes:

Format

Layout

Numbers

Text

Other

[PROGRAMMER: Randomize Qs 16-17. Q16 and 16a should be on the same screen at the same time. Q17 and 17a should be on the same screen at the same time.]

Please indicate your agreement with the following statements.

Q16. I can effectively communicate risk numerically (probability, percent).

Strongly agree
Somewhat agree
Somewhat disagree
Strongly disagree

Q16a. I consider this important to my practice.

Strongly agree
Somewhat agree
Somewhat disagree
Strongly disagree

Q17. I can effectively communicate risk qualitatively ('high,' 'low').

- Strongly agree
- Somewhat agree
- Somewhat disagree
- Strongly disagree

Q17a. I consider this important to my practice.

- Strongly agree
- Somewhat agree
- Somewhat disagree
- Strongly disagree

Q18. (Objective numeracy) Now here are some questions that require you to use numbers to solve the problem. Some are easy and others are more difficult. No calculators please- we'd like you to answer on your own.

[PROGRAMMER: DO NOT randomize Q18a-c]

a. Imagine that you flip a fair coin 1,000 times. What is your best guess about how many times the coin would come up heads in 1,000 flips?

___ times out of 1,000 [PROGRAMMER: set acceptable range from 0 to 1,000]

b. In the BIG BUCKS LOTTERY, the chance of winning a \$10 prize is 1%. What is your best guess about how many people would win a \$10 prize if 1,000 people each buy a single ticket to BIG BUCKS LOTTERY?

_____ people [PROGRAMMER: set acceptable range from 0 to 1,000]

c. In ACME PUBLISHING SWEEPSTAKES, the chance of winning a car is 1 in 1,000. What percent of tickets to ACME PUBLISHING SWEEPSTAKES will win a car?

___ percent

Now please answer the following questions for classification purposes.

Q19. What year were you born? _____

Q20. How many years have you been in practice? _____

Q21. Thinking about prescriptions of all kinds, about how many prescriptions do you write in an average week, including hospital and institutional orders?

_____ per week

Q22. How many prescriptions for chronic pain do you write in an average week?

_____ per week

Q23. How many prescriptions for cardiovascular outcomes do you write in an average week?

_____per week

Q24. About what percentage of your patients are you treating for chronic pain?

_____%

Q25. About what percentage of your patients are you treating for cardiovascular risk factors?

_____%

Q26. How would you rate your familiarity with prescription treatments for chronic pain?

- Very familiar
- Somewhat familiar
- Somewhat unfamiliar
- Not familiar at all

Q27. How would you rate your familiarity with prescription treatments for improving cardiovascular outcomes?

- Very familiar
- Somewhat familiar
- Somewhat unfamiliar
- Not familiar at all

Q28. How many hours in a typical week do you use the internet for work purposes, if at all?

_____ hours

Q29. How many hours in a typical week do you use the internet for personal use, if at all?

_____ hours

Q30. Are you part of any of the following health-care arrangements? You may say yes to more than one. (check all that apply)

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- A solo practice
- A small group practice or partnership
- A multispecialty group practice
- A health maintenance organization or HMO
- A preferred provider list or network of physicians
- None of the above

Q31. Overall, how would you say direct-to-consumer advertising has affected your patients and your practice?

- Very positively
- Somewhat positively
- Has not affected the quality at all
- Somewhat negatively
- Very negatively

Q32. What caused you to answer as you did in the previous question? ([open-ended](#))

Possible codes:

Helps dialog

Hinders dialog

Takes too much time

Creates false expectations

Other

Thank you for taking the time to participate in this study. This study has been designed by the Food and Drug Administration to explore the ways physicians use approved prescription drug labels in an attempt to improve these documents for future use. Your participation has been valuable.