

Physician Pretest

Sample: Primary care physicians

N = 50

- 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 = 12	n = 13
	Large Difference	n = 13	n = 12

Total N = 50

Administer informed consent

Pretest 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 drug, Milarix (lexisalicyclic acid and milaristatin calcium). The document contains hyperlinks. This means you will be able to read the important information in the highlights section and explore each section in further detail by clicking on the section that interests you.

[PROGRAMMER: New screen]

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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.]

[PROGRAMMER: Randomize the order of Q1 and Q2]

Q1. How thoroughly did you read the PI? (check all that apply)

- I did not read any of it
- I skimmed the highlights section
- I read the highlights section thoroughly
- I clicked on and skimmed a few links
- I clicked on and read only a few links, but I read those links thoroughly
- I clicked on and skimmed many links
- I clicked on and read many links thoroughly
- I clicked on and read every link

Q2. How similar is this to how much information you usually read about a new drug?

- I read more information than I usually read about a new drug
- I read about the same amount of information
- I read less information than I usually read about a new drug

Q3. How easy or difficult was it for you to find the information you were interested in?

- | | | | | |
|-----------|---------------|-------------------------------|-----------------------|----------------|
| 1 | 2 | 3 | 4 | 5 |
| Very Easy | Somewhat Easy | Neither Easy nor
Difficult | Somewhat
Difficult | Very Difficult |

Q4. How believable was the information in this PI?

- | | | | | |
|--------------------------|---|------------------------|---|-----------------|
| 1 | 2 | 3 | 4 | 5 |
| Not at all
believable | | Somewhat
believable | | Very believable |

Q4a. What made you answer the previous question as you did? (open-ended)

Possible Codes:

Drug not realistic

Sections of PI not realistic

Was told it was fictitious

Formatting

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Other

[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.

Q5. How easy or difficult was it to find information about the effectiveness of the drug?

1	2	3	4	5
Very Easy	Somewhat Easy	Neither Easy nor Difficult	Somewhat Difficult	Very Difficult

Q6. How easy or difficult was it to distinguish your task in the second viewing of the PI from your task in the first viewing of the PI?

1	2	3	4	5
Very Easy	Somewhat Easy	Neither Easy nor Difficult	Somewhat Difficult	Very Difficult

[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]

Q7. 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

]

Q7a. (open-ended) What about the different versions caused you to rank them this way?

Possible Codes:

- Format*
- Visuals*
- Numbers*
- Colors*
- Other*

Q8. How easy or difficult was this task?

1	2	3	4	5
Very Easy	Somewhat Easy	Neither Easy nor Difficult	Somewhat Difficult	Very Difficult

Q9. How clear were the instructions for this task?

1	2	3	4	5
Very Clear	Somewhat Clear	Neither Clear nor Unclear	Somewhat Unclear	Very Unclear

Q10. 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.

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

Q10a. (open-ended) What about the different versions caused you to rank them this way?

Possible Codes:

Format

Visuals

Numbers

Colors

Other

Q11. How easy or difficult was this task?

1	2	3	4	5
Very Easy	Somewhat Easy	Neither Easy nor Difficult	Somewhat Difficult	Very Difficult

Q12. How clear were the instructions for this task?

1	2	3	4	5
Very Clear	Somewhat Clear	Neither Clear nor Unclear	Somewhat Unclear	Very Unclear

Q13. 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 Q20a-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

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Q14. How did you feel about being asked the previous three questions? (open-ended)

Possible codes:

Positive

Negative

Other

Now please answer the following questions for classification purposes.

Q21. What year were you born? _____

Q22. How many years have you been in practice? _____

Q23. About what percentage of your patients are you treating for chronic pain?

_____ %

Q24. About what percentage of your patients are you treating for cardiovascular risk factors?

_____ %

Q25. How would you rate your familiarity with prescription treatments for chronic pain?

Very familiar

Somewhat familiar

Somewhat unfamiliar

Not familiar at all

Q26. How would you rate your familiarity with prescription treatments for improving cardiovascular outcomes?

Very familiar

Somewhat familiar

Somewhat unfamiliar

Not familiar at all

Q27. How many hours in a typical week do you use the internet for work purposes, if at all?

_____ hours

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

_____ hours

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Q29. 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

Q30. 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*

Q31. Do you have any thoughts or comments on this study? (open-ended)

Thank you for taking the time to participate in this study. This study has been designed by the Food and Drug Administration to develop materials 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.

This concludes the study. Thank you for your time.