[FDA LOGO]
[To appear on paper and web versions though the placement might vary based on formatting for the web versus paper]

OMB Control No: TBD
Expiration: TBD

National Survey on Numerical Claims in Prescription Drug Advertising

Information on Participating: Consent Form

We request that an adult household member with the next birthday and who is at least 18 years of age or older participate in this survey sponsored by the U.S. Food and Drug Administration.

Purpose:

- Westat is conducting this study on behalf of the FDA to understand how people interpret different claims used in prescription drug advertising.

What is involved:

- You are being asked to complete a survey, which will take approximately 20 minutes.
- You are one of about 2,500 people from around the United States being asked to participate in this survey. Your participation is voluntary, and you don't have to answer any questions you are not comfortable answering. You can also stop participating at any time.
- You will read some claims used in prescription drug advertising and respond to multiple choice questions as well as a few open-ended questions for additional input.

Confidentiality:

- Your responses collected through this survey will be kept secure and confidential to the full extent of the law.
- We will report our results in a summary aggregate report.

Risks:

- There are minimal psychological, social, or legal risks to participating in this study. The survey questions are not sensitive in nature.

Benefits:

- There are no direct benefits to you for participating in this study.
- You will be helping with an important research study to help improve claims made in prescription drug advertising.

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Cost and Compensation:

- There are no costs to you for completing the survey.
- We have included $5 cash to thank you for your consideration for completing the survey. [Included in the post-paid condition: After you have completed and submitted the survey, you will receive an additional $10 as a token of appreciation.]

Questions:

- If you have questions about the study, you may contact the Westat Project Director, Naomi Yount, at [toll-free number] or [study email address].
- If you have any questions or complaints about your rights as a research participant, please contact Westat's Human Subject 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 (National Survey on Numerical Claims in Prescription Drug Advertising), and a phone number beginning with the area code. Someone will return your call as soon as possible.

Consent [Web Survey]:

I have read the consent form. Completing this survey means that I understand the information and I consent to participate in this study.

Consent [Paper Survey]:

By completing the survey you are indicating that you are at least 18 years old, have read and understood this consent form and agree to participate in this study. Please keep this consent form for your records and return the survey to the researchers. Please DO NOT write your name on the survey.

FDA National Survey on Numerical Claims in Prescription Drug Advertising

This survey focuses on different claims made in prescription drug advertising. Each question includes one or more examples of claims that you might see in a prescription drug advertisement. The claims are not always about the same topic or related to each other. These are just examples of information about prescription drugs you might get from your doctor or pharmacy, or that you might read online or in advertisements.

Findings from this study will help to improve claims that use numbers, or "numerical claims." Understanding these claims can help consumers make more informed decisions about their health and treatment options. This survey will take about 20 minutes to complete.

Instructions: Please answer the questions to the best of your ability. Although this survey is not meant to be a quiz, we ask that you do not consult with others when completing the survey. We are trying to learn how easy or hard these claims may be to understand and how we can make them easier to understand.

Section A. We would like to learn how you feel about numerical claims. Here are some examples of what we mean by numerical claims:

- "FIBEREX lowers your cholesterol by 30%"
- "Mammograms lower a woman's chance of dying from breast cancer by a third"
- "Smokers are 10 times more likely to develop lung cancer"

1. **In general, how easy or hard do you find it to understand numerical claims?**
   o Very hard
   o Hard
   o Easy
   o Very easy

2. **I am confident that I can make sense of numerical claims.**
   o Strongly disagree
   o Disagree
   o Neither agree nor disagree
   o Agree
   o Strongly agree

3. **I feel like I do not know how to interpret numerical claims.**
   o Strongly disagree
   o Disagree
   o Neither agree nor disagree
   o Agree
   o Strongly agree

4. How good are you at working with	$\bullet_1$	$\bullet_2$	$\bullet_3$	$\bullet_4$	$\bullet_5$	$\bullet_6$

	Not at all good	•2	•3	•4	•5	Extremely good
fractions?						
5. How good are you at figuring out how much a shirt will cost if it is 25% off?	•1 Not at all good	•2	•3	•4	•5	•6 Extremely good
6. How often do you find numerical information to be useful?	•1 Never	•2	•3	•4	•5	•6 Very often

How familiar are you with the following terms?

	Not at all familiar	Somewhat familiar	Familiar	Very familiar
7. Clinical Trial	•	•	•	•
8. Mean	•	•	•	•
9. Median	•	•	•	•
10. Placebo	•	•	•	•

Section B. In this section, you will read claims similar to what may be found in prescription drug advertising. After reading each set of claims, you will be asked a series of questions on how you interpreted the claims.

Please choose the answer that comes closest to your understanding. The claims may or may not have included the information needed to answer each question, so your best guess is fine.

Please read the claim below and answer the following questions.

> **Claim 1:** **"People with advanced colon cancer treated with DRUG-A lived for a median length of time of 18 months, compared with 11 months for people treated with chemotherapy."**

1. **What do you think Claim 1 means?**
   o All people taking DRUG-A will live at least 18 months, and some may live more than 18 months
   o Most people taking DRUG-A will live for more than 18 months
   o Half of people taking DRUG-A will live for more than 18 months and half will live less than 18 months
   o On average, people taking DRUG-A will live for 18 months

   o Other, please specify: _____

Sometimes more information changes people's understanding of claims like Claim 1. Please read the claims below (Claim1 is identical to above) and answer the following questions.

Claim 1:	**"People with advanced colon cancer treated with DRUG-A lived for a median length of time of 18 months, compared with 11 months for people treated with chemotherapy."**
Claim 2:	**"A median is the middle number in a group of numbers ordered from smallest to largest."**
Claim 3:	**"In people receiving DRUG-A, this means that about half lived more than 18 months and about half lived less than 18 months."**

2. **What do you think Claim 1 means?**
   o All people taking DRUG-A will live at least 18 months, and some may live more than 18 months
   o Most people taking DRUG-A will live for more than 18 months
   o Half of people taking DRUG-A will live for more than 18 months and half will live less than 18 months
   o On average, people taking DRUG-A will live for 18 months

   o Other, please specify: _____

How did Claims 2 and 3 impact your understanding of Claim 1?

	Made Claim 1 more confusing	Neither helped nor made it more confusing	Helped me understand Claim 1
3. Claim 2…	•	•	•
4. Claim 3…	•	•	•

5. **Which claim was more helpful in explaining Claim 1?**
   o Claim 2 was more helpful
   o Claim 3 was more helpful
   o They were both equally helpful
   o Neither was helpful

"6 out of 10 arthritis patients had at least 25% improvement in joint pain after taking DRUG-B."

6. **How easy or hard is it to understand this claim?**
   o Very hard
   o Hard
   o Easy

o   Very easy

7. **What level of improvement do you expect 6 out of 10 arthritis patients taking Drug-B to have? Provide your best estimate.**

    Between ___% and ___% improvement in joint pain.

8. **How likely do you think it is that a person taking DRUG-B might experience 100% improvement in joint pain?**
    o   Very unlikely
    o   Somewhat unlikely
    o   Somewhat likely
    o   Very likely

"For some people, DRUG-C cut the frequency of seizures by 50% or more."

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9. **How many people taking DRUG-C do you think will experience a cut in their frequency of seizures by 50% or more?**
    o   Less than half of people
    o   Half of people
    o   Most people
    o   All people
    o   It is unclear

    o   Other, please specify: _____

10. **How much do you expect the frequency of seizures to be cut "for some people" taking DRUG-C? Provide your best estimate.**

    Cut between ___% and ___%.

11. **Please fill in the blank. For some people, DRUG-C cut the frequency of seizures by 50% or more compared to _____. Select all that apply.**
    o   People before they started taking DRUG-C
    o   People taking a different drug
    o   People not taking any drug or taking a placebo (sugar pill)
    o   It is unclear
    o   Other, please specify: _____

> **"DRUG-D helped reduce monthly migraine days by as much as 75% for some people. And up to nearly half had their monthly migraine days reduced by 55% or more."**

12. **How many people taking DRUG-D do you think will experience a reduction in monthly migraine days of "as much as 75%"?**
    o   Less than half of people
    o   Half of people
    o   More than half but less than 75% of people
    o   Between 75% and 99% of people
    o   All people
    o   It is unclear
    o   Other, please specify: _____

13. **How many people taking DRUG-D do you think will experience a reduction in monthly migraine days of "55% or more"?**
    o   Less than half of people
    o   Half of people
    o   55% of people
    o   75% of people
    o   All people
    o   It is unclear
    o   Other, please specify: _____

14. **For a typical person taking DRUG-D, what would you expect the reduction in monthly migraine days to be? Provide your best estimate.**

    o   _____% fewer migraine days [allow 7 characters for ranges]

> **Claim 1:**   **"In lung cancer patients, DRUG-E reduced the risk of death by half."**

15. **What impact do you think DRUG-E has on the *risk of death* when you read claim 1 above?**
    o   It could prevent or stop patients dying from lung cancer
    o   It could slow down how fast patients die from lung cancer
    o   It has no impact on patients dying from lung cancer
    o   It is unclear

    o   Other, please specify: _____

16. **How many people taking DRUG-E do you think will experience a reduction in risk of death?**
    o   Less than half of people
    o   Half of people
    o   Most people
    o   All people

o   It is unclear
o   Other, please specify: _____

> **Claim 1:** "In lung cancer patients, DRUG-E reduced the risk of death by half."
>
> **Claim 2:** "The median time to death was 24 months for patients taking DRUG-E, compared with 11 months for patients on chemotherapy."
>
> **Claim 3:** "Results are from a 3-year clinical trial."

After reading Claims 2 and 3, how, if at all, did they impact your understanding of Claim 1?

	Made Claim 1 more confusing	Neither helped nor made it more confusing	Helped me understand Claim 1
17. Claim 2…	●	●	●
18. Claim 3…	●	●	●

19. After reading all three claims, what impact do you think DRUG-E has on the *risk of death*?
- o   It could prevent or stop patients dying from lung cancer
- o   It could slow down how fast patients die from lung cancer
- o   It has no impact on patients dying from lung cancer

- o   Other, please specify: _____

20. How, if at all, did Claim 3 change your confidence in DRUG-E?
- o   It made me less confident in DRUG-E
- o   It did not change my confidence in DRUG-E
- o   It made me more confident in DRUG-E
- o   Other, please specify:_____

> **Claim 1:** "DRUG-F is proven to offer 30% more protection from a heart attack or stroke."
>
> **Claim 2:** "DRUG-F is proven to reduce the risk of heart attack or stroke by 30%."

21. Do Claims 1 and 2 mean the same thing to you, or do they mean different things?
- o   They mean the same thing to me
- o   They mean different things to me. Please describe the difference: _____

22. Which claim do you think is easier to understand?
- o   Claim 1
- o   Claim 2
- o   Both are equally easy to understand
- o   Neither are easy to understand

23. Please fill in the blank. DRUG-F offers 30% more protection compared to _____
- o   People before they started taking DRUG-F
- o   People not taking any drug or taking a placebo (sugar pill)
- o   People taking a different drug
- o   It is unclear
- o   Other, please specify: _____

24. Looking at Claim 2, let's pretend the risk of a heart attack or stroke is 50%. For those taking DRUG-F, what is their risk of a heart attack or stroke?
- o   15%
- o   20%
- o   30%
- o   35%
- o   Do not know
- o   Other, please specify: _____

Claim 1:   **"After taking DRUG-G, half of the people in the study were able to maintain cancer remission for about 26 months."**

Claim 2:   **"In similar treatment settings as the study, we would expect that half of the patients would maintain their cancer remission for about 26 months after taking DRUG-G."**

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25. Do Claims 1 and 2 mean the same thing to you, or do they mean different things?
- o   They mean the same thing to me
- o   They mean different things to me. Please describe the difference: _____

How effective do you think DRUG-G is based on each claim:

	Not very effective	Somewhat effective	Effective	Very effective
26. Claim 1	•	•	•	•
27. Claim 2	•	•	•	•

Claim 1	**"People with eczema who took DRUG-H had 53% fewer flare-ups."**
Claim 2	**"The average number of flare-ups people had in one year was 17 with DRUG-H vs. 36 with a placebo (sugar pill)."**
Claim 3	**"27% of people taking DRUG-H had flare-ups compared with 46% of people taking a placebo."**

28. Do Claims 1 and 2 mean the same thing to you, or do they mean different things?
- o They mean the same thing to me
- o They mean different things to me. Please describe the difference: _____

29. Do Claims 1 and 3 mean the same thing to you, or do they mean different things?
- o They mean the same thing to me
- o They mean different things to me. Please describe the difference: _____

How did Claims 2 and 3 impact your understanding of Claim 1?

	Made Claim 1 more confusing	Neither helped nor made it more confusing	Helped me understand Claim 1
30. Claim 2…	●	●	●
31. Claim 3…	●	●	●

32. Which claim was more helpful in explaining the effect of DRUG-H?
- o Claim 1 was more helpful
- o Claim 2 was more helpful
- o Claim 3 was more helpful
- o They were all equally helpful
- o None were helpful

How effective do you think DRUG-H is based on each claim:

	Not very effective	Somewhat effective	Effective	Very effective
33. Claim 1	●	●	●	●
34. Claim 2	●	●	●	●

35. Claim 3	•	•	•	•

Claim 1	"DRUG-J was studied in a clinical trial of 125 people with arthritis. Results showed that people taking DRUG-J had significantly improved range of motion compared with people taking placebo."
Claim 2	"Information on range of motion was not available for 16 of 62 people taking DRUG-J and for 17 of 63 people taking placebo. It was not possible to know if the people with data missing were experiencing worse range of motion than people with data available."

36. **After reading Claim 2, do you think information was not available because: [Select all that apply]**
   o The researchers made a mistake
   o The researchers couldn't reach all the participants to complete the study
   o The participants with missing data had severe side effects or died
   o DRUG-J did not work for participants with missing data
   o The researchers did not want to provide all the data or wanted to hide some data
   o Other, please specify: _____

37. **After reading Claim 2, how much, if at all, does this change your confidence in DRUG-J?**
   o It made me less confident in DRUG-J
   o It did not change my confidence in DRUG-J
   o It made me more confident in DRUG-J
   o Other, please specify:_____

Section C. About You

1. **Are you:**
   Mark all that apply.
   o Female
   o Male

   o Transgender, non-binary, or another gender identity

2. **What is your current age?**
   o 18-29 years
   o 30-39 years
   o 40-49 years
   o 50-59 years
   o 60-69 years

o   70 years and over

3. **Are you of Hispanic, Latino, or Spanish origin?**
   o   Yes

   o   No

4. **What is your race? Select all that apply.**
   o   American Indian or Alaskan Native
   o   Asian
   o   Black or African American
   o   Native Hawaiian or Other Pacific Islander
   o   White

   o   Prefer not to answer

5. **What is the highest level of education you have completed?**
   o   Less than high school
   o   High school graduate or GED
   o   Some college or technical school or 2-year degree
   o   College graduate (4-year degree)
   o   Some graduate school

   o   Graduate school degree

6. **Do you currently work for any of the following? Select all that apply.**
   o   A pharmaceutical company
   o   A healthcare organization or in the healthcare field
   o   U.S. Department of Health and Human Services or U.S. Food and Drug Administration
   o   None of the above

7. **What state do you live in?**

   o   [Drop down of states on web survey and write-in field for paper survey]

8. **In general, how would you rate your overall health?**
   o   Excellent
   o   Very good
   o   Good
   o   Fair

   o   Poor

9. **Have you or someone you have provided care for ever had any of the following conditions? Select all that apply.**
   o   Arthritis
   o   Eczema
   o   Heart attack or stroke
   o   Colon cancer
   o   Lung cancer
   o   Cancer (other types)

- o Migraines
- o Seizures

Section D. Please complete the following problem. Please do not use a calculator or lookup answers for this question but feel free to use scratch paper for notes. We are interested in what *you* think.

1. **Imagine that you have a five-sided die (the sides of which show 1, 2, 3, 4, 5), and we throw it 150 times. On average, out of these 150 throws how many times would this five-sided die show an odd number (1, 3, 5)?**

    _____ throws (3 characters)

Thank you for completing the survey!