

An Assessment of Terms and Phrases Commonly Used in Prescription Drug Promotion

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Introduction

Prescription drug promotional communications often contain terms and phrases that can have varied interpretations or connotations. Examples include use of “prevent” versus “help prevent” regarding an unfavorable disease outcome (with “help” serving as a qualifier), and descriptors such as “a few,” “some,” “many,” “the majority,” and “most.” Little is known about the meanings members of the general population or health care providers assign to these terms and phrases. In response, a two-part study was designed to investigate what these terms and phrases mean to these populations, including what they imply about drug efficacy and risk.



Materials and Methods

First, through virtual semi-structured interviews, impressions were gathered from 30 general population consumers and 30 primary care physicians on approximately 30 terms and phrases. The complete list of terms and phrases assessed is shown in Figure 1.

Next, a nationally representative survey involving 1,069 general population consumers and 1,080 primary care physicians gathered insights on the same set of terms and phrases. Phase 2 survey response options were developed based on responses to phase 1 interviews.

Across phases, participants were excluded if they worked for the Department of Health and Human Services; RTI International; in market research; or for a pharmaceutical company; and if they were under 18 years of age. Additionally, consumer participants could not have worked as a medical professional, and physician participants needed to spend at least 32 hours a week practicing medicine and 50% or more of their time providing direct patient care.

Informed consent was gathered from all participants, and the study protocol was granted an exemption by RTI’s Institutional Review Board.

Materials and Methods Cont.

Consumers	Primary Care Physicians
<ul style="list-style-type: none"> Convenient; straightforward to use; simple to use; easy to use Prevent; help prevent; reduce the risk Proven to help; proven effective Natural Targeting; acts locally; targeted mechanism of action Powerful; potent #1 prescribed New; works differently; first and only; novel mechanism of action FDA-approved Off-label Reverses Individual results may vary Not statistically significant Manageable safety profile; established safety profile; well-studied safety profile; well-tolerated Restores; rebuilds A few; some; many; the majority; most Prescription drug promotion; prescription drug advertising Reaction; serious reaction; severe life-threatening reaction Endpoint Pure; purity 	<ul style="list-style-type: none"> Convenient; straightforward to use; simple to use; easy to use Prevent; help prevent; reduce the incidence Proven to help; proven effective Natural Targeting; acts locally; targeted mechanism of action Powerful; potent #1 prescribed New; works differently; first and only; first in class; novel mechanism of action FDA-approved Off-label Reverses Individual results may vary Not statistically significant Manageable safety profile; established safety profile; well-studied safety profile; well-tolerated Restores; rebuilds A few; some; many; the majority; most Prescription drug promotion; prescription drug advertising Scientific exchange Overall response rate Response duration Randomized controlled trial Non-inferiority randomized controlled trial Intent-to-treat analysis Per-protocol analysis

Figure 1. Complete list of terms and phrases assessed for consumers and primary care physicians. Differences in lists are bolded.

Questions addressed both how participants interpreted the meaning of each term or phrase, and perceived implications for drug safety and efficacy. For example, one question intended to address meaning read:

- Which of the following come to mind when you read that a prescription drug is used “off-label”?
- It does NOT have FDA approval for the specific medical condition for which it is being used.
 - It does NOT have FDA approval for *any* use.
 - It is used for an unapproved age group or dose.
 - It is used illegally.
 - It is a generic drug (not the brand name drug).
 - It is available over the counter.
 - Other (please specify):

Select Results and Discussion

Use of “prevent” regarding an unfavorable disease outcome tended to suggest a guarantee of efficacy, while using the phrase “help prevent” partially mitigated this issue.

This drug is...	Perceived Likelihood of Asthma Attack	
	Consumers Mean (SD)	Primary Care Physicians Mean (SD)
...shown to “prevent” severe asthma attacks.*	2.78 (.06)	2.41 (.05)
...shown to “help prevent” severe asthma attacks.	3.07 (.04)	2.72 (.03)
...shown to “reduce the risk” of severe asthma attacks.	3.21 (.04)	NA
...shown to “reduce the incidence” of severe asthma attacks.	NA	2.87 (.03)
...“proven to help” prevent severe asthma attacks.	3.25 (.05)	2.79 (.04)
...“proven effective” at preventing severe asthma attacks.	3.10 (.06)	2.60 (.05)

Figure 2. Q4 read, “When you read each statement, how likely do you think it is that a patient taking each drug would experience a severe asthma attack? (1 = not at all likely, 5 = extremely likely)
* Results of significance testing showed means for “prevent” were significantly lower than for all other means in both samples.

Regarding the descriptors “a few,” “some,” “many,” “the majority,” and “most,” there was wide variation in terms of how many people out of 100 these were thought to refer to, indicating these terms and phrases mean different things to different people.

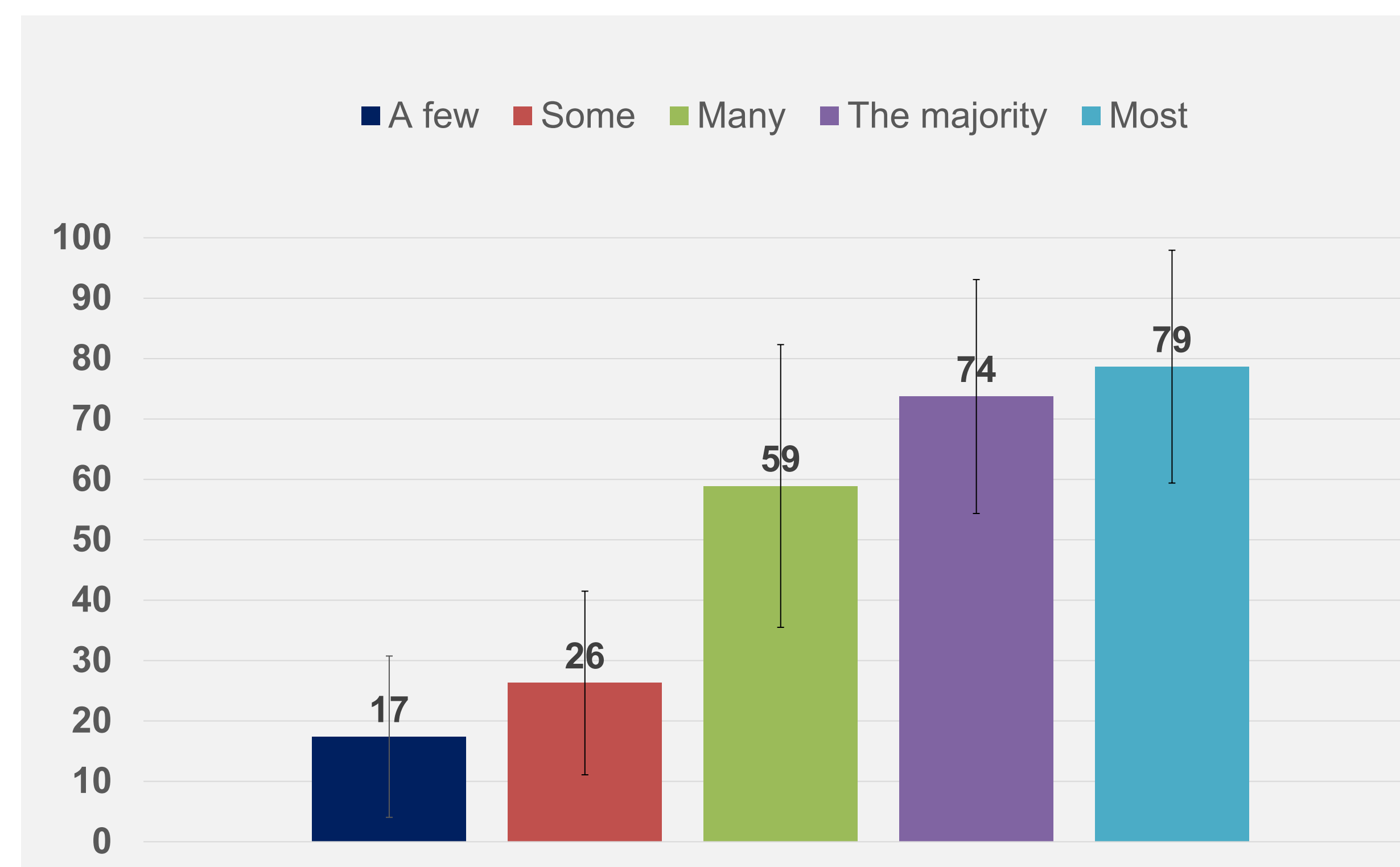


Figure 3. Q25 read, “How many people out of 100 do you think of when you see each of the following? If you are thinking of a range, please enter the midpoint of that range.” Consumer results are shown, including means and standard deviations (error bars). Results for primary care physicians were highly similar.

As additional highlights from the results:

- The phrase “proven effective” implied a guarantee of success to 42% of consumers and 36% of primary care physicians.
- About half of the consumers thought “targeting” meant the drug would not affect any other parts of the body. Similar findings were observed for “acts locally.” About half of the primary care physicians thought “acts locally” meant the drug would not affect any other parts of the body. About one-third of primary care physicians thought the same about “targeting.”
- Twenty percent of consumers and 13% of primary care physicians thought a drug that was “FDA approved” must not have any serious side effects.
- Fifty-five percent of consumers and 42% of primary care physicians thought “restores” meant to return tissue to its original condition. However, the same was not true for “reverses” for which only 20% of consumers and 5% of primary care physicians chose “will return bone density to normal.”
- Nearly all primary care physicians knew what “off-label” meant. About half of consumers knew what this meant.

Conclusion

This research studied consumer and primary care physicians’ understanding of terms and phrases commonly used in prescription drug promotion. Findings offer important implications for the promotion of prescription drug products in terms of ensuring the studied terms and phrases are interpreted as intended, and that such interpretations adequately reflect the safety and efficacy of the products being promoted.

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