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Word 'breakthrough' dramatically affects perceptions of a new drug's effectiveness

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When it comes to our perception of a new drug's benefits and effectiveness, "breakthrough" just may be the "magic" word. Dartmouth Institute researchers Lisa Schwartz and Steven Woloshin and Tamar Krishnamurtia and Baruch Fischhoff from Carnegie Mellon University, took a look at how catchphrases such as "breakthrough" and "promising" affect public perception of a new drug. And, the findings of their research study, published recently in *JAMA Internal Medicine*, show the answer is pretty significantly.

In everyday usage, the term "breakthrough" represents a highly significant or definitive advance. However, since the U.S. Food and Drug Administration (FDA) Safety and Innovation Act became law in 2012, the FDA can assign the breakthrough designation to a drug that "treats a serious or life-threatening condition" and "may demonstrate a substantial improvement...over available therapies" based only on preliminary evidence. Such drugs often receive what's known as accelerated approval.

And, in fact, since the creation of the Safety and Innovation Act, all FDA press releases announcing the approval of a breakthrough-designated drugs have used the term "breakthrough" while about half use the term "promising."

"Today, patients and their families can easily find FDA press releases on the Internet, or they often hear about them in the news," Woloshin said. "But the reality is that unless patients fully understand how the FDA is

using the term 'breakthrough,' they may have unwarranted confidence in the evidence supporting drug claims. So, we thought it was important to test how these terms affect the judgement of people without medical training."

Participants in the online study were randomly given 1 of 5 short descriptions of a recently approved drug. The descriptions were based on an FDA press release for a metastatic lung cancer breakthrough-designated drug conditionally approved based on the surrogate outcome tumor shrinkage. The facts-only description described the drug as meeting the breakthrough-criteria, but did not actually use the term "breakthrough." A second and a third description added the terms "breakthrough" and "promising" respectively, while a tentative explanation used FDA-required language for professional labeling. A final description, classified as 'definitive,' changed "maybe be contingent" to "is contingent." Study participants were then asked to judge the drug's benefit, harm and strength of evidence.

The researchers found that adding either "breakthrough" or "promising" in the description significantly increased the percentage of participants who rated the drug as "very" or "completely" effective compared with the facts-only description (23% and 25% vs 11 %). Adding those terms to the description also significantly increased the number of people who reported believing that evidence supporting the drug is "strong" or "extremely" strong (59% and 63% vs 43%). At the same time, adding either the tentative or definitive explanations significantly reduced the percentage of study participants who believed (incorrectly) that the drug been "proven to save lives" (16% -tentative and 10%-definitive vs 31% -breakthrough).

Finally, when participants were asked which of two drugs—one described as "breakthrough," the other as meeting the breakthrough criteria—they would take for a potentially deadly condition, 92% chose

the "breakthrough" drug.

"Our findings clearly indicate that words like 'breakthrough' and 'promising' increase people's beliefs in a drug's effectiveness (sometimes incorrectly)," Schwartz said. "In light of (the findings), press releases with neutral terms and that clearly explain the limited evidence supporting what breakthrough-designation and accelerated approval mean might help consumers make more accurate judgements about these drugs."

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