AD BLITZ

Supplements' claims not backed by the FDA

By BOB CLIFFORD

Who hasn't seen advertisements targeting older people to buy Prevagen, a supplement claiming to improve memory? Television commercials in paid testimonials claim:

"I was struggling with my memory. It was going downhill. My friend recommended that I try Prevagen and over time it made a very significant difference in my memory and in my cognitive ability. I started to feel a much better sense of well-being."

"I've been taking Prevagen for three years now. People say to me periodically, 'Man, you've got a memory like an elephant!'"

Do such claims require substantiation? The side of the box now reads: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

But is that enough?

Prevagen's aggressive marketing has led to false advertising claims brought by attorneys general in several states as well as class-action lawsuits against the supplement maker for simply not doing what it claims it can do.

Prevagen reportedly has made millions of dollars as people living longer attempt to stave off cognitive decline, but lawsuits have alleged the company simply doesn't have the science to back up its claims.

Because supplements are not considered to be part of the pharmaceutical industry, they are not regulated by the FDA. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), it is illegal for supplements to claim they prevent, treat or cure diseases. However, they can declare they aid certain health functions as long as they are backed by scientific evidence that substantiates that the claims are "true and not misleading."

Prevagen claims its advertising is clinically proven, but the Federal Trade Commission and the New York attorney general in 2017 sued the makers of the product, Wisconsin-based Quincy Bioscience, in one of four nationwide class actions for fraud.

A January 2019 JAMA article co-authored by Joanna Hellmuth, a neurologist at the University of California-San Francisco Memory and Aging Center entitled "The Rise of Pseudomedicine for Dementia and Brain Health," criticized the product for quoting studies that lack "sufficient participant characterization."

Quincy Bioscience agreed to a nationwide class action settlement out of Florida requiring the company to add the wording above its label and offer partial refunds to as many as three million consumers for the supplement. The refunds, available online, are for $25 to $80 a bottle and at various national chain stores including Walmart, CVS and Walgreens.

Compare that to the FDA's decisive action June 22 when it announced that Juul, manufacturer of vaping products containing nicotine, must stop selling its products throughout the United States. In doing so, the FDA said the maker's applications for approval "lacked sufficient evidence regarding the toxicological profile of the products to demonstrate that marketing of the products would be appropriate for the protection of the public health." That means the product must be more likely to help people quit smoking than to entice young people to start using its potentially addictive product.

The Seventh Circuit recently held that a company's claims were so far-fetched that they fell outside the bounds of false advertising. In *Martin v. Living Essentials*, LLC, 160 F. Supp. 3d 1042 (N.D. Ill.), *aff'd*, 653 F. App'x 482 (7th Cir. 2016), *reh'g denied* (7th Cir. July 21, 2016), the court affirmed the district court's dismissal of false advertising claims brought by a user of 5-hour ENERGY drink. The advertisement depicted a person who had "mastered origami while beating the record for Hacky Sack," swam the English Channel and found Bigfoot all within the five-hour span of consumption.

The court held that the commercial was so "grossly exaggerated" that "no reasonable buyer would take it at face value" and that it was "an obvious joke that employ[ed] hyperbole and exaggeration for comedic effect." Because it amounted to puffery, there was "no danger of consumer deception and hence, no basis for a false advertising claim." *Id.* 1049, 1051.

Much of the public doesn't understand that the FDA does not test supplements for safety or approve such products before they are sold. Consumers must beware when manufacturers try to appeal to one's sense of hope instead of relying on clinical trials and science when making purchases. CL

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