

Vinpocetine: An Unapproved Drug Sold as a Dietary Supplement

To the Editor: In the United States, the law governing dietary supplements permits vitamins and minerals, botanical products, amino acids, and protein powders to be sold as supplements. The laws regulating supplements have one safeguard to give the US Food and Drug Administration (FDA) the opportunity to intervene before manufacturers introduce an unapproved drug as a supplement: before introducing a new ingredient into supplements, the manufacturer is required to submit a “new dietary ingredient notification” to the FDA. The FDA assesses the application and responds as to whether the ingredient is appropriate for sale as a dietary supplement.

If a manufacturer proposes selling an unapproved prescription drug, the FDA would be expected to inform the manufacturer that it is not a legal dietary supplement ingredient. However, the FDA has not always enforced the law. An example is vinpocetine, a pharmaceutical agent prescribed in Germany, Russia, China, and other countries at dosages from 5 mg to 40 mg for acute stroke and cognitive impairment.¹ Vinpocetine has never been approved by the FDA as a prescription drug in the United States. Data regarding vinpocetine’s neuroprotective effects are conflicting, with a recent Cochrane review suggesting no benefit,¹ and vinpocetine can lead to flushing, headaches, and decreased blood pressure.²

In 1997, a supplement manufacturer submitted a new dietary ingredient notification for vinpocetine to the FDA.³ Rather than responding that an unapproved drug may not be sold as a supplement, the FDA permitted the introduction of vinpocetine into supplements. Today, more than 340

brands of supplements contain vinpocetine.⁴ The FDA may have assumed that vinpocetine was a botanical extract, but it is not. Vinpocetine can be synthesized from vincamine, an alkaloid extracted from the leaves of the lesser periwinkle (*Vinca minor*).¹ However, to my knowledge, vinpocetine itself has never been identified in lesser periwinkle or any other plant.

Recently, my colleagues and I analyzed all supplements labeled as containing vinpocetine that are available for purchase online from GNC (General Nutrition Centers, Inc) or The Vitamin Shoppe, two of the largest supplement retailers in the United States.⁵ Vinpocetine supplements were most commonly sold as sports supplements, brain enhancers, and weight loss supplements. We found that only 6 of the 23 supplement labels (26%) provided consumers with accurate dosages of vinpocetine.⁵

The FDA has permitted an unapproved new drug with unproven efficacy and known adverse effects to be sold directly to consumers. By permitting the sale of a drug as a dietary supplement, the FDA has created a dangerous precedent by which new drugs can bypass the rigorous drug approval process and be sold directly to consumers without FDA approval. When this happens, consumers are unable to obtain accurate dosing information and are not aware of adverse effects. The FDA should not permit unapproved drugs, even semisynthetic derivatives of natural compounds, to be sold as dietary supplements.

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Teachable Action for Leaders Committed to Improving Physician Work Life: Continuing Education

To the Editor: We read with great interest the article by Shanafelt et al¹ on the impact of organizational leadership on physician burnout and satisfaction published in the April 2015 issue of *Mayo Clinic Proceedings*. In their article, the authors identified several specific leadership qualities of physician supervisors as predictors of physician burnout and career satisfaction, including encouraging physicians to develop their talents and skills. We recently conducted a survey of the approximately 1850 clinically active academic physicians at Massachusetts General Hospital focused on physician burnout, career satisfaction, and administrative burden (response rate, 96% [1774]). Our results similarly support the finding that physician leaders can improve the well-being of physicians. In our study, physicians who were satisfied with the control they have over their practice environment, their call and coverage schedule, and their overall workload were less likely to report symptoms of burnout. Each of these factors, with the exception of call and coverage schedule, was also predictive of career satisfaction.

In addition, a majority of our physicians (1227 of 1758 [70%]; 16