

Study discovers multiple unapproved drugs in 'brain boosting' supplements

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Supplements that claim to improve mental focus and memory may contain unapproved pharmaceutical drugs and in potentially dangerous combinations and doses, according to a new study published in the September 23, 2020, online issue of *Neurology Clinical Practice*, an

official journal of the American Academy of Neurology. Researchers found five such drugs not approved in the United States in the supplements they examined. The supplements are sometimes called "nootropics," "smart drugs" or "cognitive enhancers."

"Over-the-counter cognitive supplements are popular because they promise a sharper mind, but they are not as closely regulated as pharmaceutical drugs," said study author Pieter A. Cohen, M.D., of Harvard Medical School in Boston, Mass. "Use of these supplements poses potentially serious health risks. Not only did we detect five [unapproved drugs](#) in these products, we also detected several drugs that were not mentioned on the labels, and we found doses of unapproved drugs that were as much as four times higher than what would be considered a typical dose."

Cohen said the supplements could be especially risky if used in combination with prescription drugs or instead of seeking medical advice.

Unlike [pharmaceutical drugs](#) that must be proven safe and effective for their intended use before they are marketed to consumers, the law does not require the U.S. Food and Drug Administration (FDA) to approve [dietary supplements](#) for safety or effectiveness before they reach the consumer. The FDA takes action after the products reach the market if they are mislabeled or contain unapproved products.

For the study, researchers searched the National Institutes of Health Dietary Supplement Label Database and the Natural Medicines Database for cognitive supplements that listed drugs similar to piracetam, a drug previously found in supplements but not approved in the U.S. They were looking for analogs of piracetam, drugs with a similar but slightly different chemical structure. Analogs are sometimes introduced into supplements to circumvent laws.

Researchers identified 10 supplements, eight that promised to enhance mental function, one that was marketed as "workout explosives" and another that had the words "outlast, endure, overcome" on the label.

Researchers examined the contents of each [supplement](#) using various methods and measured quantities of each drug present.

In the 10 supplements they examined, researchers detected five unapproved drugs. Two were analogs of piracetam called omberacetam and aniracetam. The others were the unapproved drugs vinpocetine, phenibut and picamilon. The FDA has issued a warning that vinpocetine should not be consumed by women of childbearing age. While all of the risks of these drugs are not known, side effects include increased and decreased blood pressure, agitation, sedation and hospitalization.

All 10 supplements contained omberacetam, which is prescribed in Russia for traumatic brain injury and mood disorders. A typical pharmaceutical dose would be 10 milligrams (mg). The doses in a recommended supplement serving size were as high as 40 mg, four times greater than in pharmaceutical dosages.

Some supplements contained more than one unapproved drug. One product combined four of the unapproved drugs.

"With as many as four unapproved drugs in individual products, and in combinations never tested in humans, people who use these cognitive enhancement supplements could be exposing themselves to potentially serious health risks," said Cohen. "The effects of consuming untested combinations of unapproved drugs at unpredictable dosages are simply unknown and people taking these supplements should be warned."

Researchers also found that for those products with [drug](#) quantities provided on the labels, a majority of the declared quantities were

inaccurate.

"The fact that these supplements are listed in official databases does not mean the labeling is accurate or the dosage levels of ingredients in these supplements are safe," said Cohen. "U.S. law does not permit unapproved pharmaceuticals to be introduced into dietary supplements, but the law places the burden of eliminating those products on the FDA. The FDA has issued a series of warnings to companies selling supplements with unapproved drugs, yet such drugs remain openly listed on databases as ingredients in supplements. Our study also raises concerns regarding the quality and legality of supplements listed in supplement databases."

One limitation of the study was that it didn't look at all unapproved drugs that are marketed in cognitive supplements.

Provided by American Academy of Neurology

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