The risks of ignoring scientific evidence

On Feb 11, 2019, the US Food and Drug Administration (FDA) took action against 17 companies that sell dietary supplements, for claiming that they can treat Alzheimer's disease. Scott Gottlieb, the FDA Commissioner at the time, released a statement explaining this action as an initial step of the agency's new, more aggressive policy plans to regulate dietary supplements. These products can cause harm, interfere with prescription drugs, and lead patients to avoid seeking medical treatment. Physicians have a responsibility to help patients make informed decisions on treatment choices, and that includes exposing any unscientific claims from providers of alternative therapies. The Alzheimer's disease community have therefore welcomed the FDA plans, which should be also applauded and supported by brain-health professionals everywhere.

The FDA sent warnings to foreign and domestic companies selling many products, ranging from avocado oil to vitamins and herbal extracts, that were illicitly marketing them for the prevention or treatment of Alzheimer's disease, and other conditions. According to the US Dietary Supplement Health and Education Act, vendors of these products can claim certain health benefits (eg, "improves memory"), but not efficacy in preventing or treating a disease. The lucrative industry of dietary supplements could invest in the randomised clinical trials necessary to prove such claims; but because the use of most of these substances cannot be patented, commercial incentives are lacking and, unfortunately, scientific integrity does not seem to be a core value of this trade. Many companies fail to include disclaimers in their products and to inform customers on the best available evidence; they rely instead on either bogus claims or, at best, preliminary findings. For instance, well-designed and executed phase 3 trials have failed to show any efficacy of ginkgo biloba extract in preventing cognitive decline. However, a company that received an FDA warning for its ginkgo biloba capsules, among other products, has nevertheless marketed them for the treatment of Alzheimer's disease.

Many dietary supplements make unproven or misleading claims of efficacy, not only for the treatment of neurodegenerative diseases, but also for other uncurable conditions, such as cancer. These patients are particularly vulnerable as they might not pursue or abandon palliative treatment, and instead rely on rogue methods at advanced stages of disease. Remarkably, the 2018 National Cancer Opinion Survey found that almost 40% of responders believed that cancer could be cured using alternative therapies. In this context, it is not surprising that our sister journal *The Lancet Oncology* runs a section named *Quackery*, "to cover the latest news about fraudulent or ignorant practices". The FDA advise healthcare professionals to report adverse effects that might be associated with dietary supplements and other alternative therapies. Neurologists must therefore be vigilant, and bear in mind that unexpected signs and symptoms could be the consequence of the use of these products. In our *Correspondence* section, neurologists are encouraged to disseminate adverse effects and any instances of spurious claims, which Joanna Hellmuth and colleagues have fittingly termed pseudomedicine (ie, "supplements and medical interventions that exist within the law and are often promoted as scientifically supported treatments, but lack credible efficacy data").

The potential customer base for dietary supplements is huge and increasing. The number of people with dementia worldwide has more than doubled from 1990 to 2016. The latest Facts and Figures report of the Alzheimer's Association concludes that, just in the USA, one in 10 people aged 65 years and older has Alzheimer's disease; that is, almost 6 million people. This number is projected to reach 14 million by 2050. As acknowledged by Gottlieb in his statement, it seems implausible that regulators in the USA, or elsewhere, will have the "capacity to manage emerging risks" from these products if this industry and its potential market keep growing. As this issue of *The Lancet Neurology* went to press, Ned Sharpless, Director of the National Cancer Institute, was named FDA Acting Commissioner. Under this new leadership, the FDA must continue to implement the plans to strengthen the regulation of dietary supplements and protect neurological patients from vendors that profit by smoke and mirrors, and plain untruths. Physicians cannot cure dementia yet, but can provide symptomatic treatments and palliative care. They should also warn their patients of the illusions of pseudomedicine and its risks. Mounting evidence shows that low-cost lifestyle changes (exercise, a healthy diet, social engagement) are the best interventions to improve brain health and prevent cognitive decline—let's please spread the word. ■ *The Lancet Neurology*

US Food and Drug Administration

For more on the **FDA actions** see https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631064.htm

For **Scott Gottlieb's statement** see https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631065.htm

For more on the **reaction of the Alzheimer's disease community** see https://www.alzforum.org/news/community-news/dementia-researchers-commend-fda-crackdown-supplement-hype

For more on the **phase 3 trials of ginkgo biloba extract** see **Articles** *Lancet Neurol* 2012; **11:** 836–37

For the **National Cancer Opinion Survey** see https://www.asco.org/research-progress/reports-studies/national-cancer-opinion-survey

For more on **Quackery in cancer** see **Perspectives** *Lancet Oncol* 2019; **20:** 191–92

For reporting **adverse effects to the FDA** see https://www.fda.gov/food/dietarysupplements/reportadverseevent/

For more on **pseudomedicine** see *JAMA* 2019; **321:** 543–44

For more on **dementia prevalence** see **Articles** *Lancet Neurol* 2019; **18:** 88–106

For the **Alzheimer's Facts and Figures report** see https://www.alz.org/alzheimers-dementia/facts-figures

For more on **dementia prevention** see *The Lancet* **Commissions** 2017; **390:** 2673–734