

For the US FDA compliance guide on structure and function claims see <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-structurefunction-claims>

inpatient medical records for TBI is necessary for guaranteeing a high quality data source.

For guaranteeing the ability of the hospital quality-monitoring system to handle the high number of patients, which is essential when using hospital administrative data as a comprehensive data source, this monitoring system should be used in the majority of tertiary and secondary hospitals that admit the most cases of TBI. Also, it is important to propose new policies (similar to those reporting cancer diseases, infectious diseases, and maternal mortality) that make it mandatory to input TBI data in the system. We hope that the use of hospital administrative data to evaluate TBI will be feasible in the near future.

We declare no competing interests.

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The risks and uses of dietary supplements

Your Editorial¹ on “*The risks of ignoring scientific evidence*” did not clarify that the actions of the US Food and Drug Administration (FDA) do not strengthen regulations on dietary supplements or further protect patients from unsafe or ineffective supplements. The agency merely enforced the long-standing Dietary Supplement Health and Education Act of 1994 (DSHEA, Code of Federal Regulations title 21, parts 101 and 111), which regulates supplements and prohibits manufacturers from making illegal disease or health claims. They warned dietary-supplement manufacturers that they must comply with DSHEA, not make health claims about treating Alzheimer’s disease and dementia, and must restrict their advertising to

the allowed structure and function claims or claims of wellbeing. In effect, the FDA is protecting the marketers who follow the rules from those who do not.

US consumers will continue to face edgy advertisements that are allowed with DSHEA. Examples of advertisements that are likely to be familiar to elderly television viewers are those for unspecified components of jellyfish and silkworm cocoons, which purportedly “help mild memory loss associated with aging”, “improves memory”, “uniquely supports brain function”, or “keeps your mind sharp and your memory strong”. The advertisements that make these claims say nothing explicit about treating or preventing Alzheimer’s disease or dementia, which would be an illegal health claim, but the implication is clear. Nevertheless, these promotional statements are legal structure and function claims, that are permitted under DSHEA.

It is important to know that the FDA does not approve any dietary supplement or structure and function claim that might be associated with it. A manufacturer needs only to provide a basis for concluding that a certain supplement is expected to be safe, and to notify the FDA that a structure and function claim will be made. The manufacturer needs also to provide a disclaimer that the product is not intended to diagnose, treat, cure, or prevent any disease—often delivered at a low volume at the end of the commercials.

By merely enforcing DSHEA—ie, by regulating what a dietary supplement manufacturer can say about a product—the FDA does not protect the public as much as your readers might think. Rather, their enforcement actions protect the manufacturers so that they can fairly compete with each other on the basis of structure and function claims and of claims of general wellbeing, and suppress any temptation to skirt the law by making disease claims. Thus, television viewers

only have to sort out what “healthy brains” and “sharp minds” are, and not claims about dementia or Alzheimer’s disease.

For the FDA to protect the public from ineffective dietary supplements, DSHEA must be amended to require efficacy evidence for the proffered structure and function claims and claims of wellbeing. Making this amendment, however, requires taking on the dietary-supplement industry, which in turn requires an Act of Congress, for which the US Congress has no appetite.

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1 The Lancet Neurology. The risks of ignoring scientific evidence. *Lancet Neurol* 2019; 18: 415.

I am writing to comment on your Editorial about the risks of ignoring scientific evidence on dietary supplements.¹ While I support sanctioning the unscientific use of some dietary supplements, I wish to emphasise that accepted scientific evidence supports the use of several dietary supplements in medical conditions. For example, betaine and folic acid are effective at reducing hyperhomocysteinemia, an established risk factor for cardiovascular disease,² and Cochrane evidence shows that creatine can improve muscle strength in muscular dystrophies.³ By contrast, your Editorial risks casting an ominous shadow on all dietary supplements, and to discredit them within the medical community. While nobody can disagree with the need to avoid and denounce claims not supported by scientific evidence, we should be aware that dietary supplements have a role in the treatment of several neurological conditions, as in the aforementioned examples. As it is often the case,

For the FDA actions on dietary supplements see <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-new-efforts-strengthen-regulation-dietary>

For DSHEA, Code of Federal Regulations title 21, part 101 and 111 see <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=101> and <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm?cfrpart=111>

generalisation is dangerous, and we should not generalise from the correct criticism that the Editorial raises to discredit a branch of therapy that is often useful and even necessary in the armamentarium of the neurologist.

I am President and a founding member of NovaNeuro Srl, an academic spin-off that creates and commercialises creatine-based dietary supplements.

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- 1 The Lancet Neurology. The risks of ignoring scientific evidence. *Lancet Neurol* 2019; **18**: 415.
- 2 Kang S-S, Rosenson RS. Analytic approaches for the treatment of hyperhomocysteinemia and its impact on vascular disease. *Cardiovasc Drugs Ther* 2018; **32**: 233–40.
- 3 Kley RA, Tarnopolsky MA, Vorgerd M. Creatine for treating muscle disorders. *Cochrane Database Syst Rev* 2013; **6**: CD004760.