Basing regulation of commercial speech about pharmaceuticals on scientific evidence

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Regulation of commercial speech about pharmaceuticals should require informative content based on scientific evidence, not just formalistic truth.

Regulation of commercial speech about pharmaceuticals should be informed by the state of scientific evidence rather than mere formalistic truth, according to a Policy Forum article authored by Spencer Hey and Aaron Kesselheim from Harvard Medical School, Boston, USA, in this week's *PLOS Medicine*.

Hey and Kesselheim examined a lawsuit filed by Amarin Pharmaceutical in May 2015 that sought permission to distribute "truthful and non-misleading" statements relating to an off-label use of its product Vascepa, a pill derived from fish oil. While the United States Food and Drug Administration (FDA) generally does not permit pharmaceutical manufacturers to promote their products for non-FDA-approved ("off-label") indications, a federal court ruled, on the grounds of the First Amendment's protection of commercial speech, that Amarin had the right to make those statements. Faced with this adverse decision, the FDA on March 8 formally settled the case, relenting to Amarin's demands. Hey and Kesselheim argue that the court's reasoning was in error: The central claim that Amarin wished to distribute off-label was perhaps true as written, but was constructed in a strategic way to not impart any useful scientific information to physicians. Therefore, the authors argue, this statement is only likely to serve the company's economic interest on the presumption that it will be misinterpreted by

physicians.

The authors conclude that "informativeness," understood as asserting scientific facts—beyond mere logical truth—"ought to be the standard for regulating commercial speech about pharmaceuticals".

More information: Spencer Phillips Hey et al. An Uninformative Truth: The Logic of Amarin's Off-Label Promotion, *PLOS Medicine* (2016). DOI: 10.1371/journal.pmed.1001978