

Statement of Commissioner Christine S. Wilson
Concurring In Part and Dissenting in Part
FTC v. Neurometrix, Inc., et al.

File No. 1723130

February 28, 2020

Today the Commission authorizes staff to file a complaint and settlement against Neurometrix, Inc., and its founder, Chairman, President, and Chief Executive Officer Shai Gozani. The complaint alleges that Neurometrix and Gozani made false, misleading, and/or unsubstantiated advertising claims about their wearable transcutaneous electrical nerve stimulation devices (TENS), Quell and Quell 2.0.

I fully support the Commission’s enforcement efforts to challenge false, unsubstantiated, and misleading claims. Accurate and complete information contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and cause economic injury to consumers.

In this case, I concur with the allegation that defendants made unsubstantiated claims regarding Quell’s ability to achieve widespread pain relief, in areas of the body distant from the application site below the knee “by activating areas of the brain responsible for central inhibition of pain.” Complaint ¶ 27. I also concur with the allegation that defendants lacked substantiation for claims that Quell provides widespread relief from chronic or severe pain in areas of the body distant from the application site that fall outside spinal nerve and root segments. I dissent, though, to the extent that the complaint challenges all claims that the device can deliver non-localized pain relief and with respect to the allegation that the defendants falsely claimed that the devices were “FDA cleared” for widespread pain relief.

The Commission has long interpreted Section 5 of the FTC Act to require that advertisers have a reasonable basis for claims about their products. The Commission’s evaluation of the substantiation necessary to constitute a reasonable basis for a particular claim begins with consideration of the factors articulated in the *Pfizer* decision. These factors examine the type of claim and product coverage, the benefits of a truthful claim, the consequences of a false claim, and the type of evidence that experts in the field believe is reasonable to substantiate a claim.¹

My predecessors on the Commission and learned commentators have cautioned that, when evaluating an advertiser’s reasonable basis, the Commission must be careful not to impose an unduly high standard of substantiation that risks denying consumers useful information, diminishing incentives to conduct research, and chilling manufacturer incentives to introduce new products to the market.² As Former FTC Chairman Robert Pitofsky has noted, “the

¹ *Pfizer, Inc.*, 81 F.T.C. 23, 64 (1972).

² See, e.g., Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC v. Avrom Boris Lasarow, et al.* (Feb. 2015), <https://www.ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health>; Statement of Commissioner Joshua D. Wright, *FTC v. Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), <https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin>; Statement of

protection of consumers against advertising fraud should not be a broad, theoretical effort to achieve Truth, but rather a practical enterprise to ensure the existence of reliable data which in turn facilitate an efficient and reliable competitive market process.”³

The complaint in this matter challenges pain relief claims for a wearable device, Quell, “an over-the-counter [TENS] device, consisting of a flexible band that houses an electronic stimulator and four electrodes. Consumers wear the device around the upper calf, below the knee.” Complaint ¶ 11. The Complaint challenges defendants’ claims that Quell provides “widespread pain relief from chronic or severe pain, including pain experienced in areas of the body distant from the application site below the knee, such as in the lower back, shoulder, and opposite leg.” *Id.* at ¶ 27. The Complaint further challenges claims that Quell achieves this widespread pain relief “by activating areas of the brain responsible for the central inhibition of pain.” *Id.*

Considering the Commission’s allegations in light of the *Pfizer* factors is illuminating. Here, there is no allegation that the product is unsafe⁴ and the Complaint acknowledges that “TENS technology has been used for decades to relieve pain locally.” *Id.* at ¶ 10. The Complaint discusses the randomized controlled trials (RCTs) and other substantiation defendants proffered in support of their claims. *Id.* at ¶¶ 15-19. The Complaint alleges, however, that “neither RCTs on Quell (or on any substantially similar device with comparable dosing and placement), nor the entire body of relevant scientific literature, demonstrate that Quell is effective in relieving chronic and severe pain *beyond the site of application.*” Complaint ¶ 15 (italics added).

I agree with the Commission that the defendants did not possess adequate substantiation for the claim that Quell provides widespread pain relief by activating areas of the brain responsible for the central inhibition of pain. I also concur with the conclusion that the substantiation did not establish Quell’s efficacy for pain relief in *all* areas distant from the device application site, as claimed in the challenged advertising. In my view, though, the body of relevant scientific literature and other evidence before the Commission provides a reasonable basis for a claim that TENS devices can provide some non-localized pain relief, *i.e.*, to certain zones or areas of the body within spinal nerve and root segments.

Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), <https://www.ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru>; Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), <https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part>; Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC v. Springtech 77376, et al.* (July 2013), <https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen>; *see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12-49 (May 2012), available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776

³ Robert Pitofsky, Beyond Nader: Consumer Protection and the Regulation of Advertising, 90 Harv. L. Rev. 661, 681-83 (1977).

⁴ The Complaint notes that defendants’ device was cleared by the FDA for localized pain relief based its equivalency to substantially similar predicate devices. Complaint ¶ 22.

The Complaint also alleges that the defendants falsely claimed the FDA cleared Quell for use for widespread pain relief, as well as other uses challenged in Count I of the Complaint. Complaint ¶ 33. The Commission acknowledges in the Complaint that “the FDA has cleared Quell for use as a TENS device to relieve [localized] pain.” Complaint ¶ 22. In addition, it is not disputed that the FDA cleared Quell for overnight use, a feature not available on other TENS devices. The Complaint asserts, however, that because the “FDA has not cleared Quell for use providing widespread relief of chronic or severe pain that is experienced beyond the site of application,” defendants’ use of the phrase “FDA cleared” constitutes a false claim. But the Commission does not cite evidence in the Complaint to support the assertion that consumers interpreted the “FDA cleared” phrase in the advertising to apply to the widespread pain relief claims. And, based on the evidence presented to me, I do not have a sufficient reason to believe that a reasonable consumer would reach this net impression.

I question whether our evaluation in this matter crossed the line from ensuring the existence of reliable data for advertising claims to a quest for “Truth.” This case is unlike other advertising substantiation cases I have reviewed in my time as a Commissioner that involved disease claims for which the scientific evidence was either completely lacking or woefully deficient.⁵ Here, the defendants commissioned RCTs and relied on an existing body of literature evaluating TENS devices for pain relief.

In the midst of the opioid crisis, consumers are rightly seeking drug-free alternatives. Imposing on marketers a substantiation standard higher than needed to support advertising claims can chill the dissemination of useful information and thwart the efforts of consumers to find feasible alternatives to addictive prescription pain medicines. The FTC’s balancing of these considerations in its evaluation of Kellogg’s marketing campaign for its high fiber cereal in 1984 is instructive here. Although then-Food & Drug Administration (FDA) rules considered such claims to constitute drug claims requiring approval, Kellogg developed the claims based on National Cancer Institute recommendations that diets higher in fiber could reduce the risks of some kinds of cancer.⁶ The Commission declined to challenge the claims, despite the fact that Kellogg lacked the level of substantiation that the FDA required, because it concluded that consumers and the market benefitted from the dissemination of this information.⁷

⁵ See, e.g., *FTC v. Quantum Wellness Botanical Institute, LLC*, No. 172-3131 (Feb. 2020) (supplement that purportedly stimulated the production of HGH and stem cells that reversed the aging process and treated heart attack damage, brain damage, blindness, and deafness), <https://www.ftc.gov/enforcement/cases-proceedings/172-3131/quantum-wellness-botanical-institute-llc>; *FTC v. Nobetes Corp.*, No. 172-3119 (Aug. 2019) (pill that defendants claimed treated diabetes), <https://www.ftc.gov/enforcement/cases-proceedings/172-3119/nobetes-corp>; *FTC v. Regenerative Medical Group, Inc.*, No. 172-3062 (Apr. 2019) (clinic offering “amniotic stem cell therapy” that purportedly treated Parkinson’s disease, autism macular degeneration, cerebral palsy, multiple sclerosis, and heart attacks), <https://www.ftc.gov/news-events/press-releases/2018/10/ftc-stops-deceptive-health-claims-stem-cell-therapy-clinic>; See also J. Howard Beales III and Timothy J. Muris, Striking the Proper Balance: Redress Under Section 13(b) of the FTC Act, George Mason University Law & Economics Research Paper No. 16-17 (2013) (discussing past FTC advertising substantiation cases challenging strong health or disease claims backed by little to no scientific research), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2764456.

⁶ See Beales and Muris, In Defense of the *Pfizer* Factors, *supra* n. 1 at 1-2 (describing the Kellogg campaign).

⁷ *Id.* at 2.

I respectfully submit that the Commission should focus our scarce resources on marketers that make serious health and disease claims with little to no scientific support. And I encourage the Commission in future cases to give careful weight and consideration to all evidence submitted in support of claims, including emerging science, trends, and real world consumer data. Finally, I note that when deciding whether to take enforcement action, we must balance the risks of chilling research, innovation, and the dissemination of useful information against the potential benefits of enforcement.