

# Pain Point: FTC Settles With Pain Relief Marketer For \$4 Million

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The [FTC](#) announced a settlement with NeuroMetrix, Inc., and its CEO, Shai Gozani, relative to allegations that the marketers made deceptive pain relief claims on a medical device called Quell. Quell is an FDA-cleared transcutaneous electrical nerve stimulation device (TENS) – which provides pain relief through the use of mild electrical signals.

The FTC [alleged](#) that the defendants marketed Quell, intended to be worn just below the knee, as “clinically proven” to provide “widespread chronic pain relief” throughout the body. The advertising included claims that the device sends neural pulses to the brain, triggering a natural response that blocks pain signals in the body. Some ads also referenced users being able to discontinue use of pain medications because of the benefit they received from Quell.

The FTC alleged that the defendants lacked scientific evidence to support widespread chronic pain relief claims. Further, although the product is FDA-cleared to provide localized pain relief, the FTC alleged that it was not FDA-cleared to provide pain relief throughout the body.

In addition to injunctive relief, the settlement requires the defendants to pay \$4 Million and requires them to turn over up to an additional \$4.5 million in future foreign licensing payments. Ouch.

***So, what's the takeaway?*** There is no question that Quell is an FDA-cleared medical device based on recognized pain relief technology. Further, it appears that the defendants conducted clinical studies to test effectiveness of their product. But, the core of the FTC’s complaint is that by claiming that the device could be worn below the knee but provide relief from chronic pain throughout the body, Quell simply went beyond their FDA clearance, and beyond the limits of their scientific substantiation.

This is a departure from the more recent health claims enforcement we’ve seen from the FTC over the past few years. Quell has a recognized benefit and is supported by clinical research. Commissioner Wilson’s [statement](#) acknowledges this and questions whether the Commission has gone too far in this case, potentially stifling innovation. However, as the country struggles to recover from the opioid crisis and consumers search for effective alternatives, marketers of pain relief products should take note that the FTC is watching not just for products that provide no relief, but also for those that promise relief beyond what they can actually provide.