

Another Lawsuit To Suppress Legitimate Criticism – This Time SBM

[Steven Novella](#) on July 23, 2014



I suppose it was inevitable. In fact, I'm a bit surprised it took this long. SGU Productions, the Society for Science-based medicine, and I [are being sued](#) for an [article that I wrote in May of 2013 on Science-Based Medicine](#). My SBM piece, which was inspired by an article in the *LA Times*, gave this summary:

The story revolves around Dr. Edward Tobinick and his practice of perispinal etanercept (Enbrel) for a long and apparently growing list of conditions. Enbrel is an FDA-approved drug for the treatment of severe rheumatoid arthritis. It works by inhibiting tumor necrosis factor (TNF), which is a group of cytokines that are part of the immune system and cause cell death. Enbrel, therefore, can be a powerful anti-inflammatory drug. Tobinick is using Enbrel for many off-label indications, one of which is Alzheimer's disease (the focus of the *LA Times* story).

The claims and practice of Dr. Tobinick have many of the red flags of a dubious medical practice, of the sort that we discuss regularly on SBM. It seems that Dr. Tobinick does not appreciate public criticism of his claims and practice, and he wants me to remove the post from SBM. In my opinion he is using legal thuggery in an attempt to intimidate me and silence my free speech because he finds its content inconvenient.

Of course, we have no intention of removing the post as we feel it is critical to the public's interest. This is what we do at SBM – provide an objective analysis of questionable or controversial medical claims so that consumers can make more informed decisions, and to advance the state of science in medicine.

We also feel it is critical not to cave to this type of intimidation. If we do, we might as well close up shop (which I suspect the Tobinicks of the world would find agreeable). Defending against even a frivolous lawsuit can be quite expensive, but we feel it is necessary for us to fight as hard as we can to defend our rights and the work that we do here at SBM.

An interesting wrinkle of this suit is that Tobinick is claiming that my blog post is an "advertisement." This is a legal maneuver as the threshold for forcing someone to remove an advertisement is much lower than the threshold for suppressing their free speech. I can only assume that he and his attorneys are not bothered by the fact that blog posts on SBM are blatantly not advertisements.

In the case of the Enbrel article he had to make the absurd claim that the post (which does not mention my own practice) was an advertisement for my neurology practice at Yale, designed to attack a "competitor." He would have us believe that Yale neurology in Connecticut is concerned about a distant clinic. Further, Yale Neurology is an academic practice. Our problem is too many referrals and long wait times, not competitors. To see how desperate the claim is, he argued that because I use Botox, which can be used to treat symptoms following stroke, that his treatments for stroke represent a competitor. However, I don't use Botox to treat stroke patients. I mostly use it to treat migraines, as I am a headache specialist.

Perhaps he feels that my 18-year career promoting science, critical thinking, and science-based medicine is just a cover so I can occasionally attack distant tangential "competitors."

In any case, the fight is on. Here is a review of the salient points of my criticism of Tobinick:

Tobinick is not a neurologist, and yet he feels it is appropriate for him to treat multiple neurological conditions with an experimental treatment. It is generally considered unethical for physicians to practice outside of their area of competence and expertise. He is trained in internal medicine and dermatology and is certified in those specialties. He has never completed a neurology residency nor is he board certified in neurology.

Despite his lack of formal training and certification, he feels he has ushered in a “paradigm shift” in the treatment of Alzheimer’s disease – a disease that has proved challenging for actual neurologists for decades.

His treatment of choice is perispinal etanercept (Enbrel), which basically is an immunosuppressant drug. He is using this treatment for not only Alzheimer’s disease, but neurological deficits following stroke, traumatic brain injury, and pain resulting from vertebral discs. He therefore claims that the neurological deficits in these various conditions result from active inflammation (specifically tumor necrosis factor – TNF) and by inhibiting TNF “rapid improvement” in neurological function is possible.

These claims are highly implausible, and in my opinion reflect his lack of training and expertise as a neurologist. Strokes cause ischemic damage to the brain – brain cells in severe stroke die. Inflammation following stroke is incidental, not causative. Yet Tobinick claims that 10 years following a stroke, long after any neurological recovery would have occurred, patients can improve by inhibiting TNF.

He makes the same claim for Alzheimer’s disease, despite the fact that this is a neurodegenerative disease resulting in loss and destruction of brain cells. An anti-inflammatory drug is not going to bring back dead brain cells, yet he claims “rapid improvement” is possible.

The simplest explanation for the apparent response to his treatments is simply placebo effects. Stroke neurologists, for example, are acutely aware of the so-called “cheerleader” effect. Take a patient with chronic deficits, get them off the couch, give them any treatment and tell them it will make them better, and they will likely demonstrate increased functionality simply because they are making an effort they had not made for a while.

The only way to really know if the treatment itself is having any neurological benefit is with careful double-blind placebo-controlled clinical trials. Tobinick, however, has not produced such evidence. He has a long list of publications – all case series, observational studies, pilot studies, case reports, and reviews. I could not find a single double-blind placebo-controlled trial establishing the efficacy of his treatment for any of the conditions I listed above. (There are small studies for disc herniation showing conflicting results.)

At best his treatment should be considered experimental. I think the plausibility of the effects he is claiming is extremely low. It’s possible that an anti-TNF effect may be of some use, but given the type of evidence we have it is likely we are seeing mostly (if not completely) placebo effects.

Despite the preliminary nature of his evidence, the “paradigm shift” such claims would represent, and his lack of formal training in neurology, Tobinick has obtained [a number of use patents](#) for his treatments. Use patents for medical procedures are still legal in the US, although they have been banned in many other countries, and many consider them unethical. [The AMA has this to say:](#)

The intentional withholding of new medical knowledge, skills, and techniques from colleagues for reasons of personal gain is detrimental to the medical profession and to society and is to be condemned.

The case highlighted in the *LA Times* story involved Ken Chiate, who brought his wife who was suffering from Alzheimer’s disease to Tobinick’s clinic for 165 injections of Enbrel over four years, at a cost of \$800 each (that’s \$132,000). During that time there were questionable subjective effects from the treatment, typical of placebo-only effects. Meanwhile his wife’s condition continued to relentlessly progress, as is typical of the disease, until she finally died in 2011.

I am not the only one to have concerns about Tobinick’s practices. The Medical Board of California filed an accusation in 2004, amended in 2005 and 2006, [stating](#):

- From about 2000 to 2002, Tobinick, owned and operated a medical practice under the name “Institute for Neurological Research” in Los Angeles and Newport Beach.
- During those years, Tobinick promoted and advertised a new off-label use for an FDA-approved drug, etanercept (Enbrel). He referred to his drug as DiskCure® [sic] and advertised it as “a new and innovative approach for back or neck pain without surgery,” and as a “breakthrough” in the treatment of disc-related back and neck pain.
- Enbrel is a genetically engineered protein and immune response modifier approved by the FDA for treating several types of arthritis but not for back pain. Tobinick’s treatment involved injecting it near the spine.
- Until May 2002, there had been no published, peer-reviewed, scientific studies showing the effectiveness of the treatment for back pain in humans. Nor had there been an approved, pending, or investigational drug application for this use of etanercept.
- Tobinick’s advertisements for DiskCure constituted unprofessional conduct under the California Business and Professions Code.
- Tobinick had also failed to obtain a fictitious name permit for the Institute for Neurological Research as required by law.

Tobinick agreed to serve one year on probation during which he was required to complete courses in ethics and prescribing practices and have his practice monitored by another physician or complete a professional enhancement program.

But now he is not only up to his old tricks, but he has greatly expanded the scope of his Enbrel claims and practice. He has his own “Institute for Neurological Recovery” in which he shows videos of select patients to promote his patented treatments.

This is all, unfortunately, a far too common pattern, one with which we at SBM are very familiar. There is definitely a need here to provide critical analysis of such extraordinary medical claims. That means, also unfortunately, that we will occasionally need to spend our time and resources defending our right to do so.

- Posted in: [Announcements](#), [Legal](#)
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Posted by Steven Novella

Founder and currently Executive Editor of Science-Based Medicine **Steven Novella, MD** is an academic clinical neurologist at the Yale University School of Medicine. He is also the president and co-founder of the [New England Skeptical Society](#), the host and producer of the popular weekly science podcast, [The Skeptics' Guide to the Universe](#), and the author of the [NeuroLogicaBlog](#), a daily blog that covers news and issues in neuroscience, but also general science, scientific skepticism, philosophy of science, critical thinking, and the intersection of science with the media and society. Dr. Novella also contributes every Sunday to [The Rogues Gallery](#), the official blog of the SGU.

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