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# THE FIRST AMENDMENT: NOT ONE SIZE FITS ALL

*Caroline Poplin\**

## INTRODUCTION

In the last twenty years or so, the Republican conservatives on the U.S. Supreme Court have relished overturning settled constitutional doctrine, particularly to benefit corporations at the expense of their customers, workers, investors, and ordinary people in general. The First Amendment has been one of their favorite tools.

The poster case for this successful effort is, of course, *Citizens United*, where the court majority overturned restrictions on corporate campaign contributions that had stood for almost a century.<sup>1</sup>

Less well known, but still important, the Court has challenged the traditional restriction of First Amendment protection to political speech, and extended constitutional protection to “commercial speech”, speech—such as advertising—by a business to promote a product to make money.<sup>2</sup> Or maybe the product itself is speech, or data. Speech is speech, the Court seems to say, and as long as it is truthful and not misleading, maybe there are people who want to listen and learn. The Supreme Court case is *Sorrel v. IMS Health* 131 S. Ct. 2653 (2011).

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<sup>1</sup> *Citizens United v. Fed. Election Comm’n*, 558 U.S. 310, 318–19 (2010).

<sup>2</sup> *Sorrel v. IMS Health*, 131 S. Ct. 2653, 2672–74, 2677 (2011).

In 2010, the Second Circuit went the Supreme Court one better, in *United States v. Caronia*, 703 F.3d 149 (2nd Cir. 2012).<sup>3</sup> The case involved a pharmaceutical salesman, Alfred Caronia, who promoted Xyrem, a drug approved by the Federal Drug Administration (FDA) only for cataplexy in narcolepsy, and excessive daytime sleepiness in narcolepsy.<sup>4</sup> Caronia was recorded telling a physician that Xyrem could be used for insomnia, fibromyalgia [a common but not well-understood pain syndrome], Parkinson's disease, chronic fatigue, obesity and other common problems.<sup>5</sup> Also that neurologists use it for children between eight and ten, and patients over 65.<sup>6</sup> "It's a very safe drug," said Mr. Caronia.<sup>7</sup> The FDA prosecuted the salesman for "misbranding", the conviction was upheld by the District Court, and overturned by the Second Circuit.<sup>8</sup>

Speech, written or other material promoting a drug for a use not approved by the FDA, has always been considered good evidence of "misbranding," so prohibited by the Food, Drug and Cosmetic Act (FDCA).<sup>9</sup> As "commercial speech," such promotion had never been entitled to any special protection: large pharmaceutical companies have paid billions of dollars in fines in recent years to settle Federal government allegations of misbranding evidenced by off-label marketing.<sup>10</sup> Nevertheless, in *Caronia* the Second Circuit held that the drug representative's promotion of off-label uses of Xyrem was now protected by the First Amendment as long as it was "truthful and not misleading".<sup>11</sup>

In August 2015, a judge in the Southern District of New York, following what he called "[the] modern First Amendment law" as set out by the Second Circuit in *Caronia*, upheld pharmaceutical manufacturer Amarin's constitutional right to promote its drug, Vascepta, for an off-label use,<sup>12</sup> since it

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<sup>3</sup> *United States v. Caronia*, 703 F.3d 149 (2nd Cir. 2012).

<sup>4</sup> *Id.* at 152, 155.

<sup>5</sup> *Id.* at 157, 171.

<sup>6</sup> *Id.* at 157.

<sup>7</sup> *Id.* at 156–57.

<sup>8</sup> *Id.* at 152.

<sup>9</sup> *See generally*, 21 U.S.C. § 331 (2012) (stating that the adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce is prohibited).

<sup>10</sup> *See* Lena Groeger, *Big Pharma's Big Fines*, PROPUBLICA (Feb. 24, 2014), <http://projects.propublica.org/graphics/bigpharma>.

<sup>11</sup> *Caronia*, 703 F.3d at 175.

<sup>12</sup> *Amarin Pharma Inc. v. U.S. Food and Drug Admin.*, No. 15-03588, 2015 U.S. Dist. LEXIS 103944, at \*80 (S.D.N.Y. 2015).

found that Amarin’s message was “truthful and non-misleading.”<sup>13</sup> Judge Engelmeyer noted in passing how common—and important—off-label use of drugs is: “And the therapeutic—indeed, sometimes life-saving—value of off-label uses of FDA approved drugs has been widely recognized.”<sup>14</sup> He apparently finds this sweeping proposition so intuitively obvious he offers no support for it.

One more point to keep in mind. Congress, the FDA and Department of Justice (DOJ) have always been clear that nothing in the FDCA, from its original passage in 1906 to the present day, constrains in any way a licensed physician’s right and responsibility to prescribe any drug legitimately on the market for any condition he or she thinks appropriate.<sup>15</sup> The Second Circuit uses this, though, as an argument to support off-label marketing—it helps ‘educate’ the physicians.<sup>16</sup>

Nevertheless, these decisions have caused great consternation in the medical community: anxious editorials have appeared in JAMA,<sup>17</sup> the New England Journal of Medicine,<sup>18</sup> and the Annals of Internal Medicine.<sup>19</sup>

Were the statements by Alfred Caronia about Xyrem, and later by Amarin about Vascepta, in fact “truthful and non-misleading”?

## I. SOME BACKGROUND

The story of medicinal pills, powders, and potions is colorful, and doubtless goes back to the beginning of human history. Sick people are desperate and vulnerable, they want to be cured, many will try anything. In the U.S., the market has always responded: in the nineteenth century, the wild west

<sup>13</sup> *Id.* at \*2.

<sup>14</sup> *Id.* at \*6.

<sup>15</sup> See Monique C.M. Leahy, Off-Label Use of Prescription Medications § 1, 124 Am. Jur. Trials 487, (2012) (stating that the off-label use of drugs approved by the FDA generally comports with the FDCA).

<sup>16</sup> See *Caronia*, 703 F.3d at 166 (stating that “prohibiting off-label promotion by a pharmaceutical manufacturer. . . interferes with the ability of physicians to receive potentially relevant treatment information” and that “such barriers to information about off-label use could inhibit, to the public’s detriment, informed and intelligent treatment decisions.”).

<sup>17</sup> Joshua M. Sharfstein & Alta Charo, *The Promotion of Medical Products in the 21st Century: Off-label Marketing and First Amendment Concerns*, JAMA (Nov. 3, 2015), <http://jama.jamanetwork.com/article.aspx?articleid=2442407&resultClick=1>.

<sup>18</sup> Jerry Avorn et al, *Forbidden and Permitted Statements about Medications—Loosening the Rules*, NEW ENG. J. MED. (Sep. 3, 2015), <http://www.nejm.org/doi/full/10.1056/NEJMhle1506365>.

<sup>19</sup> Jerry Avorn, *In Opposition to Liberty: We Need a “Sovereign” to Govern Drug Claims*, ANNALS OF INTERNAL MEDICINE (Aug. 2015), <http://annals.org/article.aspx?articleid=2375121&resultClick=1>.

was not just along the frontier. All kinds of concoctions were peddled as miracle cures: this is when the term “snake oil” became a synonym for a product fraudulently offered as a cure-all. Many of these drugs were ineffective, some were dangerous: Mrs. Winslow’s Soothing Syrup, for example, sold to comfort crying babies, was compounded with morphine.<sup>20</sup>

The first national law to protect consumers from such practices, the Pure Food and Drug Act of 1906, required that the active ingredients of medicinal compounds be listed on the label, and meet purity standards.<sup>21</sup> Each major subsequent revision of the law was passed in the wake of a preventable tragedy.<sup>22</sup>

In 1937, to make a liquid preparation of the early antibiotic sulfanilamide, Massengill, a pharmaceutical manufacturer, dissolved the chemical in the solvent diethylene glycol. You might know a closely related compound, ethylene glycol, a potent human toxin used today for antifreeze. Massengill checked its product for appearance, taste and fragrance, but not for safety—that was not required by the 1906 law.<sup>23</sup> In short order, over 100 people died, including 35 children.<sup>24</sup> Congress quickly amended the law in 1938 to require manufacturers to demonstrate the safety of their drugs to the FDA before they could legally market them.<sup>25</sup>

In 1962, Congress tightened the FDCA again,<sup>26</sup> this time in response to the thalidomide disaster, which readers of a certain age will remember well: thalidomide, a non-barbiturate sedative, was thought to be so safe it was marketed over the counter in Europe to everyone, including pregnant women for morning sickness. It was widely taken up. As the world found out to its

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<sup>20</sup> *Mrs. Winslow’s Soothing Syrup*, THE WOOD LIBRARY MUSEUM, <http://www.woodlibrarymuseum.org/museum/item/529/mrs.-winslow’s-soothing-syrup> (last visited Feb. 6, 2016).

<sup>21</sup> See *Federal Food and Drugs Act of 1906: Regulatory Information*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/ucm148690.htm> (last updated May 20, 2009) (stating the act was enacted by Senate and the House of Representatives).

<sup>22</sup> Regulatory Information: *Legislation*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/RegulatoryInformation/Legislation/> (last updated July 7, 2015).

<sup>23</sup> See Wood Library Museum, *supra* note 22 (detailing the requirements of the Federal Food and Drugs Act of 1906).

<sup>24</sup> Carol Ballentine, *Taste of Raspberries, Taste of Death, The 1937 Elixir Sulfanilamide Incident*, FDA.GOV (June 1981), <http://www.fda.gov/aboutfda/whatwedo/history/productregulation/sulfanilamidedisaster/default.htm>.

<sup>25</sup> See *supra* Wood Library Museum, note 22.

<sup>26</sup> Michelle Meadows, *About FDA: Promoting Safe and Effective Drugs for 100 Years*, FDA.GOV (Feb. 2006), <http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsfor100Years/>.

horror, however, thalidomide is a potent teratogen: more than 10,000 children were born with serious, often fatal, birth defects before the drug was taken off the market. (A determined FDA officer, Francis Kelsey, kept it out of the U.S.)<sup>27</sup> Within the year, Congress amended the FDCA to require manufacturers to demonstrate safety and effectiveness, based on adequate and well-controlled clinical studies, conducted by qualified experts, to the FDA *for each use* for which they planned to market a drug.<sup>28</sup>

Congress understood that just because a drug was safe and effective for one condition did not mean it was safe and effective for a different one. To give a notorious recent example, the FDA found a powerful anti-psychotic, Risperdal, safe and effective for schizophrenia (its first indication), under certain conditions for Bipolar I disorder, and for irritability associated with autistic disorder.<sup>29</sup> It is not, however, safe and effective for dementia-related psychosis, even though it was widely marketed and prescribed for that purpose: patients died.<sup>30</sup> DOJ prosecuted Johnson & Johnson for illegal off-label marketing; the FDA added a black box warning against this use to the label for Risperdal.<sup>31</sup>

Therefore, Congress designed the 1962 amendments—in particular, the definition of a “new drug”—explicitly to prevent a sponsor from getting a new drug on the market for an easy, narrow indication, then marketing it off-label for wider, more lucrative, but more problematic, uses. Senator Kefauver, a sponsor of the amendments, noted that if a manufacturer were not required to demonstrate safety and effectiveness for each use, “the expectation would be that the initial claims would be quite limited.” However, once the drug received its initial approval, “the sky would be the limit and extreme claims of any kind could be made. . . .”<sup>32</sup>

## II. MODERN MEDICINE

Starting in the years after World War II, and accelerating with passage of Medicare, American medicine has undergone tremendous transformation and

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<sup>27</sup> Marilyn T. Miller & Kerstin K. Strömmland, *What can we learn from the thalidomide experience: an ophthalmologic perspective*, U.S. NAT'L LIBRARY OF MED. (July 17, 2013), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3713624/>.

<sup>28</sup> *Id.*

<sup>29</sup> *Risperdal Black Box Warning*, YOUR HEALTH ALERT, <http://www.yourhealthalert.com/risperdal/black-box-warning/>.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> S. Rep. No. 87-1774 (1962), as reprinted in 1962 U.S.C.C.A.N. 2884, 2901-2903.

expansion. Scientists developed whole new classes of more powerful and better targeted drugs, new laboratory tests and imaging equipment, more detailed understanding of the physiology of health and disease down to the molecular and genetic level. At the same time, scientists and physicians developed appreciation for what has come to be called “evidence-based medicine” and in particular, the importance of randomized, controlled clinical trials (RCTs).

When a doctor prescribes a new medication for a very sick patient, and the patient dies, the doctor has no way of knowing whether the patient died from the disease or the medication—there is almost nothing in medicine that is 100%. If the patient recovers, it may be the effect of the medication, or the condition resolved spontaneously, as many do. That’s why clinical trials need decent numbers of subjects—and a control arm.

Far more often than we expected, treatments that seemed logical, intuitive even, turned out to be ineffective, even dangerous. For example, physicians assumed for many years that because premenopausal women suffered fewer heart attacks than men of the same age (the women caught up after menopause), female hormone replacement therapy would continue to protect women after menopause. The Women’s Health Initiative, three randomized controlled trials including more than 27,000 women, launched by the National Institution of Health (NIH) in 1991, showed that it did not.<sup>33</sup> In fact, the women on replacement therapy slightly suffered *more* heart attacks, strokes and breast cancer than the women who took nothing.<sup>34</sup> Hormone replacement therapy also failed to prevent Alzheimer’s disease or colon cancer.<sup>35</sup> Earlier clinical guidelines recommending hormone replacement for most women were reversed within the year.

Conversely, as one Dr. Sinak noted, “The best way to improve the outcome of a therapeutical trial is to leave out the controls.”<sup>36</sup>

Or, as another article put it:

Evidence-based medicine requires a critical appraisal of the literature based upon study methodology and number of subjects. Not all

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<sup>33</sup> *Questions and Answers about the WHI Postmenopausal Hormone Therapy Trials*, WOMEN’S HEALTH INITIATIVE (April 2004), [https://www.nhlbi.nih.gov/whi/whi\\_faqs.htm](https://www.nhlbi.nih.gov/whi/whi_faqs.htm).

<sup>34</sup> *Id.*

<sup>35</sup> *Id.*

<sup>36</sup> Ulrich Trohler, *A Very Short History of Evidence Based Medicine*, SLIDESHARE (April 2, 2008), <http://www.slideshare.net/Cochrane.Collaboration/troehler-symposium>.

references are equally robust. The findings of a large, prospective, randomized and blinded trial should carry more weight than a case report.<sup>37</sup>

### III. THE NEW BUSINESS MODEL

As American medicine became much better, it also became much bigger: Health care now accounts for about 17% of U.S. Gross Domestic Product (GDP).<sup>38</sup> Pharmaceutical manufacturing in particular flourished, producing thousands of new, powerful compounds: it is the most profitable sector in health care. Since the 1990's in particular, Wall Street has taken notice, and financial considerations now drive the operation of the pharmaceutical industry: the second largest corporate merger of all time is now planned between two pharmaceutical manufacturers, Pfizer and Allergan, to create the largest pharmaceutical company in the world. The deal is said to be worth \$160 billion.<sup>39</sup>

In particular, the business model of the pharmaceutical industry is now geared to Wall Street expectations. Financiers demand huge and increasing profits, blockbuster drugs, each and every year: they punish the stock of those companies that don't produce. Since the markets for individual diseases—other than hypertension and high cholesterol—are rarely big enough to generate Wall Street-scale profits, most of the pharmaceutical companies do exactly what Senator Kefauver tried to prevent in 1962: they get a drug on the market for one or two indications, based on legitimate, randomized controlled trials scrutinized and approved by experts at the FDA—then aggressively market the new drug off-label for other, more common diseases, based on, perhaps, some small clinical trials without controls, “expert” opinion, a case report or two, or maybe nothing at all, just as in the old days before 1962.

This is not just about hiring sales representatives like Alfred Caronia. The large pharmaceutical manufacturers shape the ostensibly independent medical reference literature that clinicians rely on: the pharmaceutical firms engage international medical “communications companies”, like Excerpta Medica,

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<sup>37</sup> Christopher B. Willoughby, *Complications Of Acute Coronary Syndromes: References*, E.B. MEDICINE (Dec. 29, 2015, 3:07 PM), [http://www.ebmedicine.net/topics.php?action=showTopicSeg&topic\\_id=287&seg\\_id=5396](http://www.ebmedicine.net/topics.php?action=showTopicSeg&topic_id=287&seg_id=5396).

<sup>38</sup> *Health expenditure, total (% of GDP)*, THE WORLD BANK, <http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS> (last visited Jan. 29, 2016).

<sup>39</sup> Jackie Wattles & Heather Long, *Pfizer and Allergan combine in Biggest Drug Merger Ever*, CNN MONEY (Nov. 23 2015), <http://money.cnn.com/2015/11/23/investing/pfizer-allergan-merger/>.

which was owned by giant scientific publisher Elsevier, to design and develop study protocols likely to produce favorable outcomes for the off-label uses, to cherry-pick the data, write puff-pieces, pay co-operative academic authors, in general, create market “buzz” as if they were selling smart phones. At the same time, the manufacturers try to suppress unfavorable information, from clinical trials and elsewhere.

In this way, they try to bootstrap their way onto the market. Once enough physicians have prescribed their medication for the new use, the pharmaceutical company will claim it is standard of care, it becomes difficult to recruit patients for randomized trials, and it will take an independent body like the NIH to prove, with a randomized controlled trial, that the drug is actually ineffective or harmful.

Why is this a problem? A smart phone, or a faulty dishwasher, won’t kill a customer: the wrong medication, prescribed to the wrong patient for the wrong disease, just might, as thalidomide (and no doubt Mrs. Wright’s Soothing Syrup, full of morphine) did in the past.

In a long form article in the *Huffington Post*, Steve Brill recounts how Johnson & Johnson used all these techniques to market Risperdal, a potent anti-psychotic designed to treat schizophrenia, to children for disruptive behavior, and elderly demented people in nursing homes for agitation.<sup>40</sup> The company made billions of dollars, Wall Street cheered, but hundreds of unknowing, non-schizophrenic patients suffered serious, irreversible adverse side effects, including death.

#### IV. *CARONIA* AND *AMARIN*, REVISITED

I will leave to others the questions of whether corporations should have the same right to free speech as ordinary mortals, and whether commercial advertising should be protected like traditional political speech. However, the *Caronia*<sup>41</sup> and *Amarin*<sup>42</sup> cases themselves demonstrate why it is important for experts at the FDA to carefully regulate sales messages from pharmaceutical manufacturers about their products, First Amendment “rights” notwithstanding.

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<sup>40</sup> Steve Brill, *America’s Most Admired Lawbreaker*, HUFFINGTON POST: HIGHLINE, <http://highline.huffingtonpost.com/miracleindustry/americas-most-admired-lawbreaker/> (last visited Jan. 29, 2016).

<sup>41</sup> *Caronia*, 703 F.3d at 149.

<sup>42</sup> *Amarin Pharma Inc.*, 2015 U.S. Dist. LEXIS 103944, at \*2.

Jazz Pharmaceutical followed the by now well-worn path to commercial success. It succeeded in getting a limited indication for Xyrem from the FDA. (In 2010, the agency turned down Jazz’s subsequent application for use in fibromyalgia, based on some problems with its clinical trial and overwhelming opposition—20 to 2—from the FDA outside Advisory Committee.)<sup>43</sup> Jazz hired sales reps and assigned them sales quotas that could not possibly be satisfied in the on-label market: there were not enough patients in the sales territories with narcolepsy with excessive daytime sleepiness or cataplexy.

So what does Mr. Caronia say about Xyrem? “It’s a very safe drug.”<sup>44</sup> This, despite the fact that GHB, the date-rape drug of which Xyrem is the sodium salt, is classified by the U.S. Drug Enforcement Agency as Schedule 1, no appropriate use, along with drugs like heroin.<sup>45</sup> Xyrem is now legitimately on the U.S. market, for narcolepsy, but safe? From the start, it has carried a black box warning, the strongest warning the FDA can issue, reminding doctors and patients that even at recommended doses, it can cause confusion, depression, neuropsychiatric events, and respiratory depression.<sup>46</sup> At higher doses, especially in combination with alcohol, or dozens of other drugs, Xyrem can cause seizures, coma and death.<sup>47</sup> It is addictive: withdrawal symptoms can be severe.<sup>48</sup> It is so dangerous it can only be prescribed within a strict risk management system.<sup>49</sup> If Xyrem is safe, it is hard to imagine a drug the Second Circuit would find dangerous. I doubt most people would consider “it’s a very safe drug” a truthful and non-misleading statement.

Mr. Caronia goes on to suggest that Xyrem is useful for such common conditions as Parkinson’s disease, even though these patients are generally on a complicated regimen of other central nervous system (CNS) medications, fibromyalgia, chronic pain, chronic fatigue syndrome, insomnia and weight loss.<sup>50</sup> But how do we know these assertions are truthful and non-misleading? Evidence-based medicine tells us that scattered anecdotes provide no useful

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<sup>43</sup> *Summary Minutes of the Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee*, FDA.GOV (Sept. 13, 2010), <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ArthritisAdvisoryCommittee/UCM227134.pdf>.

<sup>44</sup> *Caronia*, 703 F.3d at 157.

<sup>45</sup> *Drug Fact Sheet: GHB*, DEA.GOV, [http://www.dea.gov/druginfo/drug\\_data\\_sheets/GHB.pdf](http://www.dea.gov/druginfo/drug_data_sheets/GHB.pdf).

<sup>46</sup> *Id.*

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Xyrem Risk Management Program*, FDA, [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2002/211961bl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/211961bl.pdf) (last visited Jan. 29, 2016).

<sup>50</sup> *Caronia*, 703 F.3d at 156.

information about the safety or efficacy of a drug, yet it is not clear Caronia is offering even these. Nowhere does the court mention a clinical trial, let alone a RCT, supporting Caronia's assertions. Yet the Second Circuit finds his statements truthful and not-misleading—on the basis of nothing at all.

Judge Engelmayer in *Amarin*<sup>51</sup> does only a little better. He believes the FDA's statement, “. . .the available evidence does not establish that reducing triglycerides with a drug reduces the risk of cardiovascular events among patients already treated with statins,” means that “‘the available evidence’ had affirmatively established that reducing triglycerides with a drug does not reduce cardiovascular risk in the relevant populations.”<sup>52</sup> But, as Dr. Sharfstein, a physician used to precision in analyzing clinical trial results, pointed out in his Viewpoint article in JAMA, these two statements are not the same.<sup>53</sup>

If ever there were cases demonstrating the importance judicial deference to specialized Federal agency expertise, these are they.

As the late U.S. Senator Daniel Patrick Moynihan said, “Everyone is entitled to his own opinions, but not to his own facts.”<sup>54</sup>

Most distressing, perhaps, is the heedless credulity with which these judges swallow whole what can only be described as pharmaceutical industry propaganda. Despite the well-documented history of tragedy from reckless pharmaceutical marketing, from Mrs. Winslow's Soothing Syrup to antipsychotics such as Risperdal today, the courts don't see a single problem. Instead, Judge Engelmayer confidently asserts that “. . .the therapeutic—indeed sometimes life-saving—value of off-label uses of FDA-approved drugs has been widely recognized.”<sup>55</sup> In support of this sweeping statement, he offers—nothing. He criticizes the FDA's position that off-label marketing violates the FDCA “[n]otwithstanding the potential benefits of off-label use of approved drugs.”<sup>56</sup> Again, no reference. Off-label prescribing due to off-label marketing is an unalloyed good. Judge Engelmayer concurs with *Amarin*'s claim that

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<sup>51</sup> *Amarin Pharma Inc.*, 2015 U.S. Dist. LEXIS 103944, at \*57-58.

<sup>52</sup> *Id.*

<sup>53</sup> Joshua M. Sharfstein, *supra* note 19.

<sup>54</sup> *Daniel Patrick Moynihan Quotes: Quotable Quotes*, GOODREADS, <http://www.goodreads.com/quotes/1745-everyone-is-entitled-to-his-own-opinion-but-not-to> (last visited Jan. 29, 2015).

<sup>55</sup> *Amarin Pharma Inc.*, 2015 U.S. Dist. LEXIS 103944, at \*10.

<sup>56</sup> *Id.* at \*9.

“doctors desire. . .this information,”<sup>57</sup> despite the fact that the very *New England Journal of Medicine* article from which he takes his figure for off-label use (21% of all prescriptions) *disapproves* of such common off-label prescribing: “most off-label drug uses (73%) were shown to have little or no scientific support. Atypical antipsychotics and antidepressants were particularly likely to be used off-label without strong evidence. . . .”<sup>58</sup> Indeed, the author of the article, Randall Stafford M.D., Ph.D., is concerned that the FDA has been unduly intimidated by the courts: he calls for stronger FDA oversight of illegal off-label marketing.<sup>59</sup> Dr. Stafford concludes:

I believe that the FDA must take an active role in fostering evidence-based practice, *eliminating subversion of the approval process*, and requiring a balanced and fair presentation of scientific evidence. . . .The FDA might consider undertaking a range of new activities in regulating off-label use, including. . . *scrutinizing marketing efforts to restrict materials on off-label uses that don't have strong support*,”<sup>60</sup> [emphasis added].

The First Amendment contemplates a vigorous marketplace of ideas and opinions in which anyone can participate, from which the truth emerges. However, today medicine is not such a marketplace: the pharmaceutical industry has a disproportionate, well-financed and often highly biased voice, driven by powerful, dangerous forces on Wall Street. Busy clinicians do not have the time and expertise to carefully sort through unsupported pharmaceutical claims, or even the access to proprietary information the FDA can require manufacturers to provide: many of us, overwhelmed by the avalanche of information, depend on the FDA to do heavy lifting for us, at least in the first instance.

Whatever values the courts seek to advance in their “new First Amendment” jurisprudence, in matters of medicine they would be wise to heed instead the admonition of the ancient Greek physicians, “First do no harm.”

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<sup>57</sup> *Id.* at \*12.

<sup>58</sup> Randall S. Stafford, *Regulating Off-Label Drug Use—Rethinking the Role of the FDA*, 358 *NEW ENG. J. MED.* 1427–29 (April 3, 2008), <http://www.nejm.org/doi/full/10.1056/NEJMp0802107>.

<sup>59</sup> *Id.*

<sup>60</sup> *Id.* (emphasis added).