

## **In Pursuit of Science-based Regulation: FDA, FTC, and the Regulation of Pseudoscience**

### **What does “natural” mean?**

The Food and Drug Administration (“FDA”) has posed this seemingly innocuous question to the public in a recent request for information.<sup>1</sup> Aside from it being a truly interesting, if overly philosophical question to ask the public, the move is emblematic of a recent trend, both from the (“FDA”) and the Federal Trade Commission (“FTC”), to regulate based on some articulable scientific premise, rather than allowing various actors to make wide-ranging claims about their products without repercussion.<sup>2</sup> In particular, the agencies have begun targeting dietary supplement manufacturers, homeopathic remedies, and most recently, Lumosity.

### **Lumosity and the FTC**

Lumosity advertises copiously on networks and websites that include “CNN, Fox News, the History Channel, National Public Radio, Pandora, Sirius XM, and Spotify.”<sup>3</sup> Created by “Lumos Labs,” Lumosity is a web-based product consisting of 40 games, which Lumosity claimed that, when played “10 to 15 minutes three or four times a week could help users achieve their ‘full potential in every aspect of life.’”<sup>4</sup>

The FTC got involved because Lumos Labs claimed playing Lumosity’s games would

1) improve performance on everyday tasks, in school, at work, and in athletics; 2) delay age-related cognitive decline and protect against mild cognitive impairment, dementia, and Alzheimer’s disease; and 3) reduce cognitive impairment associated with health conditions, including stroke, traumatic brain injury, PTSD, ADHD, the side effects of chemotherapy, and Turner syndrome, and that scientific studies proved these benefits.

Neuroscientists have challenged such statements, noting that there is “little evidence that playing brain games improves underlying broad cognitive abilities, or that it enables one to better navigate a complex realm of everyday life.”<sup>5</sup> In fact, at least one study seems to show that the

Xbox and PlayStation games actually offer some measurable benefits, while the Lumosity-type “brain training” games offer none.<sup>6</sup> When commercial actors make claims that are deceptive, misleading, or outright false, the FTC can and should step in.<sup>7</sup>

The FTC’s mission is to “prevent business practices that are anticompetitive or deceptive or unfair to consumers; to enhance informed consumer choice and public understanding of the competitive process.”<sup>8</sup> In 2014, the FTC brought an action for injunctive and equitable relief against Lumosity.<sup>9</sup> The FTC brought the action pursuant to its powers under the FTC Act (15 U.S.C. §§ 41-58, as amended); in particular, those provisions involving labeling and false or misleading advertising.<sup>10</sup>

Lumosity’s settlement with the FTC includes two million dollars in redress, notification to customers regarding the action, and an easy method of canceling auto-renewed subscriptions, as well as a suspended \$50 million judgment against Lumos Labs.<sup>11</sup> As Forbes listed Lumosity’s revenue at \$23.6 million in 2013, this may prove to be a serious financial blow to the company and may also be indicative of the future trends in FTC enforcement actions.<sup>12</sup>

Critics of the settlement could say that no one is harmed by false claims, such as those Lumos Labs and Lumosity made about its product, but the prices Lumosity charged for its games—with options ranging from monthly (\$14.95) to lifetime (\$299.95) memberships—are ostensibly supposed to reflect the benefits consumers expect to achieve from the products.<sup>13</sup> If consumers could receive the same (or greater) benefits from, for example, free games on Kongregate or Addicting Games, or from console games, then Lumosity is doing nothing more than selling digital snake oil. The free market demands that consumers know there is no meaningful difference between the two, and that one may not benefit—to the detriment of the other—based upon misleading or untrue statements.

Lumosity's claims, while misleading and injurious to the market, are surely worth the regulatory scrutiny applied by the FTC. Another pseudoscientific menace—dietary supplements—deserve at least equal regulatory scrutiny; however, the regulatory scheme for them has fallen woefully short of being in the best interest of public health.

### **The FDA and Supplements**

The FDA is charged with the regulation of food and drugs under the Food, Drug, and Cosmetics Act.<sup>14</sup> It seems like supplements would fall into one of those categories and until the mid-nineties, the FDA had done a good job of regulating them. Then do-it-yourself healthcare and “alternative medicine” became trendy, and the public (aided greatly by the moneyed-interests in the supplements industry) decided it wanted supplements to exist in their own realm of little-to-no regulation, resulting in the current regulatory scheme, which leaves them largely unregulated and thus, in a position to do the public great harm.<sup>15</sup>

The first example of the fallout from deregulation has to do with what is actually in the supplements themselves; to wit... no one can really know, unless they actually test the supplements (which are already for sale on the market, over the counter) to see if they contain the advertised product. The pertinent question, when performing such tests, isn't always “how much of the product does it contain?” That remains an important question, especially since toxicity is a possibility, and the quantity of product actually contained in the pill may have no relation whatsoever to any claims on the bottle. The pertinent questions are often “does this actually contain the product advertised?” and “what other products does it contain?” The answers are often, respectively: “no” and “several, which are not on the label.”

When New York tested supplements from GNC, Target, Walgreens, and Wal-Mart, it found that four out of five of the products tested contained none of the actual herb on the label.<sup>16</sup>

Moreover, those products often contained nothing more than houseplants, asparagus, or rice.<sup>17</sup> A Canadian study of herbal products found similar results, and added that some of the substances found posed “serious health risks.”<sup>18</sup> Some of these risks include chronic diarrhea and liver damage.<sup>19</sup>

Even when the product actually reflects the labeling, other risks abound, particularly the risk of overdose and dangerous drug interactions. The “appeal to nature” fallacy—in which one poses that a product is “good” or “healthy” because it is “natural”—entirely dominates the world of alternative medicine, yet remains without scientific support.<sup>20</sup> That is, it is not logical to assume that “natural” nightshade mushrooms are healthier than a Twinkie. And again, what “natural” means is a live debate. But this fallacious thinking can lead to dangerous overconsumption of supplements.<sup>21</sup> For example, herbs like comfrey and aristolochia can cause liver and kidney failure.<sup>22</sup> St. John’s Wort—commonly used as an over-the-counter antidepressant—can interact dangerously with other antidepressants, and other drugs.<sup>23</sup> And since most patients don’t tell their physicians about their supplement use, dangerous interactions and effects can go undiagnosed, and untreated.<sup>24</sup> While it may be incumbent upon physicians to ask their patients what supplements they are using, full disclosure by the patients does not guarantee an accurate appraisal.

Supplement doses can also vary wildly from their labels, and with dangerous results. For example, an outbreak of selenium poisoning in 2010 was traced to a supplement containing more than 200 times the amount of selenium labeled, and led to acute hair and fingernail loss before being pulled from the market.<sup>25</sup> And a study reported by the Journal of the American Medical Association found that, among 12 brands of vitamin D, pills tested could contain anywhere from

52 to 135 percent of the dosage found on the label, and dosage could vary not only bottle-to-bottle, but pill-to-pill.<sup>26</sup>

Finally, even the effectiveness of supplements is in doubt. As one medical professor has said, “It seems reasonable that if a little bit of something is good for you, then more should be better for you. It's not true. Supplementation with extra vitamins or micronutrients doesn't really benefit you if you don't have a deficiency.”<sup>27</sup> A science-based approach to medicine has consistently shown that any benefits from “complementary and alternative medicine” (“CAM”) either disappear as placebo effects or anecdotal anomaly.<sup>28</sup> Some have gone as far as to say that “alternative medicine” is illusory. Dr. Paul Offit, a leading pediatrician, has observed “there’s no such thing as alternative medicine. If clinical trials show that a therapy works, it’s good medicine. And if a therapy doesn’t work, then it’s not an alternative.”<sup>29</sup> Those who believe that “alternatives” to conventional health care are easy victims for modern day snake oil salesmen who, not coincidentally, benefit from the lack of regulation.<sup>30</sup> Thus, Congress’ leashing of the FDA makes no sense, when regulating supplements could easily remedy these problems.

Sometimes, though, acutely dangerous instances arise in supplements, and the government can actually take direct action. For example, in November 2015, the FDA announced results of a yearlong sweep of the supplements industry that resulted in civil injunctions and criminal actions (in partnership with the Department of Justice) against 117 supplements manufacturers.<sup>31</sup> Included among those manufacturers was USPlabs, a popular fitness supplements producer.<sup>32</sup> Their product, OxyElitePro, was linked to many cases of hepatitis, including some so severe that they resulted in liver transplants and at least one death.<sup>33</sup> Because supplement manufacturers need not prove the safety of their products before bringing them to market, USPlabs’ indictment was not for the introduction of a dangerous product to customers. Instead, when the FDA

brought the danger to USPlabs attention, its principals said they would take the supplement off the market, but instead “engaged in a surreptitious, all-hands-on-deck effort to sell as much OxyElite Pro as it could as quickly as possible.”<sup>34</sup> It was their *knowing* introduction of the supplement to the market that brought the indictment. Thus, if an industry actor does not knowingly introduce a harmful supplement into the marketplace, it is not criminally liable. In other words, the less a manufacturer knows about adverse health effects of supplements, the less susceptible it is to prosecution. The supplements industry, then, has an interest in not knowing whether one of its products harms the public. This perversion of the regulatory scheme can only be fixed through an act of Congress. And while Congress is at it, perhaps it will finally take a closer look at another pseudoscientific scheme that has escaped regulatory notice for too long: homeopathy.

### **FDA, FTC, and homeopathy**

Homeopathy is a theory of “medicine” developed in Germany in the late 1700s:

Supporters of homeopathy point to two unconventional theories: “like cures like”—the notion that a disease can be cured by a substance that produces similar symptoms in healthy people; and “law of minimum dose”—the notion that the *lower* the dose of the medication, the *greater* its effectiveness.<sup>35</sup>

To give you a better grasp of what this means practically, imagine that you have an allergy to cats, which causes a runny nose and itchy eyes. A homeopathic remedy for that allergy may contain red onion (“*Allium Cepa*”), because red onion also causes runny nose and itchy eyes.<sup>36</sup> The red onion will then often be diluted to “30C,” which means it is diluted, with water to 10<sup>60</sup>-fold dilution.<sup>37</sup> Effectively, this means it is doubtful that even one molecule of the active ingredient can still be found in the product.<sup>38</sup>

Homeopathy is exactly as implausible and ineffective as it sounds.<sup>39</sup> Despite any scientific evidence for its effectiveness, homeopathy has gained a sizeable following in the U.S., such that

in 2012, an estimated 5 million adults and 1 million children used homeopathic “remedies,” and it is a billion-dollar industry.<sup>40</sup>

The FDA’s current regulatory scheme for homeopathic “drugs” is light, to say the least. In order to sell a homeopathic “drug,” a manufacturer must only show that its “drug” is found in the Homeopathic Pharmacopeia of the United States (“HPUS”) and its supplements, and conform to all other labeling provisions for over the counter (“OTC”) drugs.<sup>41</sup> If found in the HPUS, it is presumed to be generally recognized as safe and effective (“GRASE”), despite the fact that no one has ever (nor could they plausibly) proven the effectiveness of homeopathy.

Recently, the FDA opened the subject to public comment and, interestingly, the FTC was one of the commenters.<sup>42</sup> The FTC is interested in homeopathy specifically because “[f]or health, safety, or efficacy claims, the FTC has generally required that advertisers possess ‘competent and reliable scientific evidence.’”<sup>43</sup> As noted above, homeopathic “drug” manufacturers cannot point to any such evidence for any claims. They are thus technically in conflict with the FTCA; but the FTC had deferred to FDA, because the Agency regulates homeopathy.

While consumers may wonder what harm exists in allowing the uninformed to buy potentially ineffective remedies, in the area of health care, the remedies that patients choose to pursue may exclude other remedies. For example, someone who prefers homeopathy to real medicine may choose to forgo a flu vaccine in favor of the homeopathic alternative.<sup>44</sup> Influenza and pneumonia are one of the leading causes of death in the U.S. and worldwide, leading to almost 58,000 deaths in the U.S. in 2013, and between 250,000 and 500,000 deaths worldwide, annually.<sup>45</sup> If even one of those deaths could be prevented by a person choosing a real flu vaccine over its homeopathic “alternative,” it is more than worth regulating homeopathy.

Consumers are better served by having a health care system, and a regulatory structure in general, that is science-based. Homeopathy is a belief in magic, not science. It is fundamentally no different than faith healing, or leeching out bad humours. It is anachronistic and fundamentally flawed. Giving it the legitimacy of a free pass from our regulatory agencies stains the esteem of the United States' medical prowess and our stance among the finest medical elites in the world. We as a nation have made great strides toward medicine based upon science; we should have a regulatory structure, and a legal system, similarly subject to scientific rigor.

### Conclusion

Who knows what “natural” means? In the end, does it really matter? One can hope that the FDA's question actually leads to a better understanding of science, and the arbitrariness of some of the words we use. But more importantly, the FDA and FTC must continue what looks like a trend of protecting the public from pseudoscience and the horrors of the anti-science community. Let's have science-based law, to go along with our health policy.

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<sup>1</sup> Use of the Term “Natural” in the Labeling of Human Food Products; Request for Information and Comments; Extension of Comment Period, 80 Fed. Reg. 80718-80719 (Dec. 28, 2015) (to be codified at 20 C.F.R. pt. 101).

<sup>2</sup> For an excellent philosophical discussion regarding the nature of the natural, see Alex Johnson, *How to Queer Ecology, One Goose at a Time*, ORION MAGAZINE <https://orionmagazine.org/article/how-to-queer-ecology-once-goose-at-a-time/> (last visited Apr. 13, 2016). See discussion, *infra*.

<sup>3</sup> Press Release, Federal Trade Commission, Lumosity to Pay \$2 Million to Settle FTC Deceptive Advertising Charges for Its “Brain Training” Program (Jan. 5, 2016) available at <https://www.ftc.gov/news-events/press-releases/2016/01/lumosity-pay-2-million-settle-ftc-deceptive-advertising-charges>

<sup>4</sup> *Id.*

<sup>5</sup> Emily Underwood, *Neuroscientists Speak Out Against Brain Game Hype*, SCIENCE, (Oct. 22, 2014, 4:30 PM), <http://www.sciencemag.org/news/2014/10/neuroscientists-speak-out-against-brain-game-hype>.

<sup>6</sup> See Steven Novella, *Brain-Training Products Useless in Study*, SCIENCE-BASED MEDICINE (Apr. 21, 2010), <https://www.sciencebasedmedicine.org/brain-training-products-useless-in-study/>.

<sup>7</sup> See *About the FTC*, FEDERAL TRADE COMMISSION, <https://www.ftc.gov/about-ftc> (last visited Apr. 13, 2016).

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

<sup>9</sup> Complaint For Permanent Injunction And Other Equitable Relief, Federal Trade Commission v. Lumos Labs, Inc. et al., No. 3:16-cv-00001 (N.D. Cal. 2016).

<sup>10</sup> *Id.* at 2-3.

<sup>11</sup> See Press Release, *supra* note 3.

- <sup>12</sup> See *America's Most promising Companies*, FORBES.COM (2015), <http://www.forbes.com/companies/lumosity/>.
- <sup>13</sup> See Press Release, *supra* note 3.
- <sup>14</sup> 21 U.S.C.S. § 301 (LexisNexis, Lexis Advance through PI 114-139, approved 3/18/16, with a gap of PI 114-125)
- <sup>15</sup> See generally Alessa Thomas, Comment, *Making Sense of Supplements: Suggestions for Improving the Regulation of Dietary Supplements in the United States*, 2010 Mich. St. L. Rev. 203 (2010) (discussing in depth the history and shortfalls of this regulatory process).
- <sup>16</sup> See Anahad O'Connor, *New York Attorney General Targets Supplements at Major Retailers*, THE NEW YORK TIMES (Feb. 3, 2015 12:00 AM) [http://well.blogs.nytimes.com/2015/02/03/new-york-attorney-general-targets-supplements-at-major-retailers/?\\_r=1](http://well.blogs.nytimes.com/2015/02/03/new-york-attorney-general-targets-supplements-at-major-retailers/?_r=1).
- <sup>17</sup> *Id.*
- <sup>18</sup> CBC News, *Herbal product contamination 'considerable,' DNA tests find*, CBCNEWS.COM (Oct. 11, 2013 7:21 AM), <http://www.cbc.ca/news/health/herbal-product-contamination-considerable-dna-tests-find-1.1959278>
- <sup>19</sup> *Id.*
- <sup>20</sup> See, e.g., NATURALNEWS.COM, FOODBABE.COM
- <sup>21</sup> See, e.g., Scott Gavura, *Side effects of your supplement may include liver failure*, SCIENCE-BASED PHARMACY (Sept. 22, 2014), <https://sciencebasedpharmacy.wordpress.com/2014/09/22/side-effects-of-your-supplement-may-include-liver-failure/>.
- <sup>22</sup> Federal Trade Commission, *Dietary Supplements*, <http://www.consumer.ftc.gov/articles/0261-dietary-supplements> (last visited Apr. 13, 2016).
- <sup>23</sup> University of Maryland Medical Center, *Possible Interactions With: St. John's Wort*, <https://umm.edu/health/medical/altmed/herb-interaction/possible-interactions-with-st-johns-wort> (last visited Apr. 13, 2016).
- <sup>24</sup> Nissa Simon, *Most Patients Don't Tell Their Doctors They Take Supplements*, AARP BULLETIN (Nov. 16, 2010), [http://www.aarp.org/health/drugs-supplements/info-11-2010/most\\_patients\\_dont\\_tell\\_their\\_doctors\\_they\\_take\\_supplements.html](http://www.aarp.org/health/drugs-supplements/info-11-2010/most_patients_dont_tell_their_doctors_they_take_supplements.html).
- <sup>25</sup> Ashiq Zaman, *Supplements lack oversight and can pose health risks*, NONDOC (Jan. 12, 2016), <http://nondoc.com/2016/01/12/supplements-lack-oversight-and-can-pose-health-risks/>.
- <sup>26</sup> *Supplement Label Lies?* BERKELEY WELLNESS (JAN. 30, 2014) <http://www.berkeleywellness.com/supplements/vitamins/article/supplement-label-lies>.
- <sup>27</sup> Nancy Shute, *The Case Against Multivitamins Grows Stronger*, NPR.ORG (Dec. 17, 2013), <http://www.npr.org/sections/health-shots/2013/12/17/251955878/the-case-against-multivitamins-grows-stronger>.
- <sup>28</sup> David Gorsky, *Authority versus science on integrative medicine*, SCIENCE-BASED MEDICINE (Nov. 2, 2015), <https://www.sciencebasedmedicine.org/authority-versus-science-on-integrative-medicine/>.
- <sup>29</sup> Paul Offit, *Alternative medicines are popular, but do any of them really work?*, THE WASHINGTON POST (Nov. 11, 2013), available at [https://www.washingtonpost.com/national/health-science/alternative-medicines-are-popular-but-do-any-of-them-really-work/2013/11/11/067f9272-004f-11e3-9711-3708310f6f4d\\_story.html](https://www.washingtonpost.com/national/health-science/alternative-medicines-are-popular-but-do-any-of-them-really-work/2013/11/11/067f9272-004f-11e3-9711-3708310f6f4d_story.html).
- <sup>30</sup> See, e.g., Steven Novella, *The Hidden Cancer Cure*, SCIENCE-BASED MEDICINE (Feb. 23, 2011), <https://www.sciencebasedmedicine.org/the-hidden-cancer-cure/>.
- <sup>31</sup> Press Release, Food and Drug Administration, *FDA takes action to protect consumers from potentially dangerous dietary supplements* (Nov. 17, 2015), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473099.htm>.
- <sup>32</sup> *Id.*
- <sup>33</sup> See Rachael Rettner, *Diet Supplement Causes Nearly 100 Hepatitis Cases*, LIVE SCIENCE (Apr. 2, 2014 05:33PM), <http://www.livescience.com/44581-hepatitis-outbreak-supplement.html>.
- <sup>34</sup> FDA Press Release, *supra* note 31.

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<sup>35</sup> National Institutes of Health, Homeopathy, <https://nccih.nih.gov/health/homeopathy> (last visited Apr. 13, 2016).

<sup>36</sup> See Consumer Reports, *Homeopathic drugs: No better than placebos?*, THE WASHINGTON POST (Dec. 21, 2015), available at

[https://www.washingtonpost.com/national/health-science/homeopathic-drugs-no-better-than-placebos/2015/12/18/037b3976-7750-11e5-a958-d889faf561dc\\_story.html](https://www.washingtonpost.com/national/health-science/homeopathic-drugs-no-better-than-placebos/2015/12/18/037b3976-7750-11e5-a958-d889faf561dc_story.html).

<sup>37</sup> See David Gorsky, *A truly homeopathic defense of homeopathy*, SCIENCE-BASED MEDICINE (Dec. 17, 2012),

<https://www.sciencebasedmedicine.org/homeopathy-as-nanoparticles/>

<sup>38</sup> *Id.*

<sup>39</sup> See Consumer Reports, *supra* note 36 (finding no difference between homeopathic drugs and placebo); see also Press Release, Australian Government National Health and Medical Research Council, NHMRC releases statement and advice on homeopathy (Mar. 11 2015),

<http://www.nhmrc.gov.au/media/releases/2015/nhmrc-releases-statement-and-advice-homeopathy> (announcing results of metastudy conclusively finding homeopathy no more effective than placebo).

<sup>40</sup> See National Institutes of Health, *supra* note 35.

<sup>41</sup> See FDA Compliance Policy Guide, CPG § 400.400, available at

<http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm>.

<sup>42</sup> Food and Drug Administration, Homeopathic Product Regulation: Evaluating FDA's Regulatory Framework After a Quarter-Century, available at

<http://www.fda.gov/Drugs/NewsEvents/ucm430539.htm>. Federal Trade Commission, In Response to a Request for Comments Related to its Public Hearing on Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century (Aug. 21, 2015),

[https://www.ftc.gov/system/files/documents/advocacy\\_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/150821fdahomeopathic.pdf](https://www.ftc.gov/system/files/documents/advocacy_documents/ftc-staff-comment-food-drug-administration-regarding-current-use-human-drug-biological-products/150821fdahomeopathic.pdf).

<sup>43</sup> *Id.*, at 4.

<sup>44</sup> See, e.g., Scott Gavura, *Beyond the flu shot: A closer look at the "alternatives"*, SCIENCE-BASED MEDICINE (Dec. 5, 2013),

<https://www.sciencebasedmedicine.org/beyond-the-flu-shot-a-closer-look-at-the-alternatives/>.

<sup>45</sup> See Centers for Disease Control and Prevention, Deaths and Mortality,

<http://www.cdc.gov/nchs/fastats/deaths.htm> (last visited Apr. 13, 2016); World Health Organization, Influenza, <http://www.who.int/mediacentre/factsheets/fs211/en/> (last visited Apr. 13, 2016).