

“Let’s Not Waste a Crisis” – The 2009 Novel H1N1 influenza and Heightened Attention to Dietary Supplements Marketed to Prevent, Treat or Cure Swine Flu

By Amy M. Lecocq, J.D., LL.M. Candidate (Health Law)
amlecocq@central.uh.edu

Cynics say: “Let’s not waste a crisis.” The 2009 novel H1N1 influenza pandemic presents such a crisis. Between April and September 2009, the World Health Organization (WHO) recorded 277,607 cases of the 2009 novel H1N1 strain of influenza virus (H1N1) and 3,205 deaths due to H1N1.¹ The Director of the Congressional Budget Office opines that “beyond the human suffering that a pandemic would engender, policymakers are also concerned about the potential for economic disruptions that might be layered on top of an economy already in recession.”² As a result, world-wide organizations, federal, state and local governments, pharmaceutical companies, businesses, hospitals and other health care facilities, schools, summer camps, travel agencies, doctors and families have been vigorously and predictably preparing for this novel flu strain. For its part, the U.S. Food and Drug Administration (FDA) has approved four vaccines to prevent H1N1 flu³ and two drugs to treat an individual who has contracted H1N1 flu – Tamiflu (oseltamivit phosphate) and Relenza (zanamivir).⁴ However, this article focuses on one of the more obscure outgrowths of this “crisis” – a surge of interest and attention to the historically under-regulated use of “dietary supplements” which are unlawfully marketed to prevent, treat, or cure swine flu.

Regulation of Dietary Supplements

The FDA regulates “dietary supplements” more like foods, than drugs.⁵ A dietary supplement is a product taken by mouth (i.e., tablets, capsules, softgels, gelcaps, liquids, powders or bars) that contains a dietary ingredient (i.e., vitamins, minerals, herbs, or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars and metabolites).⁶ Dietary supplements are intended to enhance a person’s dietary intake in a manner similar to food items. Popular dietary supplements include Vitamin C, Calcium, Fish Oil, Ginkgo biloba, St. John’s Wort, Echinacea, Ginseng, Chinese herbs

¹ World Health Org., Global Alert and Response (GAR), *Pandemic (H1N1) 2009: Update 65*, Sept. 11, 2009, available at http://www.who.int/csr/don/2009_09_11/en/. However, “given that countries are no longer required to test and report individual cases, the number of cases reported actually understates the real number of cases.” *Id.*

² Dir.’s Blog, Cong. Budget Office, *The Current Outbreak of Swine Flu in the U.S.*, <http://cboblog.cbo.gov/?p=240> (last updated Apr. 28, 2009).

³ U.S. Food & Drug Admin., FDA News Release, *FDA Approves Vaccines for 2009 H1N1 Influenza Virus: Approval Provides Important Tool to Fight Pandemic*, Sept. 15, 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm182399.htm>.

⁴ Nat’l Ctr. For Complementary and Alternative Medicine, Message from the Dir., *Caution: Using CAM to Prevent the H1N1 Flu*, May 8, 2009, <http://nccam.nih.gov/about/offices/od/2009-05.htm>.

⁵ 21 U.S.C. § 321(ff) (2009); see also *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033 (10th Cir. 2006), *cert.denied*, 550 U.S. 933 (2007).

⁶ 21 U.S.C. § 321(ff) (2009).

and Ephederin (now banned), among many others. However, manufacturers are permitted to make general claims of well-being or claims related to the human structure or function, provided the claims are not misleading and the maker has some substantiation for its claims.⁷ The FDA requires the manufacturer to add a disclaimer to its marketing label that statements or claims contained therein have not been evaluated by the FDA and the product is not intended to diagnose, treat, cure or prevent any disease.⁸ If a manufacturer or distributor makes such claims, the product is deemed to be misbranded. Historically, the FDA has had very limited resources for enforcement actions. Since dietary supplements have been regulated under the general umbrella of food products, most of the regulatory action taken by the FDA has involved post-marketing efforts to address products that are either determined to be unsafe after marketing or making misleading or false claims, including those more suitable for drugs (diagnose, mitigate, treat, cure or prevent a specific disease).⁹

Heightened Public Interest in Dietary Supplements

The National Center for Health Statistics recently released a report addressing the costs of complementary and alternative medicines in 2007. Although the costs were not broken down into “dietary supplements,” it found that the public spent \$14.8 billion to purchase non-vitamins, non-mineral, and natural products – approximately 31 percent of the amount that the public spent out-of-pocket on pharmaceutical drugs in 2007 (\$47.6 billion).¹⁰ The last time our country faced the possibility of a widespread swine flu epidemic was in 1976. That year, 45 million Americans were vaccinated against swine flu.¹¹ Innoculations were halted because the anticipated pandemic did not materialize and the incidence of Guillain Barre disease raised questions about the safety of the vaccine itself.¹² Since that time, the U.S. has not contemplated a mass vaccination. Today, parents associate vaccines with questions about safety, not only regarding Guillain Barre, but also autism and other maladies.¹³

Beyond the popularity of dietary supplements, several other factors distinguish today’s consumers from those in 1976. The public has become skeptical of our government, our media and our own medical professionals. Many people obtain at least some of their medical or health information from the internet. Others are purchasing dietary supplements and drug products over the web. Dietary supplements and other products

⁷ 21 U.S.C. § 343(r)(6) (2009).

⁸ *Id.*

⁹ See, News Release, Office of the U.S. Attorney, West. Dist. of Mo., *Michigan Business Owner Pleads Guilty to Fraudulently Marketing Dietary Supplements: Internet Business Generated Nearly \$12 Million with False Claims to Prevent, Cure Diseases*, July 2, 2009, <http://www.usdoj.gov/usao/mow/news2009/pham.ple.htm>.

¹⁰ Richard L. Nahin, et al., *Costs of Complementary and Alternative Medicine (CAM) and Frequency of Visits to CAM Practitioners: United States, 2007*, 18 NAT’L HEALTH STAT. RPTS. (July 30, 2009), available at <http://nccam.nih.gov/news/camstats/costs/nhsrn18.pdf>.

¹¹ Andrew Pollack, *Fear of a Swine Flu Epidemic in 1976 Offers Some Lessons, and Concerns, Today*, N.Y. TIMES, May 9, 2009, <http://www.nytimes.com/2009/05/09/health/09vaccine.html>.

¹² *Id.*

¹³ See Bruce Patsner, *Childhood Vaccines and Autism, Special Courts and Torts*, HEALTH L. PERSPECTIVES (Feb. 18, 2008), available at [http://www.law.uh.edu/healthlaw/perspectives/2008/\(BP\)%20autism.pdf](http://www.law.uh.edu/healthlaw/perspectives/2008/(BP)%20autism.pdf).

referencing the H1N1 flu are advertised on websites,¹⁴ chat rooms or YouTube sites¹⁵ or other topical blogs.¹⁶ Dietary supplements, available without a doctor's prescription, are more convenient, possibly less expensive, and less painful than an FDA-approved shot. Dietary supplements cannot, however, legally, medically or ethically substitute for a vaccine in the face of a flu pandemic.

FDA and FTC Compliance and Enforcement Action

Inasmuch as the internet played no role in the last anticipated swine flu epidemic in 1976, the federal government faced for the first time, the intersection of a burgeoning fraudulent dietary supplement market fueled by the unwieldy web communication modes and a true public health crisis. Thus, the FDA and the Federal Trade Commission (FTC) announced plans to pursue an aggressive compliance and enforcement strategy to fulfill their respective obligations to the public.

In a rare joint effort, the FDA¹⁷ and the FTC¹⁸ issued strong warnings to the public concerning “many website and email promotions for products that claim to prevent, treat, or cure (2009 H1N1 flu)”¹⁹ and advised “operators of offending web sites that they must take prompt action to correct and/or remove promotions of these fraudulent products or face enforcement action.”²⁰ Acting FDA Associate Commissioner for Regulatory Affairs Michael Chappell is quoted in the FDA Press Release explaining:

[C]onsumers who purchase products to treat the novel 2009 H1N1 virus that are not approved, cleared or authorized by the FDA for the treatment or prevention of influenza risk their health and the health of their families...In conjunction with the Federal Trade Commission, the FDA has developed an aggressive strategy to identify, investigate, and take regulatory or criminal action against individuals or businesses that wrongfully promote purported 2009 H1N1 influenza products in an attempt to take advantage of the current flu public health emergency.²¹

Also, somewhat uncharacteristically, the federal agencies took prompt action against a number of websites who had not heeded their advice and warnings. Forty-five days after its initial announcement, the FDA announced that it had surfed the internet daily and had issued 50 warning letters, with at least two-thirds of the web sites having removed the

¹⁴ See generally [newlifehealthsolutions.com](http://www.newlifehealthsolutions.com) at <http://www.newlifehealthsolutions.com>.

¹⁵ YouTube, *Mandatory H1N1 Swine Flu Forced Vaccinations-NWO Depopulation Program Coming Soon*, available at http://www.youtube.com/watch?v=6h8j3j_yGrk.

¹⁶ The Swine Flu Blog, *60 Minutes Piece on the 1976 Swine Flu Fiasco*, available at <http://www.healthdiaries.com/swineflu/60-minutes-piece-on-the-1976-swine-flu-fiasco.html>.

¹⁷ U.S. Food & Drug Admin., FDA News Release, *FDA, FTC Warn Public of Fraudulent 2009 H1N1 Influenza Products*, May 1, 2009, available at <http://www.fda.gov/NewsEvents/20Newsroom/PressAnnouncements/ucm149576.htm>.

¹⁸ U.S. Fed. Trade Comm., FTC Consumer Alert, *RX for Products that Claim to Prevent H1N1?*, (May 1, 2009), <http://www.ftc.gov/bcp/edu/pubs/consumer/alerts/alt83.shtm>.

¹⁹ *Id.*

²⁰ FDA News Release, *supra* note 17.

²¹ *Id.*

products or offending claims.²² Examples of unapproved or unauthorized dietary supplements include one “that claimed to protect infants and young children from contracting the H1N1 flu virus...[and one] that claimed to cure H1N1 flu infection within four to eight hours.”²³ In addition to requiring a response to the warning letters within 48 hours, the FDA is posting the offending web sites on its own web site and as of September 15, 2009, they had 136 entries on the list, including 62 marketing dietary supplements.²⁴ Fifty-one of these web sites had removed the offending product or language and 11 had not as of that date.²⁵ The FDA, calling this a “major priority,” will consider further enforcement action for those that do not resolve the violations cited in the warning letters including immediate seizure or injunction of the offending websites and referral for criminal prosecution.²⁶

Calling them “scam artists . . . (who) prey on concerned people,” the FTC has also acted promptly against web site operators claiming that their products can prevent, treat or cure the H1N1 flu virus, and the FTC also reminded the public that the FDA has approved only two prescription anti-virals, Tamiflu and Relenza, for this use.²⁷ In the first two weeks of monitoring and enforcement, the FTC had identified ten websites that made suspect flu treatment, prevention or cure claims. Four of those sites removed the questionable web pages, one site was referred to the FDA, three sites were foreign and were referred to the FTC foreign counterparts and the remaining two sites are still under review. All sites will continue to be monitored by the agency.²⁸

The Director of the National Center for Complementary and Alternative Medicine (NCCAM) warned consumers to be skeptical when it comes to dietary products claiming to provide beneficial health remedies and noted:

[The FDA and FTC’s] latest advisory reinforces the need for consumers to educate themselves and be wary of unsupported health claims. All too often, we see claims being made for unproven products, seeking to take advantage of people who are simply trying to protect the health and wellness of themselves and their loved ones. If a claim seems too good to be true, it probably is.²⁹

²² U.S. Food & Drug Admin., FDA News Release, *FDA Warns Web Sites Against Marketing Fraudulent H1N1 Flu Virus Claims*, June 15, 2009, <http://www.fda.gov/NewEvents/Newroom/pressAnnouncements/cm166801.htm>.

²³ *Id.*

²⁴ *Id.* See also, U.S. Food & Drug Admin., *Fraudulent 2009 H1N1 Influenza Products List*, <http://www.accessdata.fda.gov/scripts/h1n1flu/> (last updated Oct. 8, 2009).

²⁵ FDA New Release, *supra* note 22.

²⁶ *Id.*

²⁷ U.S. Fed. Trade Comm., News Release, *FTC Warns Internet Peddlers that Potentially Bogus H1N1 Influenza Products May Violate Federal Law*, May 14, 2009, <http://www.ftc.gov/opa/2009/05/swineflu2.shtm>.

²⁸ *Id.*

²⁹ Nat’l Ctr. For Complementary and Alternative Medicine, Message from the Dir., *supra* note 4.

An Opportunity for Improved Public Safety Beyond the “Crisis”?

Although the FDA, FTC and NCCAM have joined voices in warning the public of the potentially dangerous marketing claims made concerning dietary supplements, the scope of the agencies’ investigation fails to include an examination of the actual benefits and detriments of these supplements. The Director of NCCAM notes, “that although many CAM products (and some prescription drugs) come from natural sources, ‘natural’ does not always mean ‘safe.’” Here, a flu pandemic compounds the ordinary danger to the person mislead into purchasing and then ingesting a dietary supplement being advertised as a drug, but not tested for safety as a drug. In the setting of a pandemic, there is an additional risk to the public — the risk of exposure from persons who failed to effectively inoculate or treat themselves or their families. Clearly, the crisis has drawn common ground for these three agencies for the moment and they have responded in unison and in the public’s best interest.

FDA issued a Note to Correspondents on September 10, 2009, advising of three changes to the FDA web page regarding warning letters.³⁰ In addition to improving the format and the ease of searching and browsing, the FDA will post recently issued warning letters every Tuesday and add the post date. They will also post the Close Out Date and detailed information about the Close Out Program. These upgrades are not explicitly tied to the H1N1 fraudulent products program, but one could speculate that they were suggested by the heightened interest in fraudulent dietary supplements.

One of the difficulties in regulating the ever-more-popular dietary supplement industry has been that while the vast majority of manufacturers and marketers are honest and intend to provide a highly desired product to an informed community, there are a number of scam artists or shysters who only intend to make a quick buck. Perhaps the common ground found as a result of the anticipated flu crisis can be used to continue frank and realistic debate about how best to isolate and remove the “offenders” while minimizing the impact on the remainder of the dietary supplement community. The decisive and prompt response of the FDA, FTC and NCCAM ignites the tentative hope of a cynic that improved enforcement can result from our most recent “crisis.”

Health Law Perspectives (October 2009)

Health Law & Policy Institute

University of Houston Law Center

<http://www.law.uh.edu/healthlaw/perspectives/homepage.asp>

³⁰ U.S. Food & Drug Admin., FDA Note to Correspondents, *FDA Updates “Warning Letters” Web Page*, Sept. 10, 2009, <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm181945.htm>.