

Federal Enforcement Regarding Marketing Claims in Light of the 2009 H1N1 Pandemic

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In the wake of the worldwide 2009 H1N1 pandemic, makers of products from drugs and medical devices to dietary supplements and household consumer products have tried to capitalize on the health concerns associated with this virulent new strain of influenza. Federal agencies such as the U.S. Food and Drug Administration (FDA), Federal Trade Commission (FTC) and Environmental Protection Agency (EPA), have closely scrutinized claims in advertisements and on labels of products that claim they are effective against the H1N1 flu virus and have dedicated substantial resources to rooting out deceptive or unauthorized claims. These agencies are taking aggressive enforcement action against companies that are marketing products with unapproved, uncleared, unauthorized or unsubstantiated H1N1 claims. The response to the 2009 H1N1 pandemic likely foreshadows the enforcement efforts these same agencies will implement in response to future emerging pathogens, be they naturally occurring or an act of terrorism.

Federal Response to the 2009 H1N1 Pandemic and Unauthorized H1N1 Claims

The FDA has been at the lead on the H1N1 enforcement initiative. Pursuant to section 564 of the federal Food Drug and Cosmetic Act, (FDCA), 21 U.S.C. § 360bbb-3, as amended by the Project Bioshield Act of 2004, P.L. 108-276, the FDA has the power to authorize the use of unapproved or uncleared medical products, or unapproved or uncleared uses of approved or cleared medical products, once a public health emergency has been declared. Only those FDA-regulated products that have received an "emergency use authorization" (EUA) for H1N1 are allowed to make H1N1 claims. The FDA has issued EUAs for only a limited number of H1N1 medical products, including three antiviral drugs, disposable N95 respirators, and sixteen diagnostic tests.

Since May 2009, the FDA has issued 77 warning letters in connection with fraudulent marketing of products making H1N1 flu claims. The sheer number of these letters demonstrates the FDA's active investigation and enforcement of fraudulent claims. Moreover, the FDA's H1N1 warning letters contain a statement that the marketing of products with fraudulent H1N1 claims "is a potentially significant threat to the public health," and an admonition that failure to take corrective action could result in referral to the FDA's Office of Criminal Prosecution for violations of the FDCA and other federal laws. *See, e.g.*, Oct. 19, 2009 Warning Letter to Weil Lifestyle LLC. This is much stronger language than is typically found in FDA warning letters. A further indication of the agency's ramped up enforcement with respect to H1N1 claims is its provision of 48 hours for the recipient to take corrective action and so inform the FDA, as opposed to the 15 days the FDA has provided for in other instances. *Compare id.*; Jan. 5, 2009 Warning Letter to Mountain Health Line *with* Jan. 20, 2004

Warning Letter to Alliance Medical, Inc.; Jan. 15, 2010 Warning Letter to CloveCigarettesShop.com.

The FDA maintains a running list of fraudulent H1N1 influenza virus products. See <http://www.accessdata.fda.gov/scripts/h1n1flu/>. The products included on this list are widely varied, ranging from herbal supplements to air filters to hand sanitizers to test kits, among others. And even if a company takes corrective action to remove fraudulent H1N1 marketing statements, the company and its product remain on a list, with a notation that the company it is not currently engaging in fraudulent marketing. The FDA has also created a "widget" that can be added to any webpage and that allows consumers to search for and report fraudulent 2009 H1N1 flu products within the FDA's jurisdiction. The widget can be found at: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm186340.htm>.

The FDA has coordinated its enforcement activities in this area with the FTC, whose broad consumer protection jurisdiction extends to marketing claims for FDA-regulated products as well as products regulated by other agencies such as the EPA. See 15 U.S.C. §§ 41–58. The FDA and FTC have taken unprecedented action in aggressively identifying, investigating and taking regulatory action against companies marketing unapproved and unsubstantiated H1N1 flu products. The agencies have issued two joint press releases in connection with their monitoring of H1N1 flu claims and are specifically targeting "promotions or Internet sites offering products for sale that claim to diagnose, prevent, mitigate, treat or cure the 2009 H1N1 virus." See FDA News Release: FDA, FTC Issue Joint Warning Letter to Web Site Offering Fraudulent H1N1 Flu Supplements (Oct. 19, 2009); FTC News Release: FDA, FTC Warn Public of Fraudulent 2009 H1N1 Influenza Products (May 1, 2009). In October 2009, the FDA and FTC issued their first ever joint warning letter to owners of a website making claims that products sold on the site will help prevent the spread of the H1N1 virus. See Oct. 19, 2009 Warning Letter to Weil Lifestyle LLC.

The FTC is similarly independently monitoring websites making H1N1 flu claims and is issuing warnings to site operators making unsubstantiated H1N1 flu claims. See FTC News Release: FTC Warns Internet Peddlers that Marketing Unproven H1N1 Flu Products May Be Illegal (Nov. 16, 2009). The FTC has also created a Consumer Alert, available on its website, cautioning the public to be skeptical about H1N1 flu claims. See <http://www.ftc.gov/bcp/edu/pubs/consumer/alerts/alt083.shtm>.

The regulatory attention being paid to H1N1 flu claims also includes the EPA, which has jurisdiction over sanitizers, disinfectants and other antimicrobial products (including wipes or sprays) intended for use on inanimate surfaces. At the Ninth Annual Antimicrobial Workshop late last year, EPA officials stressed the importance of ensuring compliance with the requirements of the Federal Insecticide, Fungicide and Rodenticide Act – the federal law that governs these products. The EPA expressly reminded industry participants that claims of efficacy against H1N1 viruses cannot be made without express EPA authorization. The EPA allowed some claims through establishment of a special, expedited procedure for approving the inclusion on labels of limited, specific statements that a product is effective against the 2009 H1N1 flu virus. The basis for allowing these claims was that efficacy data had already been submitted to the EPA based on certain products' ability to show minimum

reductions against Influenza A virus. The EPA expressly noted, however, that only those products with demonstrated efficacy against Influenza A and explicit EPA approval could make such claims. The EPA issued a guidance document to this effect: *Guidance for Testing and Labeling Claims against Pandemic 2009 H1N1 Influenza A Virus (Formerly called Swine Flu)* (2009 H1N1 Guidance). See <http://www.epa.gov/oppad001/h1n1-guide.html>. In rolling out this new policy, the EPA was careful to note that only the specific claims approved by the Agency, as set forth in the guidance, would be allowed. Any other claims or any unapproved claims would subject manufacturers, distributors and retailers to enforcement action by the EPA.

Authorized H1N1 Claims

The FDA, FTC and EPA have not entirely foreclosed companies' ability to label or market a product as effective against the H1N1 flu virus. Indeed, the agencies have expressly permitted companies to make H1N1 claims with respect to products, provided that certain criteria are met.

Medical Devices, including H1N1 Diagnostic Tests: If claims are made that a product can be used to diagnose, prevent, mitigate, treat or cure the 2009 H1N1 virus, the FDA may deem that produce a medical device subject to the FDA's labeling requirements. As noted above, the FDA has approved disposable N95 respirators used as personal protective equipment to make 2009 H1N1 flu label claims and has approved 16 tests to be used to diagnose infection with the 2009 H1N1 flu virus. <http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>. Making 2009 H1N1 flu label claims for any other medical device could lead to an FDA enforcement action for causing a threat to public health and inclusion on the FDA's Fraudulent 2009 H1N1 Flu Products list. Similarly, advertising any medical device as effective against the 2009 H1N1 flu virus, without support from well-controlled human studies at the time the claim is made, could lead to an FTC enforcement action. See FTC Policy Statement Regarding Advertising Substantiation, <http://www.ftc.gov/bcp/guides/ad3subst.htm>.

Drugs and Herbal/Dietary Supplements: The FDA has approved three drugs to make 2009 H1N1 flu label claims: Tamiflu, Relenza, and Permaivir. See <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm>. Making 2009 H1N1 flu label claims for any other drug or dietary supplement, including hand sanitizers, teas, elixirs or pills could lead to an FDA enforcement action for causing a threat to public health and inclusion on the FDA's Fraudulent 2009 H1N1 Flu Products list. Similarly, advertising any such product as effective at preventing or treating the 2009 H1N1 flu virus, without support from well-controlled human studies at the time the claim is made, could lead to an FTC enforcement action. See FTC Policy Statement Regarding Advertising Substantiation, <http://www.ftc.gov/bcp/guides/ad3subst.htm>.

Pesticides: The recently-issued 2009 H1N1 Guidance is limited only to certain antimicrobial pesticides applied to hard surfaces (for example, wipes, sprays, powders) and already registered by the EPA. Under the 2009 H1N1 Guidance, if the product label currently makes claims against human, avian, or swine influenza A

viruses that are supported by the necessary efficacy data and approved by the EPA (i.e., registered), the label may be modified to include specific, EPA-approved 2009 H1N1 flu statements. In order to modify the label to include the approved statement, a registrant need only submit a Notification to the EPA, but need not submit any additional efficacy data. The Notification process is an expedited review process whereby the EPA normally takes 30 to 60 days to review a request for modification to an approved label under an applicable EPA issued registration. Under the accelerated time frame of the 2009 H1N1 Guidance, the EPA expects to respond to Notifications within 20 days of receipt.

If a registrant wants to make a 2009 H1N1 flu claim but does not have efficacy data to support an influenza A label claim, the 2009 H1N1 Guidance is inapplicable. Instead, such registrants must go through the formal registration amendment process that can take several months and require the review of submitted efficacy data. In that instance, the registrant must comply with the Pesticide Registration Improvement Act and generate and submit efficacy data for any influenza A strain.

A Glimpse Into the Future

The 2009 H1N1 pandemic is not the last health crisis that will strike the world and cause a public panic. Terrorism experts predict that a future attack using biological pathogens is likely. See Bob Graham and Jim Talent, *H1N1 Response Shows Need For Better Medical Emergency Plans*, Wash. Post, Jan. 4, 2010. Even if such an attack is not forthcoming, it is inevitable that a new health crisis will naturally emerge, just as the 2009 H1N1 pandemic came on the tails of the SARS, West Nile and the avian flu crises. The response of the FDA, FTC and EPA to the 2009 H1N1 pandemic likely foreshadows how these agencies will respond to future health threats caused by emerging pathogens.

As companies become more sophisticated in their marketing efforts, regulatory agencies have responded in kind, which is evidenced in the latest warning letters. More recently, at least one company has avoided using the term "H1N1" in its web marketing, but has brought consumers to its websites by using terms such as "H1N1" and "swine flu treatment", among others, as metatags. The FDA has treated these metatags in the same manner as explicit textual marketing and issued a warning letter instructing the company to cease this practice. See Dec. 1, 2009 Warning Letter to www.secretsofbetterhealth.com. In addition, the FDA discovered masked text (white text on a white background) on another website that would drive traffic to the site based on searches for H1N1-related terms, and likewise issued a warning letter to that site's operators. See May 3, 2009 Warning Letter to Rebuilder Medical Technology, Inc. The FDA, and similarly the FTC, will likely continue to search for and take enforcement action against metatag or masked text marketing regarding biological pathogens that emerge in the future.

Likewise, the FDA and FTC will likely continue their practice, evident in 2009 H1N1 enforcement, of looking at the entire context of an ad in determining whether to take any enforcement action. They will not overlook swine flu claims that are couched in marketing that claims a product contains immunity-boosting characteristics. See Nov. 30, 2009 Warning Letter to Hyde Park Holistic Center; Oct. 19, 2009 Warning

Letter to Weil Lifestyle LLC; July 16, 2009 Warning Letter to Master Supplements, Inc. They will likely also look beyond traditional forms of marketing and examine advertisements that may be found in other fora, such as YouTube or social networking websites. See July 22, 2009 Warning Letter to Q-Based Solutions, Inc. (noting YouTube video containing marketing claims). And, if the level of public concern approaches that which surrounded the H1N1 pandemic, it would not be surprising for either agency to continue to require expedited, 48-hour responses to warning letters.

Like the FDA and FTC, the EPA will scrutinize and review the claims companies make about the effectiveness of products against emerging pathogens. The starting point for determining what the EPA will do in the future is the *Implementation of the Emerging Pathogens and Disinfection Hierarchy for Antimicrobial Products* (EPA Emerging Pathogens Guidance), which facilitates approval for statements about emerging pathogens. The goal of this document is to provide "timely information to the public" about the "effectiveness of disinfectant products" against emerging pathogens. *Id.*

The EPA Emerging Pathogens Guidance permits the use of "approved statements" about emerging pathogen such as H1N1 on the master label of a registered product, as well on web sites and other similar media. Claims regarding emerging pathogens that are covered by this Guidance cannot be used on labels used on the actual product until approval is obtained. In application, this means that a company seeking to refer to any emerging pathogen on its Master Label and media of the products described above should follow the prescribed process for approval. The application to the EPA for approval to refer to the emerging pathogen should be made at the earliest possible time. Any changes to the Master Label or other media cannot be made until the EPA gives its approval. Following this procedure will permit companies to get out EPA approved statements in a timely manner and avoid risks of violating EPA labeling regulations. As evident with the H1N1 virus, the EPA has a system in place to ensure the veracity of the labels used on relevant products. Any statements made that do not comply with the Emerging Pathogens Guidance could be subject to an enforcement action from the EPA.

The response of federal agencies to the H1N1 pandemic makes clear that companies must carefully consider all labels and advertising of a product's effectiveness against an emerging pathogen. The steps needed to avoid liability are not necessarily difficult, but do require companies and their lawyers to consider carefully each applicable agency's rules, regulations and formal guidance. Failure to vet claims carefully at the outset could lead to enforcement actions from federal agencies that have shown a willingness to devote time, resources and effort to searching out questionable marketing claims.

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