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The Warning Letter Is Only the Start

All About Advertising Law Blog

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So you've had a bad day — FDA has told you to stop marketing your product. The good news, things can only get better, right? Maybe not if a class action follows hot on the heels of FDA's order. This, in brief, is the recent tale of woe of 23andMe. *See Casey v. 23andMe, Inc.*, No. 3:13-cv-02847 (S.D. Cal. Nov. 27, 2013).

The 23andMe example is only the most recent example of an FDA Warning Letter inspiring a class action. *See, e.g., Trujillo v. Avon Prods., Inc.*, No. CV12-09084 (C.D. Cal. filed Oct. 23, 2012) (class action filed less than three weeks after FDA Warning Letter); *Nino v. L'Oreal USA, Inc., Lancôme, Inc., and Lancôme Luxury Prods., LLC* , No. 1:12-cv-23462 (S.D. Fla. Sept. 21, 2012) (class action filed two weeks after FDA Warning Letter); *Huey v. General Mills, Inc.*, No. 09-01368 (E.D. Cal. May 15, 2009) (class action filed less than two weeks after FDA Warning Letter); *Mason v. The Coca-Cola Co.*, No. 1:09-cv-00220 (D.N.J. Jan. 14, 2009) (class action filed about a month after FDA Warning Letter).

As we wrote in a previous **post**, 23andMe manufactures and markets an at home genetic test which promises to provide information about potential health conditions and diseases. On November 22, FDA issued a Warning Letter to the company ordering the company to stop marketing the product. In FDA's view, the company had failed to substantiate that the test actually worked. A class action lawsuit alleging unfair business practices, misrepresentation, and false advertising, among other claims, followed on November 27, only five days after the Warning Letter.

The allegations of the **complaint** make clear that "but for" the Warning Letter plaintiffs had no basis to initiate a lawsuit. The Warning Letter is the sum and substance of the complaint, and plaintiffs make no attempt to suggest to the contrary.

The complaint does not allege, for example, that the sole named plaintiff, Ms. Lisa Casey of San Diego, or any unnamed class member actually received a false positive or a false negative 23andMe test result. Similarly, the complaint does not allege that Ms. Casey or any class member received any unnecessary or inappropriate medical care or treatment as a result of relying on 23andMe test results. Nor does the complaint allege that anyone failed to receive any necessary medical care or treatment in reliance on 23andMe test results.

The theory of plaintiffs' claims is that 23andMe made various promises about its product – for example, that it would provide information about a person's health and assist in planning for the future – and that the test "does none of those things and the results it provides are not supported by any scientific evidence." Complaint at ¶ 41. The sole factual basis for these allegations about what the test won't do is FDA's Warning Letter. *Id.* ¶¶ 15-21.

Basing a federal class action lawsuit on a Warning Letter raises at least two quite fundamental types of questions. First, when a lawyer files a lawsuit on behalf of a party, his/her signature on the complaint is a certification "that to the best of the person's [lawyer's] knowledge, information, and belief, formed after an inquiry reasonable under the circumstances," the legal and factual claims have support. Fed. R. Civ. P. 11(b) (emphasis added). But here, there is no allegation of any inquiry beyond simply reasserting what is in FDA's Warning Letter. Moreover, given that the lawsuit was filed a mere five days after issuance of the Warning Letter, there was little time for an "inquiry" beyond reading the Warning Letter. Was there a "reasonable inquiry under the circumstances" when the target of the letter has yet to answer, as is its right, and when no independent third party has reviewed the conclusions of the letter and made any determination as to their validity? Nestle was recently able to have a class action

dismissed when the action was premised on little more than an FTC complaint and settlement.

Second, is merely buying a product that makes marketing claims which a government agency says are unproven "injury" sufficient to sustain federal jurisdiction, or does a plaintiff in a "follow-on" class action lawsuit have to demonstrate more? The constitutional authority of the federal courts is limited to "cases and controversies," a limitation which has long been interpreted to require that a plaintiff have "standing" to bring a case. "Standing," in turn, requires that the plaintiff has suffered or is at imminent risk of suffering "injury-in-fact."

One recent **case** suggests that it may not be sufficient in these types of cases to simply demonstrate that a company made false or misleading claims and that he or she purchased the product in reliance upon those claims and, thereby, suffered an economic loss. In *In re Cheerios Marketing & Sales Practices Litigation*, No. 09-cv-2413, 2012 WL 3952069 (D.N.J. Sept. 10, 2012), six class action suits were filed shortly after an FDA Warning Letter regarding representations of the health benefits of Cheerios. The district court held that the plaintiffs had not met the injury-in-fact requirement—and thus did not have standing to sue—because, for one, they continued to eat Cheerios after learning of the FDA letter. The ruling suggests that in such a case, the plaintiff might have to show reliance upon the alleged misrepresentation *and* that he or she did not otherwise benefit by purchasing the product (*e.g.*, eating Cheerios for their taste).

Of course 23andMe may have a more difficult time demonstrating a lack of reliance or that the plaintiff received some other benefit but as we discuss in more detail tomorrow, being served with a class action complaint increasingly does not mean that you are without the means to strike back. In the meantime, however, the message of the 23andMe case and similar cases which have preceded it is clear: an FDA Warning Letter, and by implication similar governmental directives, may trigger private class action litigation.