

Merck Has Some Explaining To Do Over Its MMR Vaccine Claims

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By Lawrence Solomon, Contributor

Columnist

Sep 25, 2014, 05:29 AM EDT | Updated Nov 27, 2014

Merck, the pharmaceutical giant, is facing a slew of controversies over its Measles-Mumps-Rubella (MMR) vaccine following numerous allegations of wrongdoing from different parties in the medical field, including two former Merck scientists-turned-whistleblowers. A third whistleblower, this one a scientist at the Centers for Disease Control, also promises to bring Merck grief following his confession of misconduct involving the same MMR vaccine.

The controversies will find Merck defending itself and its vaccine in at least two federal court cases after a U.S. District judge earlier this month [threw out Merck's attempts](#) at dismissal. Merck now faces federal charges of fraud from the whistleblowers, a vaccine competitor and doctors in New Jersey and New York. Merck could also need to defend itself in Congress: The staff of representative Bill Posey (R-Fla) -- a longstanding [critic of the CDC](#) interested in an alleged link between vaccines and autism -- is now reviewing some [1,000 documents that the CDC whistleblower turned over](#) to them.

The first court case, [United States v. Merck & Co.](#), stems from claims by two former Merck scientists that Merck "fraudulently misled the government and omitted, concealed, and adulterated material information regarding the efficacy of its mumps vaccine in violation of the FCA [False Claims Act]."

According to the whistleblowers' court documents, Merck's misconduct was far-ranging: It "failed to disclose that its mumps vaccine was not as effective as Merck represented, (ii) used improper testing techniques, (iii) manipulated testing methodology, (iv) abandoned undesirable test results, (v) falsified test data, (vi) failed to adequately investigate and report the diminished efficacy of its mumps vaccine, (vii) falsely verified that each manufacturing lot of mumps vaccine would be as effective as identified in the labeling, (viii) falsely certified the accuracy of applications filed with the FDA, (ix) falsely certified compliance with the terms of the CDC purchase contract, (x) engaged in the fraud and concealment describe herein for the purpose of illegally monopolizing the U.S. market for mumps vaccine, (xi) mislabeled, misbranded, and falsely certified its mumps vaccine, and (xii) engaged in the other acts described herein to conceal the diminished efficacy of the vaccine the government was purchasing."

These fraudulent activities, say the whistleblowers, were designed to produce test results that would meet the FDA's requirement that the mumps vaccine was 95 per cent effective. To the whistleblowers' delight, the judge dismissed Merck's objections to the case proceeding, finding the whistleblowers had plausible grounds on all of the claims lodged against Merck.

If the whistleblowers win, it would represent more than a moral victory (they repeatedly tried to stop Merck while still in its employ). Under the False Claims Act, the whistleblowers would receive a share -- likely 25 per cent to 30 per cent -- of the amount the government recovers. Previous settlements involving extensive fraud by pharmaceutical companies under the False Claims Act have run into the hundreds of millions of dollars, and in some cases such as against GlaxoSmithKline and Pfizer, into the [billions](#).

The second court case, [Chatom Primary Care v. Merck & Co.](#) relies on the same whistleblower evidence. This class action suit claims damages because Merck had fraudulently monopolized the mumps market. Doctors and medical practices in the suit would be able to obtain compensation for having been sold an overpriced monopolized product, and a defective one to boot, in that the mumps vaccine wasn't effective (indeed, the suit alleged that [Merck expected outbreaks to occur](#) and, as predicted, they did -- mumps epidemics occurred in 2006 in a highly vaccinated population and again in 2009-2010).

"Plaintiffs have argued sufficient facts to sustain a claim for proximate causation, detailing the significant barriers that other companies would face to enter the mumps vaccine market," the court ruled.

The third whistleblower -- a senior CDC scientist named William Thompson -- only indirectly blew the whistle on Merck. He more blew it on himself and colleagues at the CDC who participated in a 2004 study involving the MMR vaccine. Here, the allegations involve a cover-up of data pointing to high rates of autism in African-American boys after they were vaccinated with MMR. In what could be high-profile House hearings before Congressman Posey's Science Committee -- hearings made all the more explosive given the introduction of race into the mix -- Merck could find itself under unprecedented scrutiny. The [CDC still stands by its study](#) although Frank DeStefano, the CDC's Director of Immunization Safety and a co-author in the CDC study, also stated that [he plans to review his notes](#) with an eye to reanalyzing the data.

Some say all publicity is good. In Merck's case, regardless of the ultimate merits, the publicity will be all bad.

AUTISM

FALSE VACCINE CLAIMS

MERCK

MERCK PHARMACEUTICALS

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