

<http://www.forbes.com/sites/gerganakoleva/2012/06/27/merck-whistleblower-suit-a-boon-to-anti-vaccination-advocates-though-it-stresses-importance-of-vaccines/>

Gergana Koleva, Contributor

I write about the intersection of consumer fraud, bioethics and health

Pharma & Healthcare

|

6/27/2012 @ 4:48PM |1,827 views

Merck Whistleblower Suit A Boon to Vaccine Foes Even As It Stresses Importance of Vaccines

Anyone who falls on either side of the debate about vaccines' alleged potential to cause harm is sure to have heard the big news this week — the unsealing of a [whistleblower suit](#) against Merck, filed back in 2010 by two former employees accusing the drugmaker of overstating the effectiveness of its mumps, measles, and rubella vaccine.

The scientists claim Merck defrauded the U.S. government by causing it to purchase an estimated four million doses of mislabeled and misbranded MMR vaccine per year for at least a decade, and helped ignite two recent mumps outbreaks that the allegedly ineffective vaccine was intended to prevent in the first place.

"As the single largest purchaser of childhood vaccines (accounting for more than 50 percent of all vaccine purchasers), the United States is by far the largest financial victim of Merck's fraud. But the ultimate victims here are the millions of children who every year are being injected with a mumps vaccine that is not providing them with an adequate level of protection against mumps. And while this is a disease the CDC targeted to eradicate by now, the failure in Merck's vaccine has allowed this disease to linger with significant outbreaks continuing to occur," the suit alleges.

It refers to a 2006 mumps outbreak in the Midwest, in which 6,500 cases were reported among a highly vaccinated population, and another in 2009, in which 5,000 cases were confirmed. By comparison, the annual average of mumps cases in the U.S. in the two decades preceding the 2006 outbreak was 265; before the introduction of the single-shot Mumpsvax vaccine in 1967, there were approximately 200,000 cases of the disease, according to the 55-page document.

If the accusations are true — thus far Merck has [denied wrongdoing](#) — the case would lend credence to the perception held by many that pharmaceutical companies are more interested in pursuing profits and preserving their market share than in protecting consumers' health.



Specifically, the suit claims Merck manipulated the results of clinical trials beginning in the late 1990s so as to be able to report that the combined mumps vaccine, known as MMR-II (a

revised version of the 1971 MMR shot containing a different strain of the rubella virus), is 95 percent effective, in an effort to maintain its exclusive license to manufacture it. This percentage is the benchmark used by the FDA to grant Merck approval to sell its original mumps vaccine in 1967. It is believed by vaccine authorities to guarantee herd immunity for people who have skipped on the shots.

However, instead of reformulating the vaccine whose declining efficacy Merck itself has acknowledged, the company reportedly launched a complicated scheme to adjust its testing technique so that it would yield the desired potency results. The virologists say they witnessed firsthand the fraud and were asked to directly participate in the dishonest testing, which was dubbed “Protocol 007” and is outlined in great detail in the complaint.

While the Justice Department has refused to rule on the case after conducting its own two-year investigation, the allegations are crucial for a couple of reasons.

Without doubt, if true, they offer an extremely damaging view into the inner process of a company accused of misleading both regulators and consumers about a vital medical product. This is exactly the kind of profit-centered, patient-careless attitude many consumer advocates, vaccine opponents, and non-believers of all stripes ascribe to Big Pharma.

But the suit also serves to remind that vaccines are essential to preventing disease and that any drop in their efficacy is likely to result in disease resurgence and endanger the public’s health.

Unfortunately, what should be a clear distinction between scientific truth and a single alleged case of scientific misconduct is all too readily muddied by anti-vaccination advocates who conflate the two in order to advance their particular kind of dogma.

The opening salvo against immunizations triggered by Merck’s alleged dishonesty comes courtesy of the International Medical Council on Vaccination, an association of medical professionals that lobbies against vaccines. The group is using the lawsuit to actually recast the recent mumps outbreaks as the result of a weak and ineffective vaccine, rather than as the likely outcome of a large enough failure to vaccinate, which is encouraged by messages like the ones the group produces. In a [blog post](#), it essentially argues that had the vaccine been more potent, the outbreaks might have been averted – in the same breath that it boldly declares on its website that “vaccination is an unacceptable risk to every member of society.” Go figure.

Unsurprisingly, the blog’s author also refers to herd immunity as a “fairy tale goal” and uses the opportunity to mock the entire domain of science.

Updated on 06/28/2012: In a statement, a spokesman for Merck said the lawsuit is without merit and the company intends to vigorously defend itself in court. He noted the vaccine's ability to prevent disease remains the same, and reiterated that MMR-II continues to be recommended for routine administration to children by public health authorities around the world.

“Nothing is more important to Merck than the safety and effectiveness of our vaccines and medicines and the people who use them. It’s important to understand that none of the allegations in the

complaint relate to the safety of MMR-II, and we remain confident that MMR-II helps protect against measles, mumps and rubella as described in the labeling for the vaccine,” the spokesman said.

Comments

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- [Hilary Butler](#) 2 days ago

Gergana, are you saying that all the parents who sought for decades to have the truth about antidepressants killing their children, are anti-anti-depressants?

Are you saying that all those who fought with the car industry, to have seat belts and air bags are anti-cars?

Are you saying that all the people who fought Merck to prove that the drug Vioxx, which has maimed and killed so many and about which Merck serially LIED, are “anti-vioxx”

Of course this case is a boon to people who don’t vaccinate, and it’s not about the fact that they are anti-vaccine. It’s about the fact that it’s yet one more lie that BigPharma perpetrates, which should never have been lied about in the first place.

So don’t start pointing one finger at those who will legitimately use this information, which can rightly be used, because the ONLY reason it can be used points right back at Merck in the first place.

If the allegations are true, and they did indeed do this, then like all the other Merck fiascos in the past, Merck have only their own dishonesty and corruption to blame.

So how about talking about the real message, instead of indulging in journalistic epithet?

- Called-out comment

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- [drsuzanne](#) 2 days ago

I knew the pro-vaccine camp would take this stance and say that because we criticize the lack of efficacy of this vaccine we are arguing for vaccination. But here’s the glitch: No vaccine has ever eradicated any disease on this earth...ever. Not mumps even though it’s been heavily used since 1967, not measles, not polio, and that’s right not even smallpox. Do vaccines suppress disease in some cases? Yes they do, like

measles, but eradication is truly a fairy tale. Smallpox is not dead, but has been hiding under the witness protection program with dark glasses and a hat, and renamed monkeypox. No way the smallpox vaccine with all the damaging history and lack of efficacy it had and has been clearly demonstrated, and only given to a minority of the earth's inhabitants eradicated smallpox. It's still here. And in fact smallpox declined when vaccination stopped and living conditions and nutrition improved. The reason smallpox was declared eradicated was because many people in the information age were realizing that the vaccine was causing more problems than it could ever solve. Nobody has ever come up with anything remotely scientific about what titer is protective or about how often it was supposed to be given. But now that is all in the past now isn't it?

Enter the upcoming eradication of polio. Again, polio is still here and never went anywhere. It hides under many other names. Since you are fan of my writing please do visit IMCV and read up on the facts of polio. The plan to eradicate polio simply entails replacing the wild strains with vaccine strains that are and always will be completely capable of causing poliovirus outbreaks with concomitant paralysis in vaccinated communities. Isn't the purpose of polio eradication to decrease the rate of paralysis? Well in the face of numerous polio vaccines in India, the rate of AFP is directly associated with those kids who get the most vaccines. So you tell me where polio has gone. And please while you are considering that, let us know what you learn about the change of diagnostic criteria that occurred after the vaccination came to be in 1954.

OK, measles not eradicated and never will be, mumps same. How can you eradicate a disease when the very vaccine you use can lead to outbreaks of the disease you are trying to eradicate? Mumps vaccine is associated with mumps outbreaks. It's well documented in medical literature.

Chicken pox, not eradicated and never will be. Shingles only on the rise. Pertussis, don't even try to defend that dud of a vaccine that leaves pertussis victims in the 86% vaccinated category.

Please tell us of any vaccine that has eradicated the disease you think it has and I will tell you exactly how it hasn't.

The blind faith that people hold in vaccines is being eroded by stories like this Merck story because many parents know vaccines are not safe- but they think the diseases are terrible enough to take the chance. Now they know that there is no guarantee that the government that supports the vaccines is not hiding out with the crooked scientists that are cooking the books in order to pump dud vaccines into their children.

And the more their doubts are verified by issues like this, the more they will find out that the bogeymen diseases they have been told are so deadly – are not, and they will learn where to go and how to get their children through the illnesses. And then their kids will be all the stronger, less likely to be Merck's customers for life long illnesses that occur as a result of their vaccines. Ask any autism parent what the cost of raising an autistic child is. Ask a parent of a dead gardasil vaccinated child what the emotional cost is. Autoimmune diseases very expensive, allergies and on and on –

\$\$\$ will be taken from Merck and put back in the pockets of the parents who blindly trusted and now know better. That has to hurt – Merck and friends.

- Called-out comment

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- [whiteandnerdy](#) 1 day ago

Isn't it interesting how different people have different interests?

I think that it is important that citizens have a basic science education so that they can:

1. understand the testing done that confirms monkeypox is not smallpox and follow the data to see that IMCV claims are an utter fabrication.
2. similarly understand how the testing done and basic thinking demonstrates that the claim that that the decrease in polio cases was due to changes in the diagnosis criteria is utterly bogus. And that the AFP rate is an artifact of testing—and example of the anti-vaccs complete inability to understand data.
3. all it takes is middle-school math to understand/analyze the distribution of outbreaks in highly vaccinated populations. Yet despite many decades of having the math explained to them, the anti-vaccs still can't get the math or the logic correct.
4. there are a number of recent examples of modern, developed countries that have listened to the anti-vaccs and stopped (or markedly reduced) the use of vaccines. The only result is more sick or dead children. A stark reminder of the complete immorality of the anti-vacc arguments.
5. there are lots of basic logic primers available on the web, that clearly explain the numerous Logical Fallacies in the IMCV arguments about autism, autoimmune disease, money....

Bottom line; IMCV is most harmless—it doesn't stand up to any good-faith effort at fact-checking.

But then the truth is there are some people that still believe in homeopathy and the tooth fairy so one can't conclude it is entirely harmless.

W&N

- Called-out comment

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• [whiteandnerdy](#) 1 day ago

Ms Koleva,

This is purely speculative, but one can't help but suppose that the DOJ spent a good part of their two year investigation doing potency testing on released lots of vaccine.

And after testing how every many lots they deemed necessary, they concluded the suit was entirely without merit and thus choose not to join it.

I would suggest waiting to see what evidence is presented and what the final ruling is.

My 2 cents: I think the correct way to characterize the “International Medical Council on Vaccination” is a group that makes money scaring parents about vaccines and who are complete strangers to the truth.

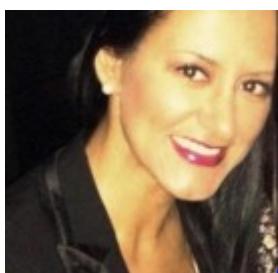
W&N

- Called-out comment

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- Author



[Gergana Koleva](#), Contributor 13 hours ago

W&N,

We're in agreement. I don't know whether the allegations are true or not, and I don't presume that they are. I just think it's fair when writing about such a charged topic to show what the vaccine manufacturer is being accused of, so one can judge for themselves whether the response from the vaccine skeptics makes sense.

- Called-out comment

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• [whiteandnerdy](#) 4 hours ago

Fair enough,

How about turning the question around.

Is there any examples of a vaccine skeptic site that is fair in their coverage of the issues?

This is our children's health.....fairness seems like a pretty modest standard to expect...

W&N

- Called-out comment

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• [Hilary Butler](#) 4 hours ago

Gergana, why are you in agreement with W& N who has got the facts so wrong? W&N says: "they concluded the suit was entirely without merit and thus choose not to join it."

That is not true, so why do you agree with it?

YOU incorrectly said that, "Justice Department has refused to rule on the case after conducting its own two-year investigation". The Justice Department didn't REFUSE to rule on the case. They chose NOT to join in with the case.

Both of you have ignored the facts that the DOJ filed a joint motion with the whistleblowers lawyers to unseal the complaint. The DOJ did not find the allegations false. Quite the opposite – the DOJ also stated that they reserve the right to join in the case at any time in the future. They could also have filed a motion to dismiss the case, but they refused to do so, or to recommend that it be dismissed. That speaks volumes.

The ONLY thing that lack of DOJ participation indicates, is that the FDA is severely exposed on the issue.

As a journalist, it's your job to show the public the facts and flesh out the message, and that is something you are failing to do.

You say, “I don’t know whether the allegations are true or not, and I don’t presume that they are. I just think it’s fair when writing about such a charged topic to show what the vaccine manufacturer is being accused of, so one can judge for themselves whether the response from the vaccine skeptics makes sense.”

Then show what the vaccine manufacturer is being accused of, represent the situation accurately, and allow people to judge the issues on your accurate reporting, because right now, you and W&N are just showing a woeful lack of research on the topic.

- o Called-out comment

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- Author



[Gergana Koleva](#), Contributor 4 hours ago

An example of fair coverage by anti-vaccination site might be hard to find. But I aim to do better than publish scientific myths, so I describe the relevant facts/ allegations regardless of which side they seem to favor.

In this case I don’t see how the allegations, even if true, support anti-vaccination rhetoric. If anything, the company is being accused of exaggerating the potency of MMR-II – something vaccine skeptics should greet as relatively good news if they stand by the idea that vaccines cause harm.

- o Called-out comment

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- Author



[Gergana Koleva](#), Contributor 4 hours ago

Hilary,

I have shown exactly what the vaccine manufacturer is being accused of. In fact it takes the better part of my post. I've also given a link to the original document (the complaint) for anyone who cares to comb through 55 pages.

The lawsuit was unsealed because the Department of Justice decided not to join. It did not say the allegations were false, but neither did it say they were true. The DOJ did conduct a two-year independent investigation and based its decision not to join on that review.

- o Called-out comment

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- o [Hilary Butler](#) 3 hours ago

Gergana, I am a journalist. You are a journalist. The DOJ doesn't base its decision based on THAT review. They base their decision on the implications of that review. If the DOJ had found the case had absolutely no basis in fact, they would have moved to dismiss and would have clearly stated that the case had no merit. They certainly would not have reserved the right to JOIN the case with the whistleblowers, in the future, if they so chose.

Over half of your article was NOT directed at the issues at hand, but at what comes across as a very thinly veiled attack revealing a personal bias.

As my other comment below states very clearly, this issue should NOT be a pro/anti vaccine divide.

Let me combine this with another of your comments above: You said, "In this case I don't see how the allegations, even if true, support anti-vaccination rhetoric. If anything, the company is being accused of exaggerating the potency of MMR-II – something vaccine skeptics should greet as relatively good news if they stand by the idea that vaccines cause harm."

This comment makes no sense to me. How would inflating a potency be good news to anyone who considers that a vaccine could cause harm? Are you assuming that it is always the “potency” of any vaccine which is alleged to cause harm?

Excess antigen (which is not the same as potency) was certainly (alleged) to be the case with the CSL influenza vaccine in australia causing serious side effects in babies, but a vaccine can have zero potency and still have very serious side effects.

Yet you call this case a “single” instance. What you fail to appreciate, perhaps because you are too young to know, (and the provaccine aren’t about to tell you), is that this is just the latest in a long line of vaccine fraud, most of which is brushed aside, or ignored, just as you have done.

I have on my shelves a hefty USA Senate Hearing from 1976, which listed 32 useless vaccines sold prior to 1972, which had serious side effects, no efficacy, and were only removed from the market when another whistleblower used the Senate to call the manufacturers out on the issue – hence the hearing records. Many vaccine companies were landed up with their tails between their tales. Yet how many journalists know their own country’s murky history?

That is why I think you should have done some more homework on the issue, instead of spending so much time fingering others and betraying your own bias.

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o [Hilary Butler](#) Just posted

I note you changed your comment from “single” instance, after I called you on it. Why did you do that? Unfortunately, I failed to take a screen shot, but I consider your amendment somewhat underhand, because it leaves my comment with nothing to hang onto. Reader would have no idea why I made that statement, and think I was talking to thin air.

I feel your edit on your own comment above mine, was unethical and unfair.

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- collapse comment



o [The Refusers](#) 16 hours ago

Big profit in the vaccine market, big profit, big profit
Drug makers got doctors tight, in their pocket, in their pocket
Every kid is a customer, can't stop it, can't block it
School is their ATM, their vaccine marketing department

Big Profit, Big Market, Big Profit — Vaccine Profit!

Vaccination Uber Alles!

Listen to Vaccination Uber-Alles by The Refusers

http://www.reverbnation.com/play_now/song_11347439?utm_campaign=opengraph&utm_content=song&utm_medium=link&utm_source=facebook

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• [Jeff Simon](#) 15 hours ago

... Craving for a time when a journalist could actually unbiasedly show both sides of an issue...

It's amazing how people can completely take leave of their sense of reason or proportion when it comes to vaccines. Like there's so much money in being anti-vaccine (cause, you know, vaccine makers are non-profit ?!). Or that _____ (fill in the blank with any person or organization who even asks to review the science) is completely biased and the drug companies are virtuous and pure. And I can't read a vax article without some doctor/public health master authority type claiming that there is no proof in the history of humankind that vaccines have harmed a single person (VAERS, anyone? Or, how about explaining to me in simple English why vax companies are immune from prosecution for the design defects of vaccines—like that couldn't possibly happen?) and that we all have to drop to our knees and pray that the earth would have split in two wiping out all life as we know it if it weren't for vaccines (cause we have such mastery over viruses ?!), and their holier-than-thou manufacturers..

It's like watching a sportsbar argument. Riveting.

You cannot have an unbiased view of vaccines and not see the manipulation the medical/government/Pharma complex practices as a matter of routine.

I didn't wake up one morning and decide to be "anti-vax." I believed in vaccines. I asked my doctor an honest question about the ingredients as I read them on the manufacturers documentation. And the doc got defensive and lied to me. "Now, what was all that about?" I wondered. Newsflash, Doc. If I ask you a question, and you disrespect the question, I don't go home and forgetaboutit.

Look, people' how's about we expect a reciprocal amount of transparency from the vaccine makers. That doesn't sound reasonable? Show us what you can prove. Acknowledge what you can't. Agree to independent peer-review, clean up your study methodology. And quit trying to wring us for profit.

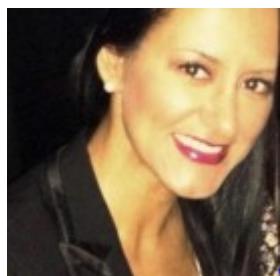
I'd just really appreciate not having to make some fire or the frying pan choice to keep my kid healthy. Or to have an exploratory conversation—that doesn't erode into some ridiculous holy war—with a vaccine believer anytime I try to unearth the truth.

- Called-out comment

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- Author



[Gergana Koleva](#), Contributor 14 hours ago

Jeff,

I think the line of reasoning here is pretty straightforward. If the allegations against Merck are true and it did indeed misrepresent facts about the MMR's potency (not about its safety – the suit is about the vaccine's level of effectiveness), then that is clearly reprehensible. It would justifiably give people reason to doubt and question the company's motives — I've said as much in my post. I have not skipped on describing the specific nature of the allegations, so I don't see how you could argue that my writing is anything but unbiased.

It's worth noting, however, that at this point the allegations are just that. Nothing has been proven, the Justice Department has investigated the claims independently and decided not to pursue, and MMR continues to be the only scientifically tested method to prevent mumps and measles outbreaks. This is not an opinion – it is fact supported by the CDC's immunization program, the FDA, any number of international public health authorities, as well as the decision of most U.S. schools and colleges to require immunization as a condition for admittance.

The only opinion I offer in my post is that it is disingenuous of vaccine skeptics to use the lawsuit (which, again, is not about vaccines causing harm, but about the MMR's declining potency – not a safety issue per se) to amplify the idea that vaccines are inherently harmful.

- Called-out comment

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- [whiteandnerdy](#) 5 hours ago

OK,

Some comments:

1. A physician is the wrong person to ask about the science
2. No one claims that vaccines have never harmed anyone
3. Design defects claims are prohibited because of a large number of successful lawsuits were won with this argument which when reviewed appear to be entirely without merit. Have you read any of the lawsuits filed against vaccine manufacturers?
4. Both Pubmed and the FDA site are good/transparent ways to find the relevant data.

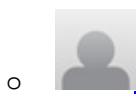
W&N

- Called-out comment

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- [Hilary Butler](#) 3 hours ago

Your comment went further than that Gergana. You stated that IMCV “an association of medical professionals that lobbies against vaccines” when they never have lobbied against vaccines. They have an opinion, just like you do, and they have a right to express that opinion.

You stated: “The group is using the lawsuit to actually recast the recent mumps outbreaks as the result of a weak and ineffective vaccine, rather than as the likely outcome of a large enough failure to vaccinate, which is encouraged by messages like the ones the group produces”

FACT: the outbreaks were a result of a weak and ineffective vaccine, and if you had done as W&N stated (but chose not to do him/herself) and read the medical articles on the topic on Pubmed, you would have seen that that comment was accurate.

Put these titles in Pubmed and read them:

Peltola et al. 2007. Mumps outbreaks in Canada and the United States: Time for new thinking on mumps vaccines.

Brunell. 2007. The effectiveness of evaluating mumps vaccine effectiveness.

Everyone is entitled to their opinion as to whether or not vaccines are warranted for them as individuals and their families based on their own health history and their lifestyles. This issue is not a PRO versus ANTI vaccine issue.

I felt that your responses directed at the “anti” vaccine POV, was an unjustified red herring to divert attention from the FACTS.

it would have been of more benefit to readers for you to have discussed the case more accurately and also fleshed it out with a resume of Merck’s previous fraud history, and the fact that when the CEO of Merck volunteered to lead Penn State’s inquiry into the Sandusky allegations, people were unilateral in their condemnation that the ethically-challenged company should lead an investigation into somebody else’s wrongdoing.

Your narrative narrowly also implied the conclusion that the allegations are false, (for instance, using the word DOH “refused” implying that the case was unwarranted) rather than addressing the factual issues.

The pro-vax argument should be outrage at Merck, and then they should turn around and say what this means, is that those who wish to vaccinate, deserve not only a mumps vaccine that works, but to make an informed choice based on fact, not (should the allegations prove to be true) to be mislead for decades, by fraud.

There should be no pro-vax/anti-vax divide on any form of systemic corporate fraud.

By making this a pro-vax/anti/vax divide, you are handing Merck a free pass.

The irony is that if this were some other pharmaceutical product than a vaccine, like a worse form of Vioxx, or any one of the many other drugs that the FDA has to scratch because of corporate fraud (most of which go undiscussed by you), the pro-vaccine tribe would be jumping all over Merck crying foul. (Particularly if one of their own had been maimed or killed as a result.)

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