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UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

United States of America *ex rel.*, Stephen A. Krahling and Joan A. Wlochowski, Plaintiffs, v. Merck & Co., Defendant.	Civil Action No. 10 4374 **COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT** **JURY TRIAL DEMANDED**

FILED
AUG 27 2010
MICHAEL E. KUNZ, Clerk
By ____ Dep. Clerk

Stephen Krahling and Joan Wlochowski bring this *qui tam* action as Relators on behalf of the United States against their former employer, Merck & Co., Inc. ("Merck"), under the False Claims Act, 31 U.S.C. §§ 3729-3733, and allege -- upon knowledge with respect to their own acts and those they personally witnessed, and upon information and belief with respect to all other matters -- as follows:

INTRODUCTION

1. This case is about Merck's efforts for more than a decade to defraud the United States with respect to the efficacy of Merck's mumps vaccine.

2. Specifically, in an effort to maintain its Food and Drug Administration ("FDA") approval and exclusive license to sell the vaccine, Merck has used improper testing techniques and falsified test data to fabricate a vaccine efficacy rate of 95 percent or higher. This is the efficacy threshold on which the FDA insists for its licensing and approval of the vaccine. In truth, the efficacy rate of Merck's mumps vaccine is, and has been since at least 1999, significantly lower than this requisite threshold.

3. Relators Krahling and Wlochowski were employed as virologists in the Merck lab that performed this fraudulent efficacy testing. They witnessed firsthand the improper testing and data falsification in which Merck engaged to artificially inflate the vaccine's efficacy findings. In fact, they were pressured by their Merck superiors and senior Merck management to participate in the fraud and subsequent cover-up.

4. As a result of Merck's fraudulent scheme, the United States has over the last decade paid Merck hundreds of millions of dollars for a vaccine that does not provide adequate immunization. Had the government known the true efficacy of the vaccine, the government's decision to purchase the product surely would have been different, either purchasing the vaccine from another source, requiring that Merck produce a new vaccine with the requisite immunizing effect, or re-negotiating the contract for the existing product.

5. As the single largest purchaser of childhood vaccines (accounting for more than 50 percent of all vaccine purchases), 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. And while this is a disease that, according to the Centers for Disease Control ("CDC"), was supposed to be eradicated by now, the failure in Merck's vaccine has allowed this disease to linger with significant outbreaks continuing to occur.

6. Relators bring this case on behalf of the United States to recover the funds that the government spent for a vaccine that -- in the absence of Merck's fraud -- it would not have otherwise purchased, and for all associated penalties. They also bring this case to stop Merck from continuing with its scheme to misrepresent the true efficacy of its mump vaccine.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a).

12. This Court has personal jurisdiction over Merck under 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because a substantial part of the events giving rise to this Complaint occurred in this District. Indeed, Merck's fraudulent scheme with respect to its mumps vaccine was originated and continues to be carried out in this District at Merck's vaccine division facility in West Point, Pennsylvania.

13. Pursuant to 31 U.S.C. § 3732(a), venue is proper because Merck can be found in and transacts business within this District. Throughout the time period relevant to the allegations of this Complaint, Merck engaged in substantial business transactions within this District and committed many of the violations proscribed by 31 U.S.C. § 3729 in this District.

BACKGROUND

14. For more than thirty years, Merck has had an exclusive license from the FDA to manufacture and sell a mumps vaccine in the U.S. The FDA first approved the vaccine in 1967. It was developed by Dr. Maurice Hilleman, at Merck's West Point research facility, from the mumps virus that infected his five year-old daughter Jeryl Lynn. Merck continues to use this "Jeryl Lynn" strain of the virus for its vaccine today.

15. Merck's original mumps vaccine was delivered to patients in a single, stand-alone injection. In 1971, Merck developed a combination vaccine which delivered Merck's vaccines for measles, mumps and rubella ("MMR") in one injection. The same year, the FDA gave Merck the exclusive U.S. license to manufacture and sell this MMR vaccine. In 1978, the FDA approved and gave Merck the exclusive U.S. license for the manufacture and sale of "MMRII," a

replacement for MMR containing a different strain of the rubella virus. Since that time, Merck has sold more than 450 million doses world-wide, with approximately 200 million doses sold in the U.S. Merck currently sells more than seven million doses of the vaccine in the U.S. annually.

16. In order to obtain its original FDA approval and license to sell the mumps vaccine, Merck conducted tests which demonstrated that the vaccine had an efficacy rate of 95 percent or higher. This meant that 95 percent of those taking the vaccine would be immunized against mumps. The FDA insists on such a high efficacy rate because only then can the disease ultimately be eradicated through what is commonly referred to as "herd immunity." Short of that, there remains a real risk of continued outbreaks of the illness. When outbreaks of mumps occur in vaccinated populations, the disease afflicts older children who are at greater risk of complications. It also presents greater risks for infants.

17. Merck's mumps vaccine originally seemed well on its way to achieving this herd immunity threshold. Before the introduction of the vaccine, there were approximately 200,000 cases of mumps in the U.S. annually. This number dropped off precipitously after the widespread administration of Merck's vaccine. In the 1980s, outbreaks of mumps still occurred but these too petered out for a while with the requirement beginning in 1989 that children receive two doses of the MMRII vaccine (at 12-18 months, and again at 4-5 years). The CDC projected that by 2010, mumps would be completely eradicated. Unfortunately, that has not happened. Beginning in 2006, there has been a resurgence in mumps outbreaks with the most recent one starting last year and ongoing now.

18. The reason for these continued outbreaks is that Merck's vaccine does not have a 95 percent efficacy rate. The vaccine may have been 95 percent effective when it was originally licensed in 1967, but the vaccine virus has been waning as it is continually "passaged" to create

more vaccine virus for distribution. Vaccine propagation further attenuates the virus, a problem which is compounded with each additional passage of the virus to create more vaccine. This is especially evident in the case of Merck's mumps vaccine because the vaccine strain was established more than forty years ago and has been used to manufacture hundreds of millions of doses.

19. Rather than develop a new mumps vaccine with the requisite efficacy rate, Merck has instead taken pains to maintain before the FDA and the public that its forty-year old vaccine continues to have an efficacy rate of 95 percent or higher. This was easy to do for a while because Merck was able to rely on the efficacy testing it conducted in connection with the FDA's original granting of Merck's exclusive license. However, in 1997, the FDA required Merck to conduct renewed efficacy testing of the mumps vaccine in MMRII. The FDA's demand also coincided with Merck's development and quest for FDA approval of a new vaccine called "ProQuad" which would combine its vaccine against varicella (*i.e.* chickenpox) with MMRII.

20. Without demonstrating that its mumps vaccine continued to be 95 percent effective, Merck would lose its exclusive license to manufacture and sell its MMRII vaccine. And if Merck lost the license for MMRII, Merck would also be unable to secure FDA approval for its ProQuad vaccine. So, Merck set out to conduct testing of its mumps vaccine that would guarantee an efficacy rate of 95 percent or higher. It did this through manipulating its testing procedures and falsifying the test results. Relators Krahling and Wlochowski participated on the Merck team that conducted this testing and witnessed firsthand the fraud in which Merck engaged to reach its desired results. Merck internally referred to the testing as Protocol 007.

the virus. The "seroconversion" rate is the scientific term for measuring the percentage of children that are successfully immunized from the vaccine. A seroconversion occurs when the pre-vaccination blood sample is "negative" (meaning, insufficient antibodies to neutralize the virus) and the post-vaccination sample is "positive" (meaning, sufficient antibodies to neutralize the virus). For the purposes of its testing, Merck needed a seroconversion rate of 95 percent or higher. This was the efficacy threshold the FDA required.

25. While Merck's PRN test was modeled after the efficacy test generally accepted in the industry, it diverged from this "gold standard" test in a significant way. It did not test the vaccine for its ability to protect against a "wild-type" mumps virus. A wild-type virus is a strain of the virus as it exists in nature and would confront a person in the real world. That is the type of real-life virus against which vaccines are generally tested. Instead, Merck tested the children's blood for its capacity to neutralize the same Jeryl Lynn mumps strain with which the children were vaccinated. The children's vaccine response was not tested for its capacity to neutralize virulent, disease-causing mumps virus. The use of the Jeryl Lynn strain, as opposed to a virulent wild-type strain, subverted the fundamental purpose of the PRN test which was to measure the vaccine's ability to provide protection against a disease-causing mumps virus that a child would actually face in real life. The end result of this deviation from the accepted PRN gold standard test was that Merck's test overstated the vaccine's effectiveness.

26. Even with a deviation that could only overstate vaccine effectiveness, the results from Merck's preliminary testing yielded a seroconversion rate of only 79.5 percent. This was more than 15 percent lower than the 95 percent efficacy threshold on which Merck's original FDA approval and exclusive license was based and which the FDA still required. Merck knew that a seroconversion rate so far below 95 percent would not be acceptable to the FDA and

would not support Merck's continued license to exclusively sell the mumps vaccine (or a new license to sell ProQuad). Indeed, during the testing process, Krah on several occasions stressed to his staff (including to Relators Krahling and Wlochowski) that if Merck could not show a minimum 95 percent seroconversion rate in conducting these mumps efficacy tests, the FDA would rescind Merck's exclusive licensing rights to MMRII.

27. So, Merck abandoned the PRN test and the unsatisfactory results it yielded and worked towards developing a new efficacy test that would yield the desired seroconversion results.

B. Merck's Improper Use of Rabbit Antibodies In Its "Enhanced" PRN Test

28. The second test Merck employed under Protocol 007 was formally called the Anti-IgG Enhanced Mumps Plaque Reduction Neutralization Assay. It was commenced in 2000 and again led by Krah and his staff at Merck's West Point facility. Relators Krahling and Wlochowski participated on the team that conducted this supposedly enhanced test. Each of them witnessed firsthand the falsification of the test data in which Merck engaged to reach its 95 percent efficacy threshold. In fact, each was significantly pressured by Krah and other senior Merck personnel to participate in this fraud.

29. From the outset, the objective of this newly devised procedure was clear. It was not to measure the actual seroconversion rate of Merck's mumps vaccine. It was to come up with a methodology that would yield a minimum 95 percent efficacy threshold regardless of what the vaccine's true efficacy actually was. The very first page of an October 2000 Merck presentation on the newly devised efficacy test states just that:

> **Objective:** Identify a mumps neutralization assay format . . . that permits measurement of a ≥ 95% seroconversion rate in M-M-R®II vaccines.

Notably, nowhere in this presentation or anywhere else did Merck provide any kind of justification or explanation for abandoning its original PRN test and the unsatisfactory efficacy results the test yielded.

30. To reach the stated objective for its "enhanced" test and increase the measured seroconversion rate to the predetermined 95 percent threshold, Merck continued to use its scientifically flawed PRN test but with one additional change. Merck added antibodies made in rabbits, sometimes referred to as anti-IgG, to both the pre and post-vaccination blood samples. The use of rabbit antibodies in laboratory testing is not uncommon. They can serve as a highlighter of sorts to mark human antibodies that might not otherwise be identifiable on their own. Significantly, in those experiments where rabbit antibodies are added as an enzyme to identify human antibodies, the rabbit antibodies do not alter the outcome of the experiment. However, Merck added rabbit antibodies for the singular purpose of altering the outcome of the test by increasing the virus neutralization count.

31. In a laboratory setting, rabbit antibodies can combine with human antibodies to cause virus neutralization that would not otherwise occur from the human antibodies alone. Without applying a proper "control" to the process, there is no way to isolate whether virus neutralization is caused by the human antibodies alone or in combination with rabbit antibodies. Merck did not employ this kind of control. It included in its seroconversion measure all virus neutralizations regardless of whether they resulted from human antibodies or by their combination with the rabbit antibodies. This "enhanced" PRN procedure thereby allowed Merck to increase dramatically the recordable instances of mumps virus neutralization and to count those neutralizations toward seroconversion and its measure of the vaccine's success.

32. Merck knew that the neutralizations attributable to the rabbit antibodies would never exist in the real world. This is because the human immune system, even with the immunity boost provided by an effective vaccine, could never produce rabbit antibodies. And adding rabbit antibodies as a supplement to a vaccine was not an option because it could result in serious complications to a human, even death. Thus, the "uncontrolled" boost to neutralization Merck designed using rabbit antibodies in its laboratory did not in any way correspond to, correlate with, or represent real-life (*in vivo*) virus neutralization in vaccinated people.

33. But the use of the rabbit antibodies allowed Merck to achieve its high seroconversion objectives. In fact, the exact same paired blood samples that were found under Merck's original PRN test to lack sufficient virus neutralizing antibodies were now considered seroconverted under the "enhanced" test. Indeed, in one panel of sixty paired blood samples that had failed the original PRN test, Merck measured a seroconversion rate of 100 percent! In other words, non-neutralizing concentrations of antibodies that would never protect a child from mumps in the real world were under Merck's "enhanced" test treated as vaccine successful solely because of the additional neutralization provided by the rabbit antibodies.

34. Krah defended the use of rabbit antibodies in the "enhanced" PRN test by pointing to the FDA's purported approval of the process. However, whatever approval Merck may have received for this testing, the FDA was not fully aware of the extent of Merck's manipulation, including Merck's wholesale fabrication of test data to reach its preordained 95 percent efficacy threshold.

C. Merck's Falsification of the "Enhanced" PRN Test Results

35. There was one significant problem with Merck's improper use of rabbit antibodies to boost its virus neutralization counts. Rabbit antibodies boosted neutralization counts not only

in the post-vaccination blood samples. They also boosted them in the pre-vaccination samples. However, too much virus neutralization in the pre-vaccinated sample created a "pre-positive," enough virus neutralization to pass the seroconversion threshold without the vaccine.

36. Pre-positives will ordinarily occur in a small percentage of the child population that will be immune to mumps even without vaccination. This immunity would principally come from a previous exposure to the mumps virus, or from immunity that is transferred to a child from the mother in utero. However, the incidence of this immunity is small, generally measured by the scientific community at around 9 percent of the child population.

37. The problem for Merck was that with the addition of the rabbit antibodies to the pre-vaccination blood samples, its test was finding a significantly higher percentage of pre-positives than the 9 percent industry recognized standard. In the results of one test that Relators Krahling and Wlochowski both witnessed, the pre-positive rate was more than 80 percent. Krah instructed Wlochowski to throw out the results of that particular test.

38. The existence of such a high percentage of pre-positives threatened the viability of Merck's "enhanced" test because the high pre-positive rate would red flag the procedure itself as flawed. The FDA would question the results of a test that had such a high level of pre-positives. And Merck was well aware that the FDA would never accept the results of an efficacy test that manipulated rabbit antibodies to inflate the virus neutralization counts in the pre-vaccination blood. Further, when there was a pre-positive in the pre-vaccinated sample, any favorable results in the post-vaccinated sample could not be used as a vaccine success toward the 95 percent efficacy requirement.

39. In the October 2000 presentation, Merck acknowledged that its initial "enhanced" PRN testing results yielded a level of pre-positives that was too high. Merck also made clear that

they needed to "optimize" the amount of rabbit antibodies used in the process so that the test would yield a pre-positive rate of 10 percent or less and a seroconversion rate of 95 percent or more: "Pre-positive rate is higher than desirable," and "Continue evaluation of results using optimized anti-IgG amount (target ≤ 10% pre-positive rate and ≥ 95% seroconversions)."

40. The problem was that no amount of tinkering with the level of rabbit antibodies would produce a pre and post-vaccination virus neutralization for Merck's vaccine within the desired range. Without rabbit antibodies, Merck could not support a sufficient level of post-vaccination neutralization. Conversely, by adding rabbit antibodies, Merck could not avoid having too high a level of pre-vaccination neutralization (*i.e.*, too many pre-positives). This left only one way for Merck to reach its desired seroconversion outcome -- falsify the test results.

41. Specifically, Krah and Yagodich and other members of Krah's staff falsified the test results to ensure a pre-positive neutralization rate of below 10 percent. They did this by fabricating their plaque counts on the pre-vaccination blood samples, counting plaques that were not actually there. With these inflated plaque counts, Merck was able to count as pre-negative those blood samples that would have otherwise been counted as pre-positive because of the increased neutralization caused by the rabbit antibodies.

42. Merck's falsification of the pre-vaccination plaque counts was performed in a broad-based and systematic manner:

- Krah stressed to his staff that that the high number of pre-positives they were finding was a problem that needed to be fixed.
- Krah directed his staff to re-check any sample found to be pre-positive to see if more plaques could be found to convert the sample to a pre-negative.
- Krah and Yagodich falsified plaque counts to convert pre-positives to pre-negatives, and directed other staff scientists to do the same.

- Krah appointed Yagodich and two others to "audit" the testing that other staff scientists had performed. These audits were limited to finding additional plaques on pre-positive samples thereby rendering them pre-negatives.

- Krah instituted several measures to isolate the pre-positive samples, facilitate their "re-count" and consequent conversion to pre-negatives, and minimize the chances of detection. These included destroying test results, substituting original counting sheets with "clean" sheets, and entering and changing test results directly onto electronic (excel) spreadsheets that left no paper trail.

- Merck cancelled a planned outsource of the efficacy testing to a lab in Ohio because the outside lab was unable to replicate the seroconversion results Krah was obtaining in his lab. Krah and his staff conducted all the testing instead.

43. Unsurprisingly, none of the "recounting" and "retesting" that Merck performed as part of its "enhanced" PRN testing was performed on any post-vaccination samples or on any pre-vaccination samples that were pre-negative. This additional "rigor" was only applied to the pre-positive samples, the very samples that were keeping Merck from achieving the requisite 95 percent seroconversion threshold.

44. In July 2001, Relators Krahling and Wlochowski conducted their own test to confirm statistically what they already knew to be true. They reviewed approximately 20 percent of the data that Merck had collected as part of the "enhanced" PRN test. In this sampling, they found that 45 percent of the pre-positive data had been altered to make it pre-negative. No pre-negatives were changed to pre-positives. No post-positives were changed to post-negatives. No post-negatives were changed to post-positives. All changes were in one direction -- reducing the incidence of pre-positives. The statistical probability of so many innocent changes occurring in just the pre-positive data and in no other data was more than a trillion to one. And that is a conservative measure given the likelihood that an even greater number of pre-positives were changed but remained undetected because the changes were not recorded in Merck's files.

D. The Complicity of Merck's Senior Management

45. Krah did not act alone in orchestrating the falsification of Merck's mumps vaccine test results. He acted with the authority and approval of Merck's senior management.

46. In April 2001, for example, Emilio Emini, the Vice President of Merck's Vaccine Research Division, held a meeting with Krah and his staff where he directed them to follow Krah's orders to ensure the "enhanced" PRN testing would be successful. He also told the staff that they had earned very large bonuses for their work so far on the project and that he was going to double the bonuses and pay them once the testing was complete.

47. In July 2001, Relator Krahling met with Alan Shaw, Merck's Executive Director of Vaccine Research, and complained to him about the fraudulent vaccine testing. Krahling presumed that Shaw already knew about the fraud since he visited Krah's lab frequently and almost certainly would have witnessed the changing of pre-positive data that Krah was openly directing. Nevertheless, Krahling wanted to put Shaw on formal notice of the fraud and told him of the falsification of the pre-positive data. He also complained about the improper use of the rabbit antibodies to inflate the post-vaccine neutralization counts. Shaw responded that the FDA permitted the use of rabbit antibodies and that that should be good enough for Krahling. Shaw refused to discuss anything further about the matter. Instead, Shaw talked about the significant bonuses that Emini had promised to pay once the testing was complete.

48. Relator Krahling then met with Bob Suter, Krahling's human resources representative at Merck. Krahling told Suter about the falsification of testing data and Shaw's refusal to get involved. Krahling told Suter that he was going to report the activity to the FDA. Suter told him he would go to jail if he contacted the FDA and offered to set up a private meeting with Emini where Krahling could discuss his concerns.

49. Shortly thereafter, Emini agreed to meet with Krahling. Krahling brought to the meeting actual testing samples and plaque counting sheets to demonstrate to Emini the fraudulent testing that Krah was directing. Emini agreed that Krah had misrepresented the data. Krahling also complained about the use of rabbit antibodies to inflate the seroconversion rate. Emini responded that the rabbit antibodies were necessary for Merck to achieve the project's objective. Krahling proposed a scientific solution to lower the pre-positive rate and end the need to falsify data -- stop using rabbit antibodies. When Emini declined, Krahling asked him what scientific rationale justified using the rabbit antibodies. Emini explained that Merck's choice to use these antibodies was a "business decision."

50. To assuage Krahling's concerns, Emini promised to conduct an "internal audit" of the Protocol 007 testing. Krahling countered that the FDA should be contacted since only the FDA could perform an audit that was truly independent. Emini ordered Krahling not to call the FDA. Immediately after the meeting, Suter approached Krahling and threatened that he would be put in jail if he contacted the FDA.

51. The next morning, Krah arrived early to the lab and packed up and destroyed evidence of the ongoing Protocol 007 efficacy testing. This included garbage bags full of the experimental plates that would have (and should have) been maintained for review until the testing was complete and final. Despite the threats he received from Suter and Emini, Krahling called the FDA to report this activity and Merck's ongoing fraud.

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E. The FDA Interview of Krah and Shaw

54. On August 6, 2001, in response to Krahling's call, an FDA agent came to Merck to question Krah and Shaw. Krahling was able to situate himself near the interview and listen to the agent's questions and what Krah and Shaw said in response. The FDA agent's questions were largely centered around Merck's process for counting plaques in the "enhanced" PRN test. Krah and Shaw misrepresented the process that Merck was actually conducting and the fact that Merck was falsifying the pre-positive test data.

55. In fact, the FDA agent asked Krah if it was typical laboratory procedure to re-check the original plaque counts. Krah replied that plaque counts were being rechecked only in the control plates, and only in order to verify the results. Krah also told the FDA agent that data is not changed once it is entered into the excel spreadsheet. When the FDA agent pressed Krah on what criteria he used to alter data on the counting sheets, Krah left the room without giving her an answer. Shaw stepped in and told the FDA agent that a memo would be added to the

experimental procedure to explain the data alterations. When the FDA agent asked Shaw why this had not been done before the project started, Shaw replied that Krah had identified problems and trends with the original counts that only became noticeable after the results were analyzed. Krah re-entered the room and told the FDA agent that no revisions had been made to the experimental plates. These responses were patently false and kept the FDA agent from finding out what was really going on with Merck's manipulation of the testing procedure to reach its targeted seroconversion rate.

56. The entire interview with Krah and Shaw was short, probably less than half an hour. She did not question Krahling, Wlochowski or other members of Krah's staff in order to corroborate what Krah and Shaw told her. As far as Relators witnessed, she did not attempt to substantiate Krah's or Shaw's responses by reviewing any of the testing samples or backup data that had escaped destruction. And she did not address the actual destruction of evidence that Krah had already facilitated.

57. The FDA issued a one page deficiency report identifying a few relatively minor shortcomings in Merck's testing process. These principally related to flaws in Merck's record-keeping and in its validation/explanation of changes to the test data.

58. The report did not address nor censure Merck for any issues relating to Merck's improper use of rabbit antibodies or Merck's wide-scale falsification of pre-positive test data. The FDA did not discover this fraudulent activity in the course of their perfunctory visit because of Krah's and Shaw's misrepresentations to the FDA.

59. In order to comply with the deficiency report, Merck made minor adjustments to its testing procedure relating to its heretofore *ad hoc* procedure for counting plaques. The new, more formalized procedure explicitly provided for supervisory oversight and review of plaque

counts in pre-vaccinated blood samples and where plaques were difficult to read because of the condition of the sample. In other words, under the "new" procedure, Merck continued to falsify the test data to minimize the level of pre-positives and inflate the seroconversion rate. Merck simply used the deficiency report as a vehicle to "legitimize" the scheme.

60. After the FDA visit, Krahling was barred from any further participation in the Protocol 007 project. He was also prohibited from accessing any data related to the project. Shortly thereafter, he was given a poor performance review and barred from continuing to work in Krah's lab on any matter. He was offered a position in a different lab within Merck's vaccine division, but it involved work for which Krahling had no prior experience or interest. At this point, Krahling felt that his only option was to resign from the company, which he did in December 2001.

61. Wlochowski continued to work in Krah's lab until she too was transferred out of Krah's lab at the end of September, 2001. She spent an additional year working at Merck in a lab overseen by Dr. Palker before she too left Merck.

62. Merck completed its Project 007 testing in late summer or early fall 2001. Unsurprisingly, the results Merck reported fell within the 95 percent seroconversion target Merck had from the outset. This is the result Merck provided the FDA and the public at large. What no one knew outside of Merck -- not the FDA, the CDC or any other governmental agency -- was that this result was the product of Merck's improper use of rabbit antibodies and the wide-scale falsification of test data to conceal the inflated seroconversion numbers these antibodies generated.

MERCK'S ON-GOING MISREPRESENTATION OF A 95 PERCENT EFFICACY RATE

63. Since the conclusion of the Protocol 007 testing and continuing through the present, Merck has represented that its mumps vaccine has at least a 95 percent efficacy rate. It has done so even though Merck is well aware that the efficacy rate is far lower and even though it recognizes that the FDA would rescind Merck's exclusive license if it were aware of the true efficacy rate of the vaccine.

A. Merck's Misrepresentations Through Package Inserts

64. Merck principally has made these false representations in the package insert that accompanies each dose of Merck's vaccine. This is the product material that the FDA requires which, among other things, informs the government, health care providers and the public of the composition of the vaccine and its overall efficacy at immunizing the recipient from contracting mumps.

65. Merck's mumps vaccine insert has changed over the years, but at least one thing has remained constant – Merck's reporting of at least a 95 percent efficacy rate. The current insert provides that "a single injection of the vaccine induced mumps neutralizing antibodies in 96% of susceptible persons." As support for this representation, Merck cites the studies it conducted about forty years ago to obtain its original license and vaccine approval. Merck's insert has contained this exact language and backup support since at least 1999.

66. The current insert also provides that "following vaccination, antibodies associated with protection can be measured by neutralization assays." The citation for this statement is "unpublished data from the files of Merck Research Laboratories." While the source for this unpublished data is not specified, it would appear to be from the falsified results of the Protocol 007 efficacy testing.

67. Merck's product insert is a clear misrepresentation of the efficacy rate of its mumps vaccine. It relies on outdated studies that are not reflective of the vaccine's current effectiveness. It ignores the unfavorable seroconversion results from Merck's 1999 PRN test which Merck ultimately abandoned. And it ignores the fraud and manipulation that was intrinsic to the "enhanced" PRN test. In short, as Merck well knows, the efficacy rate of its mumps vaccine is no where near 95 percent, and has not been for a very long time. Yet, Merck continues to misrepresent a 95 percent efficacy rate to ensure its continued sale of the vaccine in the U.S. and Europe.

B. Merck's Misrepresentations Through Expanded Distribution of the Vaccine

68. Merck's misrepresentations relating to its mumps vaccine have not been limited to its sales of MMRII in the U.S. Merck has also obtained approval to sell the vaccine in Europe and to sell the MMRII/Varicella combination vaccine, referred to as ProQuad, in both the U.S. and Europe. Merck obtained these approvals by again misrepresenting to the FDA (in the U.S.) and the EMA (in Europe) the efficacy rate of its mumps vaccine.

69. In 2005, the FDA granted Merck approval and an exclusive U.S. license for its ProQuad vaccine. Merck obtained the license continuing to misrepresent the efficacy of its mumps vaccine. Merck sold ProQuad in the U.S. until the vaccine became unavailable in June 2007 because of certain manufacturing constraints. Merck is resuming sale of the vaccine in the U.S. after obtaining the necessary approvals in an ongoing misrepresentation of the efficacy of its mumps vaccine.

70. In 2006, the EMA approved Merck's sale of an MMRII analogue (called MMR Vaxpro) through the joint venture Sanofi Pasteur MSD. Merck used the falsified results of the "enhanced" PRN test to obtain this approval. The EMA actually cited Protocol 007 test

results in support of its decision to grant the approval. Since then, Merck has been manufacturing MMRVaxpro at its West Point facility for Sanofi Pasteur MSD to sell in Europe.

71. Around the same time, the EMA also approved Sanofi Pasteur MSD's application for sale of Merck's ProQuad in Europe. As with MMRVaxpro, Merck's joint venture submitted the falsified results of Protocol 007 to the EMA as supportive clinical information in its vaccine application. Relying on this information, the EMA found "no major concern" about the efficacy of the mumps component of the vaccine.

72. Thus, by 2006, Merck had exclusive licenses to sell MMRII and ProQuad in the U.S., as well as licenses to sell MMRII and ProQuad in Europe. Throughout this time, Merck misrepresented an efficacy rate of 95 percent or higher and backed it up with scientifically deficient testing and outright fraud.

C. Merck's Misrepresentations Through Recent Mumps Outbreaks

73. Without the requisite 95 percent efficacy for Merck's vaccine and the herd immunity that it would bring about, there remained a significant risk of a resurgence of mumps outbreaks. That is exactly what Krah -- who was well aware of the vaccine's failings -- predicted would occur. In a conversation he had with Relator Krahling in the midst of the "enhanced" PRN testing, Krah acknowledged that the efficacy of Merck's vaccine had declined over time, explaining that the constant passaging of virus to make more vaccine for distribution had degraded the product. Krah predicted that because of this, mumps outbreaks would continue. Krah said all of this in an effort to justify Merck's falsification of the test data because, according to Krah, the Merck vaccine was still the safest one available. Krah was correct in his prediction of renewed mumps outbreaks.

1. *The 2006 Mumps Outbreak*

74. In 2006, more than 6,500 cases of mumps were reported in the Mid-West. This was the largest mumps outbreak in almost twenty years (since the two-dose MMRII requirement was implemented) and a significant spike from the annual average of 265 cases that had been reported for the years leading up to the 2006 outbreak. The outbreak began in Iowa with a group of college students and ultimately spread to the states of Kansas, Illinois, Nebraska, Missouri, South Dakota, Pennsylvania and Wisconsin.

75. The CDC, FDA and Merck publicly worked together to determine the cause of this 2006 outbreak. Of course, only Merck knew that the primary cause was the insufficient efficacy of its vaccine. But Merck continued to maintain its inflated efficacy rate and the government continued to believe that there was no problem with the vaccine. During the investigation of the 2006 outbreak, the CDC's Director, Julie Gerberding, reaffirmed the CDC's position -- no doubt fed by Merck's fabricated scientific studies and continued misrepresentations -- that there was no problem with the vaccine:

> We have absolutely no information to suggest that there is any problem with the vaccine. ... What is going on here in the context of the outbreaks is a number of people who have not received both doses, coupled together with people who have received the vaccine but are susceptible anyway because it is not perfect, living in crowded conditions like college dormitories or mixing up with other students at spring break or during holidays, and setting off a cascade of transmission that is going to take a while to curtail.

Ms. Gerberding and the CDC emphasized that "[t]he best protection against the mumps is the vaccine."

76. The scientific community has not been so accepting of Merck's vaccine or the perception Merck has falsely propagated that the efficacy of its vaccine had nothing to do with the 2006 outbreak. Scientists and public health officials world-wide have continued researching

the 2006 outbreak to understand the origins of such a large epidemic among a highly vaccinated population. One of the leading studies led by Dr. Gustavo Dayan, then a doctor at the CDC, and published in 2008 in the *New England Journal of Medicine*, concluded that "[a] more effective mumps vaccine or changes in vaccine policy may be needed to avert outbreaks and achieve elimination of mumps." Dayan, "Recent Resurgence of the Mumps," *New England Journal of Medicine*, 358;15 (Apr. 10, 2008) 1580.

77. In another study, several scientists questioned Merck's use of the Jeryl Lynn strain, instead of the wild-type virus, in Merck's efficacy testing. They noted that with this kind of testing, vaccine efficacy can be significantly overstated because "good results can be obtained that do not reflect the actual ability of the vaccine to provide protection from disease. A vaccine failure is investigated properly only if, in addition to avidity testing, the ability of antibodies to neutralize wild mumps virus has been checked." Heikki Peltola, *et al.*, "Mumps Outbreaks in Canada and the United States: Time for New Thinking on Mumps Vaccine," *Clinical Infectious Diseases*, 2007;45 (15 Aug. 2007) 459, 463.

78. What is perhaps most notable about this study is that it scientifically questioned Merck's stated efficacy based solely on Merck's use of the vaccine strain instead of the wild type virus to test efficacy. The critique did not (and could not) even account for Merck's concealed efforts to further inflate its efficacy results with the improper use of rabbit antibodies and the falsification of test data.

79. Currently, Emory University is conducting a clinical trial of its university students in yet another attempt to explain the cause for the 2006 mumps outbreak among college-age students who had received both doses of the vaccine. However, Merck is listed as a collaborator on that study, thus continuing to position itself to perpetuate its fraudulent efficacy findings.

80. Merck's continuing misrepresentations with respect to its efficacy testing has prevented a true understanding of what was actually behind the 2006 outbreak – Merck's vaccine failure and an efficacy rate well below 95 percent.

81. Dr. Dayan is unlikely to pursue his conclusion that it may be time for a new vaccine, or to conduct future studies to help evaluate national vaccine policy. Dr. Dayan has since left the CDC to work in the Clinical Department of Sanofi Pasteur. This is the vaccine division of the Sanofi Aventis Group, Merck's partner in manufacturing and selling the mumps vaccine in Europe. To date the CDC has not acted on Dr. Dayan's conclusions either.

82. Dr. Gerberding, the head of the CDC during the 2006 outbreak, has also left the CDC. In January 2010, she became the president of Merck's Vaccine Division.

2. *The Current Mumps Outbreak*

83. In his 2008 study, Dr. Dayan also predicted another mumps outbreak would follow three years after the 2006 outbreak. This followed from the three-year cycles in which outbreaks occurred in the pre-vaccine era: "In the pre-vaccine era, mumps activity followed 3 year cycles, so the current low activity rate [at the time of his 2008 study] may be transient while another critical mass of susceptible persons accrues." Dayan, "Recent Resurgence of the Mumps," *New England Journal of Medicine*, 358;15 (Apr. 10, 2008) 1580, 1587-88.

84. In August 2009, roughly three years after the 2006 outbreak and just as Dr. Dayan predicted, another mumps outbreak began. As with the 2006 outbreak, the ongoing 2009 outbreak occurred despite high vaccination coverage among the U.S. children's population. As of August 2010, more than 3,700 cases had been reported to the CDC.

85. Because of the 2006 and 2009 outbreaks, the CDC has pushed back its target date for eradicating mumps from its original 2010 goal to no earlier than 2020. But no amount of

extra time will be enough to eliminate the disease if Merck continues to misrepresent the efficacy of its vaccine and is thereby able to maintain an exclusive license for a vaccine that does not provide adequate immunization.

THE UNITED STATES' PAYMENT OF HUNDREDS OF MILLIONS OF DOLLARS FOR A VACCINE THAT DOES NOT PROVIDE ADEQUATE IMMUNIZATION

86. Over the past decade, Merck's fraudulent scheme to misrepresent the efficacy of its mumps vaccine has cost the U.S. hundreds of millions of dollars through the government's annual purchases of the vaccine under the National Vaccine Program ("NVP"). The NVP was created by the National Childhood Vaccine Injury Act in 1986 to coordinate all federal activities related to vaccines and immunization programs and is operated by the U.S. Department of Health and Human Services. The CDC plays the critical role of identifying and recommending which vaccines should be administered as part of the NVP. The CDC has recommended Merck's mumps vaccine for more than thirty years, a recommendation premised on the CDC's belief that the vaccine had an efficacy rate of 95 percent or higher.

87. The CDC also negotiates and contracts for the government's purchase of vaccines. Federal funding for the NVP traces back to the 1962 Vaccination Assistance Act which established the Section 317 Program to support immunization programs. Currently, the CDC spends approximately $3.4 billion each year on federal and state programs to provide vaccines for free. This amount represents approximately 52 percent of all spending for childhood vaccines in the U.S. The two government programs for which the CDC principally purchases vaccines are the 317 Program and the Vaccines for Children Program.

88. The 317 Program provides federal grants to state and local health departments to pay for vaccines in support of mass immunization campaigns. The Vaccines for Children

Program provides vaccines to children who are uninsured, are on Medicaid, are Native Americans, or who may have insurance but which does not cover the cost of vaccines. In addition, certain states participate in Universal Purchaser Programs which provide free vaccines to all children who do not otherwise qualify for the two federal programs. The CDC coordinates these state programs but they are funded by the participating states.

89. The CDC contracts for the purchase of vaccines directly from the license holder. In the case of MMRII and ProQuad, the CDC directly contracts with and purchases from Merck. The CDC purchases vaccines in batches of varying size throughout the year for administration to the public. As negotiated, Merck ships its vaccines to the CDC's designated repositories together with the relevant product information to be disseminated to the doctors and health clinics responsible for administering the vaccine. Merck thereafter submits a claim for payment which the CDC subsequently pays.

90. The CDC annually purchases from Merck anywhere from $60 million to $75 million for its MMRII vaccine. This comes from the following approximate calculation:

4 million (annual number of U.S. births)
X
.95 (childhood vaccination rate)
X
2 (number of doses per vaccinated child)
X
.52 (rate of vaccine spending attributed to CDC)
X
15 to 18.6 (dollar price range of MMRII dose from 2000 to present)

The mumps component of the vaccine represents about 40 percent of the vaccine's total cost.

91. Since 2000, the CDC has thus paid Merck more than $600 million for its MMRII vaccine. These amounts are likely conservative because they do not account for the CDC's

purchases of ProQuad, which is significantly more expensive than MMRII, and purchases of adult doses of MMRII and ProQuad, which Merck also sells to the CDC.

92. Over this period, the U.S. has therefore paid between a half and three-quarters of a billion dollars for a vaccine that does not provide adequate immunization. Had the U.S. been aware of the actual efficacy rate of Merck's mumps vaccine, the government's decision to purchase the product surely would have been different, either purchasing the vaccine from another source, requiring that Merck produce a new vaccine with the requisite immunizing effect, or re-negotiating the contract for the existing product.

CLAIM FOR RELIEF
(Merck's Violation of the False Claims Act)

93. Relators reallege and incorporate by reference herein the allegations contained in paragraphs 1 through 92 of this Complaint.

94. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

95. As set forth above, in violation of 31 U.S.C. § 3729(a)(1), since at least 1999, Merck knowingly presented, or caused to be presented, to the United States government, false or fraudulent claims for payment or approval when it billed the government for its purchases of a mumps vaccine that Merck knew was significantly less effective than Merck represented it to be and did not provide the minimal level of immunization the government required or understood the vaccine to have.

96. In addition, at least for conduct occurring on or after May 20, 2009, Merck violated 31 U.S.C. § 3729(a)(1)(A) (formally 31 U.S.C. § 3729(a)(1) as amended by the Fraud Enforcement and Recovery Act of 2009) by knowingly presenting or causing to be presented false or fraudulent claims for payment or approval when Merck billed the government for its

purchases of a mumps vaccine that Merck knew was significantly less effective than Merck represented it to be and did not provide the minimal level of immunization the government required or understood the vaccine to have.

97. In violation of 31 U.S.C. § 3729(a)(2), Merck also knowingly made, used, or caused to be made or used, false records or statements through its use of improper testing techniques and falsification of test data to artificially derive the government mandated 95 percent efficacy rate. Merck engaged in this fraudulent scheme to maintain its FDA approval and exclusive license for the mumps vaccine and ultimately, to get the approval and payment by the government of Merck's false or fraudulent claims for its sales of the mumps vaccine.

98. In addition, at least for conduct occurring on or after June 7, 2008, Merck violated 31 U.S.C. § 3729(a)(1)(B) (formally 31 U.S.C. § 3729(a)(2) as amended by the Fraud Enforcement and Recovery Act of 2009) by knowingly making, using, or causing to be made or used, false records or statements material to its false or fraudulent claims for payment for its mumps vaccine.

99. In violation of 31 U.S.C. § 3729(a)(7), Merck also knowingly made, used, or caused to be made or used, these false records or statements to conceal, avoid, or decrease its obligation to produce a mumps vaccine with the minimum 95 percent efficacy rate the government required and believed existed when it made its purchases.

100. In addition, at least for conduct occurring on or after May 20, 2009, Merck violated 31 U.S.C. § 3729(a)(1)(G) (formally 31 U.S.C. § 3729(a)(7) as amended by the Fraud Enforcement and Recovery Act of 2009) by knowingly making, using, or causing to be made or used, these false records or statements material to its obligations to provide the mumps vaccine to the government and by knowingly concealing or knowingly and improperly avoiding or

decreasing its obligation to produce a mumps vaccine with the minimum 95 percent efficacy rate the government required and believed existed when it made its purchases.

101. These false statements, records, and data were material to the government's purchases of and payments for Merck's vaccine, its approval and exclusive licensing to Merck of the vaccine, and the CDC's long-term recommendation to have the public vaccinated with Merck's mumps vaccine. This materiality is reflected in: (i) the CDC's setting of a mumps eradication date based on its ability to use Merck's mumps vaccine, (ii) the FDA's call for efficacy testing of Merck's mumps vaccine pursuant to its authority to oversee vaccine safety and efficacy, (iii) Merck's deviation from the standard testing procedure with its 1999 PRN study to facilitate higher efficacy results, (iv) Merck's abandonment of that test and its results in favor of a different test that would yield better results, (v) Merck's improper use of rabbit antibodies in its "enhanced" PRN test to artificially boost its seroconversion results, (vi) Merck's falsification of pre-positive test data to report the results it wanted using the rabbit antibodies in its testing, (vii) the CDC's continued belief in the face of the 2006 outbreak that there was nothing wrong with Merck's vaccine and that it should continue to be used, (viii) the call by at least one CDC doctor for a new vaccine if the Merck vaccine was not effective in preventing outbreaks, and ultimately (ix) Merck's own recognition that if it did not obtain the requisite efficacy threshold for its vaccine, it would lose its exclusive license and the right to supply the government with its supply of the vaccine.

102. Each representation Merck made to the government of a 95 percent efficacy rate - through its product package inserts, the reporting of its fabricated test results, and otherwise constituted a false statement or record. Likewise, each invoice Merck submitted to the government for payment for the purchase of the vaccines, constituted a false or fraudulent claim

for payment. Relators cannot identify at this time all of the false claims for payment caused by Merck's unlawful conduct because they were submitted at numerous times under various requests between 2000 and the present.

103. To the extent that the facts alleged in this Complaint have been previously disclosed to the public or the government in any fashion, Relators are the "original source" of the information as defined in 31 U.S.C. § 3730(e)(4).

104. The United States government, the public, and the public treasury have been damaged by and continue to be damaged by Merck's fraudulent conduct.

105. In addition, Merck's fraudulent conduct may be in violation of a 2008 Corporate Integrity Agreement that Merck entered into with the Office of Inspector General of the Department of Health and Human Services. Merck entered into this agreement as part of its settlement with the United States to resolve prior unrelated False Claims Act litigation. As part of this agreement, Merck is obligated to promote its "products (including vaccines) that are reimbursed by Federal health care programs" in compliance with the federal program requirements.

PRAYER FOR RELIEF

Wherefore Relators requests the following relief:

A. That Merck cease and desist from violating 31 U.S.C. § 3729, *et seq.*;

B. That the Court enter judgment against Merck in an amount equal to three times the damages suffered by the United States due to Merck's unlawful conduct;

C. That the Court enter judgment against Merck assessing a civil penalty of no less than $5,500 and no more than $11,000 for each violation of 31 U.S.C. § 3729;

D. That Relators receive the maximum amount of award allowed by 31 U.S.C. § 3730(d);

B. That Relators be awarded all costs of this action, including attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d);

F. That the Court award pre and post-judgment interest on any damages awarded to the United States or Relators; and

G. That the United States and Relators be awarded all such other relief that the Court deems just and proper.

JURY DEMAND

Relators hereby demand a trial by jury.

Dated: August 27, 2010

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