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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., Inc.

Defendant.

Civil Action No. 10-4374 (CDJ)

AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT

JURY TRIAL DEMANDED

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 through Merck's ongoing scheme to sell the government a mumps vaccine that is mislabeled, misbranded, adulterated and falsely certified as having an efficacy rate that is significantly higher than it actually is.

2. Specifically, in an effort to maintain its exclusive license to sell the vaccine and its monopoly of the U.S. market for mumps vaccine, Merck has fraudulently represented and continues to falsely represent in its labeling and elsewhere that its mumps vaccine has an

efficacy rate of 95 percent or higher. This is the efficacy rate on which Merck's original government approval for the vaccine was based more than forty years ago. In truth, Merck knows and has taken affirmative steps to conceal -- such as by using improper testing techniques, falsifying test data in a clinical trial, and violating multiple duties of government disclosure -- that the efficacy rate of Merck's mumps vaccine is, and has been since at least 1999, significantly lower than this 95 percent rate.

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 conceal what Merck knew about the vaccine's diminished efficacy. In fact, their Merck superiors and senior Merck management pressured them to participate in the fraud and subsequent cover-up when Relators objected to and tried to stop it.

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 the efficacy Merck claims it provides and does not provide the public with adequate immunization. Had Merck complied with its multiple duties of disclosure and reported what it knew of the vaccine's diminished efficacy -- rather than engage in fraud and concealment -- that information would have affected (or surely had the potential to affect, which is all the law requires) the government's decision to purchase the vaccine. However, since the government was not fully informed, it did not have the opportunity to consider its options, including not purchasing the vaccine from Merck, paying less, requiring a labeling change, requiring additional testing, or prioritizing development and approval of a new vaccine from Merck or another manufacturer.

5. Merck's failure to disclose what it knew about the diminished efficacy of its mumps vaccine has caused the government to purchase mislabeled, misbranded, adulterated and falsely certified vaccines in violation of Merck's contract with the Centers for Disease Control ("CDC") and in violation of the law.

6. 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 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.

7. Relators bring this case on behalf of the United States to recover the funds that the government spent for this fraudulently mislabeled, misbranded, adulterated and falsely certified vaccine, 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 mumps vaccine and require Merck to comply with its reporting, labeling and testing obligations under its contract with the CDC and under this country's vaccine regulatory regime.

PARTIES

8. Relator Stephen A. Krahling is a citizen of the United States and a resident of Pennsylvania. He was employed by Merck from 1999 to 2001 as a virologist in Merck's vaccine division located in West Point, Pennsylvania. During his employment at Merck, Krahling witnessed firsthand, and was asked to directly participate in, fraud in a clinical trial relating to

the efficacy of Merck's mumps vaccine.

9. Relator Joan Wlochowski is a citizen of the United States and a resident of Connecticut. She was employed by Merck from January 2001 to August 2002 as a virologist in Merck's vaccine division in West Point, Pennsylvania. During her employment there, Wlochowski also witnessed firsthand, and was asked to directly participate in, fraud in a clinical trial relating to the efficacy of Merck's mumps vaccine.

10. Defendant Merck is headquartered in New Jersey with its vaccine division based in West Point, Pennsylvania. Merck is one of the largest pharmaceutical companies in the world with annual revenues exceeding $20 billion. Merck is also a leading seller of childhood vaccines and currently markets in the U.S. vaccines for 12 of the 17 diseases for which the CDC currently recommends vaccination.

11. Merck is the sole manufacturer licensed by the Food and Drug Administration ("FDA") to sell mumps vaccine in the United States. Merck's mumps vaccine, together with Merck's vaccines against measles and rubella are sold as MMRII. Merck annually sells more than 7.6 million doses of the vaccine in the U.S. for which it derives hundreds of millions of dollars of revenue. The U.S. purchases approximately 4 million of these doses annually. Merck also has a license in the U.S. to sell ProQuad, a quadravalent vaccine containing MMRII vaccine and chickenpox vaccine. Under a license from the European Medicines Agency ("EMA"), Merck also sells mumps vaccine in Europe as a part of the trivalent MMRVaxpro and the quadravelent ProQuad through Sanofi Pasteur MSD, a joint venture with the vaccine division of the Sanofi Aventis Group. ProQuad has been sold intermittently in the U.S. and Europe from its approval in 2005 until 2010.

JURISDICTION AND VENUE

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

13. 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.

14. 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

15. For more than forty years, Merck has had a de-facto exclusive license from the federal government to manufacture and sell a mumps vaccine in the U.S.

16. Merck first obtained approval for the vaccine in 1967 from the Department of Biologics Standards of the National Institute of Health ("DBS"), the agency at the time responsible for licensing vaccines. The vaccine 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.

17. Merck's original mumps vaccine was delivered to patients in a single, stand-alone injection called Mumpsvax. In 1971, Merck developed a combination vaccine which delivered Merck's vaccines for measles, mumps and rubella ("MMR") together in one injection. The same year, Merck obtained DBS approval to manufacture and sell MMR vaccine. In 1978, Merck obtained approval from the FDA (which succeeded the DBS as the agency responsible for licensing vaccines) 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 of MMRII world-wide, with approximately 200 million doses sold in the U.S.

18. In September 2005, Merck obtained FDA approval for ProQuad.[1] Merck sold ProQuad in the U.S. from its approval in 2005 until June, 2007. According to Merck, the vaccine became unavailable because of certain manufacturing constraints. The vaccine was briefly available again in 2010 but has not been available since then.

19. In order to obtain its original government approval to sell its mumps vaccine, Merck conducted field studies of vaccinated children and concluded that the vaccine had an efficacy rate of 95 percent or higher. This meant that 95 percent of those given the vaccine were considered immunized against mumps. This is important because when an adequate number of people have immunity, the chances of an outbreak are reduced, and -- ultimately -- eliminated. If there is insufficient immunity, a real risk of continued disease outbreaks exists. When mumps outbreaks occur in vaccinated populations, it afflicts older children who are at greater risk of serious complications.

[1] Mumps vaccine used herein refers to any of Merck's vaccines containing a mumps component such as MMR, MMRII and ProQuad.

20. 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. The CDC projected that, by 2010, mumps could be completely eradicated. Unfortunately, that has not happened. Beginning in 2006, there has been a resurgence in mumps outbreaks.

21. Merck predicted the resurgence of outbreaks given the diminished effectiveness of its mumps vaccine. While Merck obtained its original license in 1967 stating that its vaccine was at least 95 percent effective, Merck knows that the vaccine's efficacy is significantly less than that now. Merck knows that the continued passaging of the attenuated virus to make more vaccine for distribution has altered the virus and has degraded the efficacy of the product.

22. Rather than develop a new mumps vaccine with greater efficacy, or permit other manufacturers to enter the U.S. market with a competing vaccine, Merck has instead taken pains to preserve its exclusive U.S. license by maintaining before the government and the public that its more than 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 refer back to the efficacy testing it conducted in connection with the government's original granting of Merck's license to sell the mumps vaccine. However, beginning in the late 1990s, Merck initiated new efficacy testing of its mumps vaccine. This testing coincided with an application to change the MMRII labeling in the U.S. and an application for a license to sell MMRII in Europe. This testing also coincided with Merck's development and quest for approval of ProQuad in both the U.S. and Europe.

23. Without demonstrating that its mumps vaccine continued to be 95 percent effective, Merck risked losing the monopoly it had over the sale of mumps vaccine in the U.S.

With respect to MMRII or Mumpsvax, the government might have negotiated to pay less for the vaccine, required a labeling change, or required additional testing. Or, the government might have stopped purchasing Merck's vaccine altogether as the door would be open to new manufacturers to enter the market. With respect to ProQuad, the government might not have approved the vaccine at all. Under any of these scenarios, Merck risked losing hundreds of millions of dollars in revenue from this very profitable enterprise.

24. So, Merck set out to conduct testing of its mumps vaccine that would support its original efficacy finding. In performing this testing, Merck's objective was to report efficacy of 95 percent or higher regardless of the vaccine's true efficacy. The only way Merck could accomplish this was 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.

MERCK'S FRAUD IN TESTING THE EFFICACY OF ITS MUMPS VACCINE

A. Merck's Abandonment of Its Original PRN Test and Test Results

25. The original methodology Merck employed under Protocol 007 was a Mumps Plaque Reduction Neutralization ("PRN") Assay. Preliminary testing commenced in 1999 at Merck's West Point facility and was led by Senior Investigator David Krah and his second in command, Mary Yagodich. Merck's Executive Director of Vaccine Research, Alan Shaw, approved the testing methodology Krah and Yagodich employed. Relator Krahling witnessed Krah and Yagodich as they conducted the preliminary testing.

26. As the name of the test indicates, the PRN test measures the virus neutralization that occurs after administration of the mumps vaccine. Merck's test was in some measure similar to the testing procedure regarded in the scientific community as the "gold standard" for testing how well a vaccine works. Blood samples are taken from children both before they receive the vaccine and again after they have been injected with the vaccine (after sufficient time has passed for the vaccine to produce an immune response). The paired blood samples are then individually incubated with the target virus and added to sheets of cells. Where the virus replicates in the cell sheet it leaves a plaque, or hole.

27. The pre-vaccinated child will not typically have immunity to the disease. Therefore, the pre-vaccinated blood will be unable to neutralize the virus and plaques will form where the virus has infected the cells. In contrast, if the vaccine has stimulated the child's immune system to develop antibodies against the virus, the post-vaccinated blood will neutralize the virus. The post-vaccinated blood sample will consequently show a smaller number of plaques, or holes, in the cell sheet compared to the pre-vaccinated sample.

28. A PRN test simply compares virus growth in the presence of the pre- and post-vaccinated blood samples. The number of plaques (where the virus has grown) is compared to determine if the vaccine caused the child to develop a sufficient level of antibodies to neutralize the virus. Results are reported in terms of seroconversion. 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). Seroconversion occurs, therefore, when a blood sample goes from "pre-negative" (insufficient antibodies) to "post-positive" (sufficient antibodies). Seroconversion in the lab is

the best correlate for efficacy -- how the vaccine works at successfully immunizing children. For the purposes of its testing, Merck was looking for a seroconversion rate of 95 percent or higher to support its original efficacy finding and the efficacy it continued to represent in its labeling.

29. While Merck's PRN test was modeled after the neutralizing 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 disease-causing virus, 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 attenuated Jeryl Lynn virus. This was the same mumps strain with which the children were vaccinated. The use of the attenuated 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.

30. Even with a deviation that could only overstate how well the vaccine worked, the results from Merck's preliminary testing (which involved testing blood samples of approximately 60-100 children) yielded seroconversion rates significantly below the desired 95 percent threshold. Krah admitted as much to Relator Krahling. He also admitted 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 and that because of this, mumps outbreaks would increase over time.

31. Krah further admitted to Krahling that he and Yagodich tried numerous other, often undocumented, techniques to modify the PRN test in order to improve the seroconversion results they could measure, including trying different virus dilutions, different staining procedures and even counting plaques more liberally. These other techniques -- like using the vaccine strain rather than the wild-type strain of the virus -- subverted the purpose of the PRN test. In the end, however, none of it mattered. Merck had to abandon its methodology because no matter how Krah and Yagodich manipulated the procedures, they could not reach the 95 percent seroconversion threshold.

32. So, Merck abandoned the PRN methodology that yielded unsatisfactory results and worked towards developing a new, rigged methodology that would allow Merck to report its desired seroconversion results.

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

33. The new methodology Merck devised and ultimately used to perform the mumps efficacy testing under Protocol 007 was an Enhanced Mumps Plaque Reduction Neutralization Assay. It was again led by Krah and approved by Shaw and commenced in 2000. Relators Krahling and Wlochowski participated on the team that conducted the testing using this supposedly enhanced methodology. Each of them witnessed firsthand the falsification of the test data in which Merck engaged to reach its 95 percent seroconversion threshold. In fact, each was significantly pressured by Krah and other senior Merck personnel to participate in this fraud.

34. From the outset, Merck's objective with this "enhanced" 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 seroconversion rate regardless of the vaccine's true efficacy. The very first page of an October 2000 Merck presentation on the "enhanced" methodology stated just that:

> **Objective:** Identify a mumps neutralization assay format . . . that permits measurement of a ≥ 95% seroconversion rate in MMR®II vaccinees.

Notably, nowhere in this presentation did Merck provide any kind of justification or explanation for abandoning its original PRN methodology and the unsatisfactory seroconversion results it yielded.

35. 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 methodology -- that tested against the vaccine strain rather than the wild-type strain -- but with one additional material change. Merck added animal antibodies to both the pre and post-vaccination blood samples. The use of animal antibodies in laboratory testing is not uncommon. They can serve as a highlighter of sorts to identify and count human antibodies that otherwise might not be identifiable on their own. When used in that way, animal antibodies make it easier to see the human antibodies. They do not alter what is being measured. However, Merck added animal antibodies for the singular purpose of altering the outcome of the test by boosting the amount of virus neutralization counted in the lab.

36. In a laboratory setting, animal antibodies can combine with human antibodies to cause virus neutralization that would not otherwise occur from the human antibodies alone.

Merck's "enhanced" methodology permitted various types of human antibodies to be counted as mumps neutralizing antibodies when it was actually the animal antibodies combining with those human antibodies causing the neutralization. Merck also did not apply a proper "control" to isolate whether virus neutralization was caused by the human antibodies alone or in combination with the animal antibodies. Rather, Merck included in its seroconversion measure all virus neutralizations regardless of whether they resulted from human antibodies or by their combination with the animal antibodies. This "enhanced" PRN methodology 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.

37. Merck knew that the neutralizations attributable to the animal 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 animal antibodies. And adding this external factor 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 these animal antibodies in its laboratory did not in any way correspond to, correlate with, or represent real-life (*in vivo*) virus neutralization in vaccinated people.

38. But the use of the animal antibodies allowed Merck to achieve its high seroconversion objectives. In fact, paired blood samples that were found under Merck's 1999 PRN methodology to lack sufficient virus neutralizing antibodies were now considered seroconverted using the "enhanced" methodology. Indeed, in one panel of sixty paired blood samples, 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" methodology, treated as vaccine successful solely because of the additional neutralization provided by the animal antibodies.

39. Krah defended the use of the animal antibodies in the "enhanced" PRN test by pointing to the FDA's purported approval of the process. However, whatever FDA approval Merck may have received for this testing, the FDA was not fully aware of the extent of Merck's manipulation of the testing, 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

40. There was one significant problem with Merck's improper use of the animal antibodies to boost its virus neutralization counts which would be evident to any scientist reviewing the test data. The animal antibodies boosted neutralization counts not only in the post-vaccination blood samples. They also boosted neutralization counts in the pre-vaccination samples. However, too much virus neutralization in the pre-vaccinated sample created a "pre-positive," which means enough virus neutralization to characterize the child as immune without the vaccine.

41. Pre-positives ordinarily occur in a small percentage of the child population that is immune to mumps even without vaccination. This immunity would principally come from a previous exposure to the mumps virus, or from immunity 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 10 percent of the child population.

42. The problem for Merck was that with the addition of the animal antibodies to the pre-vaccination blood samples it was seeing a significantly higher percentage of pre-positives than the 10 percent industry recognized occurrence of such immunity. In the results of one test that Relators Krahling and Wlochowski both witnessed in the summer of 2001, the pre-positive rate was more than 80 percent. Krah instructed Wlochowski to throw out the results and the actual experimental plates of that particular test thereby destroying all traces of the unwanted results.

43. The existence of such a high percentage of pre-positives threatened the viability of Merck's "enhanced" methodology. As a practical matter, with a pre-positive, any favorable results in the post-vaccinated sample could not be counted as a vaccine success toward the 95 percent efficacy target. A sample appearing positive before the vaccine, and staying positive after the vaccine, was not a seroconversion.

44. Just as important, the high pre-positive rate would red flag the methodology as flawed. The FDA would question the results of a test that had such a high level of pre-positives. Krah stated this explicitly to the members of his lab, including Relators Krahling and Wlochowski. If Merck wanted to keep the artificial boost in post-vaccination positives provided by the animal antibodies, it would have to eliminate the associated boost in pre-vaccination positives.

45. 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 it needed to "optimize" the amount of animal antibodies used in the process so that the testing 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 [animal antibodies] amount (target < 10% pre-positive rate and ≥ 95% seroconversions)."

46. The problem was that no amount of tinkering with the amount of animal antibodies added would produce a pre and post-vaccination virus neutralization for Merck's vaccine within the desired range. Without the animal antibodies, Merck could not support a sufficient level of post-vaccination neutralization. Conversely, by adding the animal 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.

47. 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 otherwise would have been counted as pre-positive because of the increased neutralization caused by the animal antibodies.

48. Merck's falsification of the pre-vaccination plaque counts was performed in a broad-based and systematic manner from December 2000 until at least August 2001:

- 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. For example, when manually changing original counting sheets proved too time-consuming, Krah employed an excel spreadsheet which would automatically highlight the undesirable pre-positives so that they could be targeted more efficiently. The data was entered, highlighted and changed before it was ever saved.

- Krah also engaged in the destruction of evidence to minimize the chances of detection. He not only employed the excel spreadsheet which left no paper trail. He also destroyed test results, substituted original counting sheets with "clean" sheets, and ordered the staff in the lab to do the same.

- Merck cancelled (in March 2001) a planned outsource of the 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 remaining testing instead.

49. Unsurprisingly, none of the "recounting" and "retesting" that Krah and his staff performed as part of the "enhanced" 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 Merck had identified as undesirable and which kept Merck from attaining its target of $\leq$ 10% pre-positive rate and $\geq$ 95% seroconversion.

50. Relators Krahling and Wlochowski engaged in numerous efforts to stop the fraud. They questioned and complained to Krah about the methodology being employed, particularly the manipulation of pre-positive data. They attempted to dissuade others from participating. They initiated numerous calls to the FDA to expose the fraud. And they attempted to document the fraud, even as evidence of it was being destroyed. But Relators' efforts were to no avail. For

every effort they took to stop the fraud, Merck adapted the scheme to assure the falsification continued. For example, when Relators objected to changing their own plaque counts, Krah appointed other staff, as so-called auditors, willing to falsify the data.

51. In July 2001, Relators Krahling and Wlochowski secretly conducted their own audit of the test results to confirm statistically the fraud that was occurring with the "enhanced" testing. They reviewed approximately 20 percent of the data that Merck had collected as part of the "enhanced" 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 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

52. Krah did not act alone in orchestrating the falsification of the "enhanced" PRN test results. He acted with the authority and approval of Merck's senior management.

53. For example, in April 2001, after Merck cancelled the planned outsourcing of the remainder of the mumps efficacy testing, Emilio Emini, the Vice President of Merck's Vaccine Research Division, held a meeting with Krah and his staff, including Relators Krahling and Wlochowski. Emini was clearly on notice of protests that had been going on in the lab because he directed Krah's staff to follow Krah's orders to ensure the "enhanced" testing would be

successful. He also told the staff that they had earned very large bonuses for the work they had completed on the project so far and that he was going to double the bonuses and pay them once the testing was complete.

54. In July 2001, after completing the secret audit, Relator Wlochowski openly accused Krah during a lab meeting of committing fraud in the mumps testing. Relator Krahling then met with Alan Shaw, the Executive Director of Vaccine Research and confronted him about the fraudulent testing. Krahling told Shaw of the falsification of the pre-positive data. He also confronted Shaw about the improper use of the animal antibodies to inflate the post-vaccine neutralization counts. Shaw responded that the FDA permitted the use of the animal antibodies and 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 the staff in Krah's lab once the testing was complete.

55. Relator Krahling then met with Bob Suter, Krahling's human resources representative at Merck. Krahling told Suter about the falsification of 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.

56. Shortly thereafter, Emini agreed to meet with Krahling. In the early August, 2001 meeting with Emini, Krahling brought actual testing samples and plaque counting sheets to demonstrate to Emini the fraudulent testing that Krah was directing. Emini agreed that Krah had falsified the data. Krahling also protested against the use of the animal antibodies to inflate the seroconversion rate. Emini responded that the animal 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 the animal antibodies. When Emini declined, Krahling asked him what scientific rationale justified using the animal antibodies. Emini explained that Merck's choice to use the antibodies was a "business decision."

57. To assuage Krahling's concerns, Emini promised to conduct an "internal audit" of the mumps 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 again threatened that he would be put in jail if he contacted the FDA.

58. The next morning, Krah arrived early to the lab and packed up and destroyed evidence of the ongoing mumps testing. This evidence included garbage bags full of the completed experimental plates, containing the cell sheets with plaques, that would have (and should have) been maintained for review until the testing was complete and final. The destruction of the plates would make it difficult to compare the actual plaque counts in the test with what was documented and changed on the counting sheets, as Krahling had done the day before in Emini's office. Despite the threats he received from Suter and Emini, Krahling called the FDA again and reported this latest activity in Merck's ongoing fraud.

E. The FDA Interview of Krah and Shaw

59. On August 6, 2001, in response to Relator Krahling's repeated calls, an FDA agent came to Merck to question Krah and Shaw. The FDA agent's questions were largely focused on 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.

60. For example, the FDA agent asked whether there was any *ad hoc* revisiting of plaque counts. Krah falsely responded that plaque counts were being rechecked only for verification, controls and to check hypervariability. Krah also misrepresented to the FDA that they did not change the data after it was entered in the excel workbook. When the FDA agent pressed Krah on the criteria for changing original counts on the counting sheets, Krah left the interview without answering the question. In Krah's absence, Shaw informed the FDA agent that a memo would be added to the standard operating procedure to address changes. The FDA agent then asked Shaw why they had not taken care of this before the project started. Shaw offered that Krah and another Merck employee had identified "trends" and "problems" with the original counts without ever explaining what those "trends" or "problems" actually were.

61. The interview proceeded in this manner with Shaw and Krah obfuscating what was happening in the lab and obstructing the FDA's efforts to find out what was really going on with Merck's manipulation of the testing procedure to reach its targeted seroconversion rate.

62. The entire interview with Krah and Shaw was short, probably less than half an hour. The FDA agent did not question Relators Krahling or Wlochowski or other members of Krah's staff in order to corroborate what Krah and Shaw said. As far as Relators witnessed, the FDA agent 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 the FDA agent did not address the actual destruction of evidence that Krah had already facilitated.

63. 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.

64. The report did not address or censure Merck for any issues relating to Merck's improper use of the animal antibodies or Merck's wide-scale falsification of pre-positive test data. The FDA did not discover this fraudulent activity in the course of the perfunctory visit because of Krah's and Shaw's misrepresentations to the FDA.

F. Merck's Completion and Use of the Fraudulent Test Results

65. In order to comply with the FDA's 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.

66. After the FDA visit, Relator Krahling was barred from any further participation in the Protocol 007 mumps vaccine testing 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. In December, 2001 Krahling resigned from the company.

67. Relator Wlochowski continued to work at Merck, though she was transferred out of Krah's lab at the end of September, 2001. She spent an additional year working at Merck in a different lab before she too left Merck.

68. Before Relators Krahling and Wlochowski left Krah's lab, Merck conducted the internal audit Emini had promised Relator Krahling would take place. However, as Krahling had warned against, the audit was anything but independent. Unsurprisingly, therefore, Merck completed its Protocol 007 testing in late summer or early fall 2001 and Merck reported the 95 percent seroconversion it had targeted from the outset. 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 animal antibodies and the wide-scale falsification of test data to conceal the significantly diminished efficacy of its vaccine.

69. Notably, while Relators Krahling and Wlochowski were immediately removed from Krah's lab for their protests against and efforts to stop the fraudulent testing, those that facilitated the fraud remained. Indeed, Krah, Yagodich and other members of Krah's staff who were instrumental in the fraud continue to work in vaccine development at Merck today and are still working together in Krah's lab.

MERCK'S ONGOING FRAUDULENT REPRESENTATION OF A 95 PERCENT EFFICACY RATE

70. Since at least the beginning of the Protocol 007 testing and continuing through the present, Merck has falsely represented to the government and the public that its mumps vaccine has at least a 95 percent efficacy rate. It has done so even though Merck is well aware, and has taken active steps to keep secret, that the efficacy rate is far lower.

A. Merck's False Representations Through Package Inserts

71. Merck principally has made these false representations in the package insert or labeling that accompanies each dose of Merck's vaccine. This is the product material that the law 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.

72. 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 package insert for MMRII provides that "a single injection of the vaccine induced . . . mumps neutralizing antibodies in 96% . . . of susceptible persons." Merck neither identifies the study performed or the date it was performed that supposedly support this representation. The current insert further provides that: "Efficacy of measles, mumps and rubella vaccines was established in a series of double-blind controlled field trials which demonstrated a high degree of protective efficacy afforded by the individual vaccine components." As support for this representation, Merck cites the more than forty-year old studies it conducted to obtain the original governmental approval for a mumps vaccine in 1967. Merck's MMRII package insert has contained this language and "support" since at least 1999.

73. Merck's product insert is a clear misrepresentation of the efficacy rate of its mumps vaccine. It cites outdated or unidentified studies that are not reflective of what Merck knows now about the vaccine's current effectiveness as confirmed by Merck's efforts to manipulate the methodology and ultimately falsify the data to report at least 95 percent seroconversion. In short, as Merck well knows, the efficacy rate of its mumps vaccine is not

anywhere near 95 percent. Yet, Merck continues to falsely represent a 95 percent efficacy rate to ensure its continued lock on the sale of the vaccine in the U.S.

B. Merck's False Representations Through Expanded Distribution of the Vaccine

74. Merck's misrepresentations relating to its mumps vaccine have not been made just to the U.S. government for MMRII. Merck has also obtained approval to sell MMRII in Europe and to sell ProQuad in 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.

75. In 2004 Merck submitted an application to the FDA for approval of ProQuad. Merck certified the contents of its application were true. In 2005, after reviewing Merck's application, the FDA approved ProQuad. According to the FDA's clinical review of the studies Merck submitted in support of ProQuad, "[c]linical efficacy of … mumps … vaccine strain w[as] shown previously … using [the] monovalent. [T]he vaccine response rates were 95.8 to 98.8% for mumps." Merck knew from its Protocol 007 testing that this falsely represented the efficacy of its mumps vaccine. Now that it is licensed, Merck's package insert continues to misrepresent the efficacy of its mumps vaccine, stating: "Clinical studies with a single dose of ProQuad have shown that vaccination elicited rates of antibody responses against measles, mumps, and rubella that were similar to those observed after vaccination with a single dose of M-M-R II" and "[a]ntibody was detected in 96.7% for mumps."

76. In 2006, Merck obtained a license from the EMA to sell the MMRII analogue (called MMRVaxpro) 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

as a "pivotal clinical study" 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.

77. Around the same time, Merck also obtained a license from the EMA for Sanofi Pasteur MSD to sell 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.

78. Thus, by 2006, Merck had the exclusive licenses to sell MMRII and ProQuad in the U.S., as well as licenses to sell MMRVaxpro and ProQuad in Europe. Throughout this time, Merck falsely represented an efficacy rate of 95 percent or higher and engaged in scientifically deficient testing and outright fraud to assure this was the efficacy rate consistently associated with its mumps vaccine.

C. Merck's False Representations Through Its Application for a Labeling Change on Potency of MMRII

79. In 2007, Merck changed its MMRII labeling to reflect a decrease in the potency of the mumps component of the vaccine. Potency measures how much of the attenuated virus is included in each dose of the vaccine. The labeling change -- approved by the FDA -- allowed Merck to represent a lower minimum potency, from 20,000 to 12,500 $TCID_{50}$ (or tissue culture infective dose, which is the scientific measure of vaccine potency). This represented a 37.5 percent reduction in how much of the attenuated virus could go into each dose of the vaccine.

80. At no time during Merck's efforts to secure approval to change its MMRII labeling did Merck disclose to the FDA what Merck knew about the diminished efficacy of the vaccine. Nor did Merck take any steps to address the efficacy information that was falsely represented in the labeling. That portion of the labeling remained unchanged.

81. Merck was thus representing throughout the approval process that it could actually *reduce* how much attenuated virus Merck put into each vaccine shot and still maintain its represented 95 percent efficacy even though Merck knew that at the *higher* potency the vaccine was nowhere near this efficacy. Clearly, if the FDA had known the truth about the vaccine's efficacy it would not have approved the labeling change to reduce the minimum potency.

D. Merck's False Representations Through Recent Mumps Outbreaks

82. With Merck's significantly degraded vaccine as the only protection against the mumps in this country, there has remained a significant risk of a resurgence of mumps outbreaks. That is exactly what Krah -- who was well aware of the mumps 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. And that is exactly what has happened.

1. <u>The 2006 Mumps Outbreak</u>

83. In 2006, more than 6,500 cases of mumps were reported in the Mid-West in a highly vaccinated population. This was the largest mumps outbreak in almost twenty years and a

significant spike from the annual average of 265 cases that had been reported for the years leading up to the 2006 outbreak.

84. The CDC, FDA and Merck publicly worked together to determine the cause of this 2006 outbreak. Of course, only Merck knew that outbreaks would occur because its vaccine had degraded over time and was weaker than what Merck represented. Nonetheless, Merck continued to represent its inflated efficacy rate and the government continued to believe that there was no problem with the vaccine. During the investigation of the outbreak, the CDC's then Director, Julie Gerberding, reaffirmed the CDC's view that nothing was wrong with the mumps vaccine, a belief fed by Merck's continued misrepresentations: "*We have absolutely no information to suggest that there is any problem with the vaccine.*" Director Gerberding and the CDC emphasized that "[t]he best protection against the mumps is the vaccine."

85. Even though Krah, the Merck investigator who ran Protocol 007, expected outbreaks to increase because of the degraded product, scientists at the CDC and elsewhere continued researching to understand the origins of such a large outbreak within a highly vaccinated population. One of the leading studies was led by Dr. Gustavo Dayan, then a doctor at the CDC, and published in 2008 in the *New England Journal of Medicine*. After considering possible causes for the outbreak, Dr. Dayan recommended that "[f]uture studies will help evaluate national vaccine policy, including whether the administration of a second dose of MMR vaccine at a later age or the administration of a third dose would provide a higher or a more durable immunity." Gustavo H. Dayan, "Recent Resurgence of the Mumps in the United States," *New England Journal of Medicine*, 358;15 (Apr. 10, 2008) 1580.

86. Dr. Dayan's study ultimately concluded that "[a] more effective mumps vaccine or changes in vaccine policy *may* be needed to avert outbreaks and achieve elimination of mumps." *Id.* (emphasis added). Of course, if Dr. Dayan had the benefit of what Merck knew but willfully withheld from the government and the public, his findings would have been significantly less equivocal on what needed to be done to stop the reemergence of mumps outbreaks.

87. At the same time Dr. Dayan published his study questioning whether it may be time for a new vaccine, Merck publicly proclaimed that its mumps vaccine had not been changed since its introduction in 1967 and that Merck had no plans to change it. So, while Dr. Dayan questioned whether it "may" be time for a new vaccine, Merck attempted to reassure the public that there was no need for any such change. The vaccine worked just fine.

88. In another study on the 2006 outbreak, several scientists questioned Merck's use of the Jeryl Lynn strain, instead of the wild-type virus, in Merck's PRN 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.

89. 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 animal antibodies and the falsification of test data.

90. 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.

91. Merck's ongoing misrepresentations and omissions with respect to the effectiveness of its vaccine continue to conceal the role its degraded product played in the 2006 outbreak.

2. The 2009 Mumps Outbreak

92. 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 before children were widely vaccinated for mumps. "[I]n 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, *New England Journal of Medicine*, 358;15 at 1587-88.

93. In August 2009, another mumps outbreak began just as Dr. Dayan predicted. As with the 2006 outbreak, the 2009 outbreak occurred despite high vaccination coverage among the U.S. children's population. In total, roughly 5,000 cases were confirmed by the CDC during the 2009 outbreak. This outbreak reaffirmed Krah's prediction that mumps outbreaks would reemerge and increase over time.

94. Faced with a mumps outbreak in 2006, and without complete information as to what might have caused it, the CDC acknowledged that it would consider the possibility of recommending a third dose of mumps vaccine. According to the Deputy Director of the CDC's Viral Diseases division in 2008, "If there's another outbreak, we would evaluate the potential benefit of a third dose to control the outbreak."

95. Because of the 2006 and 2009 outbreaks, the CDC has also pushed back its target date for eradicating mumps from its original 2010 goal to no earlier than 2020. But no amount of extra time or dosages will be enough to eliminate the disease when the vaccine does not work as represented in the labeling. It will merely allow Merck to continue to misrepresent the vaccine's efficacy and thereby maintain its exclusive hold on the mumps market with an inadequate vaccine.

96. To date, the government has not acted on Dr. Dayan's conclusion that it "may" be time for a new mumps vaccine. Instead, it continues to build its strategy around the existing vaccine. Nor is Dr. Dayan likely to pursue his own conclusion. He left the CDC to take a position in the Clinical Department of Sanofi Pasteur, the vaccine division of the Sanofi Aventis Group, Merck's partner in manufacturing and selling MMRVaxpro and ProQuad in Europe. Dr. Gerberding has also left the CDC. In January 2010, she became the president of Merck's Vaccine Division, a position she holds currently.

E. Merck's False Representations Through the Immunization Action Coalition

97. The Immunization Action Coalition (IAC) is a non-profit organization which describes itself as the "nation's premier source of child, teen, and adult immunization information for health professionals and their patients." It provides educational materials and "facilitates

communication about the safety, efficacy, and use of vaccines within the broad immunization community of patients, parents, health care organizations, and government health agencies."

98. The CDC works closely with the IAC. Indeed, "[a]lmost all of IAC's educational materials are reviewed for technical accuracy by immunization experts at the CDC." The CDC also provides the IAC with financial support for the purpose of educating health care professionals about U.S. vaccine recommendations. Several CDC physicians currently serve on IAC's Advisory Board. So does the current Director of the National Vaccine Program Office at the Department of Health and Human Services.

99. Merck also provides funding to the IAC.

100. The IAC asserts that Merck's mumps vaccine has an efficacy rate of 97 percent. This comes from the following mumps vaccine "Question and Answer" information sheet posted on the IAC's website: "**How effective is this vaccine**? The first dose of MMR vaccine produces good immunity to … mumps (97%)."

101. Merck has done nothing to correct this widely disseminated misinformation, sanctioned and supported by the CDC, about the efficacy of Merck's mumps vaccine. If anything, through its funding and support of the IAC, Merck has once again positioned itself to facilitate the spread of this false efficacy information. Clearly, if the CDC were aware of the true efficacy of Merck's mumps vaccine and the effort Merck has undertaken to conceal it, the CDC would take steps to correct the IAC's information on the vaccine.

IN FRAUDULENTLY REPRESENTING AND OTHERWISE CONCEALING THE DIMINISHED EFFICACY OF ITS MUMPS VACCINE, MERCK HAS VIOLATED ITS MULTIPLE DUTIES UNDER THE U.S. VACCINE REGULATORY REGIME

102. There are three principal components to the government regulation and purchase of vaccines in this country. The CDC is responsible for the government's purchase of vaccines and for educating the public on, among other things, the safety and efficacy of vaccines and the importance of immunization. The FDA is responsible for overseeing the licensing and approval of vaccines, their manufacture and distribution, and how they are represented to health care professionals and the public through vaccine labeling. The National Vaccine Program, of the Department of Health and Human Services, is responsible for generally overseeing the U.S. vaccine program, including coordinating with the various agencies involved in the program and manufacturers like Merck, and ensuring that vaccines are safe and effective and in sufficient supply.

103. A critical underpinning of this overlapping vaccine regulatory framework is that each agency involved has accurate and up-to-date information on the safety and efficacy of the various vaccines licensed for use in this country. This information is particularly important for the CDC which purchases the vaccines pursuant to a contract with Merck. Not only does it decide which vaccines the government will purchase. It also creates the schedule of recommended vaccinations that determines those vaccines that children in public school are required to take. Furthermore, as codified in the National Childhood Vaccine Injury Act, the CDC has the duty to warn the public about the safety and efficacy of the vaccines. Notably, this is a duty that Merck was instrumental in establishing.

104. Merck thus has ongoing and independent duties to disclose to these agencies all material information relating to the safety and efficacy of its mumps vaccine. However, in misrepresenting a falsely inflated efficacy rate for its mumps vaccine and concealing what Merck knew about the significantly diminished efficacy of the vaccine, Merck has breached these multiple duties.

A. Merck's Duties to the CDC

1. Merck's Duty to Disclose Diminished Efficacy

105. Merck has both a contractual and statutory duty to provide the CDC with accurate information regarding the safety and efficacy of its mumps vaccine. This duty is triggered by Merck's contractual and statutory delegation to the CDC of Merck's duty to warn the public about the vaccine's safety and efficacy. Without this delegation, Merck would be responsible – as any drug manufacturer would -- for providing adequate information to consumers relating to the risks and benefits of the vaccine.

106. Merck and the CDC first agreed to this delegation back in the 1970's, at Merck's suggestion. It provided a way to assure that the CDC could purchase Merck's vaccines without Merck being subjected to personal injury claims for failing to warn individual vaccinees or their parents about the safety and efficacy of vaccines administered through government vaccination programs. As a result of the parties' negotiation, the CDC assumed the duty to warn with respect to all Merck vaccines it purchases. In exchange Merck agreed to provide the CDC with all of the information the CDC needs to adequately carry out the duty to warn.

107. This means that Merck has an ongoing duty to provide the CDC with accurate information on the efficacy of its mumps vaccine, including apprising the CDC of any problems

Merck discovers, or in the exercise of reasonable care should have discovered, associated with the vaccine's stated efficacy. In the absence of any direct communications by Merck to the CDC relating to the vaccine's efficacy, the CDC principally relies on Merck's vaccine package insert for this information.

108. Merck benefits greatly from this arrangement as it protects Merck from liability for personal injury claims based on any failure to provide consumers with adequate warnings about the vaccine. All of the Merck-CDC purchase contracts (dating back from the late 1970s) contain language, originally drafted by Merck's counsel, providing that the CDC agrees to "take all appropriate steps to provide meaningful warnings [to consumers] relating to the risks and benefits of vaccination."

109. This delegation is now codified under the National Childhood Vaccine Injury Act which, among other things, requires the CDC to develop and disseminate vaccine information materials which provide: "(1) a concise description of the benefits of the vaccine, ... and (4) such other relevant information as may be determined by the Secretary [of Health and Human Services]." 42 USC § 300aa-26(c). Merck-CDC purchase contracts still contain the delegation of the duty to warn, but now also cite to this provision as the relevant authority. The CDC also cites to this provision in the Vaccine Information Statements it publishes apprising vaccinees and their parents or guardians of the purpose, risks and benefits of a particular vaccine.

110. The Act further provides a notable (and logical) exception to the statutory release from liability of a vaccine manufacturer for a failure to warn. It does not apply if the manufacturer engages in "intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval." Indeed, under such circumstances, the

manufacturer can be held liable for punitive damages for any failure to warn. 42 USC § 300aa-23(d)(2)(A) and (B).

111. As the Third Circuit has held, Merck's duty to provide accurate and up-to-date safety and efficacy information to the CDC is unequivocal and ongoing: "The manufacturer's responsibility is continuous, and it must therefore apprise the CDC of any risks it later discovers, or in the exercise of reasonable care, should have discovered." *See Mazur v. Merck*, 964 F2d 1348, 1365-66 (3rd Cir. 1992).

2. Merck's Additional Contractual Duties to the CDC

112. The Merck-CDC purchase contracts also obligate Merck to comply with various FDA regulations regarding the manufacture and sale of its vaccines. This includes the requirements that Merck only sell vaccines to the CDC that are licensed by the FDA and manufactured in conformance with the FDA's current Good Manufacturing Procedures ("cGMP"). As discussed below, a vaccine that is not manufactured in conformance with the specifications upon which the government's approval is based -- such as diminished efficacy -- fails to comply with cGMP and thus violates the CDC purchase contract. As also described below, a vaccine that is mislabeled, misbranded or adulterated (such as with a package insert that represents an inflated efficacy rate), or falsely certified as compliant with the conditions of purchase, likewise violates the CDC purchase contract.

B. Merck's Duties to the FDA

113. Merck has ongoing duties to the FDA pursuant to the Public Health Service Act, the Food Drug and Cosmetics Act and FDA regulations that control the licensing, labeling and manufacture of vaccines. 21 USC § 301 *et seq.*; 42 USC § 262 *et seq.*

1. Merck's Duty to Disclose Diminished Efficacy

114. Vaccine manufacturers have an ongoing duty to report problems with efficacy. 21 CFR § 600.12(b).

115. Vaccine manufacturers also have an ongoing duty to manufacture vaccines in conformance with cGMP. 21 CFR § 210.2. In order to ensure compliance with cGMP, vaccine manufacturers are required to test for safety, purity, and potency every lot of the vaccine to be sold. 21 CFR § 610. Per the specifications approved by the FDA for Merck's mumps vaccine, this means that the amount of attenuated virus Merck puts in its vaccine result in a minimum 95 percent efficacy. *See* 21 CFR § 600.3(s) (Potency is defined as the "[a]bility ….to effect a given result"). If a manufacturer learns of a deviation from the specifications (such as diminished efficacy), it has a duty to disclose that information to the FDA, fully investigate it and correct it. 21 CFR § 600.14; 21 USC § 331(e) and 21 CFR § 211.192. A vaccine that does not comply with these standards is considered an adulterated product that cannot legally be sold. 21 USC § 331(a).

116. Vaccine manufacturers also have an ongoing duty to report to the FDA all adverse experience events (such as diminished efficacy). *See*, 21 CFR § 600.80. Failure to report an adverse event may result in revocation of the license for the product. 21 CFR § 600.80(j). The law also imposes additional reporting requirements for vaccines, such as Merck's mumps vaccine, used in the pediatric population. It requires vaccine manufacturers to submit annual reports of any post-marketing pediatric studies to, among other things, inform the FDA of whether new studies in the pediatric population have been initiated. These reports must include

an analysis of available safety and efficacy data in the pediatric population, and an assessment of data needed to ensure appropriate labeling for the pediatric population. 21 CFR § 601.28.

2. Merck's Duty to Ensure that Its Mumps Vaccine Package Insert Is Neither False Nor Misleading

117. Vaccine manufacturers are at all times responsible for the content of their labeling, including their package insert. They are charged both with crafting adequate and accurate labeling and with ensuring that the information remains adequate and accurate. This includes an ongoing duty to self-monitor and update their labeling -- including all associated package inserts and information sheets -- when new information becomes available that causes the labeling to become inaccurate, false or misleading. 21 CFR § 601.12 (f)(2) and 21 CFR §201.56-57. A vaccine is deemed to be misbranded and mislabeled, and cannot be sold, if its labeling is "false or misleading in any particular." 21 USC §§ 352(a) and 331(a).

C. Merck's Duties to the National Vaccine Program

118. Merck also has duties under the National Childhood Vaccine Injury Act which created the National Vaccine Program and the Vaccine Injury Compensation Program. The two programs together were intended to create a simple, easy to administer system for vaccine injury compensation (which Merck wanted) and a more stable, competitive market for childhood vaccines which would lead to vaccine improvements (which the government wanted). The manufacturers were deemed stakeholders and enlisted to collaborate and cooperate with the government to improve the country's vaccination program. In exchange, under the Injury Compensation Program, Merck and other manufacturers obtained protection from liability for personal injury claims.

119. The Act also created a new system for manufacturers to report all "adverse events" related to vaccines reinforcing the reporting requirements otherwise triggered by the Public Health Service Act and the Food Drug and Cosmetics Act, described above. These adverse event reports are made on the Vaccine Adverse Event Reporting System and are supposed to encompass any problems associated with a vaccine including those associated with safety and efficacy. 42 USC § 300aa-25(b).

D. Merck's Duty to Be Truthful and Forthcoming In Its Dealings With the Government

120. Merck has a duty to be forthcoming and honest with federal officials in all of its dealings with the government. Specifically, under 18 USC § 1001, Merck is prohibited from knowingly and willfully: (1) falsifying, concealing, or covering up a material fact by any trick, scheme, or device; (2) making any materially false, fictitious, or fraudulent statement or representations; or (3) making or using any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in any matter relating to the government.

E. Merck's Breach of These Multiple Duties to the Government

121. Merck breached all of the above duties by falsely representing that the efficacy rate of its mumps vaccine is 95 percent or higher and by taking affirmative steps to conceal the vaccine's diminished efficacy.

122. These duties were triggered as soon as Merck learned that the efficacy of its now forty-five year old mumps vaccine had diminished. Merck learned this no later than 1999 as evidenced by the admission by the head of the Merck team running the Protocol 007 testing,

Krah. He even correctly predicted that the diminished efficacy of the vaccine would lead to the reemergence of mumps outbreaks. But rather than disclose this to the CDC, FDA or the appropriate individuals running the National Vaccine Program, as Merck was obligated to do, Merck instead embarked on a campaign of concealment and outright fraud.

123. First, Merck devised a scientifically flawed PRN test which attempted to measure the efficacy of its mumps vaccine based on how the vaccine performed against the less virulent vaccine strain of the virus rather than the wild-type strain that exists in the real world. Even using this scientifically dubious methodology, Merck saw that the seroconversion rate was significantly lower than the 95 percent efficacy rate that Merck was representing on its labeling and otherwise. Merck abandoned this methodology and its unfavorable results and kept them hidden rather than disclose them to the government.

124. Second, Merck devised an even more scientifically flawed PRN test when it "enhanced" its 1999 test with animal antibodies. The new methodology was not selected to provide a more accurate measure of the vaccine's efficacy. To the contrary, the methodology was concocted to measure a high seroconversion rate rather than an accurate one. To ensure that Merck's manipulation remained disguised, it falsified the test data to guarantee the pre-negative to post-positive change needed to achieve seroconversion. Having reached the desired, albeit falsified, efficacy threshold, Merck submitted these fraudulent results to the FDA (and the EMA in Europe), again breaching its multiple duties of open and honest disclosure to the government.

125. Third, Merck took steps to cover up the tracks of its fraudulent testing by destroying evidence of the falsification and lying to the FDA investigator that questioned Merck about the ongoing testing. Merck also attempted to buy the silence and cooperation of the staff

involved in the testing by offering them financial incentives to follow the direction of the Merck personnel overseeing the fraudulent testing process. Merck also threatened Relator Krahling on numerous occasions with jail if he reported the fraud to the FDA.

126. Fourth, in 2004 Merck submitted the application for approval for ProQuad, certifying the contents of the application as true even though Merck knew the statements about the effectiveness of the mumps vaccine were, in fact, false. At no time during this application process did Merck disclose to the FDA the problems of which it was aware (or should have been aware) relating to the significantly diminished efficacy of its mumps vaccine. Accordingly, in 2005, the FDA approved Merck's application for ProQuad.

127. Fifth, Merck sought and secured FDA approval to change its MMRII labeling to reflect an almost 40 percent reduction in the minimum potency of the mumps vaccine component. It did this while leaving its false representations of efficacy unchanged. And it did this fully appreciating that if the current, higher potency vaccine had an efficacy rate far lower than the falsely represented 95 percent, there was no way the vaccine would achieve this efficacy with significantly less attenuated virus in each shot. Nevertheless, at no time during the course of obtaining the FDA's approval for the labeling change did Merck disclose to the FDA the problems of which it was aware (or should have been aware) relating to the significantly diminished efficacy of its vaccine. Nor did Merck disclose its knowledge that these problems would be greatly exacerbated if the potency in the dose was reduced.

128. Sixth, Merck continued to conceal what it knew (or should have known) about the diminished efficacy of its mumps vaccine even after the 2006 and 2009 mumps outbreaks. It did

so even after the CDC -- with which Merck was supposedly working to determine the cause of the outbreaks -- publicly stated that there was nothing wrong with the vaccine.

129. Seventh, Merck has continued to conceal what it knows (or should know) about the diminished efficacy of its mumps vaccine even though the Immunization Action Coalition -- which Merck funds, and which the CDC also funds, supports and substantively contributes to -- prominently promotes an efficacy rate of 97 percent.

130. And eighth, despite what Merck knows (or should know) about the diminished efficacy of its mumps vaccine, Merck has fraudulently represented on its labeling a significantly inflated efficacy rate. Not only does this violate each of the multiple duties described above and make Merck's mumps vaccine a mislabeled, misbranded and adulterated product. This continuous misrepresentation falsely certifies to the government compliance with the terms of the contract pursuant to which the government buys Merck's vaccine.

131. Merck's broad-based scheme to falsely represent and conceal the diminished efficacy of its mumps vaccine violated the multiple duties it owes the government to report, investigate and attempt to correct any problems associated with the safety and efficacy of its vaccine, including its duty: (i) to the CDC, to provide accurate and up-to-date efficacy information and comply with cGMP requirements and not to sell mislabeled, misbranded or adulterated products; (ii) to the FDA, to provide accurate and up-to-date efficacy information, comply with cGMP requirements, fully and properly investigate, test, and correct any suspected problems with efficacy, and ensure the efficacy information reported on Merck's labeling is neither false nor misleading; (iii) under the National Vaccine Program, to report all "adverse

events" related to its vaccines including problems associated with efficacy; and (iv) to the government generally, to be forthcoming and honest in all of Merck's dealings.

IN FRAUDULENTLY REPRESENTING AND OTHERWISE CONCEALING THE DIMINISHED EFFICACY OF ITS MUMPS VACCINE, MERCK HAS ILLEGALLY MONOPOLIZED THE MUMPS VACCINE MARKET

132. As the only company licensed by the government to sell mumps vaccine, Merck has had a monopoly in the U.S. market for mumps vaccine since it obtained its original license in 1967. However, Merck has maintained this monopoly not through its business acumen or its manufacture and sale of the best quality product. Instead, Merck has willfully and illegally maintained its monopoly through its ongoing misrepresentations of the efficacy of its mumps vaccine, and its violations of the multiple duties of disclosure it owes the government. Through this misconduct, Merck has been able to maintain a falsely inflated efficacy rate for its mumps vaccine and exclude competing manufacturers from entering the market.

A. The U.S. Market for Mumps Vaccine

133. The U.S. manufacture and sale of mumps vaccine (including Mumpsvax, MMRII and ProQuad) is a relevant antitrust market in this case. For those seeking immunization for mumps, a mumps vaccine is the only product available to achieve that result. So regardless of the price Merck charges for its mumps vaccine, the extent or frequency of any price increases for the vaccine, or whether Merck incorporates the vaccine into multi-disease vaccines, as it does with MMRII and ProQuad, there are no alternative products to which the government, health care professionals or consumers can turn to obtain this immunization.

134. The U.S. market for mumps vaccine is further defined by the CDC's nationwide schedule of recommended childhood vaccinations, including a vaccination against mumps, and

the requirement around the country that all public school students be vaccinated against mumps (among other childhood diseases). If a child is to attend public school -- not to mention any private school, university, summer camp or other educational or recreational institution in this country -- he or she must take a mumps vaccine. There is no choice (but for rare exceptions). There is no alternative. No other products can substitute for this required vaccination.

B. Merck's Monopolization of the Market for Mumps Vaccine

135. Since it originally obtained government approval for the mumps vaccine in 1967, Merck has had a natural monopoly through its de facto exclusive license to sell the vaccine in this country. This has extended to multi-disease vaccines such as MMR, MMRII and ProQuad. But Merck has been able to maintain its monopoly not through providing the safest, most effective and most cost effective mumps vaccines in the market. Rather, Merck has maintained its monopoly by representing a falsely inflated efficacy rate of 95 percent or higher.

136. There are significant barriers to entry inherent in the manufacture and sale of a new vaccine. The research, development, testing and government approval process is very expensive, time-consuming and risky. Several years and millions of dollars might be spent on developing a vaccine only to find it fail in the final stages of testing, or to have the government refuse to approve it or significantly limit its application or distribution. Vaccine manufacturers will therefore invest in developing a new vaccine only where they see both a need for the vaccine and an opportunity to make a large enough return on the significant capital investment and risk involved.

137. In the case of the U.S. market for mumps vaccine, this inherent barrier to entry is substantially compounded by the falsely inflated efficacy rate of Merck's vaccine. As with the

market for any product, a potential competitor's decision to enter a market hinges on whether its product can compete with those products already being sold in the market. If an existing vaccine is represented as safe and at least 95 percent effective, as Merck has falsely represented its vaccine to be, it would be economically irrational for a potential competitor to bring a new mumps vaccine to the market unless it thought it could compete with the safety and efficacy of the existing vaccine. No one would purchase it otherwise -- not the government, nor health care providers, nor consumers.

138. This is especially true for the federal government since its goal in purchasing vaccines is to allocate its resources to reduce and eliminate disease to the fullest extent possible. Using an inferior vaccine would significantly undermine the overarching purpose of the government funded immunization programs. It would specifically interfere with the government's goal, albeit unrealistic in light of Merck's defective vaccine, of eradicating mumps by the end of the decade.

C. Merck Has Maintained Its Monopoly By Foreclosing Competition

139. Through its false representations of the mumps vaccine's efficacy rate, its efforts to conceal the significantly lower efficacy rate that the Protocol 007 testing confirmed, and its repeated violations of the multiple duties of disclosure it owes the government, Merck has foreclosed potential competitors from entering the market with a new mumps vaccine. No manufacturer is going to sink the time, energy and resources into developing the vaccine for sale in the U.S. with the artificially high bar Merck has devised.

140. Entering the market would be particularly risky in the case of the mumps vaccine given the four-decade lock Merck has had on the market.

141. But for Merck's fraud and other misconduct, one or more competing manufacturers would have entered this lucrative market -- with its guaranteed sales of almost 8 million doses a year -- with a competing mumps vaccine. For example, GlaxoSmithKline, a manufacturer of numerous FDA approved vaccines, has an MMR vaccine, Priorix, that is widely sold in Europe, Canada, Australia and other markets. Priorix is not licensed or sold in the U.S.

142. By continuing to misrepresent an artificially high efficacy rate, and engaging in all the misconduct to conceal the diminished efficacy of its vaccine, Merck has foreclosed GlaxoSmithKline and any other manufacturer from entering the U.S. market for mumps vaccine. So long as Merck continues to engage in this misconduct, these manufacturers will continue to be excluded from the U.S. market and Merck will retain its unchallenged monopoly with a vaccine that does not provide adequate immunization.

D. Merck's Harm to Competition and the Government

143. Merck's misconduct has harmed competition by foreclosing other manufacturers from entering the U.S. market for mumps vaccine. Without such competition, Merck has been able to maintain its monopoly in this market even though it is manufacturing and selling a sub-par vaccine. In the absence of this foreclosure, other manufacturers would have entered the market with a higher quality and/or cheaper vaccine. This competition, or the threat of such competition, would have forced Merck to respond by either selling its existing vaccine at a lower price or developing a better vaccine.

144. Merck's misconduct has also harmed the government. It has caused the government to pay Merck hundreds of millions of dollars for a product that is not what Merck represents it to be and not what the government needs it to be. It has also deprived the

government of a competitive market for mumps vaccine which would promote the development of new and better vaccines to improve the health of all Americans. And perhaps most importantly, it has significantly undermined the government's efforts to protect the public against a resurgence of mumps. Outbreaks of the disease have increased and threaten to continue and grow larger. And the original target date for eradication of the disease has long since passed.

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

145. 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. Had Merck complied with the U.S. antitrust laws and with its multiple duties of disclosure and reported the diminished efficacy of its vaccine -- rather than engage in fraud and concealment -- it would have affected (or certainly had the potential to affect) the government's decision to purchase the vaccine. The government would have had the opportunity to consider numerous options. For MMRII this would include not purchasing the vaccine from Merck, paying less, requiring a labeling change, requiring additional testing, or prioritizing development and approval of a new vaccine (per the mandate of the National Vaccine Program). For ProQuad this would include not licensing the vaccine at all.

146. But Merck did not comply with these duties of disclosure or with the antitrust laws. Instead, it took pains to maintain its fraudulently inflated efficacy rate and its monopoly grip on the market so it could foist on the government a vaccine without sufficient immunizing effect. In other words, over the past decade, through its scheme of fraud and concealment,

Merck has sold the government a vaccine that (i) is mislabeled, misbranded, adulterated and falsely certified; and (ii) does not comply with the FDA's labeling, reporting and testing requirements; with the CDC's reporting requirements; with the cGMP standards required by the CDC contract and the FDA; and with the requirements of the National Vaccine Program to report any vaccine failure.

147. The CDC plays the critical role of making the government's vaccine purchasing decisions. It is responsible for entering into the contracts with the manufacturers, deciding which vaccines to purchase, providing information on safety and efficacy to health care providers and the public, and promoting the benefits of widespread immunization. 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. Merck thereafter submits a claim for payment which the CDC subsequently pays.

148. The CDC annually purchases from Merck anywhere from roughly $60 million to $76 million of 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 19.33 (dollar price range of MMRII dose from 2000 to present)

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

149. Since 2000, the CDC has thus paid Merck more than $700 million for its MMRII vaccine to be administered to children. These amounts likely underestimate the CDC's total purchases because they do not account for purchases of ProQuad, which is significantly more expensive than MMRII, Mumpsvax, or purchases of adult doses of Mumpsvax, MMRII and ProQuad, which Merck also sells to the CDC. Over this period, the U.S. has therefore paid more than three-quarters of a billion dollars for a mislabeled, misbranded, adulterated and falsely certified vaccine that does not provide adequate immunization.

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

150. Relators reallege and incorporate by reference all of the allegations set forth herein.

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

152. As set forth above, in violation of 31 U.S.C. § 3729(a)(1), 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, among other things, (i) was significantly less effective than Merck represented it to be, (ii) did not provide the product the government contracted to purchase, (iii) was mislabeled, misbranded, adulterated and falsely certified and (iv) was exclusively supplied to the government by Merck because of Merck's illegal monopolization of the mumps market.

153. 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, among other things, (i) was significantly less effective than Merck represented it to be, (ii) did not provide the product the government contracted to purchase, (iii) was mislabeled, misbranded, adulterated and falsely certified and (iv) was exclusively supplied to the government by Merck because of Merck's illegal monopolization of the mumps market.

154. As set forth above, 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 to obtain payment or approval by the government of Merck's false or fraudulent claims for purchases of its mumps vaccine when Merck, among others things: (i) 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 described 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 in the vaccine the government was purchasing. Merck engaged in all of this misconduct to maintain its monopoly

of the U.S. market for mumps vaccines and to secure continued payment by the government of Merck's false or fraudulent claims for its sales of the mumps vaccine.

155. In addition, at least for false or fraudulent claims pending or made 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) when Merck knowingly made, used, or caused to be made or used, false records or statements material to its false or fraudulent claims when Merck, among others things: (i) 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 described 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.

156. These false statements, records, and data, and Merck's multiple failures to comply with its various duties of disclosure, investigation, testing and reporting, were material to the government's purchases of and payments for Merck's vaccine, and the CDC's long-standing recommendation to have the public vaccinated with Merck's mumps vaccine. This materiality is reflected in:

- Merck's contractual and statutory duties to disclose to the government all information regarding the safety and efficacy of its mumps vaccine;
- Merck's multiple intentional violations of these duties;
- The CDC's responsibility to ensure that all vaccines manufactured and sold in the U.S. are safe and effective;
- The FDA's responsibility to ensure that all vaccines manufactured and sold in the U.S. are safe and effective;
- The National Vaccine Program's responsibility to ensure that all vaccines manufactured and sold in the U.S. are safe and effective;
- The CDC's responsibility to provide health care professionals and the public with accurate and up-to-date information on the safety and efficacy of vaccines;
- Merck's decision to conduct PRN testing of its mumps vaccine which would be reported to the FDA;
- Merck's abandonment of the 1999 PRN methodology in favor of a methodology that would yield better results;
- Merck's improper use of animal antibodies in its "enhanced" PRN test to artificially boost its seroconversion results;
- Merck's falsification of pre-positive test data to report the results it wanted using the animal antibodies in its testing;
- 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;
- The call by at least one CDC doctor for a new vaccine if the Merck vaccine was not effective in preventing outbreaks;
- The prominent publication of inaccurate mumps efficacy information by the Immunization Action Coalition
- Merck's continuing efforts to improperly maintain its monopoly of the U.S. market for mumps vaccine through its false representation of an inflated efficacy rate; and ultimately

- Merck's own recognition that it would lose its exclusive license to sell mumps vaccine if it did not measure and report at least a 95 percent seroconversion rate in the mumps efficacy testing conducted in Krah's lab under Protocol 007.

157. Each representation Merck made to the government asserting that its mumps vaccine was at least 95 percent effective, including through its product package inserts, the reporting of its fabricated test results, and otherwise, as described above, constituted a false statement or record. Likewise, each invoice Merck submitted, or caused to be 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.

158. 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 each an "original source" of the information as defined in 31 U.S.C. § 3730(e)(4).

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

160. 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 award allowed by 31 U.S.C. § 3730(d);

E. 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: April 27, 2012

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