**UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| United States of America *ex rel.*, | : | |
| Stephen A. Krahling and Joan A. Wlochowski, | : | |
| Relators, | : | Case 2:10-cv-04374 (CDJ) |
| v. | : | |
| Merck & Co., Inc. | : | |
| Defendant. | : | |

**RELATORS' MEMORANDUM IN OPPOSITION**
**TO MERCK'S MOTION TO DISMISS**

# TABLE OF CONTENTS

# TABLE OF AUTHORITIES

**Cases** **Page(s)**

**Statutes**

**Regulation**



**Rules**

Relators Stephen A. Krahling and Joan A. Wlochowski respectfully submit this memorandum of law in opposition to Merck's motion to dismiss the operative complaint in this action.[1]

## PRELIMINARY STATEMENT

This case involves Merck's efforts to conceal from the government and the public that Merck's forty-five year old mumps vaccine no longer provides adequate immunization. Relators know this because they were virologists in the Merck lab at the center of this fraudulent campaign. They were even pressured by their superiors to participate in the scheme, which included, among other things, falsifying test data; destroying evidence; lying to the FDA; and most importantly, continuously hiding from the government and the public over the course of a decade -- including through two unprecedented mumps outbreaks -- the significantly diminished efficacy of the vaccine.

Relators know this not only because of their eyewitness account of the activity. They also know it because the Merck executives that led the campaign admitted it to them. They admitted that Merck's vaccine had significantly degraded through Merck's repeated passaging of it for what is now approaching five decades, to make more and more vaccine for the millions of children that take it every year. They admitted that this degradation would eventually lead to the reemergence of mumps outbreaks, which it has. Worst of all, they admitted that Merck engaged in this fraud and deception as a "business decision" necessary to ensure that Merck maintained its exclusive license to sell the vaccine in the U.S.

Merck's answer to these charges in its motion to dismiss is to ignore them entirely and invent new facts that have no grounding in either the Complaint or real world events. Most

[1] The operative complaint is the Amended Complaint for Violations of the Federal False Claims Act dated April 27, 2012 (hereinafter, "Complaint" or "Compl."). *See* Dkt. No. 12. It was unsealed on June 21, 2012.

strikingly, Merck claims that the vaccine still works "phenomenally" well and the government has found nothing wrong with it. Yet the Complaint demonstrates just the opposite. So do the actual mumps outbreaks that have caused the government to suspend its original goal of eradicating the disease by now. So does the government's recent decision to begin funding research for a new vaccine because of its emerging view, since the filing of this action, "that the current vaccine is not effective." *See infra* at 13-14.

Merck also ignores the broad scope of the False Claims Act and the critical role Congress specifically assigned to private parties, like Relators, to supplement the government's limited resources to combat fraud. In this regard, Merck offers up a novel "agency deference" argument that would gut the underlying foundation of the Act. It would severely limit cases that involve conduct that implicates FDA rules or is otherwise subject to regulatory oversight. And it would altogether bar relators from pursuing cases unless they first exhausted any available administrative remedies. Merck's attempted rewrite of the statute directly conflicts with the "expansive[] . . . all types of fraud, without qualification" reach Congress specifically ascribed to it. *Cook Cnty., Ill. v. U.S. ex rel. Chandler*, 538 U.S. 119, 129 (2003).

Finally, and perhaps most fundamentally, Merck ignores what this case is really about. It is not about enforcing any FDA rules or in any way interfering with or encroaching upon any FDA determination or authority. Nor is it about a challenge to Merck's false and misleading vaccine label. This case is about Merck's ongoing failure to disclose and efforts to conceal that its mumps vaccine no longer works the way it is supposed to work or the way Merck says it works. And it is about Merck's continuing sale to the CDC (*not the FDA*) of a product that is very different from what the government contracted to purchase. It is this case -- centered

around Merck's fraud by omission -- that Merck says nothing about in its motion to dismiss. Yet it is precisely the type of case the False Claims Act was designed to cover.

## STATEMENT OF FACTS

### I. THIS CASE IS ABOUT MERCK'S LIABILITY UNDER THE FALSE CLAIMS ACT FOR CONCEALING FROM THE GOVERNMENT INFORMATION NOT ONLY MATERIAL BUT CRITICAL TO THE GOVERNMENT'S VACCINE PURCHASING DECISION

Merck first obtained government approval for its mumps vaccine in 1967. Compl. ¶ 16. The vaccine was developed by Dr. Maurice Hilleman from the mumps virus that infected his five-year old daughter Jeryl Lynn. *Id.* Merck continues to use this "Jeryl Lynn" strain of the virus for its vaccine today. *Id.* Merck obtained its original government approval for the vaccine by demonstrating that it was 95 percent effective, meaning that 95 percent of those given the vaccine were considered immunized against the disease. *Id.* ¶¶ 2, 19, 21. However, since at least 1999, Merck has known that its vaccine is significantly less than 95 percent effective. *Id.* ¶¶ 2, 21, 70, 73. Merck has known that the continued passaging of the forty-five year old Jeryl Lynn virus to make more mumps vaccine for distribution has degraded the efficacy of the product to the point where it is no longer providing adequate immunization. *Id.* ¶¶ 4, 6, 21, 30.

This case is about Merck's efforts for more than a decade to conceal from the government and the public what Merck knows about this significantly diminished efficacy. Compl. ¶¶ 2-7, 25-101, 121-131. Merck has done this by, among other things, using improper efficacy testing techniques, falsifying efficacy test data, destroying evidence of the fraud, lying to the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), maintaining a fraudulent vaccine label, making fraudulent government submissions, and violating its multiple duties of government disclosure. *Id.* Merck has engaged in these various acts of concealment to maintain its exclusive license to sell the vaccine and continue collecting

from the government what has amounted to hundreds of millions of dollars for a vaccine that does not provide adequate immunization. *Id.* ¶¶ 4, 145-149. Relators are virologists formerly employed in Merck's vaccine division who witnessed first-hand, and were pressured by Merck to directly participate in, this campaign of concealment. *Id.* ¶¶ 3, 8-9.

Thus, this case is very different from the one Merck attacks on its motion to dismiss. It is not about a challenge to any FDA determinations or an attempt to substitute the court's judgment for that of the FDA. MTD 15-16, 23-25. It is not about trying to bypass any FDA procedure. *Id.* at 17, 26, 28. It is not about enforcing or restraining any violations of FDA rules or regulations. *Id.* at 18-19. It is not about an agency that had full knowledge of the allegations of Merck's fraud and already considered and rejected them. *Id.* at 3-4, 10, 15-16, 22-23, 26-27, 33. And, it is certainly not about a vaccine that is "phenomenally," "tremendous[ly]" or "enormously" effective. *Id.* at 5 n.2, 8, 30 n.17. This case is about Merck's continuing efforts to conceal from the government information critical to its mumps vaccine purchasing decision and to sell the CDC a product that is different from what it has contracted to purchase. That is, a vaccine that provides adequate immunization; is at least 95 percent effective; and is accompanied with accurate, current and complete information on efficacy.

## II. MERCK KNOWS THAT THE EFFICACY OF ITS MUMPS VACCINE HAS SIGNIFICANTLY DIMINISHED

For more than a decade, Merck has known that its mumps vaccine does not provide adequate immunization and is significantly less effective than the 95 percent Merck represents. *See, e.g.*, Compl. ¶¶ 1, 2, 21, 70, 73, 82, 104, 121-122, 131 (significantly less effective than 95 percent), and ¶¶ 4, 6, 146, 149 (does not provide adequate immunization). These allegations are based on Relators' first-hand witnessing of Merck's original, and ultimately abandoned, efficacy testing which yielded an efficacy rate significantly lower than 95 percent. *Id.* ¶¶ 25-32. They

are based on Relators' first-hand witnessing of Merck's subsequent fraudulent testing to fabricate an inflated efficacy rate. *Id.* ¶¶ 33-68. And they are based on Relators' first-hand discussions with David Krah, the senior virologist in charge of Merck's efficacy testing, who acknowledged the vaccine's significantly diminished efficacy. Compl. ¶¶ 30, 82, 122.

The allegations of a significantly diminished vaccine are also based on the continuing real-world failure of the vaccine which has led to two recent outbreaks of the disease, which Krah predicted, and with more feared to come (*id.* ¶¶ 82-83, 92-93, 144); the deferral by at least a decade of the government's original goal of eradicating the disease by 2010 (*id.* ¶¶ 6, 95, 144); and -- *since the filing of this action* -- the government's own recognition that the vaccine is not working and its consequent research and funding of a new vaccine. *See infra* at 13-14. Thus, far from conceding the vaccine's "tremendous efficacy" or that it remains "phenomenally" and "enormously" effective (MTD at 5 n.2, 8, 30 n.17), Relators have alleged, with detailed factual support, just the opposite.

## III. MERCK HAS ENGAGED IN AN ONGOING SCHEME TO CONCEAL FROM THE GOVERNMENT AND THE PUBLIC WHAT IT KNOWS ABOUT THE SIGNIFICANTLY DIMINISHED EFFICACY OF ITS MUMPS VACCINE

Merck's scheme to conceal the significantly diminished efficacy of its mumps vaccine began in 1999 when it initiated new efficacy testing of the vaccine. Comp. ¶¶ 22, 25. This testing coincided with various applications Merck was making in the U.S. and Europe relating to the labeling and licensing of its vaccines. *Id.* ¶ 22. Without demonstrating that its mumps vaccine continued to be at least 95 percent effective, Merck risked losing the monopoly it had over the U.S. sale of the vaccine. *Id.* ¶ 23. But the only way Merck could demonstrate this efficacy and maintain its exclusive license to sell the vaccine was through manipulating its testing procedures, falsifying the test results, lying to the government, and otherwise concealing

from the government and public what it knew about the significantly diminished efficacy of the vaccine. *Id.* ¶¶ 25-101.

**A. Merck's Abandonment of Its Original Efficacy Test**

Merck began its preliminary testing of the vaccine in 1999. Compl. ¶ 25. Even though Merck employed an improper methodology that could only overstate how well the vaccine worked, the preliminary results from this testing yielded a seroconversion rate significantly lower than Merck's desired 95 percent threshold.[2] *Id.* ¶¶ 29-30. The head of the Merck lab conducting this testing, David Krah, admitted this to Relator Krahling. *Id.* ¶¶ 30, 82, 122. Krah further admitted that Merck tried numerous other testing techniques to improve the efficacy findings but no matter how they manipulated the testing procedures, they could not reach the 95 percent threshold. *Id.* ¶ 31. Merck did not disclose these poor results to the government. *Id.* ¶¶ 32-33. Instead, Merck abandoned the testing altogether and replaced it with a new, rigged methodology intended to allow Merck to reach its desired efficacy results. *Id.*

**B. Merck's Fraudulent Efficacy Testing**

With its new testing, Merck's objective was to devise a methodology that would yield a minimum 95 percent seroconversion rate regardless of the vaccine's true efficacy. Compl. ¶ 34. Merck accomplished this by adding animal antibodies to the blood samples used in the testing to artificially boost the amount of virus neutralization that counted towards seroconversion. *Id.* ¶¶ 35-38. And Merck falsified the test results to ensure that this manipulation would not be detected. *Id.* ¶¶ 40-49. Relators not only witnessed this fraud and manipulation first-hand. *Id.* ¶¶ 3, 8-9, 24, 33. They confirmed it statistically through their own audit of the testing data and results. *Id.* ¶ 51.

[2] Seroconversion occurs when the vaccine creates a sufficient level of antibodies in the blood to neutralize the virus. Seroconversion in the lab is the best correlate for efficacy. Compl. ¶ 28.

Even the Vice President of Merck's Vaccine Research Division, Emilio Emini, in a meeting with Relator Krahling, admitted to Merck's falsification of the testing. Compl. ¶ 56. Emini further acknowledged that Merck's improper use of the animal antibodies was a necessary "business decision" to enable Merck to reach its 95 percent efficacy target. *Id.* But rather than disclose this fraudulent testing to the government, Merck took additional steps to cover it up. The morning after the Emini meeting, David Krah arrived early at the lab and destroyed garbage bags full of evidence of the fraud. *Id.* ¶ 58. He and Alan Shaw, Merck's Executive Director of Vaccine Research, also directly and repeatedly lied to the FDA about the efficacy testing. *Id.* ¶¶ 59-64. Merck also tried to purchase the cooperation of Krah's staff by offering them significant bonuses if they cooperated in the fraudulent testing. *Id.* ¶¶ 53-54, 125.

These allegations paint a starkly different picture of the agency Merck portrays as having been fully apprised and aware of Merck's fraudulent testing. *See* MTD at 3-4 (claiming Relators told the FDA "about everything," and that the agency "had access to the full scope of the allegations" of misconduct). They describe Merck's deliberate conduct to keep what it knows about its vaccine's significantly diminished efficacy within Merck and away from the government. As a result, the FDA, CDC, National Vaccine Program Office and every other governmental body remained unaware of the company's fraudulent activity and, even more importantly, the reality that the vaccine's efficacy had significantly diminished.[3] That is why in the face of the 2006 outbreak, the head of the CDC was still under the mistaken belief that there

[3] *See, e.g.*, Compl. ¶ 39 ("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"); ¶ 50 ("For every effort [Relators] took to stop the fraud, Merck adapted the scheme to assure the falsification continued."); ¶¶ 59-62 (Merck lied to the FDA about its fraudulent testing); ¶ 64 ("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."); ¶ 65 (after the FDA visit, "Merck continued to falsify the test data to . . . inflate the seroconversion rate"); ¶ 68 (the government did not know about "Merck's improper use of animal antibodies and the wide-scale falsification of test data to conceal the significantly diminished efficacy of its vaccine.").

was "absolutely no information to suggest that there is any problem with the vaccine." Compl. ¶ 84. Of course, Merck had a bounty of such information. It just chose -- and still chooses -- to conceal it from the government and the public.[4]

**C. Merck's Fraudulent Label**

The label for Merck's mumps vaccine represents that "a single injection of the vaccine induced . . . mumps neutralizing antibodies in 96% . . . of susceptible persons." Compl. ¶ 72. It further represents that the vaccine's efficacy "was established in a series of double-blind controlled field trials which demonstrated a high degree of protective efficacy . . . ." *Id.* Merck's label is a false and misleading representation of the efficacy rate of its mumps vaccine. It cites outdated or unidentified studies that are not reflective of what Merck knows about the vaccine's diminished efficacy. *Id.* ¶ 73. Whatever these studies may have shown when -- as Merck acknowledges -- they were "conducted decades ago" (MTD at 7), they do not reflect what Merck has known about its vaccine's diminished efficacy since at least 1999. Nor can Merck rewrite the allegations in the Complaint to support its assertion that its mumps vaccine still confers a "high degree of protective efficacy." MTD at 8 (citing label). It does not, as the allegations and real-world events establish in painstaking detail. *See supra* at 4-5; *infra* at 8-9, 13-14.

**D. Merck's Concealment Through Recent Mumps Outbreaks**

There have been two recent mumps outbreaks in the U.S. Compl. ¶¶ 82-96. This is exactly what Merck's David Krah predicted would occur because of the significantly diminished efficacy of the vaccine. *Id.* ¶¶ 82, 93. The first outbreak occurred in 2006 and involved more

[4] Merck points to the government's access to the articles referenced in the Complaint that reported on two studies of the 2006 mumps outbreak. MTD at 22. But, as the Complaint makes clear, these studies neither apprised the government of Merck's fraudulent conduct nor of the significantly diminished efficacy of the vaccine. Compl. ¶ 86 (noting that CDC scientist who led the study and authored the article did not have "the benefit of what Merck knew but willfully withheld from the government and the public"); ¶ 89 (noting that study "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").

than 6,500 cases. *Id.* ¶ 83. Comporting with the three-year cycles these outbreaks follow, the second one occurred in 2009 and involved roughly 5,000 cases. *Id.* ¶¶ 92-93. While Merck attempts to downplay the significance and scale of these outbreaks (MTD at 8), they were the largest outbreaks in almost twenty years and have been and remain the cause for significant concern and study by the government and medical community. *Id.* ¶¶ 84-94.

These outbreaks were also the reason why the CDC pushed back the target date for eradicating the disease from its original 2010 goal to no earlier than 2020, *id.* ¶ 95, and why the government has recently decided to conduct its own efficacy testing and fund research for a new vaccine. *See infra* at 13-14. Despite its purported efforts to work with the government and medical community to determine the reason for these outbreaks, at no time did Merck disclose what it knows about the diminished efficacy of its vaccine. Compl. ¶¶ 84, 86-91, 95. On the contrary, Merck attempted to reassure the government and the public that there was nothing wrong with the vaccine and that it had no plans to change it. *Id.* ¶ 87.

### E. Merck's Concealment Through Its Additional Dealings With the Government and Public

Merck's campaign of concealing what it knows about the diminished efficacy of its mumps vaccine has gone well beyond its manipulated and fraudulent testing and cover-up, its fraudulent label, and its silence (and misinformation) in the face of continued outbreaks. It has also extended to virtually every dealing the company has had with the government and public:

- Merck failed to disclose what it knows about the diminished efficacy in its 2004 application to the FDA for approval of ProQuad. Instead, Merck submitted studies that reported for the mumps component of the vaccine an efficacy rate of more than 95 percent. Merck's label for that vaccine likewise falsely represents a 96.7% efficacy rate. Compl. ¶ 75.

- Merck failed to disclose what it knows about the diminished efficacy in its efforts to obtain government approval in Europe for MMRVaxpro and ProQuad. Instead, Merck submitted, and the government there relied on, the falsified results of its mumps efficacy testing. Compl. ¶¶ 76-77.

- Merck failed to disclose what it knows about the diminished efficacy in its application to the FDA for a labeling change to reflect a lower potency of the mumps component of its MMRII vaccine. Instead, Merck represented that it could actually *reduce* how much attenuated virus it 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. Compl. ¶¶ 79-81.

- Merck has failed to disclose what it knows about the diminished efficacy to the Immunization Action Coalition (IAC), the Merck funded and government supported organization that acts as the "nation's premier source" of vaccine information for healthcare professionals and consumers. The IAC asserts that Merck's mumps vaccine has an efficacy rate of 97 percent. Merck has done nothing to correct this widely disseminated misinformation. Compl. ¶¶ 97-101.

- Merck has failed to disclose what it knows about the diminished efficacy on the portion of its website directed to "U.S. Health Care Professionals" detailing the "high seroconversion rates" associated with its MMRII vaccine. Instead, pointing to the same outdated studies referenced in Merck's vaccine label, Merck states that its mumps vaccine demonstrated a 96 percent seroconversion rate.[5]

## IV. MERCK HAS VIOLATED ITS MUTIPLE DUTIES TO DISCLOSE WHAT IT KNOWS ABOUT THE DIMINISHED EFFICACY OF ITS MUMPS VACCINE

Merck has ongoing and independent duties to disclose to the CDC, the FDA and under the National Vaccine Program all material information relating to the safety and efficacy of its mumps vaccine. Compl. ¶¶ 104-120. This means that Merck has a continuous duty to provide accurate information on the efficacy of its mumps vaccine, including apprising the government of any diminished efficacy or other problems Merck discovers, or in the exercise of reasonable care should have discovered, with the vaccine. *Id*. Merck likewise has a continuous duty to ensure that the contents of its vaccine labels are accurate and up-to-date. *Id.* ¶¶ 112, 117. This requires Merck to self-monitor and update its labeling when new information becomes available that causes the label to become inaccurate, false or misleading. *Id.*

[5] *See* Declaration of Marlene Koury dated October 9, 2012 (the "Koury Decl."), Ex. A (Merck website page on seroconversion rates of MMR vaccine).

With regard to the CDC, Merck's duty of disclosure is especially clear. It stems from Merck's dual obligation by statute and under each of the Merck-CDC vaccine purchase contracts to provide the CDC with all of the information the CDC needs to carry out its corollary duty to warn the public about the vaccine's safety and efficacy. Compl. ¶¶ 105-110. Merck specifically negotiated with the government for this *quid pro quo* delegation to assure that Merck could sell its vaccines to the government without being subjected to personal injury claims for failing to warn about the safety and efficacy of its vaccines. *Id*. ¶ 106. As the Third Circuit has held, Merck's respective duty to provide accurate and up-to-date safety and efficacy information to the CDC is unequivocal and ongoing: "[Merck'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." *Mazur v. Merck*, 964 F.2d 1348, 1365-66 (3d Cir. 1992). It is also a condition of purchase. *See Mazur v. Merck*, 767 F. Supp. 697, 703 (E.D. Pa. 1991) (describing history of Merck/CDC negotiations over MMR vaccine purchase contract).

Merck breached these multiple duties by failing to disclose what it knows about the diminished efficacy of its mumps vaccine and by falsely maintaining a 95 percent efficacy rate on its vaccine's label. Compl. ¶ 121. These duties were triggered as soon as Merck learned that the efficacy of its now forty-five year old mumps vaccine had diminished. *Id*. ¶ 122. Merck learned this no later than 1999, but rather than disclose it to the government, as Merck was obligated to do, Merck embarked on a campaign of concealment and outright fraud:

> (i) Merck abandoned and kept hidden from the government the poor results of its original efficacy testing; (ii) Merck then used a manipulated and falsified test to obtain an inflated result to submit to the government; (iii) Merck tried to cover up the fraudulent testing by destroying evidence of the falsification, lying to the FDA, attempting to buy the silence and cooperation of the staff involved in the testing, and threatening Relator Krahling with jail; (iv) Merck failed to disclose what it knew about the diminished efficacy in the face of the 2006 and 2009 outbreaks even though Merck was supposed to be working

> with the government to determine the cause; (v) Merck failed to disclose what it knew about the diminished efficacy in its FDA applications for ProQuad and for a labeling change on the potency of MMRII; (vi) Merck failed to disclose what it knew about the diminished efficacy in its applications for approval in Europe of MMRVaxpro and ProQuad; (vii) Merck failed to disclose what it knew about the diminished efficacy even though the IAC, which Merck funds, prominently promotes a significantly inflated efficacy rate; (viii) Merck falsely represents on its label and its website a significantly inflated efficacy rate; and (ix) Merck has continually entered into CDC vaccine purchase contracts and submitted claims for payment under those contracts while concealing information critical to the CDC's purchasing decision. *Id.* ¶¶ 123-131, 145-148, 152-157.

Each of these failures violates Merck's multiple statutory duties of disclosure to the CDC, the FDA and under the National Vaccine Program. *Id.* ¶¶ 130-31. They also violate Merck's contractual obligation of disclosure contained in the CDC purchase contracts as well as render false the certifications Merck has made and continues to make that it has complied with the terms of these contracts. *Id.* ¶¶ 130, 154-155.

## V. MERCK HAS ILLEGALLY MONOPOLIZED THE MUMPS VACCINE MARKET

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. Compl. ¶¶ 132-144. However, Merck has illegally maintained this monopoly through its ongoing efforts to conceal from the government what it knows about the diminished efficacy of its vaccine, in violation of its multiple duties of disclosure. *Id.* 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. *Id.*

## VI. THE GOVERNMENT HAS PURCHASED AND CONTINUES TO PURCHASE A VACCINE ABOUT WHICH MERCK HAS WITHELD INFORMATION MATERIAL TO THE GOVERNMENT'S PURCHASES

Over the past decade, Merck's fraudulent scheme to misrepresent and conceal the diminished efficacy of its mumps vaccine has cost the government hundreds of millions of dollars. Compl. ¶ 145. Had Merck complied with its multiple duties of disclosure and the U.S. antitrust laws and reported the diminished efficacy of the vaccine -- rather than engage in false representations and concealment -- it would have affected (or certainly had the potential to affect) the government's decision to purchase the vaccine. *Id.* ¶¶ 4, 145. With full information, the government would have had the opportunity to consider numerous options, including not purchasing the vaccine from Merck or paying less. *Id.* It also would have included requiring additional testing or prioritizing development and approval of a new vaccine, both of which are specifically contemplated under the National Childhood Vaccine Injury Act, and exactly what has happened since the commencement of this action. *Id.*; *infra* at 13-14.

## VII. SINCE THE FILING OF THIS ACTION, THE GOVERNMENT HAS BEGUN TO TAKE STEPS TO ADDRESS THE FAILURE OF MERCK'S MUMPS VACCINE

Relators filed their original complaint in this action on August 27, 2010. Dkt. 1. After investigating the action for roughly twenty months, the government declined to intervene on April 27, 2012. On the same day, Relators filed their amended Complaint that is the subject of Merck's motion to dismiss. Dkt. 12. The government has not joined in Merck's current motion and has made no decision on the current Complaint. Instead, it has taken a "wait and see" approach requesting that it be served with all pleadings, motions and court orders in this case, and that its consent be obtained before the case is settled, dismissed or discontinued. Dkt. 14.

While the Department of Justice (DOJ) has chosen to sit on the sidelines of this case for now, both the FDA and its sister agency, the National Institute of Health (NIH), have since the

complaint was filed begun to take steps to address the failure of Merck's mumps vaccine. The FDA has initiated its own study to determine the vaccine's efficacy, acknowledging that the recent mumps outbreak "indicat[es] lower vaccine efficacy than previously estimated."[6] The NIH has gone even further. It is funding the University of Georgia to develop a new mumps vaccine because the recent outbreaks "strongly suggest[] that the current vaccine is not effective."[7]

## ARGUMENT

### I. THE RELEVANT STANDARD

In deciding a motion to dismiss pursuant to Rule 12(b)(6), courts must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Muhammed v. Pawlowski*, 2012 WL 748411, at *1 n.2 (E.D. Pa. Mar. 7, 2012) (Jones II, J.) (quoting *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)). Under the Supreme Court's *Twombly/Iqbal* plausibility standard, the complaint must contain more than "[t]hreadbare recitals" or "conclusory statements" or a "sheer possibility" of the challenged conduct. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). It must contain "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007)).

This does not impose a "probability requirement." *Id.* And the plausibility threshold can be satisfied "even if it strikes a savvy judge that actual proof of those facts is improbable, and

[6] *See* Koury Decl., Ex. B (FDA Web Page on "Determining the Safety and Efficacy of Vaccines to Protect Against Viruses that Infect the Central Nervous System"). As Merck recognizes in its motion, a court on a motion to dismiss may consider matters of public record. MTD at 6 n.3 (citing *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993)). This includes information contained on a government agency's website. *See, e.g., Kos Pharms., Inc. v. Andrx Corp.*, 369 F.3d 700, 705 n.5 (3d Cir. 2004) (taking judicial notice of information on Patent and Trademark Office website); *In re Wellbutrin ST/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice of information on the FDA website).

[7] *See* Koury Decl., Ex. C (NIH Web Page on "Developing a Novel Mumps Virus Vaccine").

that a recovery is very remote and unlikely." *Twombly*, 550 U.S. at 556 (internal quotes and cite omitted). It can likewise be satisfied with "a short and plain statement of the claim and its grounds." *Phillips*, 515 F.3d at 231 (citing *Twombly*, 550 U.S. at 553). The ultimate question for the court is whether the plaintiff is "entitled to offer evidence to support the claims." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011). A court may not dismiss a case unless "it appears to a certainty that no relief could be granted under any set of facts which could be proved." *In re Merck & Co., Inc. Secs., Derivative & "ERISA" Litig.*, 543 F.3d 150, 160 (3d Cir. 2008).

## II. THE BROAD AND EXPANSIVE REACH OF THE FALSE CLAIMS ACT

The False Claims Act was enacted in 1863, long before the FDA or the Food Drug and Cosmetic Act ("FDCA") came into being. It was passed by President Lincoln to combat widespread fraud by companies selling rancid food, ailing mules and defective weapons to the Union Army during the Civil War. From the outset, and through several amendments enacted over the past twenty-five years to increase the scope and reach of the statute,[8] both Congress and the Supreme Court have repeatedly highlighted the two key features of the law. First, it is to be applied broadly and flexibly to reach all types of fraud that cause financial loss to the government. Second, private parties (relators) should be strongly encouraged to play a

[8] One major set of amendments to the False Claims Act occurred in 1986 to significantly increase the strength of the statute and provide greater incentives to relators. The changes included imposing triple damages on wrongdoers; lowering the standard of proof to include "deliberate ignorance" or "reckless disregard" of the truth; increasing the relator reward to up to thirty percent of the government's recovery; and strengthening the anti-retaliation protections for relators. Pub. L. No. 99-562, 100 Stat. 3153 (1986). The statute was expanded again in 2009 with the Fraud Enforcement and Recovery Act ("FERA") which served to legislatively abrogate a series of judicial decisions that had limited the scope of the Act. Pub. L. No. 111-21, 123 Stat. 1617 (2009). In the 2010 Patient Protection and Affordable Care Act, Congress made other important changes to the statute to ensure courts retained subject matter jurisdiction over some cases where jurisdiction had been challenged. Pub. L. No. 111-148, 124 Stat. 119 (2010). And in the July 2010 Dodd-Frank Wall Street Reform and Consumer Protection Act, Congress created an expanded and uniform three-year statute of limitations for retaliation claims brought under the False Claims Act. Pub. L. 111-203, 124 Stat. 1376 (2010).

significant role in the enforcement scheme to supplement the government's limited resources to combat fraud.

When evaluating claims under the Act, the Supreme Court has repeatedly acknowledged and deferred to these twin goals of the statute and "consistently refused to accept a rigid, restrictive reading." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968). Instead, it has applied the law as "Congress wrote [it --] expansively, meaning to reach all types of fraud, without qualification, that might result in financial loss to the government." *Cook Cnty.*, 538 U.S. at 129 (internal quotes and cite omitted). *See also Rainwater v. United States*, 356 U.S. 590, 592 (1958) ("It seems quite clear that the objective of Congress was broadly to protect the funds and property of the Government"); *Neifert-White*, 390 U.S. at 233 (the FCA "reaches beyond claims which might be legally enforced to all fraudulent attempts to cause the Government to pay out sums of money"); *Wilkins*, 659 F.3d at 306 (pointing to "Congress' expressly stated purpose that the FCA should reach all fraudulent attempts to cause the Government to pay out sums of money") (internal quotes and alterations omitted).[9]

The right of private parties to bring actions under the False Claims Act is part and parcel of this expansive approach to enforcement. "Because it would be difficult for the government to discover and prosecute all potential violations, the False Claims Act provides a *qui tam* enforcement mechanism, which allows a private party (*i.e.*, a relator) to bring a lawsuit on behalf of the government." *U.S. ex rel. Washington v. Educ. Mgmt. Corp.*, 2012 WL 1658482, at *8

[9] *See also U.S. ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Grp., Inc.*, 400 F.3d 428, 446 (6th Cir. 2005) (the "Supreme Court has broadly interpreted the statute to cover all fraudulent attempts to cause the Government to pay out sums of money … consistent with the FCA's principal goal of ensuring the integrity of the Government's dealings, which is embodied in the maxim that men must turn square corners when they deal with the Government") (internal quotes, cites and alterations omitted); *Hooper v. Lockheed Martin Corp.*, 688 F.3d 1037, 1048 (9th Cir. 2012) ("each and every claim submitted under a contract, loan guarantee, or other agreement which was originally obtained by means of false statements or other corrupt or fraudulent conduct, or in violation of any statute or applicable regulation, constitutes a false claim") (citing *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786 (4th Cir. 1999)) (quoting S. Rep. No. 99–345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274).

(W.D. Pa. May 11, 2012) (internal quotes and cite omitted). Not only does the statute provide for this "posse of *ad hoc* deputies" to supplement government enforcement. *Harrison,* 176 F.3d at 784. It also provides them with a potential reward of up to 30 percent of any government recovery, an award that must fall on the higher end of the scale in those cases where the government does not intervene. 31 U.S.C. § 3730(d).

In providing these strong financial incentives, which were significantly increased by the 1986 amendments, Congress made clear its view that relators play a critical role in False Claims Act enforcement. *See Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 130 S. Ct. 1396, 1409 (2010) ("We do not doubt that Congress passed the 1986 amendments to the FCA to strengthen the Government's hand in fighting false claims and to encourage more private enforcement suits") (internal cites and quotations omitted); H.R. Rep. No. 660, 99th Cong., 2d Sess. 22 (1986) ("[T]he purpose of the 1986 amendments was to repeal overly-restrictive court interpretations of the qui tam statute" and to encourage "private individuals who are aware of fraud being perpetrated against the Government to bring such information forward.").[10]

Merck takes no account of these driving features of the False Claims Act. In fact, Merck argues for an application of the statute that would seriously undercut them. It would severely limit or altogether bar False Claims Act cases for fraudulent conduct that may also violate FDA rules or regulations as well as other federal laws. It would severely limit or bar False Claims Act cases for fraudulent conduct that is subject to regulation or oversight by the FDA or some other agency. It would require relators to exhaust all administrative remedies available to them as a prerequisite for bringing an action under the False Claims Act. It would impose an overly

[10] Notably, in 2011 alone, the government secured more than $3 billion in settlements under the False Claims Act of which more than 90 percent ($2.8 billion) resulted from *qui tam* actions brought by private relators. *See* Koury Decl., Ex. D (December 19, 2011 DOJ Press Release) ("The 1986 amendments strengthened the act and increased the incentives for whistleblowers to file lawsuits on behalf of the government. That in turn led to an unprecedented number of investigations and greater recoveries.").

rigorous pleading standard that goes well beyond the detail required under Rule 9(b). And it would severely limit or bar the scope of the False Claims Act in instances where the government chooses not to intervene. This unbridled assault on the breadth and scope of the False Claims Act is exactly the kind of "rigid, restrictive reading" Congress has cautioned against and the Supreme Court "has consistently refused" to adopt. *Neifert-White*, 390 U.S. at 232.

## III. RELATORS' COMPLAINT ALLEGES A FALSE CLAIMS ACT VIOLATION

The False Claims Act imposes civil liability on any person who (i) "knowingly presents, or causes to be presented" to the government "a false or fraudulent claim for payment or approval," or (ii) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A&B) (formerly § 3729(a)(1&2)).[11] While there are numerous types of false or fraudulent claims that can form the basis of liability under the statute, they all tend to share one common trait -- the defendant knowingly submitting a claim for the government's purchase of a product or service that is different from what the government contracted to purchase. That is exactly the case here with Merck's ongoing sales to the CDC of a mumps vaccine that does not provide adequate immunization and does not contain the accurate and up-to-date efficacy information Merck is required to provide (and which Merck has certified it does provide). Notwithstanding Merck's

[11] For the purposes of this motion, there is no difference between finding liability under pre-FERA 31 U.S.C. § 3729(a)(1) and post-FERA 31 U.S.C. § 3729(a)(1)(A). There is a difference, however, between pre-FERA 31 U.S.C. § 3729(a)(2) (no requirement that the record or statement be "material;" explicit requirement that the false statement or record be used "to get a false or fraudulent claim paid or approved by the Government") and post-FERA 31 U.S.C. § 3729(a)(1)(B) (requirement that statement or record be "material" but no requirement that the statement or record be made with the intent to obtain payment). The Supreme Court interpreted pre-FERA 31 U.S.C. § 3729(a)(2) to require that a defendant "intended" that the false statement or record would be used to obtain government payment and that the record or statement was material to payment. *Allison Engine Co., Inc. v. U.S. ex rel. Sanders*, 553 U.S. 662, 665 (2008). FERA abrogated this decision. *See, e.g., Wilkins*, 659 F.3d at 303-304, 304 n.12 (discussing FERA and quoting a Senate Report stating that FERA added an explicit materiality requirement but removed the language the Supreme Court relied upon to find an intent requirement). Thus, for claims Merck submitted on or after June 7, 2008, there is no requirement that Relators allege that Merck used false statements or records with the intent to get a claim paid. In any event, Relators have satisfied all of the elements of both provisions as they apply both pre- and post-FERA.

multiple machinations with the Complaint -- rewriting allegations; disregarding others; inventing new ones -- Merck's fraudulent sale of its mumps vaccine to the CDC is precisely the type of conduct the False Claims Act was designed to cover.

### A. Relators Have Sufficiently Alleged Each of the Elements of a False Claims Act Violation

To establish a *prima facie* case for a violation of the Act under 31 U.S.C. § 3729(a)(1)(A) (and the former § 3729(a)(1)), a plaintiff must allege that: (i) the defendant presented or caused to be presented to an agent of the United States a claim for payment; (ii) the claim was false or fraudulent; and (iii) the defendant knew the claim was false or fraudulent. *See, e.g., Wilkins*, 659 F.3d at 304-305. To establish a violation of the Act under the former 31 U.S.C. § 3729(a)(2), which applies to false claims before June 7, 2008, a plaintiff must allege that (i) the defendant created a false record or statement; (ii) the defendant used the record or statement to get the government to pay its claim; and (iii) the defendant knew that the record or statement was false. *See, e.g., United States v. Toyobo Co. Ltd.*, 811 F. Supp. 2d 37, 48-49 n.6, 49 (D.D.C. 2011). Under 31 U.S.C. § 3729(a)(1)(B), which applies to false claims on or after June 7, 2008, a plaintiff need not allege that the false statement or record was made with the intent to obtain government payment, but must allege that the false statement or record was "material" to the government's purchasing decision. *Wilkins*, 659 F.3d at 303-304, 304 n.12. Relators have alleged each of these requisite elements with significant detail and factual support.

#### 1. Merck Presented to the Government Claims for Payment

The False Claims Act defines a "claim" as "any request or demand, whether under a contract or otherwise, for money or property" from the United States. 31 U.S.C. § 3729(b)(2). The courts have broadly interpreted this element to mean any claims that "'cause or would cause economic loss to the government.'" *U.S. ex rel. Sanders v. American-Amicable Life Ins. Co. of*

*Tex*, 545 F.3d 256, 259 (3d Cir. 2008) (*quoting Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 179 (3d Cir. 2001)). There is no dispute that Relators have readily satisfied this element. *See, e.g.*, Compl. ¶¶ 4, 144-145, 147-149, 152-55 (alleging that Merck has submitted to the CDC claims for payment, and the CDC has paid Merck hundreds of millions of dollars, for a vaccine that does not provide adequate immunization).

2. Merck's Claims for Payment Were False or Fraudulent

The False Claims Act does not define the terms "false or fraudulent." However, in line with the broad range of misconduct the statute is designed to reach, courts have been clear that it covers "all types of fraud, without qualification." *Cook Cnty.*, 538 U.S. at 129. *See also Wilkins*, 659 F.3d at 306 (pointing to "Congress' expressly stated purpose that the FCA should reach all fraudulent attempts to cause the Government to pay out sums of money") (internal quotes and cite omitted). It need only be material to the government's purchase decision and result in some financial loss to the government.

Consistent with this expansive view of the statute, courts have recognized different kinds of false or fraudulent claims that fall within its ambit. They can be "factually false" claims, where the seller "misrepresents what goods or services that it provided to the Government." *Wilkins*, 659 F.3d at 305.[12] They can be "legally false" claims, where the seller "falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for

[12] *See, e.g., United States v. Bornstein*, 423 U.S. 303, 307 (1976) (sale of tubes falsely marked as having the required quality); *U.S. ex rel. Compton v. Midwest Specialties, Inc.*, 142 F.3d 296, 302, 302 n.4 (6th Cir. 1998) (sale of Jeep brake shoe kits where defendant failed to test the product as required by the contract); *Daff v. United States*,78 F.3d 1566, 1573 (Fed. Cir. 1996) (sale of product on which defendant used a common lubricant to conceal failure of tests required under contract); *United States v. Nat'l Wholesalers*, 236 F.2d 944, 950 (9th Cir.1956) (sale of misbranded generators not complying with contract); *United States v. Kaman Precision Prods., Inc.*, 2011 WL 3841569, at *5 (M.D. Fla. Aug. 30, 2011) (sale of bomb fuses that did not meet contract specifications); *U.S. ex rel. Dye v. ATK Launch Sys., Inc.*, 2008 WL 2074099, at *3 (D. Utah May 14, 2008) (sale of flares that did not meet contractual requirements); *U.S. ex rel. Gonzalez v. Fresenius Med. Care N. Am.*, 2008 WL 4277150, at *3 (W.D. Tex. Sept. 2, 2008) (falsely representing service provided by a licensed doctor).

Government payment." *Id.*[13] And they can be "fraudulently induced" claims, where the seller's misrepresentations were material to the government's decision to enter into a contract or make the purchase in the first place.[14]

Even within these broad categories of false claims, the courts have taken a "more expansive" view of what is covered by the Act. *Id.* For example, they have considered a claim to be falsely certified even when the seller does not actually certify compliance with any rules and regulations. Instead, they have found the false certification to be implied based "on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *Id.* Courts have likewise been clear that affirmative misrepresentations are not necessary for a claim to be factually false -- misrepresentations by omission will also suffice.[15] Some courts have gone so far as to dispense

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[13] *See, e.g., U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004) (falsely certifying compliance with federal healthcare laws)*; Laymon, Jr. v. Bombardier Transp. (Holdings) USA, Inc.*, 2009 WL 793627 (W.D. Pa. May 23, 2009) (falsely certifying compliance with contract and Department of Transportation regulations); *United States. v. Albinson*, 2010 WL 3258266 (D.N.J. Aug. 16, 2010) (falsely certifying compliance with contract).

[14] *Neifert-White*, 390 U.S. at 232 (any action which has the "effect of inducing the Government immediately to part with money" would be a claim under the Act); *U.S. ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 415-416 (3d Cir. 1999) (finding liability properly alleged where defendant omitted material information in grant application which could induce government to award grant); *U.S. ex rel. Drescher v. Highmark, Inc.*, 305 F. Supp. 2d 451, 458 (E.D. Pa. 2004) (citing fraud in the inducement as an accepted theory of liability under the False Claims Act); *U.S. ex rel. Atkinson* v. *Pa. Shipbuilding Co.*, 2000 WL 1207162, at * 8 (E.D. Pa. Aug. 24, 2000) ("under the FCA, a government contractor is liable for every claim submitted under a contract if the contract was fraudulently obtained, even if the work is performed to government specifications and at the agreed price"); *Educ. Mgmt.*, 2012 WL 1658482, at *13 (allegations that government was induced to enter into agreements with defendant in part on the basis of representations that defendant would comply with law stated cause of action under fraud in the inducement theory); *U.S. ex rel. Longhi v. Lithium Power Techs., Inc.*, 575 F.3d 458, 464 (5th Cir. 2009) (fraudulently inducing government to provide funding could give rise to False Claims Act liability even if invoices submitted were true.); *Toyobo*, 811 F. Supp. 2d at 46 (government adequately pled cause of action based on fraud in the inducement in government's purchase of bullet proof vests defendant knew but failed to disclose contained defective fibers) *U.S. ex rel. Wilkins v. N. Am. Constr. Corp.*, 173 F. Supp. 2d 601, 624 (S.D. Tx. 2001) ("A claim may be false even if it is literally true, if the claimant previously made misrepresentations or omissions or committed misconduct in order to induce the government to enter into the contract in the first place.")

[15] *See, e.g., U.S. ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 416 (3d Cir. 1999) (omission of information that might be material to government decision to award grant properly gave rise to False Claims Act claim); *U.S. ex rel. Atkinson v. Pa. Shipbuilding Co.*, 255 F. Supp. 2d 351, 406 (E.D. Pa. 2002) ("When a party incurs a *duty* to prevent a fraud on the government, its failure to fulfill that duty can give rise to liability under the False Claims Act.") (emphasis in original); *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (hidden kickbacks

altogether with trying to categorize or label the various types of false claims for fear of "creat[ing] artificial barriers that obscure and distort" the broad reach of the False Claims Act. *U.S. ex rel. Hutcheson v. Blackstone Med., Inc.*, 647 F.3d 377, 385 (1st Cir. 2011). *See also U.S. ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166, 1172 (9th Cir. 2006) ("So long as the statement is knowingly false when made, it matters not whether it is a certification, assertion, statement or secret handshake; False Claims liability can attach.").

As Congress made clear when it amended the statute in 1986, the bottom line is that "a false claim may take many forms," but what they all tend to have in common is that they involve "a claim for goods or services not provided, or provided in violation of contract terms, specification, statute, or regulation." *Wilkins*, 659 F.3d at 306 (quoting S. Rep. No. 99-345, at 9 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5274). That is the essence of the False Claims Act and how courts have broadly interpreted it to go after "all types of fraud, without qualification." *Cook Cnty.*, 538 U.S. at 129. Relators' allegations of Merck's fraudulent conduct fit precisely into this paradigm.

The essence of Relators' False Claims Act case is that Merck has over the past decade knowingly presented false claims for payment to the CDC when Merck billed the agency for a mumps vaccine that was not what the agency contracted to purchase and that violated numerous contractual and statutory provisions. What the CDC contracted for but did not receive was a mumps vaccine (i) that provided adequate immunization against the mumps disease; (ii) with an efficacy rate that was equal to or above the 95 percent rate Merck represented it to be on its label,

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considered material omissions); *United States v. TDC Mgmt. Corp., Inc.*, 288 F.3d 421, 426 (D.C. Cir. 2002) (withholding of "information critical to the decision to pay is the essence of a false claim"); *U.S. ex rel. Berge v. Bd. of Trs. of Univ. of Ala.*, 104 F.3d 1453, 1461 (4th Cir. 1997) (where defendant has an obligation to disclose material information, the omission can give rise to False Claims Act liability); *Toyobo*, 811 F. Supp. 2d at 50 (liability supported from defendant's failure to disclose what it knew about the defective product); *U.S. ex rel. v. Fry v. Guidant Corp.*, 2006 WL 1102397, at * 8 (M.D. Tenn. Apr. 25, 2006) (representation rendered false by concealment of material information).

website and otherwise; (iii) with accurate, complete and up-to-date information on its efficacy; (iv) which was sold in compliance with the terms and conditions of the CDC vaccine purchase contracts, as Merck certified for every one of its sales; and (v) which was sold in compliance with all other laws and regulations. Compl. ¶¶ 152-155.

Merck's claims to the CDC for payment are thus not only plainly encompassed within the type of overarching fraud the False Claims Act was specifically designed to target. They also fall well within each of the specific false claims "categories" the courts have looked to in assessing conduct under the statute. They are "factually false" because they are based on Merck's affirmative misrepresentations to the CDC about the vaccine's efficacy and how well it works. They are also "factually false" because of Merck's fraudulent omission of all the information it knows -- but has schemed to conceal -- on the vaccine's significantly diminished efficacy.

Merck's misrepresentations and omissions have also served to "fraudulently induce" the CDC into making the vaccine purchases. Indeed, they have caused the CDC to contract exclusively with Merck for the mumps vaccine. Having accurate and up-to-date information on efficacy is more than simply material to the CDC's purchase decision. It is at the very core of the country's vaccine program.

Merck's false and fraudulent claims are likewise "legally false" because of both Merck's express and implied certifications that it has complied with all of the terms and conditions of its CDC purchase contract, not to mention its other regulatory and statutory obligations. Most importantly, this includes Merck's duty to disclose accurate and current information on efficacy. These certifications were not merely a condition of payment for Merck. They were a condition for Merck's ability to sell the vaccine at all. Compl. ¶¶ 112, 115, 117, 131. *See also Mazur*, 767

F. Supp. at 703 (describing disclosure of full and accurate efficacy information as a condition of purchase).

Merck's efforts to rewrite or ignore the allegations in the Complaint do not change the fact that this case centers around Merck knowingly making claims for payment for the sale of a product it did not actually provide and that was in violation of Merck's specific contractual and statutory obligations. Relators have readily satisfied this element of the False Claims Act, many times over.[16]

3. Merck Knew Its Statements and Records and Its Claims for Payment Were False or Fraudulent

A claim or statement or record is "knowingly" false within the meaning of the False Claims Act if the defendant has "actual knowledge," "deliberate ignorance" or "reckless disregard" of the fraudulent conduct. *U.S. ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103, 109 (3d Cir. 2007) (citing 31 U.S.C. § 3729(b)). The Complaint provides in great detail Merck's intentional and knowing conduct in failing to disclose and taking active steps to conceal the diminished efficacy of its mumps vaccine; in misrepresenting the efficacy of its vaccine through its vaccine label and in its continuous dealings with the government and public; and in contracting with the CDC and thereafter submitting to the CDC fraudulent claims for payment by selling it a product for which the government did not contract and which violated the terms and conditions of the purchase contract to which Merck certified compliance. *See, e.g.*,

[16] Pursuant to 31 U.S.C. § 3729(a)(1)(B) and the former 31 U.S.C. § 3729(a)(2), Relators have also more than adequately alleged a multitude of Merck's false statements and records regarding its mumps vaccine. These include all the misrepresentations, omissions and false records relating to the significantly diminished efficacy of the vaccine. *See supra* at 5-12.

Compl. ¶¶ 153-155 (summarizing allegations of Merck's knowing fraudulent conduct). Relators have readily satisfied this element of the False Claims Act.[17]

4. Merck's False Statements and Records Were Material to the CDC's Purchasing Decision

Materiality under the False Claims Act is defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The material nature of the information on efficacy that Merck misrepresented and withheld is evident from Merck's contractual and statutory obligation to provide accurate and up-to-date efficacy information. *See also* Compl. ¶ 156 (summarizing all the allegations detailing why Merck's misrepresentations and omissions were not only material, they were critical to the government's purchase and payment for Merck's vaccine).

Despite Merck's contentions to the contrary, its misrepresentations and omissions targeted outside the government such as to the European authorities and the public were equally material. *See Allison Engine Co., Inc.*, 553 U.S. at 671 (abrogated on other grounds) (false statement or record need not be submitted to the government to find liability). As the Third Circuit noted in *Wilkins*, for post-FERA claims, there is no requirement that false statements or records be made with the intent to obtain government payment. They need only have had a natural tendency to influence or have been capable of influencing the government's purchasing decision. 659 F.3d at 303-304, 304 n.12.

So, for example, had Merck submitted legitimate (as opposed to the falsified) test results to the European authorities, it naturally would have been capable of influencing the U.S. government's purchasing decision because it would have presented conflicting information about

[17] For the same reasons, Relators likewise have satisfied the requirement that the false statements or records were made with the intent to obtain government payment for Merck's vaccine (to the extent the Court applies the pre-FERA 31 U.S.C. § 3729(a)(2) provision to claims paid before June 7, 2008).

the vaccine -- the 95 percent efficacy Merck was reporting to the government and the diminished efficacy that Merck would have reported to the European authorities. Likewise, had the public known about the diminished efficacy of the vaccine (such as through accurate information on Merck's website or the IAC website), such knowledge would naturally be capable of causing fewer people to choose to vaccinate their children for mumps, resulting in the government making fewer purchases of the vaccine.

**B. Merck's Attempt to Rewrite, Ignore and Invent the Allegations In This Case**

In an effort to escape the expansive reach of the False Claims Act and the wide swathe of fraudulent activity it is designed to cover, Merck attempts to rewrite and ignore the key allegations in the Complaint relating to Merck's fraudulent conduct and its submission of false claims for payment to the CDC. Merck also endeavors to invent new allegations in an effort to color the Court's view of the underlying merits of this action. Merck's factual maneuverings have no place in a motion to dismiss and do nothing to undermine the clear application of the False Claims Act to the fraudulent conduct and false claims at issue here.

1. This Case Is Not Just About Merck's Fraudulent Label

*First* and foremost, Merck pretends that the fraud allegations in this case revolve solely around the vaccine label. MTD at 6 ("Every claim in this case is built on Relators' contention that the MMR product label is false.").[18] The falsity of Merck's label is certainly an important part of the fraudulent conduct Relators allege. But it is only a small part. What Merck ignores throughout its entire brief is the core fraudulent conduct at the center of this case. That is, Merck's repeated failure to disclose to, and exertions to conceal from, the government and public what Merck knows about the significantly diminished efficacy of its mumps vaccine.

[18] *See also* MTD at 6 ("every claim of 'falsity' . . . collapses unless Relators can prove that the label is, in fact, false"); at 15 (false label is "crux" of case); at 20 (false label is "fundamental theory" of case); at 30 (false label is "threshold fact" Relators must show).

Merck's duty of disclosure is "continuous" and lies at the foundation of the country's vaccine program -- Merck "must . . . apprise the CDC of any risks it later discovers, or in the exercise of reasonable care, should have discovered." *Mazur*, 964 F.2d at 1365-66. In failing to provide this critical information, not only did Merck violate its CDC vaccine purchase contracts which obligated Merck to provide accurate and up-to-date information on efficacy. It also violated Merck's statutory duty to provide this information to the CDC, FDA and under the National Vaccine Program.

Despite Merck's wholesale disregard of these core allegations of fraud *by omission*, they are meticulously detailed in the Complaint and as shown below (*infra* at 38-47) easily satisfy the specificity requirements of Rule 9(b). *See, e.g.*, Compl. ¶¶ 2, 4-5, 31-32, 46-48, 58, 59-61, 65, 75, 80, 84, 86, 91, 98-101, 121-129, 145-146, 154-155 (detailing Merck's failure to disclose and affirmative steps to conceal the diminished efficacy of its vaccine through such conduct as abandoning undesired test results; using improper testing techniques; falsifying test data; destroying evidence; lying to the FDA; failing to disclose diminished efficacy in various FDA applications; failing to disclose to the CDC during recent mumps outbreaks; failing to disclose to the CDC in connection with its IAC work; failing to disclose to the CDC in connection with its vaccine purchases and when entering into the vaccine purchase contracts; and otherwise repeatedly violating its multiple duties of disclosure ).

2. This Case Is Not About a "Phenomenally" or "Enormously" Effective Vaccine

*Second*, in a further effort to excise the core fraud allegations out of this case, Merck ignores all of the allegations in the Complaint that demonstrate that the efficacy of Merck's vaccine has diminished to the point where it no longer provides adequate immunization. *See supra* at 4-5, 8-9, 13-14. These include Relators' eye-witness accounts of the poor results from

Merck's original, abandoned efficacy testing (Compl. ¶¶ 25-32); their witnessing of Merck's subsequent fraudulent testing to fabricate an inflated efficacy rate (*id*. ¶¶ 33-68); their first-hand discussions with Merck's David Krah who acknowledged the vaccine's diminished efficacy and predicted mumps outbreaks would follow (*id.* ¶¶ 30, 82, 122); the two recent outbreaks that did follow (*id.* ¶¶ 82-83, 92-93, 144); the indefinite deferral of the government's goal of eradicating the disease by now (*id.* ¶¶ 6, 95, 144); and the government's research and funding of a new vaccine. *Supra* at 13-14. Merck's repeated characterizations of the vaccine as "tremendous[ly]," "phenomenally" and "enormously" effective -- and its assertion that the Complaint concedes as much -- pointedly demonstrate the lengths Merck has gone in its motion to rewrite the fraud out of the Complaint and ignore what is happening with its vaccine in the real world. MTD at 5 n.2, 8, 30 n.17.

3. Merck's Vaccine Label Misrepresents the Efficacy of the Vaccine

*Third*, Merck likewise ignores all of these allegations in its defense of the veracity of its vaccine label, instead pronouncing as an "unchallenged" and "indisputabl[e]" truth that the vaccine confers "a high degree of protective efficacy." MTD at 8. Of course, every bit of that assertion is not only challenged and disputed by the allegations in the Complaint. It is directly undermined by them. To the extent Merck tries to take refuge in the label's reliance on thirty and forty year-old studies, that too falls flat. MTD at 7, 29. Whatever these studies may have shown way back when, Merck knows they do not reflect the vaccine's effectiveness today. This is especially true given the efficacy testing Merck conducted subsequent to these old tests which unequivocally demonstrated the vaccine's significantly diminished efficacy -- so much so that Merck threw out the results of the first test, and falsified the results of the second.[19]

[19] Merck's reliance on some other, "separate and independent" efficacy test that supposedly yielded the requisite efficacy results to support the vaccine label is unsupported and improper and nowhere to be found in the Complaint.

4. The FDA Did Not Have Prior Knowledge of Merck's Misconduct and Has Not Concluded That Merck Did Nothing Wrong

*Fourth*, Merck further tries to sidestep the plain falsity of its vaccine label -- not to mention all of Merck's alleged wrongdoing -- through its repeated assertions that the FDA knew everything about Merck's alleged misconduct, investigated it fully and concluded that Merck has done nothing wrong and its label is sound. But the Complaint tells a very different story. It describes an agency that Merck kept in the dark about its plan of concealment and the significantly diminished efficacy of its vaccine. *Supra* at 5-10, 7 n.3. And it describes a fraudulent plan that continues to this day, well past the few phone calls Relators made to the FDA and the FDA's perfunctory visit to Merck's lab -- where Merck lied to the FDA about what it was doing, where the FDA did not even interview Relators or other members of Krah's staff, and which followed Merck's wide-scale destruction of evidence.[20] Compl. ¶¶ 59-64.

As to any investigation the FDA conducted -- and may still be conducting -- since the filing of this action, that is well outside the boundaries of the Complaint and this motion to dismiss. Thus, Merck's repeated efforts to suggest that there was such an investigation, that it was exhaustively conducted, that it has since been concluded, and that the FDA has taken no action and is not planning to take action, is not only entirely unfounded, it cannot be considered

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MTD at 33 n.19. In addition, it is implausible given the label's failure to reference this supposed other test and the label's exclusive reference instead to the tests that had been conducted decades earlier. As to Merck's proffer that Relators were informed of this test "by both Merck and DOJ, and shown FDA documentation," it is entirely unfounded and mischaracterizes and improperly delves into what occurred at a confidential settlement meeting between Relators and Merck.

[20] There is no support for Merck's contention that in the phone calls Relators made to the FDA, the agency learned "everything" about the fraud through Relators' "unobfuscated version" of what was transpiring. MTD at 3-4. The Complaint provides detailed facts about the agency's lack of knowledge and Merck's campaign of concealment to keep it that way, which has extended well beyond these phone calls and the FDA visit to Merck. Merck's challenge to Relators' detailed account of what transpired during the FDA visit is equally off-base. MTD at 3 n.1. Relators witnessed this meeting and its scope first-hand, and were fully aware of who the FDA interviewed, how long it lasted, the questions the FDA asked, and the misinformation Merck provided in response. Compl. ¶¶ 59-64. Merck's conjecture that Relators only witnessed part of the story and "have no idea" of what really transpired ignores these allegations and is yet another example of Merck's improper attempts to contest facts at this pre-discovery phase of the case.

at this stage of the litigation. Equally unsupported and inappropriate are Merck's parallel assertions that through its supposedly exhaustive and now closed investigation, the FDA has concluded there is nothing wrong with Merck's vaccine label or efficacy. *See* MTD at 15 (the "FDA does not support this view" that vaccine label misrepresents efficacy); 16 (the FDA "stands behind" the label today); 26 ("The FDA has already considered Relators' allegations and found them wanting.").

The point is that Merck has no idea what the FDA has done, may still be planning to do and what its position is on Merck's vaccine label. If anything, recent events strongly suggest that the FDA is poised to take action. Since the filing of this case, it has initiated its own study to determine the efficacy of the vaccine and has acknowledged its emerging view that the efficacy is "lower . . . than previously estimated." *Supra* at 13-14. At the same time, its sister agency, the NIH, is funding research for a new vaccine because of the strong suggestion "that the current vaccine is not effective." *Id.* Merck's inappropriate guessing game of where the government currently stands is therefore not only improper, it is completely undermined by this recent government recognition that Merck's vaccine is significantly diminished and that a new vaccine is needed.

5. The FDA's Knowledge and Response Are Irrelevant

*Fifth*, independent of Merck's inappropriate and counterfactual surmise regarding what the FDA knew about Merck's alleged fraud and what steps it has taken to address it, the law is clear that this kind of "agency knowledge" and "agency response" inquiry has no place in a motion to dismiss. This is particularly so when, like here, the subject agency (the FDA) is not even the one that makes the purchasing decision (the CDC). Since the 1986 amendments to the False Claims Act, government knowledge is no longer an automatic bar to bringing a case. *See*

S. Rep. 345, 99th Cong., 2d Sess. (1986) at 4, reprinted in 1986 U.S.C.C.A.N. 5266, 5269. Instead, it goes to the question of scienter; whether a defendant acted knowingly in the alleged fraud. Since this requires a fact intensive inquiry and relates to an affirmative defense on which a defendant carries the burden of proof, it is not a proper subject for a motion to dismiss.[21]

Even when courts do get around to considering the issue -- well beyond the motion to dismiss stage -- they routinely give little weight to what the agency knew or did because it sheds little light on whether the False Claims Act has been violated. What is important is not what particular agency staff ultimately do when presented with evidence of fraud, but what they are entitled to do under the governing law. As the Seventh Circuit so aptly explained in *United States v. Rogan*, 517 F.3d 449, 452 (7th Cir. 2008) (internal citations omitted):

> [T]he laws against fraud protect the gullible and the careless -- perhaps especially the gullible and the careless -- and could not serve that function if proof of materiality depended on establishing that the recipient of the information would have protected his own interests. The United States is entitled to guard the public fisc against schemes designed to take advantage of overworked, harried, or inattentive disbursing officers; the False Claims Act does this by insisting that persons who send bills to the Treasury tell the truth.

*See also U.S. ex rel. Feldman v. Wilfred Van Gorp & Cornell Univ. Med. College*, 2012 WL 3832087, at *16 (2d Cir. Sept. 5, 2012) (quoting same); *U.S. ex rel. Oliver v. The Parsons Corp.*, 498 F. Supp. 2d 1260, 1289-90 (C.D. Cal. 2006) ("Evidence of the government's actual conduct is less useful for FCA purposes than evidence of the government's legal rights. . . . Materiality must turn on how [the government] was authorized to respond to such failures, or else violations

[21] *See, e.g., Educ. Mgmt.*, 2012 WL 1658482, at *18 (finding defendant's contentions that government acquiesced to the alleged fraud were not appropriate on motion to dismiss since "such contentions would be affirmative defenses on which [defendant] bears the burden of proof"); *Toyobo*, 811 F. Supp. 2d at 49-50 (finding question of whether government possessed all available information and data regarding defective product was question of fact inappropriate for resolution on motion to dismiss); *In re Pharm. Indus. AWP Litig.*, 478 F. Supp. 2d 164, 174 (D. Mass. 2007) (rejecting defendant's argument on motion to dismiss that government knew of the fraud and approved where it conflicted with allegations in the complaint).

of identical provisions in separate cases could have different materiality results based on the predilections of particular program or accounting staff.").

The Second Circuit in *Feldman* raised an additional reason why agency inaction should carry little, if any, weight in a False Claims Act analysis. The standards a particular agency may use to determine whether agency action is warranted may be very different from what is necessary to make out a False Claims Act case. The district court in *Feldman* excluded as irrelevant any evidence relating to what the NIH did in response to complaints it had received regarding the alleged fraud. The court based its decision on the lack of discovery on the standards the NIH uses to trigger agency action and how they compare to the elements of a False Claims Act claim. The Second Circuit agreed, holding that "[w]ithout evidence as to what the standards of the agency were for beginning an investigation, the jury could not determine whether complaints made by [relator] should have instigated one." The Court went on to find that "nothing relevant can be ascertained without knowing for which of many possible reasons [the government] did not act." 2012 WL 3832087, at *18.

Finally, even with full knowledge of the challenged fraud, government inaction may indicate nothing more than a current inability to stop the purchase of goods or services critical to a government or public need. *See, e.g., U.S. ex rel. Thomas v. Siemens AG*, 708 F. Supp. 2d 505, 513 (E.D. Pa. 2010) (pointing to government need as reason for purchasing despite possible fraud and noting that "[a]t the pleading stage, one cannot discern the government's motivation and its process"); *Harrison,* 352 F.3d at 917 (identifying "instances in which a government entity might choose to continue funding the contract despite earlier wrongdoing by the contractor"). *See also Toyobo,* 811 F. Supp. 2d at 46 (finding continued government purchases irrelevant); *United States v. Inc. Vill. of Island Park,* 888 F. Supp. 419, 442 (E.D.N.Y. 1995) (same).

6. The Government's Non-Intervention at This Time Is Irrelevant

*Sixth*, Merck also tries to draw an adverse inference from the government's decision not to intervene at this time. But the courts are clear that government non-intervention "has no probative value and is not relevant." *U.S. ex rel. El-Amin v. George Wash. Univ.*, 533 F. Supp. 2d 12, 20 (D.D.C. 2008). *See also Anderson v. McTish, Kunkle & Assocs.*, 2006 WL 1985762, at *1 n.1 (M.D. Pa. July 13, 2006) (court is "not permitted to draw any inference from the decision of the United States not to intervene in this case"). "The Justice Department may have myriad reasons for permitting the private suit to go forward including limited prosecutorial resources and confidence in the relator's attorney." *U.S. ex rel. Chandler v. Cook Cnty.*, 277 F.3d 969, 974 n.5 (7th Cir. 2002). *See also U.S. ex rel. Cantekin v. Univ. of Pittsburg*, 192 F.3d 402, 408 (3d Cir. 1999) (noting 1986 Amendments driven by Congressional recognition that government "lacks the resources to investigate and prosecute all false claims even when the government has information revealing fraud"); *U.S. ex rel. Atkins v. Mclnteer*, 470 F.3d 1350, 1360 n.17 (11th Cir. 2006) ("government may have a host of reasons for not pursing a claim").

"Indeed, assuming the government looked unfavorably upon each *qui tam* action in which it did not intervene would seem antithetical to the purpose of the *qui tam* provision -- to encourage private parties to litigate on behalf of the government." *El-Amin*, 533 F. Supp. 2d at 21-22. It would also run directly counter to the statutorily mandated increased recovery for relators who successfully pursue non-intervened cases. *See* 31 U.S.C. § 3730(d) (providing for relator recovery of 15-25 percent in intervened cases, and 25-30 percent in non-intervened cases).

In establishing this rising scale of recovery, Congress was clearly expressing its view that non-intervened cases play a critical role in the False Claims Act enforcement scheme and that the

government's non-intervention has no bearing on the merits of the underlying action. *See U.S. ex rel. Laymon v. Bombardier Transp. Holdings*, 2009 WL 793627, at *14 (W.D. Pa. Mar. 23 2009) ("[T]he mere fact that the government chose not to intervene in no way demonstrates that it did not consider [defendant's] statements to be false, or that it 'received exactly what it paid for.' If it did, the statutory provision permitting relators to pursue this type of action would be superfluous."); *U.S. ex rel. Berge v. Bd. of Trs. of the Univ. of Ala.*, 104 F.3d 1453, 1458 (4th Cir. 1997) ("Government will not necessarily pursue all meritorious claims; otherwise, there is little purpose to the *qui tam* provision permitting private attorneys general"); *U.S. ex rel. Landsberg v. Levinson*, 2006 WL 895044, at *4 (W.D. Pa. Mar. 29, 2006) (refusing to distinguish intervened and non-intervened cases, noting "the fact that the government has declined to intervene in any given *qui tam* action does not diminish the federal interest in combating fraud against the government").[22]

In any event, the government's decision in this case is only that it is not intervening at this time. It says nothing about whether the government will choose to intervene down the road. Notably, the government has not joined Merck in its motion to dismiss and has instead specifically requested that it be kept abreast of the proceedings and have its consent solicited before this action is settled or otherwise disposed of. In addition, the government's non-

[22] A powerful testament to the vital role relators play in pursuing non-intervened cases comes from the multitude of cases successfully settled after the government initially declined to intervene in the *qui tam* case. *See, e.g., U.S. ex rel. Franklin v. Parke-Davis, Div. of Warner- Lambert Co.*, 147 F. Supp. 2d 39 (D. Mass. 2001) ($430 million settlement); *U.S. ex rel. Eckhart v. Glaxosmithkline Holdings (Americas) Inc. et al.*, (D. Mass. Case No. 1:04-cv-10375-JLT) ($750 million settlement); *U.S. ex rel. Tyson v. Amerigroup Ill.*, 488 F. Supp. 2d 719 (N.D. Ill. 2007) ($225 million); *U.S. ex rel. Taylor v. Gabelli*, 345 F. Supp. 2d 313 (S.D.N.Y. 2004) ($135 million settlement). *See also U.S. ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Abbott Labs., Inc.* (S.D. Fla. No. 95-1354-Civ)) and *U.S. ex rel. Ven-A-Care of the Fla. Keys, Inc. v. Dey Inc. et al.* (D. Mass No. 00-10698) ($2.8 billion, including companion cases).

intervention decision was based on the original complaint, not the Complaint which is the subject of Merck's motion.

7. The CDC, Not the FDA, Is the Relevant Government Purchaser Here

*Seventh*, and perhaps most fundamentally, Merck ignores that the relevant government purchasing agency here is the CDC, not the FDA. Compl. ¶ 147. Indeed, the FDA's longstanding practice has been to recuse itself from the government procurement process "to protect and preserve [its] scientific independence and judgment."[23] Yet Merck's entire brief focuses only on what fraud Merck committed against the FDA, arguing that any fraud on the CDC "derives entirely from" and "ultimately depend[s] upon" the alleged fraud on the FDA. MTD at 2, 20 n.11. Indeed, Merck goes so far as to say that the Complaint "contains no allegations of a direct misrepresentation by Merck to the CDC about the efficacy" of the mumps vaccine. MTD at 5-6.

Once again, Merck is playing loose with the facts and ignoring the detailed allegations of Merck's failure to disclose to the CDC -- as it was required to by contract and statute and as confirmed by the Third Circuit in *Mazur* -- what it knows of the significantly diminished efficacy of the vaccine. In failing to provide the CDC with this information, Merck has engaged in fraud on the CDC independent of (not derivative of) the fraud Merck has also committed on the FDA and under the National Vaccine Program. It has engaged in further fraud on the CDC through its misrepresentations of efficacy on its label and website, through fraudulently inducing the CDC to enter into the vaccine purchase contracts, and through Merck's continuous certifications that it

[23] *See* Koury Decl., Ex. E (Statement by Jesse Goodman, Director Center for Biologics, Evaluation and Research at the FDA).

has complied with all of the conditions and obligations in those contracts.[24] Compl. ¶¶ 71-73, 105-112, 121-131, 154-155.

Merck's fraud on the FDA through Merck's abandoned, manipulated and falsified efficacy testing and its subsequent cover up is certainly an important part of the story. It shows what Merck knew about the significantly diminished efficacy of its vaccine, its recognition of how material that information is to the government, and the lengths Merck has gone to withhold this information to protect its exclusive license to sell the vaccine. But it is not the sole fraud underlying the false claims that Merck submitted to the CDC. It is also Merck's multiple misrepresentations and omissions to the CDC -- which caused the agency to pay for a product it did not contract to purchase -- which forms the basis of Relators' False Claims Act claims. With respect to these central allegations of the Complaint, Merck does not make a single challenge.

## IV. THE ALLEGATIONS IN THE COMPLAINT EASILY SATISFY THE PLEADING REQUIREMENTS UNDER RULE 9(b)

### A. Rule 9(b) Does Not Require the Who, What, When, Where, How, and Why Level of Detail Merck Demands

"The standard for 9(b) is a generous one in this Circuit" and should be applied with "'the general simplicity and flexibility contemplated by the rules.'" *United States v. Kensington Hosp.*, 760 F. Supp. 1120, 1125 (E.D. Pa. 1991) (quoting *Christidis v. First Pa. Mortg. Trust*, 717 F.2d 96, 100 (3d Cir. 1983)) (other internal quotes and cite omitted). It "does not require date, time, and place allegations." *Id.* Nor is there "a mandatory checklist of what must be included in the complaint." *U.S. ex rel. Repko v. Guthrie Clinic, P.C.*, 557 F. Supp. 2d 522, 526-527 (M.D. Pa.

[24] Merck makes much of the allegation that "[i]n 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." MTD at 6, 28 (quoting Compl. ¶ 107). But this in no way supports Merck's contention that Relators' allegations of fraud on the CDC are "predicated upon" Merck's fraud on the FDA through the falsity of Merck's label. MTD at 28. As the full allegation that Merck selectively quotes from makes clear, it merely highlights the critical importance of Merck's "ongoing duty to provide the CDC with accurate information on the efficacy of its mumps vaccine." Compl. ¶ 107.

2008). A court need only "focus on whether the complaint adequately describes the nature and subject of the alleged misrepresentation." *Mendelsohn, Drucker & Assocs. v. Titan Atlas Mfg., Inc.*, 2012 WL 3135473, at *16 (E.D. Pa. Aug. 2, 2012) (internal quotes and cite omitted). "[A]s long as there is precision and some measure of substantiation in the allegations, the complaint must stand." *U.S. ex rel. Givler v. Smith*, 775 F. Supp. 172, 181 (E.D. Pa. 1991) (citing *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984)).

Merck is thus incorrect in its assertion of a mandatory "who, what, when, where and how" prerequisite for satisfying Rule 9(b). MTD at 13. While these specifics will certainly satisfy the heightened pleading requirements, "'nothing in the rule requires them.'" *Franks v. Food Ingredients Int'l, Inc.*, 2010 WL 3046416, at *4 (E.D. Pa. July 30, 2010) (Jones II, J.) (noting that plaintiffs are "'free to use alternative means of injecting precision and some measure of substantiation into their allegations of fraud'") (quoting *Seville*, 742 F.2d at 791). *See also U.S. ex rel. Schumann v. Astrazeneca PLC*, 2010 WL 4025904, at *10 (E.D. Pa. Oct. 13, 2010) ("allegations of 'date, place, or time' may fulfill the requirement of particularity, 'but nothing in Rule 9(b) requires them'") (quoting *Seville*, 742 F.2d at 791); *U.S. ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 676 (E.D. Pa. 2010) (quoting *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3d Cir. 1998)) (same); *Aluminum Bahrain B.S.C. v. Alcoa Inc.*, 2012 WL 2094029, at *2 (W.D. Pa. June 11, 2012) (same); *U.S. ex rel. Arnold v. CMC Eng'g*, 745 F. Supp. 2d 637, 641 (W.D. Pa. 2010) (same).

In all of this, courts must also recognize that "[i]n cases of corporate fraud, plaintiffs cannot be expected to have personal knowledge of the details of corporate internal affairs." *Franks*, 2010 WL 3046416, at *5. Courts must also "be sensitive to situations in which sophisticated defrauders may successfully conceal the details of their alleged fraud." *United*

*States v. Torkelsen*, 2007 WL 4245736, at *5 (E.D. Pa. Dec. 3, 2007). The ultimate purpose of Rule 9(b) is "to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges." *Aluminum Bahrain*, 2012 WL 2094029, at *2 (quoting *Lum v. Bank of Am.*, 361 F.3d 217, 223-224 (3d Cir. 2004)) (internal quotes omitted). Relators' allegations of Merck's fraudulent conduct -- when viewed in their proper light and not through the distorted lens of Merck's factual revisionism -- readily satisfy this standard. They satisfy even the overstated rigors of the Rule 9(b) standard that Merck puts forth.

### B. In Applying Rule 9(b), Merck Ignores the Central Allegations of Fraud

Merck's entire Rule 9(b) challenge is based on two fundamental misconceptions about the Complaint. One is Merck's overarching mantra that this case is just about the vaccine label. MTD at 28 ("Relators' case is predicated upon the theory that the CDC was defrauded . . . because it allegedly relied on a vaccine label which, in turn, was false."). The other is Merck's exclusive focus on its submission to the FDA of the test results from Merck's falsified efficacy test. According to Merck, this falsified submission "is the core false statement in this case." MTD at 31. Once again, Merck misconstrues the core allegations of fraud in the Complaint by completely disregarding Merck's failure to disclose, and efforts to conceal, what it knows about the significantly diminished efficacy of its mumps vaccine. *See supra* at 5-12. It is the allegations that surround this pervasive fraud *by omission* that should be at the center of any Rule 9(b) analysis here. Merck sidesteps it entirely.

### C. The Complaint Describes In Detail the Who, What, When, Where, How and Why of Merck's Fraud

Had Merck attempted to conduct a Rule 9(b) analysis of *all* the allegations in the Complaint, it would have found the rule easily met, even under Merck's more demanding

standard. That is because the Complaint describes the "who, what, when, where, how and why" details of the fraudulent conduct that has surrounded and supported Merck's ongoing scheme to secure government payments through its concealment from the government and public what Merck knows about the significantly diminished efficacy of its mumps vaccine. These allegations include, among other things, a full explication of the details of:

- **Why** Merck needed to maintain before the government an efficacy rate for its mumps vaccine of 95 percent or higher -- *to maintain its exclusive license to sell the vaccine in the U.S.* Compl. ¶¶ 19, 22-24.

- **How** Merck knew that the efficacy of its mumps vaccine had significantly diminished below this 95 percent threshold -- *the poor results from Merck's original efficacy test, which needed to be abandoned; the still poor results from Merck's "enhanced" efficacy test, which needed to be falsified; Merck Senior Investigator David Krah's understanding that the efficacy of Merck's vaccine had declined over time from the continued passaging of the forty-five year old virus to make more vaccine; Krah's understanding that this diminished efficacy would lead to mumps outbreaks; the actual occurrence of mumps outbreaks in 2006 and 2009; and Merck Vice President of Vaccine Research Emilio Emini's understanding that Merck's manipulation of the efficacy testing was a "business decision*." Compl. ¶¶ 30-32, 45-51, 56, 82-85, 93.

- **What** Merck did to conceal from the government and public what it knows about the significantly diminished efficacy of its vaccine -- *abandoning the poor results from the original efficacy test; manipulating the "enhanced" efficacy test to overstate the efficacy findings; falsifying the poor results from the "enhanced" efficacy test; providing financial incentives to Merck personnel to participate in the fraud and cover-up; destroying evidence of the falsified testing; lying to the FDA about the falsified testing; reporting the falsified test results to the FDA; misrepresenting the efficacy rate on the vaccine labels for MMRII and ProQuad; misrepresenting the efficacy rate on Merck's website; failing to disclose the significantly diminished efficacy in its applications to the FDA for ProQuad and for a labeling change on potency in MMRII; using the falsified efficacy test results to secure approval for MMRVaxpro and ProQuad in Europe; failing to disclose the significantly diminished efficacy when working with the government to determine the cause of the 2006 and 2009 mumps outbreaks; Merck's public declaration during the 2006 outbreak that its vaccine worked fine; Merck's failure to disclose the significantly diminished efficacy to the CDC or the Merck-funded IAC to correct the IAC's incorrect efficacy information; Merck's false certifications to the CDC that it has complied with the terms and conditions of the CDC vaccine purchase contract; and Merck's continuous failure to disclose the significantly diminished efficacy information at any time to the CDC, FDA or*

*under the National Vaccine Program as it was required to do by contract and statute.* Compl. ¶¶ 30-32, 35-38, 45-51, 53-54, 58-64, 68, 71-81, 83-84, 86-87, 91, 94-95, 97-101, 123-130, 154-155.

- **Who** was involved in Merck's fraudulent campaign to conceal what it knows about the significantly diminished efficacy of its vaccine -- *David Krah (Merck's Senior Investigator and the one in charge of the mumps efficacy testing); Mary Yagodich (Krah's second in command); other members of Krah's staff; Alan Shaw (Merck's Executive Director of Vaccine Research); Emilio Emini (Vice President of Merck's Vaccine Research Division); and Bob Suter (Relator Krahling's human resources representative at Merck).* Compl. ¶¶ 25, 30-31, 33, 42, 47-48, 53-62.

- **When** these various acts of concealment took place -- *1999 (the original and ultimately abandoned efficacy testing); 2000 (the commencement of the "enhanced" and ultimately falsified efficacy testing); October 2000 (Merck's presentation providing Merck's directive to come up with an efficacy testing methodology that would yield at least a 95 percent result); December 2000-August 2001 (the falsification of the "enhanced" efficacy test results); March 2001 (Merck's cancellation of the outsourcing of the bulk of the efficacy testing to assure the desired results that Merck was only able to get in Krah's lab with falsification of the data); April 2001 (meeting with Emini, Krah and Krah's staff where Emini directed the staff to follow Krah's orders on the fraudulent testing and offered them financial incentives for doing so); July 2001 (meeting between Relator Krahling and Shaw where Shaw refused to listen to Krahling's complaints about the falsification of data, speaking instead about future bonuses); July 2001 (Krahling meeting with Suter where Suter refused to do anything about the falsification); early August 2001 (Krahling meeting with Emini where Emini admitted to the falsification and described Merck's improper testing practices as a necessary "business decision"); early August 2001 (Krahling meeting with Suter, the same day as the Emini meeting, where Suter threatened Krahling with jail); early August 2001 (Krah's destruction of evidence, the day after the Emini meeting); August 6, 2001 (FDA visit where Krah and Shaw lied about the test falsification); late Summer/early Fall 2001 (Merck's reporting of falsified test results to the FDA; 2004 (Merck's failure to disclose in ProQuad application); 2006 (Merck's use of the falsified efficacy test results to secure approval for MMRVaxpro and ProQuad in Europe); 2006 (Merck's failure to disclose during mumps outbreak); 2007 (Merck's failure to disclose in application for label change on potency); early 2008 (Merck's public disclosure that vaccine worked fine); 2009 (Merck's failure to disclose during mumps outbreak); 1999-present (Merck's failure to disclose to CDC, FDA or under National Vaccine Program; Merck's false certifications of compliance with purchase contract; Merck's misrepresentation of efficacy on vaccine labels).* Compl. ¶¶ 25, 33-34, 38, 45, 48, 53, 54-62, 68, 75-77, 79-81, 83-84, 87, 93.

- **Where** these various acts of concealment originated from -- *Merck's West Point, Pennsylvania vaccine division research facility*. Compl. ¶¶ 8-10, 25.

- **What** claims for payment did Merck present to the government that were false or fraudulent -- *all of Merck's claims for payment for the sale of its mumps vaccine to the CDC since 2000 through the present.* Compl. ¶¶ 2, 70, 72, 122, 157.

- **Why** Merck's claims to the CDC for payment were false or fraudulent -- *they were based on the sale of a vaccine that Merck falsely represented in its vaccine label and otherwise provided adequate immunization; they were based on the sale of a vaccine that Merck falsely represented in its vaccine label and otherwise had an efficacy rate of 95 percent or higher; they were based on the sale of a vaccine that Merck failed to disclose had significantly diminished efficacy; they were based on the sale of a vaccine that the CDC was fraudulently induced into purchasing based on these false representations and omissions; they were based on the sale of a vaccine that Merck falsely certified, both expressly and impliedly, complied with the terms and conditions of the CDC purchase contracts; they were based on the sale of a vaccine that resulted from Merck's illegal monopolization of the mumps market.* Compl. ¶¶ 152-157.

Thus, Merck's two-prong attack on the sufficiency of the allegations, which challenges *only* the veracity of the vaccine label and the details surrounding Merck's submission of the falsified test results, skips over the guts of the Complaint and all of the detail that supports it. It skips over all of the details of the "who" involved -- Shaw, Yagodich, Shaw, Emini, Suter, etc. -- which far exceeds the level of specificity the law requires. *See, e.g., U.S. ex rel. Gibbons v. Kvaerner Phila. Shipyard, Inc.*, 2006 WL 328362, at *7 (E.D. Pa. Feb. 10, 2006) (rejecting a Rule 9(b) motion to dismiss where complaint named some of the individual employees involved in the fraudulent conduct). In fact, Rule 9(b) does not even require the specific individuals involved in the fraud be identified at all.[25]

[25] *See, e.g., Givler*, 775 F. Supp. at 181-182 (no requirement to "identify the content, time, place, or speaker of the [false] statements" when relator put defendants on notice by identifying "fraudulent statements or acts," "violations of government contract law," and the "party defrauded as the Department of Housing and Urban Development"); *U.S. ex rel. Roby v. Boeing Co.*, 184 F.R.D. 107, 110-111 (S.D. Ohio 1998) (Rule 9(b)'s "who" requirement "only requires identifications of the parties"); *U.S. ex rel. Pogue v. Am. Healthcorp., Inc.*, 977 F. Supp. 1329, 1333 (M.D. Tenn. 1997) (names of defendant's employees not required); *U.S. ex rel. Johnson v. Shell Oil Co.*, 183 F.R.D. 204, 207-208 (E.D. Tex. 1998) (Relator not required to identify a specific employee of defendant's who made a false statement to the government, reasoning that a "plaintiff cannot be expected to have personal knowledge of the details of corporate internal affairs") (citing *In re Craftmatic Secs. Litig. v. Kraftsow*, 890 F.2d 628, 645 (3d Cir. 1989)); *U.S. ex rel. Yannacopolous v. Gen. Dynamics*, 315 F. Supp. 2d 939, 945 (N.D. Ill. 2004) (same).

Merck likewise skips over all of the details of the "when" of Merck's various fraudulent acts that are catalogued in the Complaint by either the year, month or day they occurred. Again, this is far more specificity than courts require. The allegations that Merck submitted false claims for payment from 2000 to the present are alone sufficient to notify Merck of the relevant time period for the purposes of Rule 9(b).[26] The allegations of the "where" the fraud occurred,[27] and "what" claims for payment were involved are also more than enough to provide Merck with sufficient notice under Rule 9(b).[28]

But without doubt, Merck's biggest failure here, as it is with its entire motion to dismiss, is Merck's utter disregard of the litany of allegations surrounding the "what," "why" and "how" of the misrepresentations *and omissions* that are at the center of Merck's fraudulent scheme and Merck's submission of false claims to the CDC. There can be no question that this detail goes way beyond the requirements of Rule 9(b) in providing the necessary "precision and some

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[26] *See, e.g., Gibbons*, 2006 WL 328362, at *6 (finding allegations that misconduct occurred from "approximately 2000 and continued through the middle of 2004" were sufficient); *Kensington Hosp.*, 760 F. Supp. at 1125 (allegations of time frame of the fraud is sufficient); *U.S. ex rel. Landsberg v. Argentis Med. P.C.*, 2006 WL 1788381, at *5 (W.D. Pa. June 27, 2006) (finding allegation that fraud occurred "from at least 2001 through 'the present'" was sufficient); *Pogue*, 977 F. Supp. at 1333 (finding allegation "that the [defendant] participated in a systematic, fraudulent scheme, spanning the course of twelve years" was sufficient).

[27] *See, e.g., Gibbons*, 2006 WL 328362, at *6 (allegation of where fraudulent scheme occurred was sufficient); *Grubbs*, 565 F.3d at 191-192 (sufficient to allege place where fraudulent scheme took place); *Givler*, 775 F. Supp. at 181-182 (rejecting defendant's argument that "place" of fraudulent statements was required).

[28] Relators allege that *every* claim for payment for mumps vaccine that Merck has presented to the government since 2000 has been a false claim under the False Claims Act. *See Atkinson*, 2000 WL 1207162, at *8 (a government contractor is liable for every claim submitted under a contract if the contract was fraudulently obtained, even if the work is performed to government specifications and at the agreed price"); *Repko*, 557 F.Supp. 2d at 527 (no need to identify a specific false claim since *all* claims for payment were alleged to be false)*; Argentis*, 2006 WL 1788381, at *4-5 (rejecting any requirements that at the motion to dismiss stage, a relator identify a specific claim for payment); *Roby*, 184 F.R.D. at 110 (defendant was on notice because allegation was that *every* item sold, not just a subset of those items, was different than the item for which the government had contracted). *See also U.S. ex rel. Streck v. Allergan, Inc.*, 2012 WL 2593791, at *13-14, 13 n.13 (E.D. Pa. July 3, 2012) (despite lacking details of specific claims or "specific allegedly false information submitted by Defendants to the Government," complaint satisfied Rule 9(b) where it alleged the fraudulent scheme and the violation of duty of disclosure to the government); *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (presentment and details of a specific claim not required if complaint alleges "details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted").

measure of substantiation," *Franks*, 2010 WL 3046416, at *4, to put Merck "on notice of the precise misconduct with which they are charged." *Aluminum Bahrain*, 2012 WL 2094029, at *2. And it unquestionably provides far more information than could ever fit into "the first paragraph of a newspaper story," which even Merck concedes would be sufficient. MTD at 12 (quoting *U.S. ex rel. Schmidt* v. *Zimmer*, 2005 WL 1806502, at *1 (E.D. Pa. July 29, 2005)).

As to the few allegations that Merck does address in its Rule 9(b) attack, Merck misstates their relevance to the Rule 9(b) inquiry. Merck may quibble with the accuracy of the label, though its falsity is plainly demonstrated in the Complaint and through real-world events. *See supra* at 5, 8-9, 13-14. But Merck cannot honestly contend, and in fact does not contend, that the allegations do not provide enough specificity on the label and how Relators contend Merck has used it in falsely representing to the CDC the efficacy of Merck's mumps vaccine. Merck's disagreement with the merits of these allegations has no place in a Rule 9(b) analysis on a motion to dismiss.[29]

With respect to the detail surrounding Merck's submission of the falsified test results, here too Merck misapprehends where this discrete fraudulent event -- only one of an exhaustive listing of Merck's fraudulent representations and omissions -- fits into the story. It is far from "the core false statement in this case" as Merck contends. MTD at 31. It did not even go to the

[29] Merck wrongly relies on *U.S. ex rel. Hill v. Univ. of Med. & Dentistry*, 2011 WL 5008427, at *2 (3d Cir. Oct. 20, 2011), to argue that Relators' allegations on the falsity of Merck's vaccine label are insufficient because they are mere "[e]xpressions of opinion [or] scientific judgment." MTD at 30 (citing *Hill* quoting *U.S. ex rel. Jones v. Brigham and Women's Hosp.*, 750 F. Supp 2d 358, 366 (D. Mass. 2010)). But *Hill* was a *summary judgment* decision where the court found that the relator had "presented *evidence* only demonstrating a scientific disagreement," not *evidence* of any falsity). *Id.* at 317 (emphasis added). The inapplicability of *Hill* on a motion to dismiss was made clear by the First Circuit's reversal of the *Jones* decision on which *Hill* relies. *U.S. ex rel. Jones v. Brigham and Women's Hosp.*, 678 F.3d 72 (1st Cir. 2012). The Court's reversal there, again on summary judgment, was based on its finding that "a question remains as to whether the data was falsified." *Id.* at 88. That is one of the very same questions relating to the falsity of Merck's label that remains open at this pre-discovery stage of the case. *See also United States v. Honeywell Int'l*, 798 F. Supp. 2d 23, 24 (D.D.C. 2011) (rejecting challenge to falsity on motion to dismiss based on objective scientific disagreement where complaint alleged defendant "knowingly misrepresented and concealed facts"); *Roby*, 184 F.R.D. at 112 (denying motion to dismiss, distinguishing between "disputes over scientific theory" and "issues of alleged concealment and misrepresentation").

CDC. It is simply another example of where Merck acted to conceal from the government and public what it knows about the significantly diminished efficacy of its vaccine.

So all of the rhetorical questions Merck poses on the content, form and timing of this submission, are well beside the point. MTD at 29, 31. It does not matter what Merck did with this submission. What matters is that Merck falsified its efficacy testing -- *something that Merck notably never contests* -- as part of its overarching plan to conceal the significantly diminished efficacy of its vaccine. It is this constant stream of *omissions* that forms the basis of Merck's false representations of efficacy. On the sufficiency and detail of the allegations surrounding Merck's many omissions -- of which Merck's falsified testing is just one -- Merck has nothing to say.

Merck's superficial attack on the specificity of the allegations surrounding Merck's FDA applications for ProQuad and a labeling change on potency are equally off-base. MTD at 35-36. It is not that this conduct was part of any affirmative false statements to the government. It is that they were further examples of Merck's fraud by *omission*, concealing from the government what Merck knew about the significantly diminished efficacy of its vaccine. Merck's call for more detail on the actual statements or submissions it made to the FDA in connection with these applications makes little sense given their proper context as omissions in this case. *See, e.g., Johansson v. Cent. Garden & Pet Co.*, 804 F. Supp. 2d 257, 263-264 (D.N.J. 2011) (noting the difficulty in pleading the date, place or time of an omission and finding complaint satisfied Rule 9(b) where it specified "what the omissions were, the person responsible for failing to disclose the information, the context of the omission and the manner in which it misled plaintiff and what defendant obtained through the fraud") (internal quotes and cite omitted); *Gadson v. Supershuttle Int'l*, 2011 WL 1231311, at *9 (D. Md. Mar. 30, 2011) ("such particularity cannot be met in a

concealment case, because an omission cannot be described in terms of the time, place, and contents of the misrepresentation or the identity of the person making the misrepresentation") (internal quotes and cite omitted); *In re Apple & AT & TM Antitrust Litig.*, 596 F. Supp. 2d 1288, 1310 (N.D. Cal. 2008) ("Where the claim is one of fraud by omission, however, the pleading standard is lowered on account of the reduced ability in an omission suit to specify the time, place, and specific content relative to a claim involving affirmative misrepresentations.").[30]

Merck's extended reliance on *U.S. ex rel. Tessitore v. Infomedics, Inc.*, 847 F. Supp. 2d 256 (D. Mass. 2012) as a case "quite similar" to this one highlights Merck's myopic view of this case. MTD at 33. That case involved, among other things, the defendant drug company's alleged failure to submit adverse event reports to the FDA. The relator alleged that the defendant misrepresented to the FDA its intent to comply with these reporting obligations, and that had the defendant complied, it would have caused the FDA to issue warnings which would have resulted in fewer sales. In dismissing the action for lack of specificity under Rule 9(b), the court pointed to numerous deficiencies in the complaint, not one of which is present here. Most notably, the court found no allegations supporting the alleged misrepresentations, who was involved in the fraud, the alleged materiality of the withheld information, or the defendant's alleged intent to defraud the government. *Id.* at 264-65. Obviously, a very different case than this one.

But what is most telling about Merck's attempt to shoehorn this case into *Tessitore* is Merck's exclusive focus on the falsified efficacy test. MTD at 33 (claiming parallels between the

[30] *See also Educ. Mgmt.*, 2012 WL 1658482, at *13-14 (noting the difficulty of attempting to "prove a negative" and holding that relators alleged falsity with sufficient particularity when they alleged the circumstances of something defendant failed to do as the basis for finding express and implied misrepresentations used to obtain government payment); *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 451 (D.N.J. 2012) ("Nevertheless, this heightened [Rule 9(b)] standard is somewhat relaxed in a case based on a fraudulent omission. ") (cite omitted); *Kronfeld v. First Jersey Nat'l Bank*, 638 F. Supp. 1454, 1462-1465(D.N.J. 1986) (rejecting argument in a fraud by omission case that complaint must allege "the exact representations that were made or not made, in what documents or conversations they appeared, and where, when, and to whom they were made, " finding that allegations of "what information has been concealed" was sufficient).

two cases based on supposed FDA knowledge of the falsified test, lack of detail surrounding FDA submission of falsified test results and whether government even considered falsified test results in its vaccine purchasing decision). Of course, what Merck leaves out of its comparison of the cases is the core fraud at issue here and where the falsified test fits into it. That is, Merck's failure to disclose and active campaign to conceal the significantly diminished efficacy of its mumps vaccine. On this key issue of Merck's concealment, the detailed allegations irrefutably demonstrate the government's lack of awareness, Merck's panoply of misrepresentations and omissions that kept it that way, and how critically material this information is to the CDC's purchasing decision.

Merck's resort to *Tessitore* as the most instructive case on its Rule 9(b) challenge vividly demonstrates how empty that challenge really is. So do the handful of other cases to which Merck looks for support. None of them comes even close to involving the detailed allegations of the "who," "what," "where," "when," "how," and "why" of Merck's fraud that the Complaint provides in this case. Each of them was dismissed for deficiencies entirely absent here.[31] And with respect to the only Third Circuit case Merck points to, *U.S. ex rel. Quinn v. Omnicare Inc.*,

[31] *See* Merck MTD at 34, 36 (citing *Schmidt*, 2005 WL 1806502, at *3 (dismissing for failing to name any of the 1,600 health care providers that allegedly submitted false claims or to show that such claims were in fact submitted); *U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 47 (1st Cir. 2009) (dismissing for failing to provide any "details on what the alleged false, misleading and fraudulent pretenses and representations consisted of, who made them, or when they were made") (internal quotes and cites omitted); *U.S. ex rel. Williams v. Martin-Baker Aircraft Co.*, 389 F.3d 1251, 1256-1258 (D.C. Cir. 2004) (dismissing for failing to provide a date or even a time frame for when the fraud began, the roles of any of defendant's employees who engaged in the fraud, where the fraud occurred, "the fact misrepresented" or any "facts that exemplify the purportedly fraudulent scheme"); *U.S. ex rel. Bledsoe v. Cmty. Health Sys.*, 342 F.3d 634, 643 (6th Cir. 2003) (dismissing for failing to allege which defendant performed which acts of misconduct, and instead grouping them together and blaming them collectively and indiscriminately for every act of misconduct); *U.S. ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, 2010 WL 5466043, at *8 (D.N.J. Dec. 30, 2010) (dismissing for failing to allege specific facts showing that false claims actually were submitted); *U.S. ex rel. Pilecki-Simko v. Chubb Inst.*, 2010 WL 1076228, at *8-9, 11 (D.N.J. Mar. 22, 2010) (dismissing for failing to allege the specifics of the fraudulent conduct, including who was involved, where the conduct occurred, when it occurred, how it occurred, and how defendant acted knowingly); *U.S. ex rel. Provuncher v. Angioscore, Inc.*, 2012 WL 3144885, at *1-2, n.2 (D. Mass. Aug. 3, 2012) (dismissing for failing to allege which sales involved false claims, contrasting to cases where all sales involved false claims); *U.S. ex rel. Smith v. N.Y. Presbyterian Hosp.*, 2007 WL 2142312, at *5-7, n.45-46 (S.D.N.Y. July 18, 2007) (dismissing for failing to provide details supporting relator's theory of fraud or any facts showing a reasonable basis to believe that defendants had submitted false claims).

382 F.3d 432 (3d Cir. 2004), it did not even involve a motion to dismiss. The Third Circuit there dismissed the case on *summary judgment* for the relator's failure to offer *proof* of an actual false claim presented to the government. *Id.* at 439-440. That case has no application here, particularly since the relator's complaint there survived its own Rule 9(b) challenge on a motion to dismiss. *See Argentis*, 2006 WL 1788381, at *4 (rejecting relevance of *Quinn* to Rule 9(b) challenge, noting complaint there "passed muster under Rule 9(b)").[32]

## V. THE ALLEGATIONS OF MONOPOLY FORM AN INDEPENDENT BASIS FOR FALSE CLAIMS ACT LIABILITY

In arguing that Relators' allegations of monopoly cannot support False Claims Act liability (MTD at 38), Merck is once again taking an overly restrictive view of the False Claims Act and the wide range of fraudulent conduct it covers -- "all types of fraud, without qualification, that might result in financial loss to the Government." *Drescher*, 305 F. Supp. 2d at 457 (quoting *Neifert-White*, 390 U.S. at 232-33). This includes "each and every claim submitted under a contract . . . *originally obtained . . . in violation of any statute* . . . ." *Hooper*, 688 F.3d at 1048 (quoting S. Rep. No. 99–345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274) (emphasis in original). *See also U. S. ex rel. Marcus v. Hess*, 317 U.S. 537, at 542-544 (1943) (all claims submitted under contract obtained in violation of federal requirement were false). With their detailed allegations on how Merck's fraudulent conduct has allowed Merck to

[32] To the extent Merck is arguing that Relators were required, at this stage of the litigation, to identify specific claims for payment, that argument has been rejected repeatedly in this Circuit. *See, e.g., Wilkins*, 659 F.3d at 308 ("we never have held that a plaintiff must identify a specific claim for payment at the *pleading stage* of the case to state a claim for relief") (emphasis in original); *U.S. ex rel. Budike v. Peco Energy*, 2012 WL 4108910, at *8, 12 (E.D. Pa. Sept. 14, 2012) (no requirement to allege a specific claim because alleged fraud "does not turn on anything unique to an individual claim or anything that would be revealed from an examination of any claim"); *U.S. ex rel. Underwood v. Genentech, Inc.*, 720 F. Supp. 2d 671, 672 (E.D. Pa. 2010) (rejecting argument that Rule 9(b) requires that specific false claim be identified, noting "[t]here is no authority in this Circuit requiring such particularized pleadings"); *U.S. ex rel. Schumann v. Astrazeneca PLC*, 2010 WL 4025904, at *9-10 (E.D. Pa. Oct. 13, 2010) (no requirement to identify specific claim because it "would not place [defendant] in a better position to answer and defend the charges of fraud against it"); *U.S. ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 2006 WL 2642518 (W.D. Pa. Sept. 13, 2006) (same).

illegally monopolize the mumps vaccine market and foreclose the government from access to higher quality and less expensive vaccines, that is precisely what Relators have shown. Compl. ¶¶ 132-144.[33]

In doing so, the allegations here are no different than those in the numerous cases where anticompetitive conduct formed the basis for False Claims Act liability. *See, e.g., Marcus*, 317 U.S. 537 (bid rigging); *U.S. ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, 608 F.3d 871 (D.C. Cir. 2010) (same); *United States v. CFW Constr. Co., Inc.*, 649 F. Supp. 616 (D.S.C. 1986) (same), *dismissed on other grounds*, 819 F.2d 1139 (4th Cir.1987); *United States v. Beatrice Foods Co.*, 330 F. Supp. 577 (D. Utah 1971) (same). *See also Harrison*, 176 F.3d at 787-88 (observing that collusive bidding can form the basis of a False Claims Act case, citing *Marcus*, 317 U.S. 537 and *CFW Construction*, 649 F. Supp. 616).

As the court noted in *Beatrice Foods*, "[n]othing can be found in the legislative history nor on the face of the respective statutes indicating a congressional intent to repeal or limit the application of the False Claims Act whenever a conspiratorial agreement in violation of the antitrust act would be implemented or consummated by the filing of false claims. . . . Had Congress in passing Section 4A intended to preclude application of the False Claims Act to conduct also constituting an antitrust violation, it would not have been difficult, and it would be expected for it, to so indicate either in the [Clayton Act] itself or at least in the legislative history." 330 F. Supp. at 580.

[33] Far from pleading mere "labels and conclusions without underlying allegations" (MTD at 38), Relators have alleged with significant detail and support the facts underlying Merck's illegal monopolization including (i) the basis for defining a relevant antitrust market for mumps vaccine (Compl. ¶¶ 133-134); (ii) Merck's monopolization of that market and the accompanying barriers to entry (*id.* ¶¶ 135-138); (iii) how Merck has maintained this monopoly by foreclosing competition (*id.* ¶¶ 139-142); and (iv) how this foreclosure has harmed competition and the government by excluding from the market higher quality and less expensive mumps vaccines. *Id.* ¶¶ 132, 143-144.

## VI. MERCK'S AGENCY DEFERENCE ARGUMENTS ARE LEGALLY WRONG AND FACTUALLY UNSUPPORTED

Merck 's agency deference challenge is based on three interrelated arguments -- that this case is an improper challenge to enforce or restrain violations of the FDCA; that allowing it to proceed would unduly interfere with the FDA's discretion and expertise to enforce its rules and regulations; and that Relators failed to exhaust their administrative remedies before the FDA. Merck's three-part challenge here once again rests on Merck's fundamental misreading of this case. This case is not about enforcing or restraining any FDCA violations by Merck. Nor does it seek any kind of relief that the FDA is authorized to provide. This is a False Claims Act case seeking civil damages for Merck's submission of fraudulent claims to the CDC. Only the DOJ and Relators have standing to bring this case, and this case is the *only* vehicle through which they can seek relief for this misconduct. Were any of Merck's agency deference arguments to stand, it would write out of the False Claims Act what are among the most common cases currently covered -- those based on misconduct that may also independently violate an underlying regulatory scheme.[34]

### A. Relators Are Not Seeking to Enforce or Restrain Violations of the FDCA

Merck first argues that this action should be barred as a private action seeking to enforce and restrain violations of the FDCA. MTD at 17-20. This case has nothing to do with enforcing the FDCA. The only statute Relators seek to enforce is the False Claims Act. *See* Compl. ¶¶ 150-160, and 54 (providing in Claim for Relief and Prayer for Relief that Relators are seeking injunctive relief and damages *solely* under the False Claims Act). And this case has nothing to

[34] Merck also seems to be arguing that the DOJ's decision not to intervene at this time changes the Court's substantive analysis of the merits of Relator's claims. MTD at 16 ("A different case would have been presented had the government exercised its option to intervene."). None of the cases Merck cites supports such a drastic narrowing of the *qui tam* provisions of the False Claims Act. And as discussed above, *supra* 33-35, the very notion of a differentiated approach of applying the False Claims Act based on whether the government has intervened would undermine the clear Congressional directive to encourage and reward relators for enforcing the statute.

do with restraining violations of the FDCA. Merck's failure to comply with its duties of disclosure under the FDCA, which may independently constitute violations of the FDCA, are relevant to show what Merck's duties were to the government in providing accurate and up-to-date efficacy information, how material that information is to the CDC's vaccine purchasing decision, and how Merck failed to comply and misrepresented its compliance with these duties. But they do not turn this False Claims Act case into an FDCA case and strip Relators of their statutory right to pursue this *qui tam* action.

That is just what the court found in *U.S. ex rel. Franklin v. Parke-Davis, Div. of Warner-Lambert* Co., 147 F. Supp. 2d 39 (D. Mass. 2001) when the defendant pharmaceutical company there made the exact same argument Merck makes here. That *qui tam* case involved the defendant's alleged off-label marketing of drugs for uses not approved by the FDA in violation of the FDCA. The defendant argued there, like Merck argues here, that this type of challenge falls within the exclusive jurisdiction of the FDCA and cannot be brought by a private party. The court flatly rejected this argument, holding that the False Claims Act "*can* be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation made to obtain a government benefit." *Id.* at 51-52 (emphasis in original) (pointing to numerous False Claims Act cases involving regulatory violations).[35]

To hold otherwise and bar a False Claims Act case merely because it may also involve a violation of some other statute or regulation would essentially eviscerate the Act as it would bar the "most common" type of false claims. *See Wilkins*, 659 F.3d at 306 ("A false claim may take

[35] *See also U.S. ex rel. Strom v. Scios, Inc.*, 676 F. Supp. 2d 884, 890 (N.D. Cal. 2009) (denying motion to dismiss, citing *Franklin* and reasoning that "[w]hile the Court agreed that the FCA could not be converted into a private right of action to remedy all violations of regulatory law, … the FCA *can* be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation[ ] made to obtain a government benefit") (emphasis in original); *U.S. ex rel. Carpenter v. Abbott Labs., Inc.*, 723 F. Supp. 2d 395 (D. Mass. 2010) (citing *Franklin*, denying motion to dismiss based on off-label marketing); *U.S. ex rel. Colquitt v. Abbott Labs.*, 2012 WL 1081453 (N.D. Tex. Mar. 30, 2012) (denying motion to dismiss based on same).

many forms, the most common being a claim for goods or services not provided, *or provided in violation of . . . statute [] or regulation*.") (quoting Congressional Record) (emphasis added). Merck can point to no case or authority that even suggests such an outcome. There is none. It would run directly counter to the broad and flexible approach of the False Claims Act to reach "all types of fraud, without qualification." *Cook Cnty.*, 538 U.S. at 129.

It would also directly conflict with the universally recognized principle that liability under the False Claims Act does not attach to any underlying regulatory noncompliance. It attaches to the submission of false or fraudulent claims for payment. *See, e.g., U.S. ex rel. Onnen v. Sioux Falls Indep. Sch. Dist. 49-5*, 688 F.3d 410, 414 (8th Cir. 2012) ("The FCA is not concerned with regulatory noncompliance. The FCA attaches liability, not to the underlying fraudulent activity, but to the claim for payment.") (internal quotes and cite omitted). *See also Longhi*, 575 F.3d at 467 (same); *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) (same). In other words, the False Claims Act is a cause of action that is independent of whatever underlying regulatory noncompliance might be involved.

This makes particular sense in the context of the FDCA, which is very different from the False Claims Act in its scope and the relief it provides. Most importantly, the False Claims Act provides for a civil cause of action for money damages and penalties. The FDCA does not. Nor does the FDA have any authority to bring a False Claims Act case. That authority rests exclusively with the DOJ and relators. 31 U.S.C. § 3730(a). Merck's unprecedented approach would thus unduly limit the remedies available to the government in its fight against fraud by restricting its ability (through relators) to recover money damages and penalties from misconduct that might also violate the FDCA.

This is not what Congress had in mind when it enacted the False Claims Act, and then repeatedly strengthened it over the past twenty-five years with particular focus on encouraging relators to bring suit. Nor is it consistent with Congress' intention "to allow the government to choose among a variety of remedies, both statutory and administrative, to combat fraud." *Onnen*, 688 F.3d at 415. There is simply no basis in law, policy or sound judgment for Merck's contention that these two very different remedial schemes should in any way be treated as mutually exclusive. The FDCA's bar on private causes of action is just that. It precludes private parties from bringing actions under the FDCA. It "does not preempt other causes of action." *Zafarana v. Pfizer Inc.*, 724 F. Supp. 2d 545, 553 (E.D. Pa. 2010). This is particularly so when that other cause of action is the exclusive vehicle through which the government can enforce such a powerful, Congressionally-supported prerogative.

In any event, the underlying fraud behind Merck's False Claims Act liability involves a great deal more than potential violations of the FDCA. It involves violations of the CDC purchase contracts and false certifications of compliance with those contracts; fraudulently inducing the CDC to enter into those contracts; violations under the National Childhood Vaccine Injury Act; violations of the Sherman Act; and most importantly, fraudulent misrepresentations and omissions that concealed from the government that it was purchasing from Merck a vaccine that did not provide adequate immunization, did not have a 95 percent efficacy rate, and did not contain accurate and up-to-date efficacy information. Merck's attempt to package this case in its entirety as one that centers around "the fundamental theory [] that the MMR label is false" (MTD at 20), is thus clearly misguided and reason alone to reject Merck's agency deference arguments.[36]

[36] Even with respect to the falsity of the label, Merck misapplies the relevance of the FDCA labeling requirements. The Court does not have to determine whether Merck's label violates the FDCA to find Merck liable under the False

**B. Relators Are Not Seeking to Undermine or Encroach Upon FDA Authority**

It is largely for these same reasons that Merck's concerns about "usurp[ing]" or "intruding" upon the FDA's discretion, expertise or judgment are so specious. MTD at 17, 20. Relators are not seeking from the Court anything that would even implicate the FDA's decision-making process, let alone require the Court to substitute its judgment for that of the agency. Merck's doomsday depictions about how this case would undermine the FDA's authority are pure make-believe. Relators seek neither to enforce the FDCA nor have this Court override, second-guess or in any way interfere with any FDA interpretation or determination. And Relators are certainly not asking this Court to "determine that MMR is misbranded." MTD at 23. Rather, Relators seek a finding that Merck has violated the False Claims Act. Whether Merck has also violated the FDCA is beside the point.

Thus, the four cases on which Merck principally relies to support its agency deference argument are far removed from this one. Two of them do not even involve the False Claims Act. Merck's lead case, for example, *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), has never been applied to bar a False Claims Act case. The reason is obvious. That case dealt with the narrow issue of federal preemption of *state* law claims grounded *solely* on violations of

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Claims Act. As the Supreme Court made clear in *Wyeth v. Levine*, 555 U.S. 555, 577-78 (2009), the FDA's labeling requirements merely establish a "floor" or "minimum standards" that manufacturers must not fall below. Just because a label satisfies the FDA requirements, does not mean that it complies with all other requirements. As the Supreme Court stressed, it is the "manufacturers, not the FDA, [that] bear primary responsibility for their drug labeling at all times." *Id*. at 579 (finding that allegations of product mislabeling could support state tort law claims even if they did not violate the FDCA labeling requirements). Here, Merck has duties to the CDC and under the National Vaccine Program separate and apart from the FDCA to disclose -- in the label and otherwise -- all material information regarding the diminished efficacy of its mumps vaccine. As the Supreme Court in *Wyeth* recognized, "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id*. at 575. Merck made this very point in its own *amicus* brief in a subsequent Supreme Court case involving *Wyeth*: "HHS plays an active role in the research, development, and ongoing monitoring and evaluation of the safety of vaccines, even apart from the [FDA's] rigorous licensing process." *See* Brief of Merck, *et al.* as *Amici Curiae* Supporting Respondents, *Bruesewitz* v. *Wyeth Inc.*, 2010 WL 3048323, at *5 (July 30, 2010). Consequently, even if Merck's label satisfied the "floor" of its obligations to the FDA, which Relators contend it did not, that is independent of the question of whether the label represents a fraudulent representation actionable under the False Claims Act.

the FDCA. The Supreme Court's concern there was about *state* intrusion into a federal regulatory scheme. That concern is plainly not implicated by seeking to enforce the False Claims Act, or any federal law for that matter.

That is why the so-called *Buckman* bar that Merck has devised has never been applied to bar a False Claims Act case or *any* action seeking to enforce a federal statute. If it were applied to bar False Claims Act cases, it would exert the very "extraneous pull on the scheme established by Congress" that the Supreme Court warned against. *Id.* at 353. That "pull" would keep the government from freely employing the strongest tool Congress provided for combating fraud, a tool Congress has repeatedly strengthened over the years by expanding the statute's reach as well as its use by the government and private parties alike. *Buckman* has no application here.[37]

Merck's reliance on *Sandoz Pharms Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990) is equally misplaced. That too was not a False Claims Act case. And that too has never been applied in one. It was a Lanham Act case based *solely* on the claim that the defendant's labeling was false because it violated the FDCA. The Third Circuit found, on a preliminary injunction motion, that the plaintiff could not prevail on its labeling claim because it had not *proved* that the defendant's labeling was false but was instead relying on the court "to determine preemptively how [the FDA would] interpret and enforce its own regulations." *Id.* at 231. The Court refused to do so. But *Sandoz*, like the other Lanham Act cases Merck cites,[38]

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[37] Even when *Buckman* does apply to preempt state law claims, the Supreme Court was clear that it is only when the claims are based *solely* upon violations of the FDCA. 531 U.S. at 352-53 (distinguishing *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) where state law claims were not preempted because they did not arise "solely from the violation of FDCA requirements"). *See also In re Bayer Corp. Combination Aspirin Prods. Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 369 (E.D.N.Y. 2010) (*Buckman* does not bar state law claims that "incorporate, but do not depend entirely upon, an FDCA violation"). Relators' claims involve conduct that goes well beyond violations of the FDCA, not to mention violations of at least two other federal statutes in addition to the False Claims Act.

[38] *See* MTD at 25 n.13 (citing *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010) (rejecting Lanham Act claim based solely on violations of FDCA); *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, 1997 WL 94237 (D. Kan. Feb. 26, 1997) (same); *Healthpoint, Ltd. v. Stratus Pharms., Inc.*, 273 F. Supp. 2d 769 (W.D. Tex. 2001) (same)). *See also*

has no application to a False Claims Act case like this one, where the basis for liability is independent of and goes well beyond any potential violations of the FDCA. The Third Circuit's concern in *Sandoz* about "usurp[ing the FDA's] responsibility for interpreting and enforcing" its regulations simply does not apply in this context. *Id*. at 231.

Merck finds no greater support from the two False Claims Act cases it cites. *U.S. ex rel. Provuncher v. Angioscore, Inc.*, 2012 WL 3144885 (D. Mass. Aug. 3, 2012) involved a claim that the defendant knowingly sold a defective medical device to the government. The court dismissed the case not based on any agency deference rationale. Rather, it found that the relator's allegations of a 0.4 percent failure rate of a sensitive medical device did not support the claim that every device was defective. The court concluded that addressing this kind of "statistically predictable failure rate" -- of which the FDA was apparently well aware -- "is not the evil that Congress sought to root out by passage of the False Claims Act." *Id.* at *2. This has little in common with the vaccines at issue here, *all* of which Relators allege have failed to provide adequate immunization because of their significantly diminished efficacy which Merck concealed from the government and the public.

The other False Claims Act case Merck cites is *Wilkins*, where the Third Circuit rejected the relators' attempt to base False Claims Act liability solely on the defendant's alleged violations of certain Medicare marketing regulations. The Court's decision there was limited to this narrow context and followed from the Court's concern that the False Claims Act not be used as a "blunt instrument" to attack regulations that have nothing to do with the government's Medicare reimbursement decisions. 659 F.3d at 307 (internal quotes and cites omitted). Otherwise, the Court cautioned, "every time a plan participant's agent gave out a prize worth over $15.00, or

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*id.* (citing *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282 (C.D. Cal. 2008) (rejecting state law misrepresentation claim based solely on violations of FDCA)).

asked Medicare participants eligible for Medicaid to raise their hands at a meeting," it could be the basis for False Claims Act liability. *Id.* at 311.

The Court concluded that regulating these types of violations, "which are not related directly to the Government's payment of a claim," falls outside the purpose of the False Claims Act and is better handled by the administrative processes Medicare has set up to deal specifically with them. *Id.* There is no support in *Wilkins* for the across-the-board application of agency deference that Merck attempts to draw from the decision. To the contrary, Merck's overbroad reading directly conflicts with the Third Circuit's emphasis in *Wilkins* that the False Claims Act should "reach all types of fraud, without qualification, that might result in financial loss to the government." *Id.* at 306 (quoting *Neifert-White*, 390 U.S. at 232).

The Eighth Circuit's decision in *Onnen* rejected the very type of agency deference argument Merck is trying to assert through these inapposite cases. The False Claims Act liability there was based on the defendant school district's misconduct that independently violated the Higher Education Act. The district court looked to the "vast regulatory scheme" governing the school district's alleged misconduct, including the "comprehensive administrative remedies and sanctions available to the government," and found that it barred the relator's False Claims Act case. The Court of Appeals rejected the lower court's decision, finding a clear divide between a False Claims Act case and any administrative remedies that might also be available:

> The scope of regulatory requirements and sanctions may affect the fact-intensive issue of whether a specific type of regulatory non-compliance resulted in a material false claim for a specific government payment. . . . But none of these cases [including *Wilkins*, which the Court specifically cites to] has held that a complex regime of regulatory sanctions *precludes* the Attorney General from suing under the FCA when the government has been damaged by a materially false or fraudulent claim for payment . . . . Congress intended to allow the government to choose among a variety of remedies, both statutory and administrative, to combat fraud.

688 F.3d at 414-15 (emphasis in original).

In the same way, the scope of Merck's regulatory duties to the FDA, CDC and under the National Vaccine Program are relevant to the question of whether Merck's misconduct was material to the government's purchasing decision. But the existence of these duties and any administrative remedies to enforce them does not usurp the Congressionally-backed right of the government and Relators to address this misconduct under the False Claims Act. If it did, it would leave a gaping hole in the government's ability to combat fraud and recover funds fraudulently obtained from the public fisc. There is no support for such an outcome and it would go against everything the Supreme Court and Congress has said about the broad scope and purpose of the False Claims Act.

Merck's attempt to apply an agency deference rationale to bar Relators' claims here is further undermined by Merck's factual mischaracterization of what Relators are ultimately seeking from the Court. Relators are not asking the Court to "substitute [its] own regulatory, scientific and enforcement judgment for that of the FDA." MTD at 15. Nor are they trying to "force a labeling outcome" that is different from what the FDA believes is appropriate. MTD at 27. Relators are not seeking "to enlist the Court in assisting them with upsetting" anything the FDA has done or failed to do with regard to regulating Merck and its mumps vaccine. MTD at 23.

The only thing Relators are asking the Court to do here is find that (i) Merck has submitted to the CDC false claims for payment based on Merck's misrepresentations and omissions on its vaccine's significantly diminished efficacy, and (ii) the government is entitled to monetary penalties and the damages it suffered from Merck's fraud. Such a finding depends only on whether Relators have satisfied the elements of the False Claims Act. It does not depend on

any kind of "prediction of an FDA regulatory determination." MTD at 26. And it certainly does not involve "strip[ping] the FDA of discretionary authority" in any manner. No matter what the Court ultimately decides here, the FDA will remain free to continue regulating Merck and its mumps vaccine as it deems appropriate.

### C. There Is No Exhaustion of Administrative Remedies Prerequisite to Bringing a False Claims Act Case

Nor is there any merit in Merck's contention that before filing this action, Relators were first required to file a Citizen's Petition with the FDA and exhaust any other administrative remedies that might have been available. MTD at 4, 11, 17, 28 (citing 21 C.F.R § 10.30 which permits private citizens to challenge certain FDA actions or decision-making). Merck does not cite a single case or authority that imposes such a prerequisite for bringing a False Claims Act case.[39] There is none. That is because the False Claims Act is not designed to address any kind of agency challenge or decision-making. The statute does not pertain to agency conduct at all. It deals exclusively with private actors that have defrauded the government through their submission of false or fraudulent claims.

That is precisely what this case is about -- Merck's efforts to defraud the government by withholding from it material information about the significantly diminished efficacy of its vaccine. It is not about any "petition [to] the Agency for further relief," or "dissatisfaction with the FDA's findings," or "end-run around the FDA," or "review of FDA action." MTD at 4, 17, 28 n.15. It is not about any FDA conduct at all. It is about Merck's conduct; about Merck's efforts to defraud the CDC; about recovering from Merck the damages it caused to the

[39] The only case Merck cites in support of an exhaustion requirement is *Cody Labs., Inc. v. Sebelius*, 446 F. App'x 964 (10th Cir. 2011). MTD at 28 n.15. But that case was a suit *against the FDA* brought by a manufacturer challenging the FDA's refusal to exempt the manufacturer's product from needing FDA approval. That case offers no support for Merck's attempt to construct an exhaustion prerequisite under the False Claims Act, particularly when there is not even a challenge to any FDA action at issue.

government from knowingly selling the CDC a product that is not what the CDC contracted to purchase. The only vehicle through which Relators (and the government) can address this conduct and secure this relief is the False Claims Act.

## CONCLUSION

For the reasons set forth herein, Relators respectfully request that the Court deny Merck's motion to dismiss the Complaint.

Respectfully submitted,

Dated: October 9, 2012

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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, Relators, v. Merck & Co., Inc. Defendant. | Case 2:10-cv-04374 (CDJ) **DECLARATION OF MARLENE KOURY IN SUPPORT OF RELATORS' OPPOSITION TO MERCK'S MOTION TO DISMISS** |

Marlene Koury hereby declares and states, pursuant to 28 U.S.C. § 1746, as follows:

1. I am an attorney with Constantine Cannon LLP, counsel for Stephen A. Krahling and Joan A. Wlochowski, Relators in the above-captioned case. I have personal knowledge of the matters set forth herein.

2. On October 9, 2012, I accessed the website of Defendant Merck, specifically the Merck Web Page on "Seroconversion Rates" for Merck's mumps vaccine, found at https://www.merckvaccines.com/Products/mmr/Pages/seroconversion-rates.aspx. Attached as Exhibit A is a true and correct copy of a screen shot of that Web Page taken on October 9, 2012.

3. On October 9, 2012, I accessed the website of the U.S. Food and Drug Administration (FDA), specifically the FDA Web Page on "Determining the Safety and Efficacy of Vaccines to Protect Against Viruses that Infect the Central Nervous System," found at http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/BiologicsResearchAreas/ucm127315.htm. Attached as Exhibit B is a true and correct copy of a print out of that Web Page made on October 9, 2012.

4. On October 9, 2012, I accessed the website of the U.S. National Institutes of Health (NIH), specifically the NIH Web Page on the project entitled "Developing a Novel Mumps Virus Vaccine," found at http://projectreporter.nih.gov/project_info_description.cfm?aid=8371494&icde=12549650&ddparam=&ddvalue=&ddsub=&cr=10&csb=default&cs=ASC. Attached as Exhibit C is a true and correct copy of a print out of that Web Page made on October 9, 2012.

5. On October 9, 2012, I accessed the website of the U.S. Department of Justice (DOJ), specifically the DOJ Web Page containing a press release dated December 19, 2011 and entitled "Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011," found at http://www.justice.gov/opa/pr/2011/December/11-civ-1665.html. Attached as Exhibit D is a true and correct copy of a print out of that Web Page made on October 9, 2012.

6. On October 9, 2012, I accessed the website of the U.S. Department of Health and Human Services (HHS), specifically the HHS Web Page containing the April 18, 2007 statement by Jesse Goodman M.D., M.P.H., Director of the Center for Biologics, Evaluation and Research at the FDA on the "FDA's Role in the Regulation of Vaccines," made to the U.S. Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, U.S. Department of Health and Human Services. This Web Page can be found at http://www.hhs.gov/asl/testify/2007/04/t20070418c.html. Attached as Exhibit E is a true and correct copy of a print out of that Web Page made on October 9, 2012.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 9th day of October, 2012.

Marlene Koury

# Exhibit A

MERCK M-M-R II (Measles, Mumps, & Rubella Virus Vaccine Live)

- Home for M-M-R®II
- Prescribing Information
- Patient Information
- Selected Safety Information
- Product Information
- Indication
- Dosage and Administration
- Storage and Handling
- Disease Information
  - Measles
  - Mumps
  - Rubella
- Disease Incidence
- History
- Seroconversion Rates
- Recommendations
- Reimbursement Information

Quick Links

- Contact Us
- Place an Order
- Supply Status
- Patient Education
- Shipping Schedule
- Tour the Site

# Seroconversion Rates

**In clinical trials, M-M-R®II demonstrated high seroconversion rates after the first dose**


## About M-M-R®II

M-M-R®II is indicated for simultaneous vaccination against measles, mumps, and rubella in individuals 12 months of age or older.

- M-M-R®II should be given 1 month before or after administration of other live viral vaccines.

## Selected Safety Information for M-M-R®II

M-M-R®II is contraindicated in certain individuals, including those with: a history of hypersensitivity to any component of the vaccine, including gelatin; a history of anaphylactic or anaphylactoid reaction to neomycin; blood dyscrasias, leukemia, lymphomas of any type, or other malignant neoplasms affecting the bone marrow or lymphatic systems; an immunodeficient condition or receiving immunosuppressive therapy; an active febrile illness; or those who are pregnant.

Due caution should be employed in administration of M-M-R®II to persons with a history of cerebral injury, individual or family histories of convulsions, or any other condition in which stress due to fever should be avoided.

The following adverse reactions have been reported with M-M-R®II without regard to causality: fever, headache, dizziness, rash, injection-site reactions, febrile convulsions, anaphylaxis and anaphylactoid reactions, arthritis, and thrombocytopenia.

As for any vaccine, vaccination with M-M-R®II may not result in protection in 100% of vaccinees.

**Before administering M-M-R®II (Measles, Mumps, and Rubella Virus Vaccine Live), please read the Prescribing Information. The Patient Information also is available.**

VACC-1023926-0000 05/12

# Exhibit B

## Vaccines, Blood & Biologics

### Determining the Safety and Efficacy of Vaccines to Protect Against Viruses that Infect the Central Nervous System

Principal Investigator: **Steven Rubin, PhD**
Office / Division / Lab: **OVRR / DVP / LMD**

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**General Overview**

FDA regulators at CBER are now reviewing several live, attenuated (weakened versions of viruses) vaccines that are derived from neurotropic wild-type viruses (viruses that infect the central nervous system).

There are as yet no reliable markers (biological evidence) that can be used to determine whether such viruses have been successfully attenuated--other than the failure of the vaccine to produce obvious symptoms of disease in recipients. This problem is based on the lack of knowledge of 1) virus virulence factors (molecules that help viruses infect cells and cause disease); 2) characteristics of cells targeted by such viruses; and 3) how these viruses spread in the host. In addition, for many of these vaccines there are as yet no known markers of efficacy (measurable responses of the body that accurately signify that the vaccine is working effectively). This lack of markers of efficacy, such as a specific level of antibody, makes it difficult to interpret immune response data collected during clinical trials of these vaccines.

Our laboratory uses the mumps virus as a model to identify markers of successful virus attenuation as well as to identify markers in the blood that signify that the vaccine is providing significant protection. The present lack of sufficient knowledge in areas of mumps vaccine safety and efficacy is highlighted by the licensure of some mumps vaccines that have caused a complication called aseptic meningitis (inflammation of the membranes covering the brain and spinal cord) and the occurrence of mumps outbreaks in highly-vaccinated populations.

Problems with vaccine safety can be linked to an inadequate understanding of the infection process. Therefore, our research efforts are focused on identifying 1) cells that the virus naturally infects; and 2) mechanisms the virus uses to facilitate its spread in the infected host.

To help identify markers of vaccine efficacy, our laboratory is studying the ability of vaccine-induced antibodies to inactivate a broad range of variations of the virus obtained from different patients. Our goal is to determine the level of antibody that signifies that the immune response to the vaccine is providing protection against the virus.

We chose mumps virus as the model to study because, for the first time in over 40 years, new live attenuated mumps vaccines are being submitted to FDA for approval. Therefore, FDA regulators must understand what to test for in vaccines based on attenuated mumps virus to demonstrate that they are safe and effective. In response to these challenges, we are trying to learn more about mumps virus vaccine safety and efficacy and to apply this to other viral vaccines.

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**Scientific Overview**

Identification of markers of virus neuroattenuation

Understanding viral pathogenesis is key to successful development of attenuated virus vaccines. In these studies we are trying to identify cell types infected following a natural route of inoculation

(intranasal or intra-tracheal) in an animal model and follow the subsequent dissemination of the virus to other sites in the body, including the central nervous system. We inoculate animals via the respiratory route with recombinant mumps viruses expressing enhanced green fluorescent protein (eGFP). The viruses used for these studies include a highly attenuated mumps virus strain, a highly neurovirulent mump virus strain, and chimeric viruses consisting of mixtures of genes from these two viruses.

Disease-relevant host cells identified from the animal studies will then be used for in vitro testing to identify functional differences in the gene products (proteins) of both virulent and attenuated viruses. Our goal is to identify biomarkers of mumps virus neurovirulence, e.g., specific cellular targets of infection or functional properties of specific viral proteins, and to apply this knowledge to efforts at attenuating other neurotropic viruses, in order to facilitate the development and use of safer vaccines.

Examination of vaccine-induced protective efficacy

Over the past decade numerous mumps outbreaks have been reported in highly vaccinated populations in several countries. Widespread use of only one of the two recommended doses of vaccine was believed to be largely responsible. In 2006 the US experienced its largest mumps outbreak in 20 years. Multiple independently performed outbreak investigations found that between 70% and 99% of cases had received the recommended 2 doses of mumps-containing vaccine, indicating lower vaccine efficacy than previously estimated. While mumps was historically a disease of childhood, now mumps primarily occurs among young adults. The most likely explanations of this epidemiological change are (1) the ability of certain mumps virus strains to escape vaccine-induced immune responses, or (2) waning immunity.

To address the virus escape mutant theory, serum samples from recent vaccinees will be assessed for neutralizing antibody titer against a panel of phylogenetically distinct mumps virus strains, including an isolate from the 2006 US mumps outbreaks. The ability of serum to effectively neutralize all virus strains would argue against the virus escape mutant theory.

To address the waning theory, serum samples from individuals at 1 month to 15 years post vaccination will be assessed for neutralizing antibody titer against the vaccine virus itself as well as an isolate from the 2006 US mumps outbreaks. The anti-viral activity in serum will be assessed as a function of time post vaccination.

Finally, to identify a protective titer of mumps antibody, serum samples acquired via the CDC from a Red Cross blood drive at a university prior to a mumps outbreak will be assessed for pre-exposure mumps virus neutralizing antibody titer. The pre-exposure mumps virus neutralizing antibody titer in subjects who later developed or did not develop mumps during the outbreak will inform us of non-protective and protective levels of antibody.

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101. /ForConsumers/default.htm

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103. /ForHealthProfessionals/default.htm

104. http://www.hhs.gov

# Exhibit C

# Project Information

1R01AI097368-01A1

Back to Query Form | Print Version

DESCRIPTION DETAILS RESULTS HISTORY SUBPROJECTS SIMILAR PROJECTS NEARBY PROJECTS BETA LINKS NEWS AND MORE

**Project Number:** 1R01AI097368-01A1
**Title:** DEVELOPING A NOVEL MUMPS VIRUS VACCINE

**Contact PI / Project Leader:** HE, BIAO
**Awardee Organization:** UNIVERSITY OF GEORGIA (UGA)

**Abstract Text:**

DESCRIPTION (provided by applicant): Mumps virus (MuV), a paramyxovirus, causes acute inflammatory infections in humans involving most organ systems. Mumps virus infection was the most common cause of viral meningitis and encephalitis before mass immunization with the mumps virus vaccine. Advisory Committee on Immunization Practices (ACIP) recommended a single dose immunization of MuV vaccine in 1977 and in 1989 ACIP recommended to increase MuV vaccine to two doses. Even with widespread vaccination programs in place, mumps outbreaks continue to occur. The largest MuV outbreak in the US after implementation of two-dose MuV vaccination program occurred in 2006. It is considered the first failure of two-dose MuV vaccination. In 2010, a large MuV outbreak occurred in NY/NJ area. While definitive causes for the outbreaks are not known, possible reasons (not mutually exclusive) for these outbreaks include (1) waning immunity and (2) vaccine failure due to emergence of a new mumps virus strain. The fact that outbreaks had occurred in populations with over 95% coverage of two-dose MuV vaccine strongly suggests that the current vaccine is not effective. The current vaccine is based on genotype A while outbreaks were caused by genotype G MuV. All these possible causes indicate a need for a new vaccine that is effective against current outbreak strain of mumps virus. Long-term goal of this proposal is to develop a new mumps virus vaccine with long-lasting immunity. We hypothesize that MuV mutants generated using reverse genetics system are good vaccine candidates. We propose to develop a novel mumps virus vaccine by attenuating virus through introducing mutations at desirable locations within the genome and to test immunogenicity of vaccine candidates in mice and ferrets. PUBLIC HEALTH RELEVANCE: Current mumps virus vaccine (JL strain) based on genotype A has been used for over 40 years. Recently, large outbreaks in vaccinated populations have occurred at increasing frequency. The outbreaks of mumps virus (genotype G) infection in vaccinated populations underscore the urgency and importance of developing a new and effective vaccine against mumps virus (genotype G) that caused current outbreaks.

**Public Health Relevance Statement::**

Current mumps virus vaccine (JL strain) based on genotype A has been used for over 40 years. Recently, large outbreaks in vaccinated populations have occurred at increasing frequency. The outbreaks of mumps virus (genotype G) infection in vaccinated populations underscore the urgency and importance of developing a new and effective vaccine against mumps virus (genotype G) that caused current outbreaks.

**Project Terms:**

5 year old; Acute; Advisory Committees; Animal Model; Animals; Area; Attenuated; Attenuated Live Virus Vaccine; Attenuated Vaccines; base; body system; Cell Line; Child; Clinical; Clinical Trials; Disease; Disease Outbreaks; Dose; Failure (biologic function); Ferrets; Frequencies (time pattern); Genome; Genotype; Goals; Human; Human Virus; Immunity; Immunization; immunogenicity; improved; Infection; Inflammatory; Life; Location; Lung; Mass Immunization; Measles-Mumps-Rubella Vaccine; Modeling; Morphology; mouse model; Mumps; Mumps virus; Mus; mutant; Mutate; Mutation; neurotoxicity; novel; novel vaccines; Paramyxovirus; pathogen; Pathogenesis; Physiology; Point Mutation; Population; positional cloning; programs; Rattus; recombinant virus; Recombinants; Regimen; respiratory; respiratory virus; Safety; System; Testing; tissue/cell culture; Vaccinated; Vaccination; vaccine candidate; Vaccine Production; Vaccines; Vero Cells; Viral Encephalitis; Viral Genome; Viral meningitis; Virus; Virus Diseases

# Exhibit D

JUSTICE NEWS

**Department of Justice**

Office of Public Affairs

FOR IMMEDIATE RELEASE Monday, December 19, 2011

## Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011

*Department Sets Records for Recoveries in Health Care and War-Related Fraud Annual Recoveries in Whistle Blower Cases Reach All Time High*

WASHINGTON – The Justice Department secured more than $3 billion in settlements and judgments in civil cases involving fraud against the government in the fiscal year ending Sept. 30, 2011, Tony West, Assistant Attorney General for the Civil Division, announced today. This is the second year in a row that the department has surpassed $3 billion in recoveries under the False Claims Act, bringing the total since January 2009 to $8.7 billion – the largest three-year total in the Justice Department's history.

The $3 billion total for fiscal year 2011 includes a record $2.8 billion in recoveries under the whistleblower provisions of the False Claims Act, which is the government's primary civil remedy to redress false claims for federal money or property, such as Medicare benefits, payments on military contracts, and federal subsidies and loans. The department has recovered more than $30 billion under the False Claims Act since the act was substantially amended in 1986. The 1986 amendments strengthened the act and increased the incentives for whistle blowers to file lawsuits on behalf of the government. That in turn led to an unprecedented number of investigations and greater recoveries.

"Twenty-eight percent of the recoveries in the last 25 years were obtained since President Obama took office,"Assistant Attorney General West said. "These record-setting results reflect the extraordinary determination and effort that this administration, and Attorney General Eric Holder in particular, have put into rooting out fraud, recovering taxpayer money and protecting the integrity of government programs."

Assistant Attorney General West noted that the $3 billion recovered this year included $2.4 billion in recoveries involving fraud committed against federal health care programs. Most of these recoveries are attributable to the Medicare and Medicaid programs administered by the Department of Health and Human Services (HHS). They also include the TRICARE program administered by Department of Defense (DoD), the Federal Employees Health Benefits program administered by the Office of Personnel Management and Veterans Administration health programs.

Fighting health care fraud is a top priority for the Obama Administration. On May 20, 2009, the Attorney General and HHS Secretary Kathleen Sebelius announced the creation of an interagency task force, the Health Care Fraud Prevention and Enforcement Action Team (HEAT), to increase coordination and optimize criminal and civil enforcement. Since January 2009 alone, the department has used the False Claims Act to recover more than $6.6 billion in federal health care dollars. This is more recovered under the act than in any other three-year period.

The historic $2.8 billion recovered in whistle blower cases came from suits filed under the *qui tam*, or whistleblower, provisions of the False Claims Act. These provisions allow private citizens, known as relators, to file lawsuits on behalf of the government. In the 25 years since the False Claims Act was substantially amended, whistle blowers have filed more than 7,800 actions under the *qui tam* provisions. *Qui tam* suits hit a peak of 638 this past year, after hovering in the 300s and low 400s for much of the decade.

Assistant Attorney General West thanked the courageous citizens who have come forward to report fraud, often at great personal risk: "We are tremendously grateful to whistle blowers who have brought fraud allegations to the government's attention and assisted us in this public-private partnership to fight fraud," he said.

In 1986, Senator Charles Grassley and Representative Howard Berman led successful efforts in Congress to amend the False Claims Act, including enhancements to the *qui tam* provisions to

encourage whistle blowers to come forward with allegations of fraud. In this 25th anniversary year of the 1986 amendments, Assistant Attorney General West paid tribute to the bill's sponsors, saying that "without their foresight, the breadth of the recoveries we announce here today would not have been possible." He also expressed his gratitude to Senator Patrick J. Leahy, chairman of the Senate Judiciary Committee, and to Senator Grassley and Representative Berman for their support of the Fraud Enforcement and Recovery Act of 2009, which made additional improvements to the False Claims Act and other fraud statutes.

Assistant Attorney General West also applauded Congress' passage of the Affordable Care Act (ACA) in 2010, which reenforced the government's ability to redress fraud in the nation's health care system. Among many other changes, the ACA amended the False Claims Act to provide additional incentives for whistle blowers to report fraud to the government and strengthened the provisions of the federal health care Anti-Kickback Statute.

Enforcement actions involving the pharmaceutical industry were the source of the largest recoveries this year. In all, the department recovered nearly $2.2 billion in civil claims against the pharmaceutical industry in fiscal year 2011, including $1.76 billion in federal recoveries and $421 million in state Medicaid recoveries. These cases included $900 million from eight drug manufacturers to resolve allegations that they had engaged in unlawful pricing to increase their profits. Additionally, GlaxoSmithKline PLC paid $750 million to resolve criminal and civil allegations that the company knowingly submitted, or caused to be submitted, false claims to government health care programs for adulterated drugs and for drugs that failed to conform with the strength, purity or quality specified by the Food and Drug Administration.

Adding to its successes under the False Claims Act, the department obtained 21 criminal convictions and $1.3 billion in criminal fines, forfeitures, restitution, and disgorgement under the Food, Drug and Cosmetic Act (FDCA). The FDCA's criminal provisions are enforced by the Civil Division's Consumer Protection Branch.

In addition to health care, the department continued its aggressive pursuit of fraud in government procurement and other forms of financial fraud, including grant, housing and mortgage fraud that emerged in the wake of the financial crisis. In November 2009, President Obama established the Financial Fraud Enforcement Task Force to hold accountable the individuals and corporations who contributed to the crisis as well as those who would claim illegal advantage through false claims for funds intended to stimulate economic recovery. Of the $3 billion in fiscal year 2011 recoveries, these non-war related procurement and consumer-related financial fraud cases accounted for nearly $358 million.

Overall, the department recovered $422 million in fiscal year 2011 in procurement fraud cases, including $89.3 million in recoveries in connection with the wars in Southwest Asia. This brings civil fraud recoveries in connection with the wars in Southwest Asia since January 2009 to $153.4 million, and the total amount recovered in procurement fraud cases during that time to $1.5 billion, again a greater amount than in any previous three-year period.

Assistant Attorney General West expressed his deep appreciation for the dedicated public servants who contributed to the investigation and prosecution of these cases. These individuals include attorneys, investigators, auditors and other agency personnel throughout the Civil Division, the U.S. Attorneys' Offices, HHS, DoD and the many other federal and state agencies.

11-1665 Civil Division

# Exhibit E

ASL Home
ASL Mission
ASL Leadership
Grants
Testimony
Legislative Offices within HHS
Related Links

**Testimony**

Statement by
**Jesse Goodman M.D., M.P.H.**
**Director Center for Biologics, Evaluation and Research**
**Food and Drug Administration**
**U.S. Department of Health and Human Services**

on
**FDA's Role in the Regulation of Vaccines**

before
**Committee on Homeland Security**
**Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology**
**U.S. Department of Health and Human Services**

**Wednesday April 18, 2007**

Good afternoon Mr. Chairman and members of the Committee, I am Jesse L. Goodman, M.D., M.P.H., Director of the Center for Biologics Evaluation and Research (CBER) at the United States Food and Drug Administration (FDA). I am also a practicing infectious diseases physician and a microbiologist. CBER is the Center within FDA that is responsible for the regulation of most biological products, including vaccines, blood and blood products, and cellular, tissue and gene therapies. Thank you for the opportunity to discuss FDA's role in the regulation of vaccines including those intended for use in response to a threat to our national security.

At CBER, enhancing the nation's preparedness is one of our highest priorities, whether it is protecting the safety of our blood supply from emerging threats like West Nile Virus or facilitating the development of vaccines needed to face natural threats or potential deliberate threats, from pandemic flu to smallpox to anthrax. It is essential to do all we can to assure that such products be safe, and that they work. Therefore, while working closely with many partners to achieve our nation's and our global preparedness goals, our most critical and unique responsibility is to also do all that is possible to provide an objective, scientific assessment of the safety and efficacy of these and other biologic products. To help provide perspective, I am going to discuss relevant issues in vaccine development that illustrate the opportunities and challenges faced in developing these important products. As you know, under applicable laws and regulations, information provided to FDA concerning a specific investigational product is not available for public disclosure prior to licensure of the product.

Vaccines are different from most drugs in several respects and achieving the highest quality in manufacturing can be especially challenging and critical. Vaccines production frequently utilizes living cells and organisms, as well as complex growth conditions and materials often derived from living sources. The manufacturing process for vaccines usually includes many steps and requires frequent in-process monitoring of the product and components to assure that the product is safe, pure, and potent.

The production of most vaccines requires the growth of the immunizing agent (i.e. bacteria, virus, etc.) or the genetically engineered expression, in living cells, of recombinant immunizing proteins derived from that agent. The conditions for accomplishing this are complex and subtle, and even undetected or poorly understood changes in process or materials can significantly affect the composition of the vaccine and its safety, efficacy, or both. Thus, the process must be well controlled and monitored, and produce a consistent and well characterized product prior to its licensure. Even after licensure, manufacturers conduct a series of tests on the bulk, intermediate and final vaccine products and typically are required both to meet all product and process specifications and to submit the results of key tests, along with samples of the product to CBER for evaluation prior to CBER's approval of lot release and administration of vaccine. The tests performed on the final product may include those for sterility, identity, purity, and potency to assess immunogenicity and/or antigen content and, depending on the nature of the vaccine and its manufacturing process, additional tests as required by CBER to assure vaccine safety and quality.

Unlike drug products that are most often used to treat an existing illness or condition, vaccines are generally administered to large numbers of healthy individuals in order to prevent infectious diseases. Therefore, the potential adverse effects of vaccines, even if the events are rare, present unique risk-benefit considerations and may give rise to heightened concerns in the public health context.

From a regulatory perspective, there are four major stages in vaccine development. These stages include:

- The preclinical stage which consists of the development and testing of the product prior to the product being tested in humans. Early in the product development process, sponsors test candidate vaccines *in-vitro* (e.g., in laboratory assays, studies in cell lines, etc) and in animals. These early nonclinical studies give an indication of whether studies would be reasonably safe to proceed in humans and may also provide information regarding the potential effectiveness of the product.
- The Investigational New Drug (IND) stage consisting of multiple phases where the investigational product is studied in human subjects under well-defined conditions and with careful monitoring. In certain cases where studies to demonstrate efficacy in humans are not ethical or feasible, sponsors may conduct studies to demonstrate efficacy of the product in appropriate animal models.
- The license application stage is when manufacturers submit data and information regarding the results of the clinical and nonclinical studies, as well as complete information regarding the product and its manufacturing process to FDA for a complete review of product manufacturing, safety and effectiveness in support of licensure.
- Finally, for products that are approved, FDA continues its oversight during the post licensure stage to include review of post-marketing safety information from adverse event reports, periodic reports, post-marketing studies, review of lot release information and testing, and inspections of manufacturing facilities.

FDA often provides guidance to sponsors, even prior to submission of an IND, in regard to both the types of preclinical studies needed and the design of the clinical trials needed to assess the intended use(s) of the product. FDA's guidance is intended both to help protect human subjects and to assure that the studies performed are designed in such a manner that the study results are likely to provide sufficient information to allow a determination of the product's safety and efficacy.

While all medical product development is challenging, vaccine development is especially complex, and we expect that new challenging issues will arise during the development process. The issues may arise in any number of areas, and may affect product potency, quality, and safety. Such issues can raise safety or study design concerns that may result in FDA placing an IND on clinical hold. A clinical hold is an order by FDA not to initiate or continue clinical studies until the issues of concern have been satisfactorily addressed. It is important to note that most clinical hold issues are eventually

resolved, allowing product development to proceed. I'd like to describe some of the more typical reasons for FDA to place a trial on hold. FDA may determine that study participants would be exposed to an unreasonable and significant risk of illness or injury. Or, the IND application may not have sufficient information for FDA to adequately assess the risk. For later phase studies, FDA may place an IND on hold if the study plan or protocol is deficient in design to meet its stated objectives. Clinical hold is an important human subject protection safeguard and also helps prevent the conduct of studies of investigational products that are unlikely to provide information that is useful in evaluating the product. FDA staff spends a considerable amount of time interacting with sponsors to resolve clinical hold issues.

FDA strives to develop processes that facilitate product development to meet emerging public health needs, such as protection from terrorist agents and prevention of pandemic influenza and other emerging threats. The regulation known as the "Animal Rule" provides a mechanism for FDA to approve medical treatments based on effectiveness data from animal studies when human efficacy studies are unethical and/or not feasible. Under the "Animal Rule," effectiveness would be evaluated in adequate and well-controlled animal studies that establish that the product is reasonably likely to produce clinical benefit in humans. Such approvals also require the demonstration of safety in humans. These safety studies may be conducted concurrently with the animal studies.

An additional tool available to speed product availability is the ability for FDA to allow the use of unapproved products and unapproved uses (so-called "off-label" uses) of approved products, in a declared emergency, under the Emergency Use Authorization (EUA) provision of the Food, Drug, and Cosmetic Act. This authority was expanded under the Project BioShield Act. To authorize such emergency use, FDA would need to find that the agent can cause a serious or life-threatening disease or condition; that based on the available information it is reasonable to believe that the product may be effective against the disease or condition; that the known and potential benefits of the product's use outweigh the known and potential risks; and that there is no adequate, approved and available alternative.

FDA works very hard to develop and define innovative and needed pathways and evaluation tools, and to provide technical assistance to facilitate development and availability of needed products that are safe and effective. One of our most critical and core roles is to protect human subjects and to provide an independent scientific assessment of the product, both during the development process, and in reviewing product applications and requests for EUA.

To protect and preserve our scientific independence and judgment, FDA does not involve itself in specific HHS contracting decisions to award or terminate contracts. FDA's longstanding practice is to recuse ourselves from HHS decision making in specific contracting decisions. This was our process at the time of HHS's VaxGen acquisition contract and it remains so today. FDA does provide scientific and technical expertise on various HHS-led interagency counterterrorism working groups, which among other things are involved in defining the needs for medical countermeasures being pursued by HHS for the Strategic National Stockpile. In addition, FDA may provide technical comments to HHS upon request on draft Requests for Proposals for such countermeasures.

At FDA, providing the American public with safe and effective medical products is our core mission. We base important decisions, such as to allow specific human studies of an investigational product, or to approve a vaccine or allow its emergency use, on the available scientific information and a careful evaluation of risks and benefits to patients. We also are fully committed and engaged in continuing to work with our federal partners and with product developers to provide an efficient product development pathway to achieve our nation's high priority public health preparedness goals.

Thank you again for this opportunity to discuss vaccine development with the Committee. I welcome your comments and questions.

Last revised: April 19, 2011

**UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

| | |
|---|---|
| United States of America *ex rel.*, Stephen A. Krahling and Joan A. Wlochowski, Relators, v. Merck & Co., Inc. Defendant. | Case 2:10-cv-04374 (CDJ) |

AND NOW, this _____ day of _____, 2012, upon consideration of Merck's Motion to Dismiss Relators' Amended Complaint and accompanying memorandum of law, Relators' Memorandum in Opposition to Merck's Motion to Dismiss and supporting papers, and any replies thereto, it is HEREBY ORDERED that the motion to dismiss is DENIED in its entirety.

BY THE COURT:

_____
C. DARNELL JONES, II
*Judge, United States District Court*

**CERTIFICATE OF SERVICE**

I hereby certify that today, October 9, 2012, I served via e-mail and ECF, copies of Relators' Memorandum in Opposition to Merck's Motion to Dismiss, the Declaration of Marlene Koury in Support of Relators' Opposition to Merck's Motion to Dismiss and exhibits attached thereto, and the accompanying Proposed Order, on the following:

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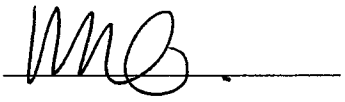

Marlene Koury, Esq.