IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA and the

STATE OF CALIFORNIA,
STATE OF COLORADO,
STATE OF CONNECTICUT,
STATE OF DELAWARE,
DISTRICT OF COLUMBIA
STATE OF FLORIDA,
STATE OF GEORGIA,
STATE OF HAWAII,
STATE OF ILLINOIS,
STATE OF INDIANA,
STATE OF IOWA
STATE OF LOUISIANA,
STATE OF MARYLAND
COMMONWEALTH OF MASSACHUSETTS,
STATE OF MICHIGAN,
STATE OF MINNESOTA
STATE OF MONTANA,
STATE OF NEVADA,
STATE OF NEW JERSEY,
STATE OF NEW MEXICO,
STATE OF NEW YORK,
STATE OF NORTH CAROLINA
STATE OF OKLAHOMA,
STATE OF RHODE ISLAND,
STATE OF TENNESSEE,
STATE OF TEXAS,
COMMONWEALTH OF VIRGINIA,
STATE OF WASHINGTON and,
STATE OF WISCONSIN

ex rel. **THOMAS JEFFERSON**
Relator,

v.

ROCHE HOLDING AG, HOFFMANN-LA ROCHE, INC., GENENTECH, INC.,
Defendants.

CIVIL ACTION NO. ~~14-cv-03665-GLR~~

AMENDED COMPLAINT

JURY TRIAL DEMAND

FILED UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730(b)(2)

Qui tam relator, Thomas Jefferson (Relator), brings this action against Defendants Roche Holding AG, Hoffmann-La Roche, Inc., and Defendant Genentech, Inc. (collectively "Roche" or "Defendants") on behalf of the United States, alleging violations of the False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq.*, as amended, and on behalf of the following states, alleging violations of their respective state law counterparts:[1]

- California (False Claims Act, Cal. Gov't Code §§ 12650 *et seq.*)
- Colorado (Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 *et seq.*)
- Connecticut (Connecticut False Claims Act, Conn. Gen. Stat. §§ 17b-301 *et seq.*)
- Delaware (Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201 *et seq.*)
- District of Columbia (District of Columbia False Claims Act, D.C. Code §§ 2-381.01 *et seq.*)
- Florida (Florida False Claims Act, Fla. Stat. §§ 68.081 *et seq.*)
- Georgia (State False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 *et seq.*)
- Hawaii (Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 *et seq.*)
- Illinois (Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1 *et seq.*)
- Indiana (False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5 *et seq.*)
- Iowa (Iowa False Claims Act, Iowa Code §§ 685.1 *et seq.*)
- Louisiana (Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437.1 *et seq.*)
- Maryland (Maryland False Health Claims Act, Md. Code Health-Gen. §§ 2-601 *et seq.*)
- Massachusetts (Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5 *et seq.*)
- Michigan (The Medicaid False Claim Act, Mich. Comp. Laws §§ 400.601 *et seq.*)
- Minnesota (Minnesota False Claims Act, Minn. Stat. §§ 15C.01 *et seq.*)
- Montana (Montana False Claims Act, Mont. Code Ann. §§ 17-8-401 *et seq.*)
- Nevada (Nevada Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. §§ 357.010 *et seq.*)
- New Jersey (New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 *et seq.*)
- New Mexico (Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 *et seq.* and Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 *et seq.*)
- New York (New York False Claims Act, N.Y. State Fin. Law §§ 187 *et seq.*)
- North Carolina (North Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 *et seq.*)

[1] In this Amended Complaint, references to "FCA" generally are intended to reference the FCA and its state law counterparts. Further, "government" generally refers to both the federal and state governments in the United States.

- Oklahoma (Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053 *et seq.*)
- Rhode Island (State False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 *et seq.*)
- Tennessee (Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 *et seq.* and Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 *et seq.*)
- Texas (Medicaid Fraud Prevention, Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.*)
- Virginia (Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 *et seq.*)
- Washington (Washington Medicaid Fraud False Claims Act, Wash. Rev. Code §§ 74.66.010 *et seq.*)
- Wisconsin (Wisconsin False Claims Act, Wis. Stat. §§ 20.931 *et seq.*)

(collectively "FCA States"). Based on personal knowledge, unless otherwise indicated, information he uncovered, findings he established, and relevant documents, Relator alleges the following:

I. INTRODUCTION

1. Just as the FCA was violated by delivering dying donkeys, faulty muskets, and bullets filled with sawdust to the government during the Civil War, Roche violated the FCA by selling the government a drug for pandemic use that could not achieve the pandemic purposes for which the government bargained and paid.[2] The FCA "is intended to protect the treasury against the hungry and unscrupulous hosts that encompass it on every side."[3] The facts here show an incredibly hungry and unscrupulous pharmaceutical company that deceitfully caused the U.S. and various state governments to spend over $1.4 billion to acquire Tamiflu for pandemic use.

[2] As colorfully reported at the time: "For sugar [the government] often got sand; for coffee, rye; for leather, something no better than brown paper; for sound horses and mules, spavined beasts and dying donkeys; and for serviceable muskets and pistols, the experimental failures of sanguine inventors, or the refuse of shops and foreign armories." *U.S. ex rel. Newsham v. Lockheed Missiles and Space Co., Inc.*, 722 F. Supp. 607, 609 (N.D. Cal. 1989) (quoting F. Shannon, *The Organization and Administration of the Union Army 1861-1865*, at 58 (Peter Smith Press 1965) (quoting Robert Tomes, *The Fortunes of War*, 29 Harper's Monthly Mag. 227-31, at 228 (July 1864))); *see also* Cong. Globe, 37 Cong., 3 Session., 952, 955 (1863) (Congress enacted the False Claims Act "to assist in ferreting out unscrupulous defense contractors who committed fraud against the Union Army by delivering bullets loaded with sawdust.").

[3] *U.S. v. Griswold*, 24 F. 361, 366 (D. Or. 1885), quoted with approval in *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 541 n.5 (1943).

2. Roche executed a successful fraudulent scheme to sell expensive courses of the drug Tamiflu (oseltamivir)[4] by positioning it as a necessary medication to thwart any frightening influenza outbreak, when in reality Tamiflu is more likely to perpetuate an influenza pandemic than to stop one. Roche's false representations caused the United States and various state governments to stockpile millions of doses of Tamiflu. More specifically, Roche aggressively marketed the drug as a means of reducing influenza spread, severity, and complications, thereby reducing hospitalization and mortality or avoiding the illness altogether. However, as Roche well knew, Tamiflu does not deliver what was promised: it does not prevent the transmission of the influenza virus, it does not reduce the severity of influenza, and it does not prevent complications or reduce hospitalization or mortality for influenza patients.

3. After Roche obtained Food and Drug Administration (FDA) approval of Tamiflu based on evidence of its "modest" reduction of the duration of influenza symptoms, Roche prepared—or caused to be prepared—purported scientific "studies" concluding that Tamiflu had certain efficacies beyond those recognized by the FDA. Focusing on the federally-adopted recommendations from the World Health Organization (WHO) to describe the attributes of an effective influenza antiviral drug, Roche used its new "studies" to tout Tamiflu as efficacious for pandemic use. Specifically, Roche claimed that Tamiflu reduced the incidence of influenza spread, severity, and complications, thereby reducing hospitalization and mortality.[5] However, Roche's newly published "studies" misrepresented Tamiflu's capabilities to achieve the desired pandemic uses. Roche's misrepresentations were successful in peddling Tamiflu to the United

[4] Tamiflu is a formulation of the generic drug oseltamivir, and the two words are used interchangeably in this Amended Complaint.

[5] Accordingly, reference to "pandemic efficacies" or "pandemic use" in the Amended Complaint means the ability of a drug to reduce the incidence of influenza spread, severity, complications, hospitalization, and mortality.

States and various state governments, and Tamiflu became the government's preferred antiviral to purchase for the Strategic National Stockpile (SNS) for influenza pandemic use.

4. Tamiflu is an oral antiviral prescription drug (not a vaccine) for influenza and is included in a class of medicines called neuraminidase inhibitors. These drugs claim to prevent any influenza virus strain from spreading inside the body. Roche claimed Tamiflu can be used to avoid transmitting influenza and, for persons with influenza, to reduce the duration of symptoms and avoid complications and hospitalization. To market these claims, Roche relied on a number of allegedly scientific studies, but the studies are flawed and affected by reporting bias (*e.g.*, written by Roche-hired ghostwriters or persons with close ties to the company). The actual clinical data does not support Roche's claims. Roche successfully hid these facts for many years, among other things, by selectively citing its studies, obfuscating and suppressing the data that runs counter to its marketing message, and utilizing lobbyists, key opinion leaders, and ghostwriters to promote what makes Tamiflu sell—a deceptive promise to alleviate the fear of an influenza pandemic. Roche has also effectively downplayed adverse effects of taking the drug, effects that may outweigh the benefit.

5. Federal and state governments have paid hundreds of millions of dollars for Tamiflu since 2004. But they have not gotten what they paid for. This classic case of traditional fraud fits squarely within the FCA and its state counterparts.

6. Relator Thomas Jefferson, a physician and medical researcher, initially accepted Roche's misrepresentations about the effectiveness of Tamiflu. But concerns about Tamiflu's efficacy caused him to examine Tamiflu's claimed effectiveness more closely. His requests for Roche's clinical study reports were initially resisted. But when he finally received and analyzed the Roche data, Relator objectively determined Tamiflu is not effective for pandemic use, and at

best, provides only a very small benefit of reducing the duration of influenza symptoms. He further determined the minimal benefit offered by Tamiflu did not outweigh the risk of negative side effects, including nausea, depression, anxiety, and psychosis. In the end, Relator identified an ineffective product, masterfully marketed to fill Roche's coffers at public expense. This is precisely the type of scheme that the FCA is designed to stop in its tracks.

7. The FCA prohibits selling goods to the government that are not what the government bargained for. In fact, the sale of decrepit mules and horses to the government in 1863 was one of the reasons why Congress enacted the FCA. The facts here are similar. Tamiflu was sold to the government to stockpile for pandemic use. Tamiflu, however, does not deliver the pandemic use benefits that the government sought and Roche said it would deliver. Contrary to Roche's representations, Tamiflu does not reduce severity, complications, hospitalization, or mortality from influenza, nor does it prevent the transmission of influenza.

8. Roche knew that its purported "scientific" evidence was severely flawed and did not support its pandemic use representations, making those representations false. Accordingly, this is not a case about scientific disputes or medical judgment. It is a case about traditional fraud. Roche's claims for payment violated the FCA because Roche fraudulently misrepresented Tamiflu's efficacy for pandemic use and delivered goods that did not conform to the specifications the government bargained and paid for. Roche sold, and the government purchased, the equivalent of bullets filled with sawdust.

II. JURISDICTION AND VENUE

9. This Court has original subject matter jurisdiction over this civil matter pursuant to 28 U.S.C. §§ 1331 and 31 U.S.C. § 3732(a), which specifically confers jurisdiction on this Court over actions under 31 U.S.C. §§ 3729 and 3730. The Court also has original jurisdiction

over the state law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under state laws for the recovery of funds paid by the FCA States and arises from the same transaction or occurrence brought on behalf of the United States under 31 U.S.C. § 3730.

10. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because Defendants can be found and transact business in this District. In addition, Defendants committed acts proscribed by 31 U.S.C. § 3729 in this District.

11. Relator Jefferson is aware of no statutorily relevant public disclosure of the allegations or transactions in this Amended Complaint. Even if such a disclosure had occurred, Relator is the "original source" of the allegations in this Amended Complaint and meets the requirements of 31 U.S.C. § 3730(e)(4)(B). During his independent investigation of Tamiflu, Relator acquired material, direct, independent, and non-public knowledge of the information on which the allegations in this Amended Complaint are based, and he voluntarily and in good faith provided this information to the government before filing this action.

III. THE PARTIES

A. Plaintiffs/Relator

12. The United States of America is the plaintiff on whose behalf Relator brings this action under the FCA. The United States acts through its various agencies and departments, including the Department of Health and Human Services (HHS) and other relevant government payors.

13. The FCA States are also plaintiffs on whose behalf Relator brings this action under their respective state law counterparts to the FCA.

14. Relator Thomas Jefferson is a citizen of the United Kingdom and a resident of Italy. He is a physician and researcher with a specialty in Public Health. He has several degrees

and certificates, and he has authored more than two hundred articles and co-authored five books. Jefferson is a member of the Cochrane Collaboration (Cochrane), a not-for-profit global organization with collaborators from over 130 countries. Cochrane does not accept commercial or conflicted funding to ensure freedom from influence by commercial interests. Jefferson works to independently gather and summarize the best evidence from research to help individuals make informed choices about treatment. Jefferson is a member of the Cochrane Acute Respiratory Infections Group and has completed extensive reviews of neuraminidase inhibitors for preventing and treating influenza. In the course of his work, he uncovered and exposed Roche's fraudulent use of so-called "studies" to claim effects and benefits that Tamiflu does not deliver.

B. Defendants

15. Defendant Roche Holding AG is an international manufacturer and developer of pharmaceuticals and diagnostic products. In business since 1896, it has over 90,000 employees worldwide. Its principal place of business is in Basel, Switzerland, and it manufactures, markets, and sells pharmaceuticals worldwide. Roche's pharmaceuticals business includes many prescription drugs in multiple therapeutic areas, including Accu-Chek diabetic testing supplies, Avastin for cancer treatment, and Tamiflu for influenza. In 2018, Roche Holding AG had more than $45 billion in worldwide pharmaceutical sales.

16. Defendant Hoffmann-La Roche, Inc. is a subsidiary of Roche Holding AG and operates Roche Holding AG's pharmaceutical development and production in the United States. It is a New Jersey corporation and has its principal place of business at 340 Kingsland Street, Nutley, New Jersey.

17. Defendant Genentech, Inc. is a Delaware corporation with its principal place of business at 1 DNA Way South, San Francisco, California. On March 26, 2009, Roche Holding

AG completed the purchase of Genentech for $47 billion. Hoffmann-La Roche and Genentech then combined their pharmaceutical operations in the United States. Genentech's San Francisco campus became their combined pharmaceutical headquarters.

IV. STATUTORY AND REGULATORY CONTEXT

A. The False Claims Act

18. This case alleges violations of 31 U.S.C. § 3729(a)(1)(A) and (a)(1)(B) and their pre-2009 counterparts, 31 U.S.C. § 3729(a)(1) and (a)(2), respectively.

19. The FCA provides:

> (a) Liability for Certain Acts.
>
> (1) . . . any person who
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [6]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;[7]
> . . . is liable to the United States Government. . . .
>
> (b) Definitions. For purposes of this section—
>
> (1) the terms "knowing" and "knowingly"—
>
> (A) mean that a person, with respect to information--
> (i) has actual knowledge of the information;
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
> (iii) acts in reckless disregard of the truth or falsity of the information, and
>
> (C) require no proof of specific intent to defraud;
>
> (2) the term "claim"—

[6]Prior to May 19, 2009, this section read "knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1).
[7]Prior to June 6, 2008, this section read "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government." 31 U.S.C. § 3729(a)(2).

> (A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that—
> (i) is presented to an officer employee, or agent of the United States; or
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest and if the United States Government
> (I) provides or has provided any portion of the money or property requested or demanded; or
> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; . .
>
> (2) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

31 U.S.C. § 3729(a)(1)(A), (b) (FCA as amended by the Fraud Enforcement and Recovery Act of 2009, Public Law 111-21).

20. The FCA is "the Government's primary litigative tool" for combating fraud.[8] It applies "expansively … 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'"[9]

B. Government Contracting

21. Under FAR 52.212-4(a), a contractor "shall only tender for acceptance those items that conform to the requirements of th[e] contract."

22. Under FAR 52.212-4(o), a contractor also "warrants and implies that the items delivered [to the government under the contract] are merchantable and fit for use for the particular purpose described in th[e] contract."

[8] S. Rep. No. 99-345, at 2 (1986).
[9] *Cook Cty. v. U.S. ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *U.S. v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)).

V. FACTUAL ALLEGATIONS

A. The Context of Roche's Fraudulent Scheme Was the Approval and Promotion of Neuraminidase Inhibitors, such as Tamiflu, as a Component of Influenza Pandemic Planning.

1. Antivirals and Tamiflu

23. Antivirals are drugs generally designed to suppress or inhibit a virus's ability to replicate.

24. Gilead Sciences, Inc. is an international manufacturer and developer of pharmaceuticals. In 1996, Gilead invented Tamiflu and licensed it to Roche under a 1996 Development and License Agreement. The two companies collaborated on its development and advancement through clinical trials.

25. Roche characterizes Tamiflu as an oral antiviral influenza treatment that belongs to a class of medicines called neuraminidase inhibitors, which are intended to prevent clinically relevant influenza virus strains from spreading inside the body.

26. Roche originally produced Tamiflu to meet the demands of seasonal influenza, but was not satisfied with the revenue it produced.

27. Two generic antiviral drugs for use against influenza are amantadine and its derivative rimantadine. They have been shown to be clinically effective in preventing illness caused by influenza A.

28. Approved by the FDA about the same time as Tamiflu, Relenza is a neuraminidase inhibitor sold by GlaxoSmithKline as a powder for oral inhalation. It is a formulation of the generic drug zanamivir and is indicated for the treatment and prophylaxis of influenza.

2. The Rise of the Pandemic Market

29. The WHO is a specialized agency, related to the United Nations, with the purpose of promoting and protecting the health of all peoples.

30. On April 1, 1999, the WHO released its *Influenza Pandemic Plan: The Role of WHO and Guidelines for National and Regional Planning* (1999 WHO Guidelines).

31. The WHO strongly recommended that all countries establish multidisciplinary National Pandemic Planning Committees (NPPCs), responsible for developing strategies appropriate for their countries in advance of the next influenza pandemic. The WHO defines a pandemic as occurring with the emergence and spread of a new influenza virus for which most people do not have immunity.

32. While the United States had already been engaged in influenza pandemic planning at the time, the 1999 WHO Guidelines provided a further template for this work.

33. The WHO described typical influenza epidemics as causing increases in incidence of pneumonia and lower respiratory disease as witnessed by excess rates of hospitalizations or mortality. Concerned about the difficulty and unlikelihood of rapidly producing a vaccine that would be effective against a pandemic influenza strain, the WHO recommended planning alternative control measures in advance to reduce the spread and severity of pandemic influenza.

34. The 1999 WHO Guidelines further discussed a wide range of measures for an NPPC to consider, including restricting travel and public gatherings, quarantine, vaccine development, and the use of antiviral drugs. It also encouraged considering whether there is a need to establish strategic stockpiles of an antiviral drug, such as rimantadine, for use by laboratory workers or medical staff at high risk of exposure to a new influenza sub-type before vaccines against it could be manufactured. To the pharmaceutical industry, the WHO's remarks

in this regard created a new, global market for the governmental stockpiling of antivirals with efficacies aligned with the WHO's pandemic response goals.

35. With respect to using antivirals as part of an influenza pandemic response plan, the 1999 WHO Guidelines noted that antiviral agents to prevent or treat influenza infection were available, including amantadine and its derivative rimantadine.

36. WHO noted that amantadine and rimantadine had been found to be effective in preventing illness caused by influenza A. It also noted that amantadine and rimantadine were "shown to be clinically effective in preventing illness, when taken throughout the period of exposure to virus in a normal epidemic or outbreak situation," and could "reduce the severity and duration of illness, when taken early after onset." Thus, amantadine and rimantadine already had claimed a track record of efficacy for pandemic uses, e.g., reducing influenza severity.

37. With much of the pandemic landscape identified, Roche saw the opportunity to position Tamiflu as more than just a drug for seasonal influenza. The worldwide market for Tamiflu could be expanded dramatically if Roche could claim the drug as effective for pandemic use; that is, reducing the incidence of spread, severity, complications, hospitalization, or mortality. And that is exactly where Roche focused its deception in the United States, as alleged below.

3. FDA Approvals, Indications, and Refusals

38. On April 30, 1999, Roche submitted its New Drug Application (NDA) for Tamiflu, seeking an indication for influenza treatment. After a lengthy review of the clinical trial data submitted, the FDA approved this indication on October 25, 1999:

> TAMIFLU is indicated for the treatment of uncomplicated acute illness due to influenza infection in adults.

39. The FDA stated in its Medical Review, however, that treatment with Tamiflu only "confers a modest benefit in terms of reducing the duration of uncomplicated influenza illness."

40. The FDA specifically concluded that the clinical trial data did **not** support an indication that treatment reduces the severity of symptoms.

41. The reason for denial was that Roche used Area Under the Curve (AUC) measures to support its claim that Tamiflu reduces severity. The FDA found this method was inappropriate and did not support the claim because the symptom scores were represented by arbitrarily chosen numbers, without giving consideration to the differing clinical significance conferred by individual symptoms.

42. The FDA further stated that the clinical trial data did **not** support any additional treatment indications. Specifically the FDA noted the absence of any information on whether Tamiflu was effective in preventing influenza-related complications such as hospitalization, secondary bacterial infections, or mortality.

43. A year later, on May 22, 2000, Roche submitted a supplemental NDA (sNDA) seeking an indication for influenza prophylaxis, as well as treatment indications for reduction of complications and hospitalizations.

44. On November 20, 2000, after reviewing the clinical trial data submitted, the FDA approved an indication for the prophylaxis of influenza in adult patients and adolescents 13 years and older.

45. In approving this indication, the FDA again limited its reach, only affirming that Tamiflu "reduced the incidence of laboratory-confirmed clinical influenza type A and type B;" that is, the FDA approved an indication that Tamiflu only prevented persons from developing symptomatic influenza.

46. The FDA specifically concluded that the clinical trial data did **not** support an indication that Tamiflu prevents persons from becoming infected with asymptomatic influenza and did **not** support an indication that Tamiflu interrupts virus transmission from a person with influenza.

47. With this sNDA Roche sought broader treatment indications aligned with the pandemic uses articulated in the 1999 WHO Guidelines. Specifically it sought an indication that Tamiflu reduces secondary complications, defined as otitis media, sinusitis, lower respiratory tract infections, bronchitis and pneumonia. Roche further tracked hospitalizations in the context of secondary complications.

48. The FDA rejected any such treatment indications, stating that the clinical trial data did **not** support an indication that oseltamivir reduced secondary complications.

49. The reasons articulated in the sNDA included: the lack of predefined minimum diagnostic criteria for complications in the protocol; insufficient radiographic evaluation in most cases and insufficient microbiologic information in one case; and inability to determine whether "acute bronchitis" was a secondary bacterial complication of influenza or a symptom of uncomplicated influenza itself.

50. In sum, in the course of responding to Roche's NDA and sNDA, the FDA refused to conclude that Tamiflu was capable of reducing the incidence of influenza spread, severity, or complications, let alone impacting hospitalization or mortality outcomes. Accordingly, Roche knew that Tamiflu's clinical trial data did not provide support that Tamiflu had efficacy for pandemic use.

51. Over the years, the FDA slightly broadened the population groups included in its indications to include treatment of uncomplicated influenza in patients 2 weeks of age and older, and prophylaxis of influenza in patients 1 year and older.

52. The prescribing information stated that the most common side effects of taking Tamiflu were nausea and vomiting in treatment studies, and nausea, vomiting, diarrhea, and abdominal pain in prophylactic studies.

53. For treatment purposes, the prescribing information stated that patients generally should take Tamiflu over a period of 5 days; while for prophylactic purposes, the regimen was 10 days after close contact with an infected individual. Generally, to confer any benefit, Tamiflu should be taken within 48 hours of the onset of symptoms.

54. Finally, from the beginning, Roche knew, and has admitted, from at least 2000 through the present, that (1) the efficacy of the drug for subjects with chronic cardiac disease or respiratory disease has not been established; (2) that no clinical trial information is available with respect to influenza treatment for any patients with sufficiently severe or unstable medical conditions to be considered at imminent risk of requiring hospitalization; and (3) that serious bacterial infections may have influenza-like symptoms or may occur at the same time or as complications during the course of influenza and that Tamiflu has not been shown to prevent such complications.

B. Relator Jefferson Exposes the Falsity of the Studies Relied on by Roche to Market Tamiflu for Pandemic Use.

55. Relator Jefferson is a physician and medical researcher, including in the areas of public health and acute respiratory infections. He has researched issues related to neuraminidase inhibitors since at least 1999. Until 2009, Relator had concluded that Tamiflu was effective in

reducing the incidence of influenza spread, severity, complications, hospitalization, and mortality. In drawing this conclusion, Relator relied on articles promoted by Roche that purported to reflect those results in clinical trials.

56. However, in the summer of 2009, a pediatrician posed a question to Relator about his early conclusions that Tamiflu was effective for reducing complications from influenza. This caused Relator to re-evaluate his assessment of Tamiflu. He embarked on a quest to conduct his own data analysis to determine whether Roche's claims about Tamiflu's effectiveness were reliable.

57. A significant context for Relator's independent analysis was his understanding that influenza antivirals such as Tamiflu (and other NIs) are used and have been stockpiled for treating and preventing pandemic influenza, as will be discussed below. Relator recognized that international and national recommendations to stockpile influenza antivirals are based on claims that the drug will reduce complications and transmission of influenza, thereby containing the spread of influenza and allowing time for production of longer term interventions such as vaccines. He recognized that if the claims about influenza antivirals are true, they could be a useful public health measure to contain the impact and spread of the virus. But since Tamiflu had become a public health drug, Relator felt the urgency to independently scrutinize all the evidence about the drug to provide policy-makers, among others, with a complete and unbiased view of the benefits and risks of the use and stockpiling of Tamiflu for pandemic influenza.

58. Relator started his investigation by seeking the underlying data for a key Roche article, *Impact of Oseltamivir Treatment on Influenza-Related Lower Respiratory Tract Complications and Hospitalizations*, 163 Arch. Intern. Med. 1667 (July 29, 2003) (*Kaiser 2003*). Relator reached out to persons named as the study's authors, Drs. Frederick Hayden and Laurent

Kaiser, asking them directly for the data they used. Dr. Hayden professed not to have the information and pointed to Dr. Kaiser, who in turn pointed to Roche. Relator then requested the information directly from Roche, which Roche refused to provide.

59. In the fall of 2009, Relator again requested the primary data from Roche. Roche refused to provide the data unless Relator signed a non-disclosure agreement, which he refused to do. Over the next 4 years, Relator persistently pursued the primary data used by Roche in its studies with the intent of performing an independent analysis of the data to uncover the true efficacy of Tamiflu for preventing and treating influenza. His efforts included multiple requests to Roche for a full set of clinical study reports. Finally, in late 2013, Roche relented and gave Relator the clinical study reports for what appeared to be most of the company-sponsored clinical studies of oseltamivir.

60. In total, Relator collected 107 clinical study reports from many sources including Roche, the European Medicines Agency (EMA), and GlaxoSmithKline. He assessed comments by the FDA, EMA, and Japanese regulators. The clinical studies included 53 trials in Stage 1 (a judgment of appropriate study design) and 46 in Stage 2 (formal analysis), including 20 oseltamivir (9,623 participants) and 26 zanamivir trials (14,628 participants). Relator concluded that inadequate reporting put most of the zanamivir studies and half of the oseltamivir studies at a high risk of selection bias. Non-identical presentation of placebo put some studies of oseltamivir at risk from performance; some oseltamivir studies had attrition biases that were too high; and there was also evidence of selective reporting for both the zanamivir and oseltamivir studies.

61. Nonetheless, after a thorough independent analysis of the raw data he collected Relator established and brought to light the following conclusions about Tamiflu:

- **Duration of Influenza Symptoms**: Relator's investigation generally confirmed Roche's claim that Tamiflu reduced the time to first alleviation of symptoms; his analysis showed about a 10% reduction.
- **Reduction of Risk of Hospitalization or Complications:** Relator's investigation found Roche's claims in this regard to be false. He found no credible evidence that Tamiflu reduced the risk of complications of influenza, particularly pneumonia, nor reduced the risk of hospitalization or death. With respect to other specific complications, Relator's analysis determined that Tamiflu had no significant effect on the rate of bronchitis, sinusitis, or otitis media. With respect to higher risk individuals, such as children with asthma or the elderly, Relator found no evidence that Tamiflu reduced risks of complications.
- **Prophylaxis**: Relator's investigation determined that a claim that Tamiflu prevented the transmission or spread of influenza from person to person was false. This was because Tamiflu minimally reduced the risk of developing symptomatic influenza, but had no effect on the reduction of asymptomatic influenza. In other words, Tamiflu did not prevent a person with influenza from infecting another person. Further, the minimal reduced risk of developing influenza symptoms was of smaller magnitude than seen in hand washing to prevent severe acute respiratory syndrome (SARS).

62. Relator found the prophylaxis result particularly troublesome in a pandemic situation, because it means that persons taking Tamiflu as a prophylaxis could be unknowingly

infected with the influenza virus. Then, rather than stay home and limit the risk of further transmission, they would go about their daily routines, including use of public transportation and international travel, and expose larger numbers of people to the pandemic virus. His analysis showed that Tamiflu therefore hinders rather than assists the government's ability to contain and combat an influenza pandemic.

63. Relator further concluded that the minimal benefit of time to alleviation of symptoms was offset by the harms of Tamiflu. His analysis showed that when Tamiflu was used as a treatment for adults there was an increase in nausea by 3.66% and an increase in vomiting by 4.56%, while there was a decrease in diarrhea by 2.33%. When Tamiflu was used as a prophylactic for adults there was an increase in headaches by 3.15% and an increase in nausea by 4.15%, as well as psychiatric effects and renal events.[10]

64. These results led Relator to further conclude that there was no evidence for clinicians or policy-makers to use Tamiflu to prevent serious outcomes in pandemic influenza outbreaks and that the drug labeling should be changed to reflect these findings.

65. Relator's thorough investigation and analysis of the available data makes his work the most comprehensive and reliable assessment of Tamiflu to date. Moreover, and as described in more detail below, Relator's conclusions have been corroborated by other persons looking at Roche's claims about Tamiflu—including Roche's own selected team to re-create the conclusions reached by its *Kaiser 2003* article.

66. In the course of his quest to get complete Tamiflu data from Roche, Relator's investigation uncovered other facts undermining the credibility of Roche's claims about Tamiflu's efficacy for pandemic use.

[10] Relator also concluded that the mode of action claimed for oseltamivir—interrupting viral transmission and reducing complications—was not supported by any data the reviewers were able to access.

67. In 2009, two former medical writers who worked for Adis International, a medical publishing service, contacted Relator privately and told him that they had worked on Roche's Tamiflu account. According to one of the medical writers,[11] Roche sent clinical trial data to Adis that Roche had already compiled and processed. Then, Adis used that secondary material to draft manuscripts. The articles produced by Adis were submitted for publication to journals, such as *JAMA, The Lancet,* and the *Archives of Internal Medicine*. The medical writer was personally involved in the drafting of several articles related to Tamiflu.

68. The medical writers were never given raw data, only data that had been previously processed by Roche. Furthermore, the Adis writers told Relator that Roche's marketing department put pressure on them to "get messages out" based on a list of key messages provided by Roche. One writer said, "In the introduction for Tamiflu, I had to say what a big problem influenza is. I'd also have to come to the conclusion that Tamiflu was the answer."

69. Learning about Adis's involvement in allegedly scholarly articles about clinical trial results further reduced Relator's confidence in the validity of the results reflected in articles published by Roche. This is due to the likelihood of reporter bias and Roche's close involvement and control of the clinical data.

70. Relator's data analysis and investigation exposed the fact that Tamiflu was not efficacious for pandemic use. His further investigation of Roche's conduct is described below, revealing a scheme built around false statements about Tamiflu designed to procure massive sales of Tamiflu to the government for its influenza pandemic stockpile.

[11] Relator is in possession of the medical writer's name and can provide it when appropriate.

C. Roche Knowingly Created Fraudulent Support for Pandemic Use of Tamiflu.

71. Undeterred by its failure to obtain the FDA's endorsement of Tamiflu as effective for pandemic use in 1999 and 2000, and with the pandemic market on the line, Roche embarked on a fraudulent campaign to convince the United States to add Tamiflu to its Strategic National Stockpile. A key aspect of this campaign involved producing and publishing journal articles tailor-made to create the appearance that, notwithstanding the lack of scientific support about Tamiflu's efficacy for pandemic uses, the drug had efficacies precisely aligned with pandemic response requirements articulated by the government.

72. Roche's first article titled *Effectiveness of Oseltamivir in Preventing Influenza in Household Contacts*, 285 JAMA 748 (Feb. 14, 2001), with first named author Robert Welliver, (*Welliver 2001*), purported to report the results of clinical study WV15799. The article claimed that postexposure prophylaxis with oseltamivir protected close contacts of influenza-infected persons against influenza illness, which would be consistent with the FDA's findings (i.e., persons did not show symptoms of influenza). However, the final paragraph of the article went further and asserted that the drug effectively prevented transmission of influenza within households following prompt initiation of short-term prophylaxis in families, implying that Tamiflu prevents person-to-person transmission of the influenza virus—which it does not.

73. As Relator's investigation uncovered, ghostwriter company Adis International participated in the writing of this article on behalf of Roche. In addition, one of the authors, Arnold Monto, was a member of Roche's advisory board and was a paid consultant to Roche.

74. Laurent Kaiser, MD, was the first named author of a subsequently published Roche article discussed above, *Kaiser 2003*.

75. Dr. Frederick Hayden also played a significant role in the development of this article. Notably, Dr. Hayden received significant payments from Roche as a paid consultant in or about the late 1990s and early 2000s. Dr. Hayden has been an advocate of Roche's claims regarding Tamiflu ever since.

76. Roche's *Kaiser 2003* article was a pooled analysis of 10 clinical studies, 9 of which Roche had previously submitted to the FDA in its NDA and sNDA. The studies purported to show that—notwithstanding the lack of scientific support—Tamiflu reduced influenza-related lower respiratory tract complications (LRTCs) measured by antibiotic use and hospitalizations. Importantly, Roche funded each of the underlying clinical trials used in the analysis, funded *Kaiser 2003* itself, and compiled, processed, and analyzed the data that Drs. Kaiser and Hayden, and the 4 Roche employee authors claimed as the basis of the article's conclusions.

77. Other than Drs. Kaiser and Hayden, the remaining authors were all Roche employees. The authors employed by Roche include:

- Cynthia Watt: employed by Roche from 1999 to present;
- Tracy Mills: employed by Roche when *Kaiser 2003* was published;
- Paul Mahoney: employed by Roche as statistician from 1998-2018;
- Penelope Ward: employed by Roche from 1996-2001 and 2003-2008.

78. Relator's investigation found that Roche's own statisticians completed the data analysis and processing, the results of which were then given to the *Kaiser 2003* authors for use in the article. Further, he found that Roche's "messages" for this article were aimed at showing reduction in influenza-related complications and hospitalizations.

79. Specifically, Roche's *Kaiser 2003* article claimed that, among persons with laboratory confirmed influenza infection, Tamiflu reduced the incidence of LRTCs (primarily

bronchitis) leading to antibiotic intervention by 55% and showed a 50% reduction in overall hospitalizations in the oseltamivir-treated, influenza-infected at-risk[12] patients, as well as a 50% overall reduction in hospitalizations due to respiratory disease among all recipients of oseltamivir.

80. As noted above, and as will be discussed in more detail below, the article's conclusions were false, among other things, because the underlying studies were inherently flawed, could not be replicated, and the person listed as the author of the study involving the largest number of subjects (M76001) disclaimed involvement in the study.

81. Roche sought publication of its "complications and hospitalizations" article in scientific journals, and it was ultimately published on July 28, 2003 in *Archives of Internal Medicine* (*Archives*).

82. Then, just three days later, on August 1, 2003, Tamiflu was added to the list of approved drugs for the Strategic National Stockpile. The close timing of Roche's *Kaiser 2003* publication and Tamiflu's addition to the SNS indicates that Roche met with the federal government about its inclusion as soon as it could tout the claimed, but fraudulent, results from that article.

83. A third article used to bolster Tamiflu sales for pandemic use was also by Dr. Hayden, and was titled *Management of Influenza in Households: A Prospective, Randomized Comparison of Oseltamivir Treatment With or Without Postexposure Prophylaxis*. 189 J. Infectious Diseases 440 (Feb. 1, 2004) (*Hayden 2004*). In the study underlying the article, the "index case" (initial person with influenza-like illness) received oseltamivir for 5 days, and all

[12] *Kaiser 2003* defined "at-risk patients" as "immunized or unimmunized community-living elderly persons 65 years or older and adults and adolescents with chronic obstructive airways disease, asthma, and/or cardiac disease of sufficient severity to require regular outpatient medical care."

household members began a 10-day course of oseltamivir within 48 hours of the index case's first onset of influenza symptoms. While the stated results showed prophylaxis efficacy only in reducing the incidence of *symptomatic* influenza (*i.e.*, persons did not show symptoms associated with influenza), the conclusion boldly misstated that "prophylaxis with oseltamivir was an effective option for preventing the *transmission* of influenza within households." In other words, the article was drafted to claim that a person with influenza who took Tamiflu could not transmit the virus to others, knowing that was not case.

84. Absent sufficient scientific support to claim that Tamiflu was effective for pandemic uses, Roche manufactured the above articles touting studies that claimed to reach the conclusion that Tamiflu could reduce influenza spread, severity, complications, hospitalization, and mortality. With those misrepresentations in hand, Roche was able to pocket over $1.4 billion from its sales of Tamiflu to federal and state governments for pandemic use.

D. The Government Relied on Roche's Fraudulent Representations in Deciding to Purchase Tamiflu.

85. In the early 2000s, Roche had numerous meetings with various United States agencies (i.e., HHS and CDC) about Tamiflu and pandemic planning and stockpiling. These included multiple presentations by the Roche marketing team, several meetings involving George Abercrombie (Roche CEO) and HHS Secretaries Tommy Thompson and Michael Leavitt and their staffs, and testimony by Roche Medical Director Dominic Iacuzio. In a 2006 legislative hearing, Abercrombie noted that Roche was "proud of our history of partnership with the Government, and pandemic preparedness and response planning."

86. Roche's efforts and "partnership" paid off. The HHS incorporated into its own draft and final pandemic plans Roche's false and misleading "evidence" of Tamiflu's pandemic

efficacies. The impact of Roche's false statements about Tamiflu, including use of articles such as *Welliver 2001, Kaiser 2003, and Hayden 2004*, is evident in activities during 2004 and 2005, culminating in purchases of Tamiflu for the pandemic influenza stockpiles.

87. In August 2004, HHS issued its draft Pandemic Preparedness and Response Plan (2004 HHS Draft Plan). At a policy level, the draft plan aligned with the 1999 WHO Guidelines, stating that the goals of a pandemic response were to (1) limit morbidity (*i.e.*, the condition of being diseased) and mortality of influenza and its complications during a pandemic and (2) decrease social disruption and economic loss. Simply put, the purchase of an antiviral drug for pandemic use was intended to reduce the incidence of influenza spread, severity, complications, hospitalizations, and death.

88. The 2004 HHS Draft Plan's comments on the use of antivirals for both prophylaxis and treatment reflect Roche's misrepresentations. The planning document could not be clearer in conveying Roche's false statements: "when administered as prophylaxis, [Tamiflu] can be effective at preventing influenza and, as treatment, in reducing complications, hospitalization, and death."

89. Expanding on this statement, the 2004 HHS Draft Plan specifically noted that Tamiflu was added to the Strategic National Stockpile in 2003 and that "[a] combined analysis of data from 10 randomized, placebo-controlled trials using oseltamivir showed a 30% to 50% decrease in pneumonia and bronchitis and in hospitalizations." This statement is a direct reference to Roche's *Kaiser 2003* article.

90. Annex 7 of the 2004 HHS Draft Plan contained additional evidence of the government's reliance on Roche's *Kaiser 2003* article. The annex noted data points that could only have been derived from that article, specifically that (1) the impacts of oseltamivir therapy

on LRTCs of influenza and on influenza hospitalizations were calculated in a pooled analysis of 10 studies that included 3,591 adults and adolescents and (2) the use of oseltamivir resulted in a 55% reduction of LRTCs.

91. Based on Roche's misrepresentations, Annex 7 further concluded that, given the impact on pneumonia and hospitalizations, oseltamivir was likely to impact mortality.

92. On October 26, 2004, after the 2004 HHS Draft Plan was promulgated, Roche presented comments before HHS regarding the pandemic stockpiling plan, stating that Tamiflu could be used both to treat the flu and as a prophylactic, preventing those at risk from becoming infected. Roche claimed that if 80% of people exposed to the flu used targeted antiviral prophylaxis, the outbreak could be effectively contained. However, Roche knew at the time it made those statements that Tamiflu could not prevent transmission, and therefore would not be an effective containment measure.

93. Subsequently, on April 20, 2005, Roche's misrepresentations were presented by Dr. Hayden in a PowerPoint presentation to the HHS National Vaccine Advisory Committee Pandemic Influenza Working Group (HHS Working Group). That group was charged with making recommendations to HHS on the use of vaccines and antiviral drugs in an influenza pandemic. Dr. Hayden's presentation cited Roche's *Welliver 2001*, *Kaiser 2003*, and *Hayden 2004* articles to advocate that Tamiflu reduced influenza spread, severity, complications, hospitalizations, and mortality—the pandemic uses identified in the 2004 HHS Draft Plan. In particular, the PowerPoint included assertions about the efficacy of oseltamivir as a treatment for infected persons, citing Roche's *Kaiser 2003* article to assert at least a 50% reduction in hospitalizations and that Tamiflu prevented complications associated with influenza.

94. As to prophylaxis, the presentation to the HHS Working Group included a slide[13] that falsely represented that prophylaxis with oseltamivir is an effective option for preventing the transmission of influenza within households." This assertion was supported by a citation to *Hayden 2004*.

95. Another slide,[14] citing *Welliver 2001* in support of oseltamivir data, provided comparative rates for reduction in secondary influenza illness. A third slide,[15] citing *Hayden 2004* in support of oseltamivir data, purported to show that oseltamivir was superior to all of the other antivirals for reduction of secondary influenza illness. Both slides used the title "Influenza Prevention in Households," yet neither slide explained that Tamiflu did not prevent the transmission of asymptomatic influenza—that is, that a person could still be infected and capable of spreading the virus to others, yet may not show symptoms of influenza. These slides therefore falsely represented that Tamiflu prevents transmission of the influenza virus, when in fact, it cannot contain or combat the spread of influenza—a critical feature needed in a pandemic.

96. In a May 26, 2005 legislative hearing, Roche's Medical Director, Dominick Iacuzio, testified to the government and falsely stated that certain antiviral drugs, such as Tamiflu, could be used as a prophylactic to prevent those at risk from becoming infected.

97. The HHS Working Group met again on July 19, 2005, and agreed to joint recommendations for implementing the Pandemic Influenza Preparedness Plan. Yet again, the primary goal stated by the group was "to decrease health impacts including severe morbidity and death." "Critical assumptions" related to antivirals included that treatment with oseltamivir "will be effective in decreasing risk of pneumonia, will decrease hospitalization by about half (as

[13] "Oseltamivir PEP [post-exposure prophylaxis] in Households: *Reduction in Influenza Illness, 2000-01*."
[14] "Influenza Prevention in Households: *PEP without index treatment*."
[15] "Influenza Prevention in Households: *Combined index treatment and PEP*."

shown for interpandemic influenza), and will also decrease mortality." Again, this is a clear reference to the results claimed in Roche's *Kaiser 2003* article. Further alluding to *Kaiser 2003*, the rationales for five of the nine proposed priority groups to receive Tamiflu include words to the effect that the antiviral will reduce the risk of complications or hospitalization.

98. As part of its recommendations, the HHS Working Group proposed maintaining a minimum stockpile of about 40 million courses of treatment, and purchasing antivirals for the stockpile in the proportion of 90% oseltamivir and 10% zanamivir.

99. On August 10, 2005, Charles M. Helms, M.D., Ph.D., Chairman, National Vaccine Advisory Committee, communicated the recommendations to Cristina V. Beato, M.D. acting Assistant Secretary for Health Director, National Vaccine Program, HHS.

100. On November 1, 2005, HHS released its final Pandemic Influenza Plan (2005 HHS Final Plan), which included, at Appendix D, its focused recommendations on pandemic antiviral drug use. Appendix D opens by noting that the HHS Working Group voted unanimously on its recommendations on July 19, 2005. This was just months after Roche's misrepresentations were presented to the government in Dr. Iacuzio's testimony and Dr. Hayden's presentation. The prefatory comments noted that the committee considered decreasing health impacts, including severe morbidity and death, as the primary goal of a pandemic response. However, the document also affirmed the goal of preventing the spread of a pandemic influenza virus, by recommending use of 60% of the stockpile purchase for prophylaxis. Yet, Tamiflu could effectuate neither goal.

101. Consistent with the plan's statement of goals, Appendix D articulated "critical assumptions" regarding antivirals. The first critical assumption was that treatment with Tamiflu

"will be effective in decreasing risk of pneumonia, will decrease hospitalizations by about half…and will also decrease mortality."

102. This critical assumption showed reliance on Roche's *Kaiser 2003* and the PowerPoint presentation to the HHS Working Group, which, as noted above, included assertions about the efficacy of oseltamivir as a treatment for infected persons, citing Roche's *Kaiser 2003* article to assert at least a 50% reduction in hospitalizations.

103. The 2005 HHS Final Plan further referenced Roche's *Kaiser 2003* article in Supplement 7, "Antiviral Drug Distribution and Use." In describing the strategy for antiviral use during a pandemic it stated that pooled analyses of clinical trials of neuraminidase inhibitors suggested that early treatment may reduce the risk of hospitalizations by approximately 50%.

104. The fourth "critical assumption" encouraged commencing treatment within 48 hours because such early administration was most effective in decreasing the risk of complications and had the added benefit of shortening illness duration.

105. With respect to prophylaxis, the 2005 HHS Final Plan painted the picture—based on Roche's misrepresentations—that antivirals would reduce the spread of influenza infection. The plan repeatedly discussed and recommended antiviral prophylaxis administration to those at highest risk of becoming infected in order to control, contain, and slow the spread of outbreaks, thereby inferring that Tamiflu prophylaxis will prevent transmission and infection, not just the onset of symptoms. The report even asked healthcare providers to report to public health agencies any breakthrough infections while on prophylaxis, further underscoring the government's erroneous belief—created by Roche—that Tamiflu could actually prevent the spread of a pandemic influenza virus.

106. Further, Appendix D described the use of Tamiflu for treatment of the general population during a pandemic as including reduction of complications and mortality and decreasing spread: "Treatment reduces the risk of complications and mortality, reduces duration of illness and shortens time off work, and decreases viral shedding and transmission."

107. Both the 2004 and 2005 HHS pandemic plans made clear what the government was bargaining and paying for in choosing to stockpile Tamiflu for pandemic uses—a drug that reduced influenza spread, severity, complications, hospitalizations, and mortality. The pandemic plans clearly illustrated reliance on Roche's misrepresentations about Tamiflu's efficacy for pandemic use.

108. On November 4, 2005**,** HHS Secretary Leavitt testified about the HHS Pandemic Influenza Plan before The Committee on Government Reform, United States House of Representatives. He requested antiviral stockpiling of $1.4 billion to achieve the goal of 81 million courses of antivirals, which includes 75 million courses to treat those infected with the pandemic virus (25% of the American population) and maintain a reserve supply of 6 million courses as well "to contain an initial U.S. outbreak." He further announced that HHS anticipated fully funding 44 million treatment courses and would work with state partners to have them acquire the remaining 31 million courses with HHS paying for approximately 25% of the drug costs.

109. On December 30, 2005, Congress passed PL 109-148 and appropriated $3.3 billion for HHS pandemic influenza planning. $731 million of that amount was designated for antivirals.

110. On June 15, 2006, Congress passed PL 109-234, appropriated another $2.3 billion for HHS pandemic influenza planning, and designated $350 million for antivirals. The two-year

designation of federal funds for antivirals was $1.3 billion. About 90% of that amount, or approximately $1.17 billion, was to be spent on Tamiflu based on Roche's false representations about its efficacy for pandemic use.

111. On January 8, 2009, HHS Secretary Michael O. Leavitt issued his final report, *Pandemic Planning Update VI*. He reported that HHS had completed its goal of purchasing 50 million courses of antiviral drugs (Tamiflu and Relenza) for the federal stockpile, which would be allocated to the states to cover 44 million people, with 6 million courses reserved "to help contain the spread of an emerging pandemic" He further reported that states had purchased 22 million treatment courses of antivirals to date.

112. Roche engaged in a scheme to create false "evidence" to sell Tamiflu for pandemic use. It claimed that Tamiflu was effective for pandemic use when, in fact, it does not reduce the incidence of influenza spread, severity, complications, hospitalizations, or mortality. These false statements were presented to the government and were tailor-made to influence—and in fact became—the government's statement of antiviral pandemic use.

113. Roche's fraudulent representations to the federal and state governments ultimately caused them to pay well over $1.4 billion for a pandemic drug that could not deliver what Roche promised.

E. Roche's Fraudulent Claims and Conduct Violated the FCA.

114. The core determinant of whether a claim is "false or fraudulent" under the FCA is whether the government received the benefit of its bargain.

115. Here, the government bargained for an antiviral drug for pandemic use that would reduce the incidence of influenza spread, severity, complications, hospitalizations, and mortality. The plain language of the HHS's pandemic planning materials makes that evident.

116. As noted above, HHS directly stated that one of the "critical assumptions" underlying its purchase of Tamiflu for the pandemic stockpile was the drug's claimed efficacy in decreasing risk of pneumonia, decreasing hospitalizations by about half, and decreasing mortality.

117. Tamiflu was incapable of providing these pandemic efficacies. Accordingly, Roche presented claims for payment that were "false or fraudulent" because Roche delivered an inferior or nonconforming product that failed to provide the pandemic efficacies for which Tamiflu was marketed and purchased. Roche's misrepresentations caused the government to purchase Tamiflu for pandemic use.

1. Tamiflu Could Not Deliver the Influenza Pandemic Efficacies for which the Government Bargained and Paid.

a. The FDA Rejected Roche's Claims that Tamiflu Provided Pandemic Efficacies.

118. The FDA approved Tamiflu for treatment of uncomplicated acute illness due to influenza infection in adults, based on the clinical study data showing that use of Tamiflu resulted in a 1.3 day reduction in the median time until symptom improvement.

119. The FDA's prophylaxis indication is similarly limited. It only approved an indication that Tamiflu reduces the likelihood of displaying symptoms associated with influenza.

120. As discussed above, in response to Roche's NDA and sNDA the FDA refused to provide indications that Tamiflu:

- reduces influenza-associated complications, or mortality;
- reduces the severity of symptoms;
- prevents persons from becoming infected with asymptomatic influenza;
- interrupts virus transmission from a person with influenza; or

- reduces secondary complications.

121. The approved use of Tamiflu—a reduction of symptoms by 1.3 days—is not what the government bargained for in its purchase of Tamiflu.[16] Instead, and as reflected in the 396-page 2005 HHS Final Plan, the government sought a drug that would reduce the incidence of influenza spread, severity, complications, hospitalizations, and mortality, which are specifically stated as the "critical" reasons for purchasing Tamiflu for pandemic use and recommending that 90% of the stockpiled influenza antivirals stockpile consist of Tamiflu..

b. Relator's Investigation Concluded Roche Falsely Represented the Scientific Data.

122. Roche's *Kaiser 2003* article was based on 10 clinical trials that were pooled together for analysis.[17] They are WV15670, WV15671, WV15730, WV15707, WV15812, WV15872, WV15819, WV15876, WV15978, and M76001.

123. Roche had already presented 9 of the 10 underlying clinical studies examined in *Kaiser 2003*'s pooled analysis to the FDA as part of earlier approval processes, and the FDA had rejected them as evidence that the drug is effective for pandemic use. That is, the clinical studies did not support assertions that Tamiflu was capable of reducing the incidence of influenza spread, severity, complications, hospitalizations, or mortality.

124. The tenth clinical trial, M76001 was critical to the conclusions reached in Roche's *Kaiser 2003* article. Relator's investigation determined that without its inclusion, there was no basis to make any assertion that Tamiflu reduces the incidence of influenza severity, complications, hospitalizations, or mortality.

[16] When purchased for seasonal treatment (i.e. a 1.3 days reduction in time to alleviation of symptoms) Roche charges a significantly higher price for Tamiflu than it charges for the drug when designated for pandemic stockpiling.
[17] As a pooled analysis, Roche's *Kaiser 2003* is not as rigorous as a meta-analysis.

125. The M76001 trial period was from December 1998 to February of 1999, and was the largest of the 10 clinical trials. Although the M76001 clinical study report was completed by March 14, 2000, Roche did not include the study in its May 22, 2000 sNDA. Ultimately, M76001 was never provided to the FDA for pandemic use indications, made available to the public, or even peer-reviewed.

126. The primary and secondary endpoints of M76001 were not aimed at demonstrating Tamiflu's efficacy for pandemic use. Rather, they were to show alleviation of symptoms and tolerability, with the potential benefit to users being a faster recovery from influenza. However, Roche used the abstract about M76001 to conclude that that Tamiflu treatment resulted in a 50% reduction in complications and reduced severity.

127. Despite being the largest clinical study (including 1,447 treated participants during the 1998-1999 influenza season), the only publication of the results of M76001 is a one-paragraph abstract from September 2000 and allegedly presented at the 38th Annual Meeting of the Infectious Diseases Society of America.

128. Dr. John Treanor, whose name actually appears as the author of the written abstract, denounced having written the abstract. Based on his investigation and review of the data provided to him by Roche, Relator believes the likely "unofficial" author was Roche employee Tim McGarty.[18]

129. Thus, Roche's *Kaiser 2003* article relied on an *abstract* claiming a 50% reduction in complications, which has no admitted author, was never peer-reviewed, and was never

[18] Relevant here, McGarty was employed by Roche from 1990-1997 as a Senior Clinical Research Associate where he wrote protocols, monitored studies, and drafted Final Study reports. He returned to Roche in 2003, after a few years with Merck, followed by work (from 2000-2003) as a Clinical Trial Consultant as President of Rx Solution, Inc.

published in in any medical or scientific journal. The only potential author of this self-serving abstract is Roche.

130. Roche knew that, at the very least, the M76001 data would not satisfy the FDA's "substantial scientific evidence" standard. Rather than go through the proper approval process, Roche created its own article to falsely state that Tamiflu was effective for the pandemic uses the government sought. These facts completely undermine the reliability or trustworthiness of the conclusions stated in the M76001 abstract.

131. Moreover, Roche's failure to provide the M76001 data to the FDA with its NDA or sNDA violates New Drug Application regulations that require submission of all pertinent studies and other information possessed by the applicant relative to an evaluation of the NDA, regardless of the information's source. 21 C.F.R. § 314.50; *see also* 21 C.F.R. § 314.50(d)(5)(iv) (requiring the "clinical data section" of the NDA that describes "the clinical investigations of the drug" to include "[a] description and analysis of any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from clinical investigations, including controlled and uncontrolled studies of uses of the drug other than those proposed in the NDA, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers").

132. Relator learned during his investigation that even after *Kaiser 2003* was published, Roche has avoided scrutiny of its self-serving clinical study and never submitted it to the FDA for pandemic use indications—casting further doubt on its validity.

133. In the course of his independent study of the raw data underlying Roche's claims about Tamiflu's efficacy for pandemic use, Relator uncovered additional major flaws and conduct contributing to the falsity of the results Roche claimed. These included that Roche:

- failed to predefine in study protocols what constituted secondary illnesses, including sinusitis, bronchitis,[19] and pneumonia, leading to inconsistent diagnoses;
- counted self-reported, unverified pneumonia as a complication rather than radiologically confirmed pneumonia;
- failed to consistently ensure the recording of complications on diary cards;
- used prescription of an antibiotic as a surrogate for the presence of complications without any knowledge of the underlying reasons for the prescription;
- failed to treat index cases in prophylaxis trials;
- failed to follow data handling rules and procedures in the clinical trials;
- allowed multiple forms of bias to taint its study results, including using ghostwriters, having its own employees perform statistical analyses, funding the publication of supposedly scientific articles, using paid consultants as article writers; use of active ingredients in placebos that could cause gastrointestinal symptoms; and failure to use identical placebo and active drug capsule caps.

134. Ultimately, Relator's investigation and analysis of the data showed that Roche misrepresented the scientific support behind its claims that Tamiflu was effective for pandemic use in order to sell Tamiflu to the government for pandemic stockpiling.

[19] Roche was aware that it is at best questionable to consider acute bronchitis as a complication of influenza. Events commonly identified as "acute" bronchitis" represent a poorly defined clinical syndrome that is frequently a catch-all diagnosis for individuals with productive cough and has not been useful for regulatory decisions.

c. No Other Study Has Replicated the Results of Roche's Kaiser 2003 Article.

135. Studies to replicate the *Kaiser 2003* results have been attempted, but none has been able to replicate or confirm the outcomes claimed in *Kaiser 2003.*

136. In late 2009, Roche requested Drs. Miguel Hernan and Marc Lipsitch to conduct a study specifically for the purpose of confirming the results of the pooled study executed in *Kaiser 2003*, plus one additional clinical trial (*Hernan-Lipsitch 2011*[20]). The article resulting from their work indicated they were unable to do so. They were unable to find that Tamiflu had an effect on reducing hospitalizations. And with respect to reduction of complications, they were only able to show a 28% reduction, which is dramatically smaller than the 55% claimed in *Kaiser 2003*.

137. Another study, wholly independent of Roche, engaged in a similar analysis using the clinical studies underlying *Kaiser 2003*, plus one additional clinical trial. Conducted by Mark Ebell, the study (*Ebell 2012*[21]) found no evidence of a reduction in either complications or hospitalizations.

138. Both *Hernan-Lipsitch 2011* and *Ebell 2012* generally corroborate the analysis Relator performed as part of his investigation into the efficacy of Tamiflu. Accordingly, no methodologically comparable study has shown similar benefits to those claimed in *Kaiser 2003* regarding the use of Tamiflu for pandemic purposes.

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[20] Hernan MA, Lipsitch M. *Oseltamivir and risk of lower respiratory tract complications in patients with flu symptoms: a meta-analysis of eleven randomized clinical trials*. Clinical Infectious Diseases 2011;53(3):277–9.[PUBMED: 21677258]

[21] Ebell MH, Call M, Shinholser J. *Effectiveness of oseltamivir in adults: a meta-analysis of published and unpublished clinical trials*. Family Practice 2012;30(2):125-33.

2. Roche Knew Tamiflu Could Not Deliver the Pandemic Use for which the Government Bargained and Paid.

139. As discussed above, Roche presented Tamiflu to the United States as effective for pandemic use in many different ways, including through its executives, marketing team, lobbyists, key opinion leaders, paid experts, and articles. In fact, Relator is aware there were numerous communications and meetings between the Roche and government personnel in the early 2000s leading up to the pandemic stockpiling purchases. Yet Roche knew at least at the time of the FDA responses to its NDA and sNDA in 1999 and 2000 that Tamiflu was not effective for pandemic use.

140. As early as April 14, 2000, the FDA began to push back on marketing statements Roche was using because they were not supported by Roche's data. In a letter to Roche, the FDA identified a series of marketing claims that were misleading because the claimed reductions in severity and incidence of secondary infections were not supported by substantial evidence. The FDA's letter further directed Roche to immediately cease dissemination of promotional materials or activities that contain these or similar claims. Those claims included:

- "The pill with the power to stop the flu;"
- "Tame-the-flu with Tamiflu;"
- "Tamiflu will reduce duration of the flu by 31%;"
- "Tamiflu will reduce the severity of influenza symptoms by 38%;" and
- "Tamiflu reduces incidence of secondary complications (*i.e.*, bacterial infections) by 45%."

141. Further evidence of Roche's scienter was its push to get *Kaiser 2003* published as a medium for promoting the false statements it needed to sell Tamiflu for pandemic use under the guise of a scientific study.

142. To that end, not long after publication of *Kaiser* 2003, Roche requested reprints of the *Archives* article for distribution. Roche's Marketing Manager, John Harrison, sent a reprint to the Relator on March 23, 2004 along with a letter saying that, "Our key messages focus on Tamiflu's ability to reduce the incidence of lower respiratory tract complications and hospitalization in influenza infected at-risk adults and elderly patients." Those "key messages" were derived from the conclusions touted by Roche's *Kaiser 2003* article.

143. It is clear from Roche's letter that the intent of distributing these reprints was to influence potential promoters and purchasers of the drug to believe that it had qualities that it did not have.

144. As of 2019, Roche has never presented the full data underlying *Kaiser 2003* to the FDA to seek approval for pandemic efficacies such as reduction of complications, hospitalizations and mortality, thus tacitly conceding its knowledge that *Kaiser 2003*, and its lynchpin M76001 study, do not provide sufficient evidence to support the claim that Tamiflu is effective for pandemic use.

145. Far from an innocent mistake or simple negligence, Roche was well aware at the time it sold Tamiflu to the government for pandemic purchases that Tamiflu had not been proven to have a positive impact on the potential consequences (such as hospitalizations, mortality, or economic impact) of seasonal, avian, or pandemic influenza.

146. Roche knew its promotion of Tamiflu for pandemic use could be challenged. It is clear Roche has worked to defend its billion dollar stockpiling investment with the government by, among other actions, seeking out Drs. Hernan and Lipsitch to recreate the conclusions of its *Kaiser 2003* article.

147. These facts constitute strong evidence of Roche's actual knowledge, deliberate ignorance, or reckless disregard in making false statements to the government about Tamiflu's ability to accomplish the pandemic goals, even though Defendants knew full well it could not.

3. Roche's Misrepresentations and Omissions Were Capable of Influencing—and Did Influence—the Government's Purchase of Tamiflu for Pandemic Use.

148. The government bargained and paid for antivirals "for pandemic use," and, as discussed above, Roche knowingly provided the government with an antiviral that could not achieve the pandemic efficacies the government sought to achieve. Roche's false statements went to the essence of the government's bargain in purchasing Tamiflu; indeed, the government parroted back those false statements in its pandemic planning materials.

149. The phrase "for pandemic use" references the fundamental antiviral pandemic efficacies detailed in the 2005 HHS Final Plan—the government intended to purchase a drug proven to reduce the incidence of influenza spread, severity, complications, hospitalizations, and mortality.

150. Roche's false statements were material because they were not only capable of influencing, but in fact did influence, the government's decision-making process. As discussed above, there is a direct match between the antiviral influenza pandemic uses the government sought and articulated in the draft and final HHS pandemic plans, and Roche's misrepresentations about the purported efficacy of Tamiflu "for pandemic use"—that it was proven to reduce the incidence of influenza spread, severity, complications, hospitalizations, and mortality. Therefore, Roche's false statements—promising what the government was seeking—were inherently material to governmental pandemic planning decision-makers' choice to purchase Tamiflu for the Strategic National Stockpile "for pandemic use."

151. Roche's actions demonstrate that it understood what types of statements (including false ones) were "capable of affecting" government decision-makers, and then delivered precisely those messages. Stated conversely, if Roche believed that reducing spread, complications, and hospitalizations were *immaterial* to the government's decision to purchase Tamiflu, it is unlikely that Roche would have sought those indications from the FDA, marketed Tamiflu for those uses, orchestrated the publication of *Kaiser 2003*, and presented those assertions to government decision-makers.

152. In making purchases, such as those in this case, the U.S. government incorporates FAR 52.212-4, which would require Roche to "only tender for acceptance those items that conform to the requirements of th[e] contract." The government further would require Roche to contractually warrant and imply that the goods it delivered were "merchantable and fit for use for the particular purpose described in th[e] contract." FAR 52.212-4(o). In other words, payment was conditioned on delivering goods that conformed with the contract.

153. Furthermore, Roche itself understood that pandemic efficacy was a material term of the contracts, and even affixed labeling on the packaging indicative that the Tamiflu was sold pursuant to government stockpiling contracts.

154. In short, Roche provided the government a drug that lacked the antiviral pandemic efficacies the government sought for its pandemic response objectives. Roche did not simply misrepresent the degree to which Tamiflu could deliver these efficacies; it sold the government the equivalent of bullets filled with sawdust.

4. Roche's False Statements Caused the Government to Purchase Tamiflu for Its Pandemic Stockpiles.

155. Roche's misconduct consisted of making false statements and submitting false claims that caused the federal and state governments to pay out money. Since the federal and state governments did not receive what they bargained for, damages are the full amount paid by the governments when they purchased Tamiflu for pandemic use.

156. As discussed above, Roche's fraudulent scheme caused the federal and state governments to recommend purchase of Tamiflu for their influenza stockpiles, Congress funded those purchases, and the Secretary of HHS reported back to Congress that the purchases had been made.

157. State purchases of Tamiflu for pandemic use included both subsidized and unsubsidized orders approved by HHS with secured state funding.

158. Roche sold Tamiflu to the government for pandemic use for about $15-$20 per course of 75 mg treatment. In contrast, Roche sold the Tamiflu to the government for non-pandemic use at the then-applicable Federal Supply Schedule price, which has ranged from about $50-$150 per course of treatment.

159. As stated above, federal and state governments purchased Tamiflu for pandemic use in amounts totaling more than $1.4 billion.

VI. CONCLUSION

160. With reckless disregard of its submission of false claims and the concomitant impact on public health and the government fisc, Roche engaged in a fraudulent scheme to sell Tamiflu to the federal and state governments for pandemic use. Roche knew that the government intended to purchase a drug for its influenza pandemic stockpile that would reduce the incidence

of influenza spread, severity, complications, hospitalizations, and mortality, and Roche claimed that Tamiflu met those requirements. All the while, Roche knew that its purported "scientific" evidence was severely flawed and did not support its pandemic use representations, making them false.

161. Absent Roche's false statements, the government would not have purchased Tamiflu, because efficacy for pandemic use was the very reason the government made the purchase at all.

COUNT I
FEDERAL FALSE CLAIMS ACT

Relator realleges each and every paragraph of this Amended Complaint.

162. By the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).[22]

163. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims in violation of 31 U.S.C. § 3729(a)(1)(B).[23]

164. Each purchase of Tamiflu for pandemic use paid for by the government was induced by Roche's fraudulent marketing practices, and each false statement made about Tamiflu constitutes a false or fraudulent record or statement. Accordingly, each claim to the

[22] To the extent that illegal conduct occurred prior to May 20, 2009, this Amended Complaint should be deemed to include violations of the federal False Claims Act prior to its amendment in 2009. Specifically Count I therefore also alleges violations of 31 U.S.C. § 3729(a)(1).

[23] To the extent that illegal conduct occurred prior to May 20, 2009, this Amended Complaint should be deemed to include violations of the federal False Claims Act prior to its amendment in 2009. Specifically Count II therefore also alleges violations of 31 U.S.C. § 3729(a)(2).

government for reimbursement for Tamiflu for pandemic use constitutes a false or fraudulent claim for payment.

165. The United States, unaware of the falsity or fraudulent nature of the claims presented or caused to be presented by Defendants, paid for claims that otherwise would not have been paid.

166. Because of Defendants' acts, and by reason of these payments and benefits given, the United States sustained damages and continues to be damaged in an amount to be determined at trial, and therefore is entitled to damages and penalties under the False Claims Act.

167. By reason of Defendants' acts, the United States Government has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT II
STATE OF CALIFORNIA

Relator realleges each and every paragraph of this Amended Complaint.

168. This is a claim for damages and penalties under California's False Claims Act, Cal. Gov't Code § 12651(a).

169. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval.

170. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the California State Government to approve and pay false and fraudulent claims.

171. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid for claims that would not be paid but for Defendants' fraudulent conduct.

172. By reason of Defendants' acts, the State of California has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT III
STATE OF COLORADO

Relator realleges each and every paragraph of this Amended Complaint.

173. This is a claim for damages and penalties under Colorado's Medicaid False Claims Act, Colo. Rev. Stat. § 25.5-4-305.

174. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Colorado State Government for payment or approval.

175. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Colorado State Government to approve and pay false and fraudulent claims.

176. The Colorado State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

177. By reason of Defendants' acts, the State of Colorado has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT IV
STATE OF CONNECTICUT

Relator realleges each and every paragraph of this Amended Complaint.

178. This is a claim for damages and penalties under Connecticut's False Claims Act, Conn. Gen. Stat. § 17b-301b.

179. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Connecticut State Government for payment or approval.

180. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Connecticut State Government to approve and pay false and fraudulent claims.

181. The Connecticut State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

182. By reason of Defendants' acts, the State of Connecticut has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT V
STATE OF DELAWARE

Relator realleges each and every paragraph of this Amended Complaint.

183. This is a claim for damages and penalties under Delaware's False Claims and Reporting Act, Del. Code Ann. tit. 6, § 1201.

184. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval.

185. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Delaware State Government to approve and pay false and fraudulent claims.

186. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

187. By reason of Defendants' acts, the State of Delaware has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT VI
DISTRICT OF COLUMBIA

Relator realleges each and every paragraph of this Amended Complaint.

188. This is a claim for damages and penalties the under the District of Columbia's False Claims Act, D.C. Code § 2-381.02.

189. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval.

190. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the District of Columbia Government to approve and pay false and fraudulent claims.

191. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

192. By reason of Defendants' acts, the District of Columbia has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT VII
STATE OF FLORIDA

Relator realleges each and every paragraph of this Amended Complaint.

193. This is a claim for damages and penalties under Florida's False Claims Act, Fla. Stat. § 68.082.

194. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval.

195. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Florida State Government to approve and pay false and fraudulent claims.

196. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

197. By reason of Defendants' acts, the State of Florida has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT VIII
STATE OF GEORGIA

Relator realleges each and every paragraph of this Amended Complaint.

198. This is a claim for damages and penalties under Georgia's State False Medicaid Claims Act, Ga. Code Ann. § 49-4-168.1.

199. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.

200. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Georgia State Government to approve and pay false and fraudulent claims.

201. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

202. By reason of Defendants' acts, the State of Georgia has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT IX
STATE OF HAWAII

Relator realleges each and every paragraph of this Amended Complaint.

203. This is a claim for damages and penalties under Hawaii's False Claims Act, Haw. Rev. Stat. § 661-21.

204. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval.

205. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Hawaii State Government to approve and pay false and fraudulent claims.

206. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

207. By reason of Defendants' acts, the State of Hawaii has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT X
STATE OF ILLINOIS

Relator realleges each and every paragraph of this Amended Complaint.

208. This is a claim for damages and penalties under Illinois' Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. § 175/3.

209. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval.

210. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Illinois State Government to approve and pay false and fraudulent claims.

211. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

212. By reason of Defendants' acts, the State of Illinois has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XI
STATE OF INDIANA

Relator realleges each and every paragraph of this Amended Complaint.

213. This is a claim for damages and penalties under Indiana's False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-2.

214. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval.

215. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Indiana State Government to approve and pay false and fraudulent claims.

216. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

217. By reason of Defendants' acts, the State of Indiana has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XII
STATE OF IOWA

Relator realleges each and every paragraph of this Amended Complaint.

218. This is a claim for damages and penalties under Iowa's False Claims Act, Iowa Code § 685.2.

219. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Iowa State Government for payment or approval.

220. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Iowa State Government to approve and pay false and fraudulent claims.

221. The Iowa State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

222. By reason of Defendants' acts, the State of Iowa has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XIII
STATE OF LOUISIANA

Relator realleges each and every paragraph of this Amended Complaint.

223. This is a claim for damages and penalties under Louisiana's Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:438.3 and 46:438.6.

224. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval.

225. By virtue of the acts alleged above, Defendants knowingly engaged in misrepresentation to obtain, or attempt to obtain payment from the Louisiana State Government.

226. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

227. By reason of Defendants' acts, the State of Louisiana has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XIV
STATE OF MARYLAND

Relator realleges each and every paragraph of this Amended Complaint.

228. This is a claim for damages and penalties under Maryland's False Health Claims Act, Md. Code Health-Gen. § 2-601(a).

229. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Maryland State Government for payment or approval.

230. By virtue of the acts alleged above, Defendants knowingly engaged in misrepresentation to obtain, or attempt to obtain payment from the Maryland State Government.

231. The Maryland State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

232. By reason of Defendants' acts, the State of Maryland has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XV
COMMONWEALTH OF MASSACHUSETTS

Relator realleges each and every paragraph of this Amended Complaint.

233. This is a claim for damages and penalties under Massachusetts' False Claims Act, Mass. Gen. Laws ch. 12, § 5B(a).

234. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Government of the Commonwealth of Massachusetts for payment or approval.

235. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the

Government of the Commonwealth of Massachusetts to approve and pay false and fraudulent claims.

236. The Government of the Commonwealth of Massachusetts, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

237. By reason of Defendants' acts, the Commonwealth of Massachusetts has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XVI
STATE OF MICHIGAN

Relator realleges each and every paragraph of this Amended Complaint.

238. This is a claim for damages and penalties under Michigan's Medicaid False Claim Act, Mich. Comp. Laws §§ 400.607 and 400.612.

239. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval.

240. By virtue of the acts alleged above, Defendants knowingly made, and presented claims that falsely represented the goods for which the claim was made to induce the Michigan State Government to approve and pay false and fraudulent claims.

241. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

242. By reason of Defendants' acts, the State of Michigan has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XVII
STATE OF MINNESOTA

Relator realleges each and every paragraph of this Amended Complaint.

243. This is a claim for damages and penalties under Minnesota's False Claims Act, Minn. Stat. § 15C.02.

244. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Minnesota State Government for payment or approval.

245. By virtue of the acts alleged above, Defendants knowingly made, and presented claims that falsely represented the goods for which the claim was made to induce the Minnesota State Government to approve and pay false and fraudulent claims.

246. The Minnesota State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

247. By reason of Defendants' acts, the State of Minnesota has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XVIII
STATE OF MONTANA

Relator realleges each and every paragraph of this Amended Complaint.

248. This is a claim for damages and penalties under Montana's False Claims Act, Mont. Code Ann. § 17-8-403.

249. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval.

250. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Montana State Government to approve and pay false and fraudulent claims.

251. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

252. By reason of Defendants' acts, the State of Montana has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XIX
STATE OF NEVADA

Relator realleges each and every paragraph of this Amended Complaint.

253. This is a claim for damages and penalties under Nevada's Submission of False Claims to State or Local Government Act, Nev. Rev. Stat. 357.040.

254. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval.

255. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Nevada State Government to approve and pay false and fraudulent claims.

256. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

257. By reason of Defendants' acts, the State of Nevada has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XX
STATE OF NEW JERSEY

Relator realleges each and every paragraph of this Amended Complaint.

258. This is a claim for damages and penalties under New Jersey's False Claims Act, N.J. Stat. Ann. § 2A:32C-3.

259. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Jersey State Government for payment or approval.

260. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the New Jersey State Government to approve and pay false and fraudulent claims.

261. The New Jersey State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

262. By reason of Defendants' acts, the State of New Jersey has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXI
STATE OF NEW MEXICO

Relator realleges each and every paragraph of this Amended Complaint.

263. This is a claim for damages and penalties under New Mexico's Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-4, and Fraud Against Taxpayers Act, N.M. Stat. Ann. § 44-9-3.

264. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval.

265. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the New Mexico State Government to approve and pay false and fraudulent claims.

266. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

267. By reason of Defendants' acts, the State of New Mexico has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXII
STATE OF NEW YORK

Relator realleges each and every paragraph of this Amended Complaint.

268. This is a claim for damages and penalties under New York's False Claims Act, N.Y. State Fin. Law § 189.

269. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the New York State Government for payment or approval.

270. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the New York State Government to approve and pay false and fraudulent claims.

271. The New York State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

272. By reason of Defendants' acts, the State of New York has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXIII
STATE OF NORTH CAROLINA

Relator realleges each and every paragraph of this Amended Complaint.

273. This is a claim for damages and penalties under North Carolina's False Claims Act, N.C. Gen. Stat. § 1-607.

274. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the North Carolina State Government for payment or approval.

275. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the North Carolina State Government to approve and pay false and fraudulent claims.

276. The North Carolina State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

277. By reason of Defendants' acts, the State of North Carolina has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXIV
STATE OF OKLAHOMA

Relator realleges each and every paragraph of this Amended Complaint.

278. This is a claim for damages and penalties under Oklahoma's Medicaid False Claims Act, Okla. Stat. tit. 63, § 5053.1.

279. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Oklahoma State Government for payment or approval.

280. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Oklahoma State Government to approve and pay false and fraudulent claims.

281. The Oklahoma State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

282. By reason of Defendants' acts, the State of Oklahoma has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXV
STATE OF RHODE ISLAND

Relator realleges each and every paragraph of this Amended Complaint.

283. This is a claim for damages and penalties under the Rhode Island's State False Claims Act, R.I. Gen. Laws § 9-1.1-3.

284. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Rhode Island State Government for payment or approval.

285. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Rhode Island State Government to approve and pay false and fraudulent claims.

286. The Rhode Island State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

287. By reason of Defendants' acts, the State of Rhode Island has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXVI
STATE OF TENNESSEE

Relator realleges each and every paragraph of this Amended Complaint.

288. This is a claim for damages and penalties under Tennessee's Medicaid False Claims Act, Tenn. Code Ann. § 71-5-182, and Tennessee's False Claims Act, Tenn. Code Ann. § 4-18-101.

289. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval.

290. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Tennessee State Government to approve and pay false and fraudulent claims.

291. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

292. By reason of Defendants' acts, the State of Tennessee has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXVII
STATE OF TEXAS

Relator realleges each and every paragraph of this Amended Complaint.

293. This is a claim for damages and penalties under Texas' Medicaid Fraud Prevention Act, Tex. Hum. Res. Code Ann. §§ 36.002 and 36.052.

294. By virtue of the acts alleged above, Defendants knowingly made or caused to be made false statements and misrepresentations of material facts to permit persons to receive a benefit or payment under the Medicaid program that is not authorized.

295. By virtue of the acts alleged above, Defendants knowingly made, induced, sought to induce or caused to be made false statements and misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program.

296. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

297. By reason of Defendants' acts, the State of Texas has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXVIII
COMMONWEALTH OF VIRGINIA

Relator realleges each and every paragraph of this Amended Complaint.

298. This is a claim for damages and penalties under Virginia's Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.3.

299. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Government of the Commonwealth of Virginia for payment or approval.

300. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Government of the Commonwealth of Virginia to approve and pay false and fraudulent claims.

301. The Government of the Commonwealth of Virginia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

302. By reason of Defendants' acts, the Commonwealth of Virginia has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXIX
STATE OF WASHINGTON

Relator realleges each and every paragraph of this Amended Complaint.

303. This is a claim for damages and penalties under Washington's Medicaid Fraud False Claims Act, Wash. Rev. Code § 74.66.020.

304. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Washington State Government for payment or approval.

305. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Washington State Government to approve and pay false and fraudulent claims.

306. The Washington State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

307. By reason of Defendants' acts, the State of Washington has been damaged and continues to be damaged in a substantial amount to be determined at trial.

COUNT XXX
STATE OF WISCONSIN

Relator realleges each and every paragraph of this Amended Complaint.

308. This is a claim for damages and penalties under Wisconsin's False Claims Act, Wis. Stat. § 20.931.

309. By virtue of the acts alleged above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Wisconsin State Government for payment or approval.

310. By virtue of the acts alleged above, Defendants knowingly made, used or caused to be made or used false records or statements, and omitted material facts, to induce the Wisconsin State Government to approve and pay false and fraudulent claims.

311. The Wisconsin State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' fraudulent conduct.

312. By reason of Defendants' acts, the State of Wisconsin has been damaged and continues to be damaged in a substantial amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Relator Thomas Jefferson requests that this Court:

A. Enter judgment for the United States Government, the FCA States, and Relator and against Defendants jointly and severally;

B. Order Defendants to cease and desist from violating the FCA and the FCA States' counterparts;

C. Award the United States Government and each of the FCA States on whose behalf this Amended Complaint has been brought damages against Defendants as required by law for Defendants' violations of the False Claims Act and its respective counterparts under state law as alleged in this Amended Complaint;

D. Assess civil penalties against Defendants as required by law for the false statements and false claims alleged in this Amended Complaint;

E. Award Relator an appropriate relator's share, in an amount to be agreed upon by the government and Relator or, if no agreement can be reached, by the Court, pursuant to 31 U.S.C. § 3730(d) and the equivalent statutory provisions in the FCA States;

F. Award prejudgment interest;

G. Award Relator statutory attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d) and its state law counterparts in the FCA States; and

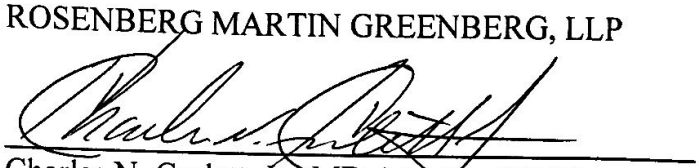
H. Grant such other relief as the Court may deem just, necessary, and proper.

PLAINTIFF DEMANDS TRIAL BY JURY ON ALL COUNTS WHERE JURY IS AVAILABLE.

Dated: September 3, 2019

Respectfully Submitted:

ROSENBERG MARTIN GREENBERG, LLP



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