UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA,
THE STATE OF CALIFORNIA,
THE STATE OF COLORADO,
THE STATE OF CONNECTICUT,
THE STATE OF DELAWARE,
THE DISTRICT OF COLUMBIA,
THE STATE OF FLORIDA,
THE STATE OF GEORGIA,
THE STATE OF HAWAII,
THE STATE OF ILLINOIS,
THE STATE OF INDIANA,
THE STATE OF IOWA,
THE STATE OF LOUISIANA,
THE COM. OF MASSACHUSETTS,
THE STATE OF MICHIGAN,
THE STATE OF MINNESOTA,
THE STATE OF MONTANA,
THE STATE OF NEVADA,
THE STATE OF NEW JERSEY,
THE STATE OF NEW YORK,
THE STATE OF NORTH CAROLINA,
THE STATE OF OKLAHOMA,
THE STATE OF RHODE ISLAND,
THE STATE OF TENNESSEE,
THE STATE OF TEXAS,
THE STATE OF VERMONT,
THE COM. OF VIRGINIA, and
THE STATE OF WASHINGTON
ex rel. JULIE LONG,

Plaintiffs,

v.

JANSSEN BIOTECH, INC.,

Defendant.

Civil Action No. 16-CV-12182-FDS

SECOND AMENDED COMPLAINT
(Leave to file granted February 11, 2020)

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1. Plaintiff relator Julie Long ("Relator") brings this action on behalf of the United States of America as well as the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Vermont, the Commonwealth of Virginia, and the State of Washington (collectively, the "Plaintiff States") against Janssen Biotech, Inc. ("Janssen" or "the Company") for violations of the federal False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "Federal FCA"), and the Plaintiff States' false claims statutes (collectively, the "State FCAs") to recover all damages, civil penalties and all other recoveries provided for under these statutes.

I. INTRODUCTION

2. Medicare and Medicaid rely upon treatment providers to exercise independent judgment and focus solely on the best interests of the patients in making treatment decisions. When a physician selects a treatment course because of some personal financial benefit, that decision is not necessarily in the patient's best interests. Kickback schemes corrupt the integrity of every treatment decision influenced by the scheme because remuneration given to those who make such decisions frequently results in a drug or service being provided that is medically unnecessary, less effective than other drugs or services, of poor quality, and/or harmful to a vulnerable patient population.

3. To protect patients and the government health care programs from the corrupting influence of remuneration in cash or kind to medical providers, the federal government enacted

the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the "Federal AKS"), which prohibits the payment of kickbacks in any form to providers who treat patients insured by a federal health care program. Like the federal government, most of the Plaintiff States have enacted anti-kickback statutes (collectively, the "State AKS").

4. In addition, falsely certifying compliance with the Federal AKS in connection with claims submitted to a federal health care program is actionable under the Federal FCA. Similarly, falsely certifying compliance with the Federal AKS and State AKS in connection with claims submitted to the state-administered Medicaid programs is actionable under the State FCAs.

5. The Federal and State FCA violations alleged herein arise from Janssen's long-running, nationwide kickback scheme that the Company employed to induce health care providers to prescribe and administer via infusion two different biologic therapy drugs, Remicade and Simponi ARIA, to patients, many of whom are Medicare and Medicaid beneficiaries, with rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriatic arthritis, ankylosing spondylitis or other diseases. Janssen's kickbacks were in the form of valuable business advisory services that the Company regularly provided free of charge to rheumatology and gastroenterology practices throughout the country to help the practices establish infusion suites (so the practices would directly administer Remicade and Simponi ARIA infusions) and then, once opened, to help the practices operate the infusion businesses more efficiently and profitably (so the practices would grow their infusion businesses by prescribing and infusing more Remicade and/or Simponi ARIA).

6. These practice management services that Janssen provided to its top rheumatology and gastroenterology practice accounts were valuable, as demonstrated by

physicians' demand for the services, the positive impact the services had on the physician practices' infusion businesses, and as also demonstrated by the normal market price of these services – over $1,200 per consultative session.

7. Janssen effectively became a business partner to rheumatology and gastroenterology practices, helping these practices establish, operate and grow their infusion businesses so they would continue using and buying Remicade and Simponi ARIA. In fact, Janssen told the rheumatology and gastroenterology practices that "we want to partner with you in your infusion business operations to help make your infusion service line seamless." Janssen used this corrupting and illegal strategy because once physician practices became invested in and profited from the "infusion business model" they desired and indeed became reliant upon the substantial revenue received from infusing Remicade and Simponi ARIA, which they could not obtain by prescribing competing drugs that the patients can self-administer at home.

8. Janssen's free practice management and business advisory services helped rheumatology and gastroenterology practices by educating and advising them how to grow and how to maximize the revenue from their infusion businesses while lowering their overhead costs. This in turn induced the practices to continue prescribing and infusing Janssen's products rather than less lucrative biologic drugs delivered more conveniently (and less expensively) through subcutaneous injection or through tablets. By providing physician practices free business support, Janssen likewise induced physicians to prescribe its infusion drugs rather than competing infusible medicines offered by manufacturers that complied with the law and did not provide these valuable services. As such, Janssen's kickback scheme induced hundreds if not thousands of health care providers to disregard their patients' best interests and self-servingly prescribe and administer Remicade and Simponi ARIA infusion therapy to patients, including

tens of thousands of Medicare and Medicaid beneficiaries, in order to maximize the profit from their infusion businesses.

9. This scheme corrupted rheumatologists' and gastroenterologists' treatment decisions for more than a decade and correspondingly caused the federal and state governments to pay for countless Remicade and Simponi ARIA infusion treatments tainted by Janssen's illegal marketing scheme.

10. Janssen's kickback scheme helped the Company generate billions of dollars in sales of Remicade and Simponi ARIA – including annual sales of over $1 billion from the treatment of approximately 60,000 Medicare beneficiaries (making it one of Medicare's top expenses). The federal and state governments have accordingly paid hundreds of millions of dollars to physician practices for infusion services that were in fact ineligible for reimbursement.

11. In addition to the substantial economic harm caused to the public fisc, Janssen's scheme also harmed unsuspecting patients suffering from rheumatoid arthritis, Crohn's disease, ulcerative colitis or other painful and often debilitating diseases. Janssen knowingly caused physicians to disregard the patients' best interests by inducing the physicians to prescribe a biologic treatment that required the patients to travel to an infusion suite—which Janssen helped establish and effectively helped operate—every eight weeks to sit for a two-hour infusion (Remicade) or 30-minute infusion (Simponi ARIA) instead of prescribing a less-profitable biologic drug that might have been more effective and appropriate for the patient and could have been self-administered in minutes in the comfort and privacy of the patient's home. These patients were subjected to Remicade and Simponi ARIA infusions as a result of orders from health care providers that were based on undisclosed financial, rather than independent clinical, considerations.

II. JURISDICTION & VENUE

12. Jurisdiction is founded upon the Federal FCA, 31 U.S.C. §§ 3729 *et seq*., specifically 31 U.S.C. §§ 3732(a) & (b) and also 28 U.S.C. §§ 1331 & 1345. The Court may exercise personal jurisdiction over Janssen because it transacts business in this District and engaged in the alleged illegal activities and practices in this District.

13. Venue in the District of Massachusetts is appropriate under 31 U.S.C. § 3732(a), in that many of the acts complained of took place in this District.

III. PARTIES

14. The United States is a real party in interest to the claims in this action. Through the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS"), the United States administers the Medicare and Medicaid programs.

15. The State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Jersey, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Vermont, the Commonwealth of Virginia, and the State of Washington are real parties in interest to the claims in this action. The Plaintiff States administer their respective Medicaid programs and agencies.

16. Plaintiff relator Julie Long worked as an Area Business Specialist for Janssen from 2003 to February 2016, advising and assisting physician practices with, among other things,

establishing and operating in-office infusion suites where Remicade and Simponi ARIA infusions were administered. In February 2016, Relator left Janssen to accept a sales position at another pharmaceutical manufacturer. For approximately ten years before joining Janssen, Relator worked as a sales representative for two other drug companies. Relator was a nurse before working in pharmaceutical sales. The allegations in this complaint are based upon information and knowledge that Relator obtained while she worked at Janssen. Based on discussions with former colleagues and her review of information, including online job postings for Area Business Specialist positions at Janssen, Relator believes Janssen was still engaged in the kickback scheme alleged herein at the time Relator commenced this action on October 28, 2016. Relator also believes that Janssen may still currently be providing many of the free business operations/practice management services that are at the center of this action.

17. Defendant Janssen Biotech, Inc. (f/k/a Centocor Ortho Biotech Inc. and Centocor, Inc.) is a manufacturer and seller of pharmaceutical products. As relevant here, Janssen manufactures and sells the biopharmaceuticals Remicade and Simponi ARIA. Janssen is a Pennsylvania corporation and maintains its headquarters at 800 Ridgeview Road in Horsham, Pennsylvania. Janssen is a wholly-owned subsidiary of Johnson & Johnson ("JNJ").

IV. LEGAL BACKGROUND

A. The Medicare & Medicaid Programs

18. ***Medicare*** is a federal program that provides federally subsidized health insurance for persons who are 65 or older or are disabled. *See* 42 U.S.C. §§ 1395 *et seq*. Medicare Part A generally covers inpatient hospital services and services for patients with end-stage renal disease (ESRD). Part B of the Medicare program provides supplemental benefits to participants to cover, among other things, physician services and prescription drugs. *See generally id.* §§ 1395j -

1395w-4. Medicare Part C allows for private companies to offer Medicare Advantage plans that include, at a minimum, all benefits covered by Parts A and B. Medicare pays a fixed monthly amount per beneficiary (capitation payment) to the private companies that offer Medicare Advantage plans. Part D of the Medicare program, which was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, provides prescription drug benefits for Medicare beneficiaries. All persons enrolled in Medicare Part B or a Part C Medicare Advantage plan are eligible to enroll in a prescription drug plan under Part D. HHS, through CMS, contracts with private companies to administer prescription drug plans. These companies, in turn, enter into subcontracts with pharmacies to provide drugs to the Medicare Part D beneficiaries enrolled in their plans.

19. ***Medicaid*** is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payment, known as the Federal Medical Assistance Percentage ("FMAP"), is based on the state's per capita income compared to the national average. *See* 42 U.S.C. § 1396d(b). The FMAP currently ranges from approximately 50% to 76%, depending on the state.

B. The Federal & State Anti-Kickback Statutes

20. The primary purpose of the Federal AKS, 42 U.S.C. § 1320a-7b(b), is to protect patients and the federal health care programs from the corruptive influence of kickbacks and bribes on treatment decisions. The Medicare and Medicaid programs rely upon physicians to provide treatment that is medically necessary and appropriate. When a drug company, like Janssen, pays kickbacks or bribes to induce a physician to use its products, it taints physicians' decisions and compromises the integrity of the physician-patient relationship.

21. To protect patients and the government health care programs from medically unnecessary treatment, treatment of inferior quality, and harmful treatment, Congress enacted the Federal AKS in 1972, barring the payment of kickbacks to physicians. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) & (c). Congress subsequently strengthened the statute in 1977 and again in 1987 to ensure that kickbacks disguised as legitimate transactions do not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93. Additionally, the AKS was "intended to strengthen the capability of the Government to detect, prosecute, and punish fraudulent activities under the [M]edicare and [M]edicaid programs, ... because fraud and abuse among practitioners ... is relatively difficult to prove and correct." *U.S. ex rel. Bawduniak v. Biogen IDEC*, Civ. No.12-10601, 2018 WL 1996829, at *2 (D. Mass. Apr. 27, 2018) (quoting H.R. Rep. No. 95-393, at 1, 27 (1977)).

22. Violation of the Federal AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation in federal health care programs. *See* 42 U.S.C. §§ 1320a-7b(b)(2) & (7).

23. Specifically, the Federal AKS makes it illegal for individuals or entities to "knowingly and willfully offer[] or pay[] remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person ... to purchase, ... order, ... or recommend purchasing ... or ordering any good ... service or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2).

24. Most of the Plaintiff States have likewise enacted an anti-kickback law that prohibits the payment or acceptance of kickbacks in connection with the purchase or ordering of

goods or the provision of any services covered by their Medicaid programs. *See* Cal. Welf. & Inst. Code § 14107.2; Colo. Rev. Stat. § 24-31-809; Conn. Gen. Stat. §§ 53a-161c & 53a-161d; Del. Code tit. 31 § 1005; D.C. Code §§ 4-802(c) & (d); Fla. Stat. § 409.920(2)(a)(5); Ga. Code § 49-4-146.1; Haw. Rev. Stat. § 346-43.5; 305 Ill. Comp. Stat. 5/8A-3; Ind. Code § 12-15-24-2; Iowa Medicaid Provider Agmt. (requiring participating providers to adhere to applicable federal laws); La. Rev. Stat. § 46:438.2; Mass. Gen. Laws ch. 118E, § 41; Mich. Comp. Laws § 400.604; Minn. R. §§ 9505.2165-4(C) & 5221.0700; Mont. Code § 45-6-313(1)(b); Nev. Rev. Stat. § 422.560; Nev. Medicaid Services Manual ch. 3303.1A; N.J. Stat. § 30:4D-17(c); 18 N.Y. Codes, Rules & Regs. § 515.2(b)(5); N.Y. Soc. Serv. Law §§ 366-d & 366-f; N.C. Gen Stat. §§ 108A-63(g) & (h); Okla. Stat. tit. 56, § 1005(A)(6); R.I. Gen. Laws § 40-8.2-3(a)(2); Tenn. Rules and Reg. § 1200-13-13-.08; Tex. Hum. Res. Code §§ 32.039(b) & 36.002(5); Tex. Penal Code § 35A.02(a)(5); Tex. Occ. Code § 102.001; 1 Tex. Admin. Code § 371.27; Vt. Medicaid Provider Manual and Provider Agmt. (requiring participating providers to adhere to applicable federal laws); Va. Code § 32.1-315; and Wash. Rev. Code § 74.09.240.

25. Free practice management and business advisory services provided by a drug company to physicians to induce them to prescribe the company's products to Medicare and Medicaid beneficiaries constitute illegal remuneration under the Federal AKS and State AKS.

26. To be eligible to participate in the Medicare program and be reimbursed for treatment provided to Medicare beneficiaries, providers are required to enter into a provider agreement in which the provider makes the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but

> not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

Medicare Enrollment Application (CMS-855B).

27. Likewise, providers participating in the Medicaid program are required to sign enrollment agreements with the states. Although there are variations in each state's Medicaid provider agreement, all of these agreements require that the provider comply with all state and federal laws, including the State AKS, Federal AKS, and Medicaid regulations, in billing the state Medicaid program for drugs and services furnished to Medicaid beneficiaries.

28. On each Form CMS-1500 submitted to Medicare or Medicaid for payment for drugs and services furnished to beneficiaries, a provider certifies, among things, that the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute":

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; … 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law); 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE ...

29. Accordingly, compliance with the Federal AKS is a material condition of payment for Medicare and Medicaid claims. Similarly, compliance with the Federal AKS and State AKS are material conditions of payment for Medicaid claims. Claims for payment for drugs and services that are tainted by illegal kickbacks are not authorized to be paid by Medicare and Medicaid and thus constitute claims that are both legally and factually false.

30. In addition to the various laws and regulations all pharmaceutical companies must comply with, the federal government offers industry guidance in an effort to police the marketing activities of the pharmaceutical industry. For instance, the Office of the Inspector General of the Department of Health and Human Services ("HHS-OIG") issued "Special Fraud Alerts" in 1994 explaining that:

> In recent years, prescription drug companies in the United States have increased their marketing activities among providers, patients and suppliers such as pharmacies. Many prescription drug marketing activities go far beyond traditional advertising and educational contacts. Physicians, suppliers and, increasingly, patients are being offered valuable, non-medical benefits in exchange for selecting specific prescription drug brands. Traditionally, physicians and pharmacists have been trusted to provide treatments and recommend products in the best interest of the patient. In an era of aggressive drug marketing, however, patients may now be using prescription drug items, unaware that their physician or pharmacist is being compensated for promoting the selection of a specific product. …

59 Fed. Reg. at 65,376 (Dec. 19, 1994). HHS-OIG has also specifically warned that free training for a physician's office staff in areas such as management techniques and CPT coding are suspect incentive arrangements that violate the Federal AKS if one of the purposes of the incentive is to influence a physician's medical decision regarding the treatment ordered for a Medicare or Medicaid patient. *See id.* As the government has observed:

> A marketing program that is illegal under the anti-kickback statute may pose a danger to patients because the offering or payment of remuneration may interfere with a physician's judgment in determining the most appropriate treatment for a patient. Further, where the patient is a Medicaid beneficiary, these drug marketing practices may increase the Federal government's costs of reimbursing suppliers for the products. …

Id.

31. Thereafter, in April 2002, HHS-OIG issued its Compliance Program Guidance for Pharmaceutical Manufacturers, a document meant to provide an overview of the fundamental elements of a pharmaceutical manufacturer compliance plan, which identifies and discusses

specific risk areas. HHS-OIG advised that "[a]nytime a pharmaceutical manufacturer provides anything of value to a physician who might prescribe the manufacturer's product the manufacturer should examine whether it is providing a tangible benefit to the physician with the intent to induce or reward referrals." HHS-OIG Guidance to Pharmaceutical Manufacturers (Apr. 2002) at 28.

32. HHS has also published safe harbor regulations that define practices that are not subject to prosecution or sanctions under the Federal AKS because such practices are unlikely to result in fraud or abuse. *See* 42 C.F.R. §1001.952. However, only those arrangements that precisely meet all of the conditions set forth in a safe harbor are afforded safe harbor protection. None of the practices at issue here meet these safe harbor regulations.

33. Moreover, to provide guidance on the Federal AKS, HHS-OIG also offers interested parties the opportunity to seek "formal advisory opinions" regarding the application of the Federal AKS and its safe harbor regulations to any existing or proposed business arrangement. *See* 42 C.F.R. Part 1008. Janssen did not seek an advisory opinion regarding the legality of the free business advisory and support services described herein.

C. The Federal & State False Claims Acts

34. On May 20, 2009, Congress enacted the Fraud Enforcement Recovery Act (FERA), Pub. L. No. 111-21, 123 Stat. 1617 (2009), which amended the Federal FCA and re-designated § 3729(a)(1) as § 3729(a)(1)(A), § 3729(a)(2) as § 3729(a)(1)(B), and § 3729(b) as §§ 3729(b)(1)(A) & (B).

35. The pre-FERA version of the Federal FCA imposed liability upon:

[A]ny person who—

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; [or]
>
> (2) 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)(1) & (2). The Federal FCA, as FERA amended it, imposes liability upon:

> [A]ny person who—
>
> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]

31 U.S.C. §§ 3729(a)(1)(A) & (B).

36. The term "knowingly" means "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b) (pre-FERA); 31 U.S.C. § 3729(b)(1)(A) (post-FERA). Proof of specific intent to defraud is not required. *See* 31 U.S.C. § 3729(b) (pre-FERA); 31 U.S.C. § 3729(b)(1)(B) (post-FERA).

37. FERA provides that amendments to the Federal FCA became effective upon enactment except for the amendment to § 3729(a)(2), which "shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act ... that are pending on or after that date." FERA § 4(f)(1), 123 Stat. at 1625.

38. Here, Janssen's alleged Federal FCA violations began prior to 2006 and were still occurring when this action was commenced (*i.e.*, providers who received Janssen's free business operations/practice management services submitted tainted/false claims for reimbursement for

Remicade and Simponi ARIA vials and related infusion services to the Medicare and Medicaid programs). Accordingly, the pre-FERA §§ 3729(a)(1) and 3729(b) apply to all alleged Federal FCA violations that occurred before May 20, 2009 and the amended versions of those Sections (§ 3729(a)(1)(A), and §§ 3729(b)(1)(A) & (B)) apply to all alleged Federal FCA violations that occurred on or after May 20, 2009. In addition, pre-FERA § 3729(a)(2) applies to all alleged Federal FCA violations that occurred before June 7, 2008, and the amended version (§ 3729(a)(1)(B)) applies to all alleged Federal FCA violations that occurred on or after June 7, 2008.

39. Section 3729(a)(1) of the Federal FCA provides that a person is liable to the U.S. government for three times the amount of damages that the United States sustains because of the act of that person plus a civil penalty of $5,000–$10,000 per violation. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101-410), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104-134) and the Federal Civil Penalties Inflation Adjustment Act of 2015 (Pub. L. 114-74), the Federal FCA's penalty range is periodically adjusted for inflation. For Federal FCA violations that occurred on or before November 2, 2015, the penalty range is presently $5,500–$11,000 per violation. And for Federal FCA violations that occurred after November 2, 2015, the penalty range is presently $11,181–$22,363 per violation. *See* 28 C.F.R. §§ 85.3 & 85.5 (2018).

40. The government is purchasing the provision of services that are conflict-free, and "[t]he Government does not get what it bargained for when a defendant is paid by [the government] for services tainted by a kickback." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011).

41. Section (g) of the Federal AKS, 42 U.S.C. § 1320a-7b, specifically provides that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the Federal FCA]." Congress added section (g) to the Federal AKS in 2010 to clarify that "all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted by the wrongdoers themselves." 155 Cong. Rec. S10854 (Oct. 28, 2009) (Sen. Leahy). Another goal of the amendment was to "strengthen[] whistleblower actions based on medical care kickbacks, which tempt health care providers to churn unnecessary medical care at great risk to patients and great cost to the taxpayer." *Id.* at S10853 (Sen. Kaufman).

42. Each of the Plaintiff States has enacted a false claims statute modeled after the Federal FCA. *See* California False Claims Act (Cal. Gov't. Code §§ 12650 *et seq*.), Colorado Medicaid False Claims Act (Colo. Rev. Stat. §§ 25.5-4-303.5 *et seq*.), Connecticut False Claims Act (Conn. Gen. Stat. §§ 17b-301b *et seq*.), Delaware False Claims and Reporting Act (Del. Code tit. 6, §§ 1201 *et seq*.), District of Columbia False Claims Act (D.C. Code §§ 2-308.13 *et seq.*), Florida False Claims Act (Fla. Stat. §§ 68.081 *et seq.*), the Georgia State False Medicaid Claims Act (Ga. Code §§ 49-4-168 *et seq.*), Hawaii False Claims Act (Haw. Rev. Stat. §§ 661-21 *et seq.*), Illinois False Claims Act (740 Ill. Comp. Stat. 175/1 *et seq.*), Indiana False Claims and Whistleblower Protection Act (Ind. Code §§ 5-11-5.5-1 *et seq.*), Iowa False Claims Act (Iowa Code §§ 685.1 *et seq.*), Louisiana Medical Assistance Programs Integrity Law (La. Rev. Stat. §§ 46:438.1 *et seq*.), Massachusetts False Claims Law (Mass. Laws. ch. 12, §§ 5A *et seq*.), Michigan Medicaid False Claims Act (Mich. Comp. Laws §§ 400.601 *et seq*.), Minnesota False Claims Act (Minn. Stat. §§ 15C.01 *et seq*.), Montana False Claims Act (Mont. Code §§ 17-8-401 *et seq*.), Nevada False Claims Act (Nev. Rev. Stat. §§ 357.010 *et seq*.), New Jersey False Claims

Act (N.J. Stat. §§ 2A:32C-1 *et seq*.), New York False Claims Act (N.Y. State Fin. Law §§ 187 *et seq*.), North Carolina False Claims Act (N.C. Gen. Stat. §§ 1-605 *et seq*.), Oklahoma Medicaid False Claims Act (Okla. Stat. tit. 63, §§ 5053 *et seq*.), Rhode Island False Claims Act (R.I. Gen. Laws §§ 9-1.1-1 *et seq*.), Tennessee Medicaid False Claims Act (Tenn. Code §§ 71-5-181 *et seq*.), Texas Medicaid Fraud Prevention Act (Tex. Hum. Res. Code §§ 36.001 *et seq*.), Vermont False Claims Act (32 Vt. Stat. §§ 630 *et seq*.), Virginia Fraud Against Taxpayers Act (Va. Code §§ 8.01-216.1 *et seq*.), and Washington Medicaid Fraud False Claims Act (Wash. Rev. Code §§ 74.66 *et seq*.).

43. Claims that arise from a kickback scheme violate the Federal FCA and State FCAs for three separate and distinct reasons:

- Claims that result from a kickback scheme are per se false because the Federal AKS and State AKS prohibit the government from paying for services or drugs tainted by kickbacks. Accordingly, claims seeking payment for services or prescriptions tainted by kickbacks are both legally and factually false.
- To participate in federally-funded and state-funded health care programs, providers must certify in their provider enrollment agreement that they will comply with the Federal AKS and State AKS.
- In submitting claims for payment to Medicare and Medicaid for services or drugs tainted by kickbacks, providers certify that they have complied with the Federal AKS and State AKS in providing such services or drugs.

44. Consequently, when a drug manufacturer, like Janssen, provides a kickback to induce the prescription of its drug, it renders false the submitter's implied or express certification that the resulting claim complies with the requirements of the Federal AKS and/or State AKS.

V. FACTUAL ALLEGATIONS

A. Janssen's Biologic Drugs - Remicade & Simponi ARIA

1. *Remicade*

45. Remicade is the brand name for infliximab, which is in a class of medications called biologic response modifiers. More particularly, Remicade is a tumor necrosis factor-alpha ("TNF-alpha") inhibitor, as it targets TNF-alpha, a substance in the body that causes inflammation. The FDA has approved Remicade for the following indications among others:

- Treatment of patients with ***moderately to severely active rheumatoid arthritis*** (administered in combination with methotrexate);
- Treatment of patients (adults and children) with ***moderately to severely active Crohn's disease*** who have had an inadequate response to conventional therapy;
- Treatment of patients (adults and children) with ***moderately to severely active ulcerative colitis*** who have had an inadequate response to conventional therapy;
- Treatment of patients with ***psoriatic arthritis***; and
- Treatment of patients with ***active ankylosing spondylitis***.

46. Remicade is administered intravenously (into a vein), a delivery process called infusion. Drug infusions are performed at doctors' offices, hospital outpatient departments, businesses that strictly administer drug infusions, and at home by mobile service providers. The chart below sets forth Remicade's approved dosage and administration by indication.

	Dosage	Frequency of Administration
Rheumatoid arthritis	3-10 mg/kg	At least a 2-hour infusion every 4-8 weeks after 3 starter doses
Crohn's disease	5 or 10 mg/kg	At least a 2-hour infusion every 8 weeks after 3 starter doses
Ulcerative colitis	5 mg/kg	At least a 2-hour infusion every 8 weeks after 3 starter doses
Psoriatic arthritis	5 mg/kg	At least a 2-hour infusion every 8 weeks after 3 starter doses
Ankylosing spondylitis	5 mg/kg	At least a 2-hour infusion every 6 weeks after 3 starter doses

47. The FDA requires that Janssen include the "black box warning" provided below on Remicade's label to warn providers and patients about Remicade's risk of serious infection

and cancer. Black box warnings are utilized for FDA-approved drugs that carry the most substantial risks to patients.

> **WARNING: SERIOUS INFECTIONS and MALIGNANCY**
> See full prescribing information for complete boxed warning.
>
> - Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens.
>
> * * *
>
> - Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including REMICADE.
>
> - Postmarketing cases of fatal hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with TNF blockers including REMICADE. Almost all had received azathioprine or 6-mercaptopurine concomitantly with a TNF-blocker at or prior to diagnosis. The majority of REMICADE cases were reported in patients with Crohn's disease or ulcerative colitis, most of whom were adolescent or young adult males.

48. JNJ combined with its subsidiaries, including Janssen, is one of the largest drug companies in the world in terms of sales. Among all of JNJ's drugs, Remicade is still number one in terms of sales, making it JNJ's flagship drug. In fact, according to JNJ's 2018 annual report filed with the U.S. Securities and Exchange Commission, Remicade is the top revenue generator of all JNJ products, with sales of the drug accounting for approximately 9.6% of JNJ's total annual revenue. At its peak in 2016, Janssen reported $4.84 billion in sales of Remicade in the U.S., growth of over 91% since 2007.

Remicade U.S. Revenue (Billions)											
2007	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**
$2.53	$2.81	$3.08	$3.09	$3.27	$3.58	$3.89	$4.15	$4.45	$4.84	$4.52	$3.66

49. At all times relevant to this action, Remicade has been among the biggest expenses for the Medicare program. To illustrate, during the five-year period spanning 2013 through 2017, Part B of the Medicare program paid nearly $6.2 billion for the drug. During this

period, an annual average of 58,641 Medicare beneficiaries received Remicade infusions. *See* CMS's Medicare Part B Drug Spending Dashboard (avail. at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB). Relator is unaware of Medicare Part C plans' combined spending on Remicade. However, it is reasonable to assume that adding the Part C plans' expenditures on Remicade would cause these figures to climb substantially.

	Medicare Part B Spending	**Part B Drug Expense Ranking**	**Beneficiaries**	**Avg. Spending Per Beneficiary**
2013	$1,096,908,345	4 out of 431	60,026	$18,274
2014	$1,171,820,499	5 out of 450	59,715	$19,624
2015	$1,242,339,355	4 out of 466	58,683	$21,170
2016	$1,336,041,105	4 out of 482	58,352	$22,896
2017	$1,341,011,663	5 out of 482	56,429	$23,765
Total	**$6,188,120,967**			

50. Remicade is likewise a substantial expense for Medicaid, including the Plaintiff States' Medicaid programs. From 2006 through 2018, the Plaintiff States' Medicaid programs have paid over $1 billion in reimbursements for Remicade. *See* CMS's State Drug Utilization Data (avail. at https://data.medicaid.gov/browse?category=State+Drug+Utilization&limitTo= -datasets&sortBy=newest).

	Prescriptions	**Reimbursements (Millions)**
2006	17,649	$25.9
2007	18,007	$28.0
2008	16,722	$27.9
2009	19,200	$31.7
2010	23,067	$44.7
2011	28,908	$60.1
2012	30,276	$72.1
2013	32,637	$80.9
2014	35,805	$96.0
2015	39,579	$122.0
2016	49,197	$159.6
2017	44,712	$148.4
2018	44,064	$155.4
	399,823	**$1,052.7**

51. After being the only infliximab product on the market for almost two decades, in 2016, the FDA approved a biosimilar, or generic version, to Remicade called Inflectra. Pfizer Inc. began selling Inflectra in the fall of 2016.

2. *Simponi ARIA*

52. Simponi ARIA is the trade name for golimumab, which like Remicade is a TNF-alpha inhibitor.[1] In July 2013, the FDA approved Simponi ARIA for treatment of patients with ***moderately to severely active rheumatoid arthritis*** (administered in combination with methotrexate). Thereafter, in October 2017, the FDA approved Simponi ARIA for treatment of patients with ***active psoriatic arthritis*** and patients with ***active ankylosing spondylitis***.

53. Like Remicade, Simponi ARIA is delivered through an infusion. Simponi ARIA's normal dosage is 2 mg/kg, and it is administered for 30 minutes every eight weeks after two starter doses.

54. Similar to Remicade, the FDA requires that Janssen include the "black box warning" provided below on Simponi ARIA's label to warn providers and patients about the drug's risk of serious infection and cancer. Again, black box warnings are utilized for FDA-approved drugs that carry the most substantial risks to patients.

[1] Simponi (as opposed to Simponi ARIA) is a formulation of golimumab that is administered through subcutaneous injection and is also available in an auto-injector. Simponi was approved in 2009 for the treatment of adult patients with ***moderately to severely active rheumatoid arthritis*** (to be administered in combination with methotrexate) and ***active ankylosing spondylitis***. Simponi is also approved for patients with ***active psoriatic arthritis*** and ***moderately to severely active ulcerative colitis*** who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or mercaptopurine. Janssen used different sales representatives to promote Simponi and Simponi ARIA.

WARNING: SERIOUS INFECTIONS AND MALIGNANCY
See full prescribing information for complete boxed warning.

- Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal (such as histoplasmosis), and other opportunistic infections have occurred in patients receiving SIMPONI ARIA

* * *

- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, of which SIMPONI ARIA is a member.

55. To get rheumatologists accustomed to using Simponi ARIA before other drug companies could begin selling bio-similar infliximab, starting in 2014 Janssen began advising its top rheumatology accounts to prescribe Simponi ARIA instead of Remicade for rheumatoid arthritis patients.

56. Sales of Simponi ARIA and Simponi in the United States have grown by nearly 160% between 2013 and 2018.[2]

2013	2014	2015	2016	2017	2018
$404 million	$544 million	$730 million	$959 million	$954 million	$1.05 billion

57. Simponi ARIA is quickly becoming one of the biggest expenses for the Medicare program. From 2014 through 2017, Part B of the Medicare program spent over $600 million on the drug. *See* CMS's Medicare Part B Drug Spending Dashboard (avail. at https://www.cms. -gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePart B). The number of Medicare beneficiaries who receive Simponi ARIA infusions nearly tripled during the four-year period. *See id.* Here again, Relator is unaware of Medicare Part C plans' combined spending on Simponi ARIA. However, it is reasonable to assume that adding the Part C plans' expenditures on Simponi ARIA would cause these amounts to increase substantially.

[2] In its periodic reports filed with the SEC, JNJ combines sales of Simponi ARIA and Simponi.

	Medicare Part B Spending	Part B Drug Expense Ranking	Beneficiaries	Avg. Spending Per Beneficiary
2014	$61,419,868	72 out of 450	4,305	$14,267
2015	$126,154,052	49 out of 466	7,737	$16,305
2016	$186,314,327	41 out of 482	10,508	$17,731
2017	$229,811,823	32 out of 482	12,631	$18,194
Total	**$603,700,070**			

58. Simponi ARIA is likewise a substantial expense for the Plaintiff States' Medicaid programs. From 2014 through 2018, the Plaintiff States' Medicaid programs have paid over $25.75 million in reimbursements for Simponi ARIA. *See* CMS's State Drug Utilization Data (avail. at https://data.medicaid.gov/browse?category=State+Drug+Utilization&limitTo= -datasets&sortBy=newest).

	Prescriptions	Reimbursements (Millions)
2014	79	$198,530
2015	721	$1,708,428
2016	1,900	$5,246,531
2017	3,015	$7,629,218
2018	4,549	$10,973,687
	10,264	**$25,756,394**

3. ***The Contract Purchase Program***

59. Starting no later than 2007, Janssen began offering certain physician practices the "Contract Purchase Program" ("CPP") through which they could qualify for discounted pricing on their purchases of Remicade. All physician practices that entered into the CPP received discounted pricing on Remicade purchases. The practices, however, could earn greater discounts by increasing the amount of Remicade they purchased. Each quarter Janssen measured these customers' purchase volumes. If they purchased more vials of Remicade in a quarter compared to the same quarter in the prior year, they earned the additional discount. And since Janssen set multiple growth tiers, the amount of the additional discount per vial increased when a physician

practice's purchase growth surpassed the minimum growth percentage assigned to each performance tier.

60. Janssen added Simponi ARIA to the CPP in 2013 and began basing the amount of the additional discounts it offered to physician practices on the combined growth of Remicade and Simponi ARIA.[3]

61. Below is a chart from a Janssen brochure that provides an overview of the CPP's discount tiers:

Tier	Total Vials % Change (Current Year Quarter vs Prior Year Quarter)	Price Per Vial	Additional Discount Per Vial	
	Less than or equal to 0%	CPP Price	SIMPONI ARIA®	REMICADE®
	CPP Performance-Based Discounts			
1	Greater than 0% and less than 5%	CPP Price and Discount	$7.50	$2.50
2	Greater than or equal to 5%	CPP Price and Discount	$25.00	$5.00

62. Importantly, Janssen only offered the CPP to health care provider entities that own, manage or control a physician, group of physicians, physician practice, or physician clinic.

63. Janssen did not offer the CPP and its volume-based discounts to hospitals or hospital-owned practices and instead charged these providers full price for the drugs. It did this to keep Remicade's and Simponi ARIA's Average Sales Prices substantially higher than the discounted prices physician practices paid for the drugs under the CPP and thereby ensured that these key customers earned a significant profit on each vial of Remicade and Simponi ARIA purchased. Moreover, hospitals and hospital-owned providers represent a smaller market for

[3] Janssen created and made available to providers a tool called the "Program Overview & Contractor Estimator" so physician practices could see how many more Remicade or Simponi ARIA infusions they needed to administer to qualify for the next discount tier.

Remicade and Simponi ARIA and are not owned by prescribers who can be influenced by the opportunity to profit from every vial of Remicade and Simponi ARIA they prescribe and infuse.

64. Inasmuch as private practices that have in-office infusion suites are the biggest purchasers of Remicade and Simponi ARIA, Janssen utilized the CPP to ensure that this market was offered the most competitive price incentives and earned the highest profit margin on each vial.

65. In addition, to participate in the CPP program a physician practice had to agree to keep the terms of the CPP agreement as well as the pricing and discounts available under the CPP confidential.

B. Rheumatoid Arthritis, Crohn's Disease, Ulcerative Colitis, Psoriatic Arthritis, and Ankylosing Spondylitis and the Various Biologic Drugs Approved to Treat These Diseases

1. *Rheumatoid arthritis*

66. Rheumatoid arthritis is an inflammatory disease that causes pain, swelling, stiffness, and loss of function in the joints. This disease occurs when the immune system, which normally defends the body from invading organisms, attacks the membrane lining the joints. Although the disease often begins in middle age and occurs with increased frequency in older people, older teenagers and young adults may also be diagnosed with the disease.

67. Rheumatoid arthritis affects people differently. In most cases it is chronic. Some people have mild or moderate forms of the disease, with periods of worsening symptoms, called flares, and periods in which they feel better, called remissions. Other people have a severe form of the disease that is active most of the time, lasts for many years or a lifetime, and leads to serious joint damage and disability.

68. Most people who have rheumatoid arthritis seek treatment from physicians who specialize in rheumatology. Rheumatologists often prescribe medications to reduce patients' pain and slow the course of the disease. Depending on the severity of a patient's rheumatoid arthritis symptoms, physicians may prescribe:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) – *e.g.,* ibuprofen, naproxen, Celebrex (Celecoxib), Mobic (meloxicam), Indocin (indomethacin), Voltaren (diclofenac), and Arthrotec (diclofenac and misoprostol);
- Disease-modifying anti-rheumatic drugs (DMARDs) – *e.g.,* methotrexate, hydroxychloroquine, leflunomide, sulfasalazine, and apremilast; or
- Biologics[4]:

  Tumor necrosis factor-alpha ("TNF-alpha") biologics (a/k/a TNF inhibitors)[5] – *e.g.,* Cimzia (certolizumab pegol), Enbrel (etanercept), Humira (adalimumab), **Remicade (infliximab)**, Simponi (golimumab), and **Simponi ARIA (golimumab)**; or

  Non-TNF biologics[6] – *e.g.,* Actemra (tocilizumab), Orencia (abatacept), Rituxan (rituximab), and Xeljanz (tofacitinib).

69. Typically, biologics are only used when NSAIDs and DMARDs do not reduce the symptoms of rheumatoid arthritis. Depending on the specific drug, biologics may be used alone or in combination with the DMARD methotrexate. Due to the risk of serious infection, biologics are not used in combination with each other.

[4] Biopharmaceuticals, unlike chemical medications, are made from material found in life, usually proteins. Many biologic treatments are proteins called antibodies, which normally are part of the body's immune defense. The antibodies used for biologic therapy have been developed to bind and interfere with the inflammatory process in a disease.

[5] Tumor necrosis factor-alpha is a substance in the body that prompts the body to create inflammation. TNF-alpha biologics can reduce inflammation and stop disease progression by targeting and blocking the activity of tumor necrosis factor-alpha.

[6] Non-TNF biologics target other substances or proteins in the body that stimulate immune responses, such as inflammation.

70. The American College of Rheumatology ("ACR") recommends that patients with early or established rheumatoid arthritis[7] start with NSAIDs or DMARD monotherapy, preferably methotrexate. If after DMARD monotherapy the disease activity progresses to a moderate or high severity, the ACR recommends that the patient use (in no order of preference) combination DMARDs, a TNF-alpha biologic, or a non-TNF biologic. *See* 2015 Am. College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis.

71. NSAIDs and DMARDs are taken orally or by subcutaneous injection. Remicade and Simponi ARIA are administered through infusion. Other biologics are administered by infusion, subcutaneous injection or by tablet. The table below provides the method of delivery for commonly prescribed biologics approved for rheumatoid arthritis:

	Method of Administration	**FDA Approval**
TNF-alpha biologics:		
Enbrel (etanercept)	Subcutaneous Injection	Nov. 1998
Remicade (infliximab)	Infusion	Nov. 1999
Humira (adalimumab)	Subcutaneous Injection	Dec. 2002
Simponi (golimumab)	Subcutaneous Injection	Apr. 2009
Cimzia (certolizumab pegol)	Subcutaneous Injection	May 2009
Simponi ARIA (golimumab)	Infusion	July 2013
Non-TNF biologics:		
Orencia (abatacept)	Infusion or Subcutaneous Injection	IV - Dec. 2005 SC - July 2011
Rituxan (rituximab)	Infusion	Feb. 2006
Actemra (tocilizumab)	Infusion or Subcutaneous Injection	IV - Jan. 2010 SC - Oct. 2013
Xeljanz (tofacitinib)	Tablet	Nov. 2012

[7] A patient who has had rheumatoid arthritis symptoms/disease for less than six months is deemed to have "early" rheumatoid arthritis, and a patient who has had rheumatoid arthritis symptoms/disease for more than six months is considered to have "established" rheumatoid arthritis.

72. Janssen has not conducted head-to-head clinical trials to determine whether Remicade or Simponi ARIA is more effective in treating rheumatoid arthritis than other biologics.

73. Remicade, Humira, and Enbrel are considered to have similar safety and efficacy profiles. (*See, e.g.*, E. Morgan DeWitt, MD, MSCE et al., Medicare Coverage of Tumor Necrosis Factor α Inhibitors as an Influence on Physicians' Prescribing Behavior, 166 Archive of Internal Medicine at 57 (Jan. 9, 2006) (avail. at https://jamanetwork.com/data/journals/ - INTEMED/5513/ioi50173_57_63.pdf)).

74. Similarly, the ACR Guideline for treating rheumatoid arthritis does not differentiate between the safety and efficacy of the various TNF-alpha biologics (a/k/a TNF inhibitors) in treating moderate to severely active arthritis. Rather, it treats them as being generally equivalent to each other in terms of safety and efficacy.

75. Accordingly, there are multiple drug options for relieving the symptoms and slowing the progression of rheumatoid arthritis.

76. Notably, rheumatoid arthritis drugs have the second highest total sales of all drugs worldwide with over $40 billion in sales. The rheumatoid arthritis drugs that had the highest market share in the United States in 2013 were Humira, Enbrel, and Remicade. *See* Eric Palmer, *Top 10 Rheumatoid Arthritis Drugs 2013*, FiercePharma (Sep. 16, 2013) (available at http://www.fiercepharma.com/sales-and-marketing/top-10-rheumatoid-arthritis-drugs-2013 (last viewed on Jan. 27, 2020)).

2. *Crohn's disease & ulcerative colitis*

77. *Crohn's disease* is a chronic disease that causes inflammation in the gastrointestinal tract. The disease most often begins gradually and can become worse over time.

Most people have periods of remission that can last for weeks or years. Complications of Crohn's disease can include bowel obstruction, fistulas, anal fissures, ulcers, malnutrition, and inflammation in the joints, eyes, and skin.

78. *Ulcerative colitis* is a chronic disease that causes inflammation and ulcers on the inner lining of the large intestine. Ulcerative colitis most often begins gradually and can become worse over time. Symptoms can be mild to severe. Most people have periods of remission that can last for weeks or years.

79. There is no cure for Crohn's disease or ulcerative colitis, but medicine can reduce the symptoms of the diseases. Most people who have Crohn's disease or ulcerative colitis seek treatment from physicians who specialize in gastroenterology. Gastroenterologists often prescribe medications to slow the course of the disease, keep patients in remission, and reduce patients' pain.

80. Conventional or first line treatment for Crohn's disease and ulcerative colitis typically involves the use of aminosalicylates (*e.g.,* sulfasalazine, mesalamine, olsalazine, and balsalazide), corticosteroids (*e.g.,* prednisone, methylprednisolone and budesonide), and/or immunomodulators (*e.g.,* methotrexate, 6-mercaptopurine (6-MP), azathioprine, and cyclosporine). When conventional treatment fails gastroenterologists usually step up the patients' treatment to one of the following biologic drugs:

- TNF-alpha biologics – *e.g.,* Cimzia (certolizumab pegol), Humira (adalimumab), **Remicade (infliximab)**, and Simponi (golimumab); or
- Non-TNF biologic – *e.g.,* Entyvio (vedolizumab), Stelara (ustekinumab), and Tysabri (natalizumab).

81. Depending on the specific biologic, it may be used alone or in combination with a first line medicine. However, due to the risk of serious infection, biologic drugs are not used in combination with each other.

82. Some biologics, such as Cimzia, Humira, and Simponi, are administered by subcutaneous injection while Entyvio, Remicade, and Tysabri are administered through infusion. Stelara, which was only recently approved for Crohn's disease, can be administered by subcutaneous injection or infusion. Xeljanz is taken orally. The table below provides the method of delivery for commonly prescribed biologics approved for Crohn's disease and ulcerative colitis.

	Method of Administration	**FDA Approval**
TNF-alpha biologics:		
Remicade (infliximab)	Infusion	Crohn's - Aug. 1998 U.C. - Sep. 2005
Humira (adalimumab)	Subcutaneous Injection	Crohn's - Feb. 2007 U.C. - Sep. 2012
Cimzia (certolizumab pegol)	Subcutaneous Injection	Crohn's - Apr. 2008
Simponi (golimumab)	Subcutaneous Injection	U.C. - May 2013
Non-TNF biologics:		
Tysabri (natalizumab)	Infusion	Crohn's - Jan. 2008
Entyvio (vedolizumab)	Infusion	Crohn's & U.C. - May 2014
Stelara (ustekinumab)	Infusion or Subcutaneous Injection	Crohn's - Sep. 2016 U.C. - Oct. 2019
Xeljanz (tofacitinib)	Tablet	U.C. - May 2018

83. Janssen has not conducted head-to-head clinical trials to determine whether Remicade is more effective in treating Crohn's disease or ulcerative colitis than other biologics.

84. Moreover, the American College of Gastroenterology's Clinical Guidelines for management of Crohn's disease and ulcerative colitis do not differentiate between the safety and efficacy of the various TNF-alpha biologics (a/k/a TNF inhibitors) approved for the management of moderate to severely active Crohn's disease or moderate to severely active ulcerative colitis. Rather, it treats them as being generally equivalent to each other in terms of safety and efficacy.

85. Accordingly, for patients who have an inadequate response to first line therapy, there are multiple biologic drug options for relieving the symptoms of Crohn's disease and ulcerative colitis.

3. *Psoriatic arthritis*

86. Psoriatic arthritis is an inflammatory arthritis that usually arises with skin psoriasis. It causes joint pain and swelling that can lead to damage of the joint if the inflammation is not controlled.

87. The disease is treatable but not curable. Most people who have psoriatic arthritis seek treatment from a rheumatologist. Rheumatologists often prescribe medications to reduce patients' pain and slow the course of the disease. Depending on the severity of a patient's symptoms, rheumatologists will prescribe, individually or in combination, corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs), disease-modifying anti-rheumatic drugs (DMARDs), such as methotrexate and sulfasalazine, and/or biologics, including Cimzia (certolizumab pegol), Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), **Remicade (infliximab)**, Simponi (golimumab), **Simponi ARIA (golimumab)**, Stelara (ustekinumab), Taltz (ixekizumab), and Xeljanz (tofacitinib). Due to the risk of serious infection, the biologic drugs are not used in combination with each other.

88. Some biologics approved for treatment of psoriatic arthritis, such as Cimzia, Cosentyx, Enbrel, Humira, Simponi, Stelara, and Taltz, are administered by subcutaneous injection while Remicade and Simponi ARIA are administered through infusion, and Xeljanz is taken orally. The table below provides the method of delivery for commonly prescribed biologics approved for psoriatic arthritis.

	Method of Administration	FDA Approval
TNF-alpha biologics:		
Enbrel (etanercept)	Subcutaneous Injection	Jan. 2002
Remicade (infliximab)	Infusion	May 2005
Humira (adalimumab)	Subcutaneous Injection	Oct. 2005
Simponi (golimumab)	Subcutaneous Injection	Apr. 2009
Cimzia (certolizumab pegol)	Subcutaneous Injection	Sep. 2013
Simponi ARIA (golimumab)	Infusion	Oct. 2017
Non-TNF biologics:		
Stelara (ustekinumab)	Subcutaneous Injection	Sep. 2013
Cosentyx (secukinumab)	Subcutaneous injection	Jan. 2016
Taltz (ixekizumab)	Subcutaneous Injection	Dec. 2017
Xeljanz (tofacitinib)	Tablet	Dec. 2017

89. Janssen has not conducted head-to-head clinical trials to determine whether Remicade or Simponi ARIA is more effective in treating psoriatic arthritis than other biologics.

90. Further, the ACR and National Psoriasis Foundation's Guideline for treatment of psoriatic arthritis does not differentiate between the safety and efficacy of the various TNF-alpha biologics (a/k/a TNF inhibitors) approved for the management of active psoriatic arthritis. Rather, it treats them as being generally equivalent to each other in terms of safety and efficacy.

91. Accordingly, there are multiple drug options for relieving the symptoms and slowing the progression of psoriatic arthritis.

4. ***Ankylosing spondylitis***

92. Ankylosing spondylitis is a form of progressive arthritis that causes chronic inflammation of the joints in the spine. Many people with ankylosing spondylitis have mild episodes of back pain that come and go. Other people who have this disease suffer severe, ongoing pain accompanied by loss of flexibility of the spine. In some people, ankylosing spondylitis can affect joints outside of the spine, like the shoulders, ribs, hips, knees, and feet, and organs, such as the eyes, bowel, and more rarely the heart and lungs.

93. There is no cure for ankylosing spondylitis, but some treatments relieve symptoms of the disorder and may possibly prevent its progression. Most people who have ankylosing spondylitis seek treatment from a rheumatologist. Rheumatologists often prescribe medications to reduce patients' pain and slow the course of the disease.

94. Depending on the severity of the symptoms, first line treatment for ankylosing spondylitis typically involves the use of NSAIDs (*e.g.,* ibuprofen, naproxen, Celebrex (Celecoxib), Mobic (meloxicam), Indocin (indomethacin), Voltaren (diclofenac), and Arthrotec (diclofenac and misoprostol)), and/or DMARDs (*e.g.,* methotrexate and sulfasalazine). If the first line therapy fails, treatment frequently steps up to a biologic (*e.g.,* Humira (adalimumab), Cimzia (certolizumab pegol), Cosentyx (secukinumab), Enbrel (etanercept), **Remicade (infliximab)**, Simponi (golimumab), or **Simponi ARIA (golimumab)**). Due to the risk of serious infection, the biologic drugs are not used in combination with each other.

95. NSAIDs and DMARDs are taken orally or by subcutaneous injection. With regard to the biologics, Cimzia, Cosentyx, Enbrel, Humira, and Simponi are administered by subcutaneous injection, and Remicade and Simponi ARIA are administered through infusion. The table below provides the method of delivery for commonly prescribed biologics approved for ankylosing spondylitis.

	Method of Administration	**FDA Approval Date**
TNF-alpha biologics:		
Enbrel (etanercept)	Subcutaneous Injection	July 2003
Remicade (infliximab)	Infusion	Dec. 2004
Humira (adalimumab)	Subcutaneous Injection	July 2006
Simponi (golimumab)	Subcutaneous Injection	Apr. 2009
Cimzia (certolizumab pegol)	Subcutaneous Injection	Oct. 2013
Simponi ARIA (golimumab)	Infusion	Oct. 2017
Non-TNF biologics:		
Cosentyx (secukinumab)	Subcutaneous injection	Jan. 2016

96. Janssen has not conducted head-to-head clinical trials to determine whether Remicade or Simponi ARIA is more effective in treating ankylosing spondylitis than other biologics.

97. Here again, the ACR's Guideline for treatment of ankylosing spondylitis does not differentiate between the safety and efficacy of the various TNF-alpha biologics (a/k/a TNF inhibitors) approved for the treatment of active ankylosing spondylitis, rather it treats them as being generally equivalent to each other in terms of safety and efficacy.

98. Accordingly, there are multiple drug options for relieving the symptoms and slowing the progression of ankylosing spondylitis.

C. How Rheumatology and Gastroenterology Practices Are Reimbursed for Biologic Drugs and Infusion Services

1. *Reimbursement for infusible biologics Remicade and Simponi ARIA*

99. There are two ways for rheumatology and gastroenterology practices that have infusion suites to obtain infusible biologics such as Remicade and Simponi ARIA:

- *Buy-and-bill* – the practice purchases the drug from a distributor, maintains an inventory of the drug and, after administering it to the patient, bills the health plan for the service of administering the infusion and for the drug itself; or
- *Specialty pharmacy* – the practice orders the drug from a specialty pharmacy and, after administering it to the patient, bills the health plan for the service of administering the infusion; the specialty pharmacy bills the health plan for the drug.

100. Most rheumatology and gastroenterology physician practices that operate an in-office infusion suite use the buy-and-bill method because it offers them an opportunity to earn a profit (also referred to as a spread) on each vial of Remicade and Simponi ARIA because their acquisition costs for the drugs are lower than the reimbursement amounts.

101. After physician practices infuse Remicade and Simponi ARIA to patients, they submit claims for reimbursement on Form CMS-1500 on behalf of those patients to their insurers, including Medicare and Medicaid.

102. ***Medicare*:** Part B of the Medicare program reimburses physicians for drugs, including Remicade and Simponi ARIA, based on the drugs' Average Sales Price ("ASP") plus 6% of the ASP. After the beneficiary's deductible is met, Medicare pays 80% of the set rate (ASP + 6%), and the patient or secondary insurance is responsible for the remaining 20%. The vast majority of Medicare patients have supplemental coverage (*e.g.*, a Medigap plan or Medicaid) that pays the 20% coinsurance. If a Medicare patient does not have a supplemental policy, there are foundations that may assist with the 20% co-pay.

103. Part C Medicare Advantage plans reimburse physicians for drugs, including Remicade and Simponi ARIA, based on the drugs' ASP plus 6% of the ASP or a similar formula.

104. Significantly, Medicare (Part B and Part C) does not require a prior authorization or that a patient first try a biologic administered through subcutaneous injection before it will cover Remicade or Simponi ARIA.

105. ***Medicaid*:** Although each Plaintiff State administers its own Medicaid program and payment policies vary by state, most states pay physicians ASP plus 6% for infusible biologics that they purchase and administer.[8]

[8] Certain state Medicaid programs require drug acquisition through a specialty pharmacy, in which case the provider is only able to bill for the infusion service.

106. ***Commercial Payers*:** The reimbursement rate that commercial payers pay physician practices is typically based on an ASP-based formula.[9] The reimbursement rates that commercial payers pay are often higher than the Medicare and Medicaid reimbursement rates (ASP + 6%). In addition, as described in paragraph 166(d) below, providers, with Janssen's assistance, are frequently able to negotiate higher reimbursement rates from commercial payers.

107. Over the last several years, the increasing trend is for commercial payers to require that patients fail one, two, or three subcutaneous injectable biologics before they will cover an infusible biologic such as Remicade or Simponi ARIA. This is referred to as "step therapy" because the insurers require that the patients try and fail other less expensive medications before "stepping up" to costlier drugs. With regard to Remicade and Simponi ARIA, many insurers require step therapy because the biologics delivered by subcutaneous injection are viewed as having similar safety and efficacy profiles as Remicade and Simponi ARIA and are significantly less expensive since they do not involve the infusion service.

2. *Reimbursement for infusion services*

108. ***Medicare*:** Medicare Part B reimburses physicians for administering the infusion by paying a service fee set forth in the outpatient Physician Fee Schedule ("PFS").

109. For the two-hour Remicade infusions, the physician practices bill the first hour under CPT code 96413 and the second hour under CPT code 96415. For the 30-minute Simponi ARIA infusions, the physician practices bill under CPT code 96413. For example, in 2013 Medicare paid physicians in Massachusetts (everywhere but metropolitan Boston) approximately

[9] Certain commercial payers may require drug acquisition through a specialty pharmacy, in which case the provider is only able to bill for the infusion service.

$151 for the first hour of an infusion and $32 for each subsequent hour. *See* 2013 Medicare Physician Fee Schedule.

110. After the patient's deductible is met, Medicare pays 80% of the set rate, and the patient or secondary insurance is responsible for the remaining 20%.

111. Medicare Advantage plans similarly reimburse providers for infusion services based on the PFS rates or a similar rate schedule.

112. ***Medicaid*:** Although each Plaintiff State administers its own Medicaid program and payment policies vary by state, states frequently reimburse physicians for office-based infusion services by applying Medicare's PFS. Several states require prior authorization.

113. ***Commercial Payers*:** Most commercial payers reimburse for infusion services based on Medicare's PFS rates plus a negotiated premium. Commercial payers typically pay a higher reimbursement fee for infusion services than Medicare and Medicaid.

3. *Reimbursement for self-injectable biologics*

114. For purposes of this Complaint, a biologic drug that is approved for the treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, and/or psoriatic arthritis and that is delivered by subcutaneous injection, including, but not limited to, Actemra, Cimzia, Cosentyx, Enbrel, Humira, Orencia, Simponi, Stelara, and Taltz, is referred to herein as a "Self-Injectable," and these drugs are collectively referred to as the "Self-Injectables."

115. Medicare (Part B and Part C) generally does not cover the cost of a Self-Injectable.

116. When purchased from a pharmacy and self-administered at home the Self-Injectables are covered under Medicare Part D. Generally, after a physician writes a prescription

for a Medicare Part D beneficiary, the patient can take the prescription to a pharmacy to be filled. When the pharmacy dispenses a Self-Injectable to the patient, the pharmacy submits a claim electronically to the beneficiary's Part D sponsor and receives reimbursement for the portion of the Self-Injectable's cost not paid by the beneficiary.

117. In view of the infusion service revenue as well as the profit earned on each vial of Remicade and Simponi ARIA purchased, physician practices earn a higher profit by prescribing and administering Remicade and Simponi ARIA than merely prescribing a Self-Injectable or biologic that is taken orally and for which the prescriber cannot earn a spread.

D. Janssen Provided Free Business Advisory Services to Induce Physicians to Prescribe and Infuse Remicade and Simponi ARIA

118. The largest and most important market for Remicade and Simponi ARIA sales is rheumatology and gastroenterology practices that operate an in-office infusion suite, which Janssen referred to as an "IOI". From at least 2003 through 2016, Janssen engaged in the illegal kickback scheme detailed below to expand the IOI market and grow sales of Remicade and Simponi ARIA within the IOI market.

119. Janssen had determined that physician practices that followed its business operations and practice management guidance in establishing and operating an in-office infusion business could generate revenue of approximately $1,400 to $2,000 per infusion chair each day from the spread on the drugs and infusion service reimbursements. Accordingly, an in-office infusion business with four or five chairs, which was the typical number for in-office infusion suites, could generate approximately $7,000 to $10,000 in revenue per day from the infusion business. Moreover, Janssen had also determined that at an efficiently operated in-office infusion suite one nurse could manage five infusion chairs at once. The average daily cost of a nurse was

$320 ($40 per hour for an eight-hour day). Consequently, a practice with an in-office infusion suite that had five chairs could net approximately $6,650 to $9,650 per day in profits.

120. One of Janssen's principal, longtime strategies for expanding the in-office infusion market and growing sales of Remicade and Simponi ARIA was to advise rheumatology and gastroenterology practices about how these drugs offer a lucrative business opportunity that Self-Injectables or other biologics taken orally do not offer – a significant payment for each Remicade and Simponi ARIA infusion in addition to a profit on every vial of the drugs purchased. Janssen touted this business opportunity to physician owners of rheumatology and gastroenterology practices as the "infusion business model" and "the Remicade model." Janssen emphasized to rheumatology and gastroenterology practices that the infusion/Remicade business model creates a "passive income" stream that could be generated without placing additional time burdens on the physicians and with little up-front investment, as the main start-up costs for an infusion business are the cost of nurses, the acquisition of Remicade and/or Simponi ARIA, an IV pole, and an infusion chair.

121. To allay physicians' concerns regarding the complexities, risks, and time commitments associated with starting a new infusion business, Janssen, as part of its infusion/Remicade business model sales pitch, assured the rheumatology and gastroenterology practices that it would help them establish and set up the infusion suites and also help them operate and grow these infusion businesses once opened. In other words, Janssen effectively became a silent business partner to the physician practices.

122. Janssen employed a large team of highly-trained medical practice advisers to serve as the dedicated business partners to Remicade's and Simponi ARIA's top customers, helping them maximize profits on their in-office infusion businesses. Janssen called these

employees "Area Business Specialists" or "ABSs," and advised practices that the close attention and assistance from its trained business specialists would be provided free of charge as part of Janssen's support of the in-office infusion suites that the Company helped establish.

123. In addition, Janssen arranged and paid for outside business consultants who had expertise in medical practice and infusion business management to provide business advisory services to top accounts. Here again, these free business consulting services from leading experts in the field were part of the package of services Janssen provided to top accounts to support their in-office infusion business and to convince the physicians to invest in and remain committed to the infusion/Remicade business model.

1. ***Janssen employed a team of Area Business Specialists who focused predominately on growing sales of Remicade and Simponi ARIA by providing business advice and support to prescribers***

124. When this action was commenced in October 2016, there were over 40 Janssen ABSs nationwide – typically one in each Remicade/Simponi ARIA account territory. Prior to re-districting and reducing the number of ABS territories in or around mid-2013, Janssen had approximately 70 ABS territories across the country. Because ABSs worked primarily with physician owners and physicians whose compensation was based, in part, upon revenue generated from the infusion drugs and services they administered (hereinafter collectively referred to as "stakeholder physicians") and managers of rheumatology and gastroenterology practices as well as hospital executives to enhance and grow their infusion businesses, Janssen typically sought out and hired former practice managers, hospital administrators, and individuals with prior managed care employment experience for ABS positions. Given their practice management expertise, many individuals who worked as ABSs later become practice management consultants after leaving Janssen.

125. Janssen trained ABSs to focus on advising health care providers regarding the establishment and operation of infusion suites and not to spend time promoting the clinical aspects of Remicade and Simponi ARIA. Janssen employed a separate team of sales representatives, referred to as "Immunology Specialists," as well as medical science liaisons ("MSLs") to promote Remicade and Simponi ARIA by providing clinical information and building relationships with rheumatologists and gastroenterologists. The ABSs' responsibilities were focused on providing business advisory and support services. However, since some clinical discussion was unavoidable when certain practice management advice was provided, ABSs occasionally had to discuss the clinical aspects of Remicade and Simponi ARIA. When an account asked an ABS a clinical question, Janssen trained the ABSs to answer the question and then tell the account that the ABS would have the Immunology Specialist and/or MSL follow-up.

126. Janssen's objective was for the ABSs' services to influence physicians and induce sales of Remicade and Simponi Aria through business support. To incentivize ABSs to grow sales of Remicade and Simponi ARIA by the accounts in their respective territory, Janssen tied a significant portion of ABSs' compensation to sales growth at the accounts to which the ABSs provided business advisory services. Tellingly, although Janssen measured account growth by the increases in the amount of Remicade and Simponi ARIA vials purchased, in internal reports used to track ABSs' performance Janssen concealed such and instead made it appear that account growth was measured by new infusion patients at the accounts irrespective of the brand of biologic infused. ABSs were also compensated based on the number of IOIs that they helped open and keep open.

127. In a 2002 internal document, Janssen's predecessor Centocor summarized the ABS position as follows:

> Responsible for securing and preserving patient access to Remicade in the optimal site of care, ideally the physician's office. Within a defined geographic territory, provides **proactive, total account management to targeted accounts with a focus on site of care specific infusion issues, practice management and selling at an executive level.** Additionally, will serve as a resource to territory's accounts and Centocor staff regarding payer policies; reimbursement regulations and processes; **practice management**; and staffing resources.

(Emphasis added). In that same document, Janssen's predecessor stated that the ABS position was comprised of the following "essential functions," among others:

- Help physician practices open IOIs;
- Serve as a resource to territory's accounts regarding practice management;
- "Mentor doctors and staff on how to develop and implement an In Office Infusion program including overall operations management, scheduling, staffing, pre-authorization, reimbursement, capacity management, inventory management, and infusion management"; and
- Serve as a resource to territory's accounts regarding the following legal requirements for operating an infusion business: Medicare and Medicaid rules and regulations; Occupational Safety & Health Act; HIPAA; the Stark Act; state-specific clinical staff licensing requirements for Remicade compounding, admixture, administration and monitoring; and staffing.

128. In a 2015 job posting for an ABS position in Missouri, Janssen described the ABSs' job responsibilities as including the following responsibilities, among others:

- "Ensuring a mix of viable sites of care are available in the local marketplace";
- "[E]ducating practices on appropriate efficiency practices to infuse the pharmaceutical product(s) to remain viable";
- "The ABS approaches each customer from a total account management perspective, by leveraging resources appropriately, collaborating with business partners and accurately articulating the value proposition for the customer";
- "[M]entor[ing] doctors and staff on how to develop and implement an In Office Infusion program including overall operations management, scheduling, staffing, pre-authorization, reimbursement, capacity management, inventory management, and infusion management/efficiencies";
- Serve as a resource to territory's accounts regarding the following legal requirements for operating an infusion business: Medicare and Medicaid rules

> and regulations; Occupational Safety & Health Act; HIPAA; the Stark Act; and state-specific clinical staff licensing/certification requirements for product compounding, admixture, administration and monitoring.

(Avail. at https://www.linkedin.com/jobs/view/13989112 (last viewed on Oct. 12, 2016)).

129. In a 2019 job posting for an ABS position in Central Pennsylvania, Janssen included these same descriptions summarizing the ABS job function. (Avail. at https://www.linkedin.com/jobs/view/area-business-specialist-immunology-central-pennsylvania-janssen-biotech-inc-at-johnson-johnson-1229106987/ (last viewed on Jan. 27, 2020)).

130. Janssen's descriptions of the ABS position demonstrate that one of the Company's primary objectives for its team of "business specialists" was to create and maintain demand for the infusion/Remicade business model among physicians to induce physicians to prescribe and administer Janssen's infusible biologics. To do this, Janssen touted the economic benefits of the infusion/Remicade business model to stakeholder physicians and executives of physician practices and thereafter provided business operations and practice management advice and support to ensure that the physician practices operated their infusion businesses profitably so that the physicians would remain committed to the Remicade business model and grow their use of Remicade and Simponi ARIA.

131. As Janssen stated in an internal document, to successfully perform the position ABSs should "utilize[] the value of Janssen products and services in relation to customer needs to influence prescribing decisions."[10]

[10] ABSs did not provide health care services. The reference to "services" in this quote was a reference to the business advisory and other support services ABSs provided to accounts for free.

2. *Janssen arranged and paid for outside business consultants to advise and support the infusion businesses run by its top Remicade and Simponi ARIA accounts*

132. Given the inherent complexities of operating an infusion business, and that many physicians lack the time and/or business expertise to optimize their business operations or address operational issues in the most effective manner, there are numerous professional consultants in the health care industry who focus on furnishing practice management and business advisory services to physicians, practice managers, and practice staff. Many physician practices retain and pay significant fees to such consulting firms to obtain guidance and assistance with, among other issues, starting infusion businesses and operating the infusion business efficiently and profitably.

133. Consulting firms that advise physician practices with in-office infusion suites regarding business operations and practice management topics include, among others: Xcenda LLC ("Xcenda"), The Lash Group ("Lash"), MCV & Associates Healthcare Inc. ("MCV"), McKesson, Mark Huizenga Systems Consulting LLC, The Resource Group, Allen Consulting, Zetter Healthcare Management Consultants, Advanced Care Consulting, Healix/CORIS, WeInfuse, LLC, and 4Front Consulting Group, Inc.

134. The hourly market rate for these business consultants can be hundreds of dollars.

135. To serve as a complement to its own team of infusion business consultants, or as it has called them, "business specialists," Janssen arranged for outside industry-leading business consulting firms, including, but not limited to, Xcenda, Lash, MCV, and The Resource Group, to provide practice management and business advisory services and support to top accounts and prospective high-volume accounts at dinner and lunch meetings paid for by Janssen, organized by Janssen, and attended by Janssen's ABSs and/or sales representatives. As described in more

detail below, the outside consultants assisted and advised Janssen accounts on many of the same business operations and practice management topics that the ABSs addressed with their accounts.

136. Inasmuch these outside consultants are for-profit businesses that make money through consulting fees, they are continuously developing new programs that health care providers value and for which there is market demand. Janssen paid these outside practice management experts to create and present several business advisory programs that assisted rheumatology and gastroenterology practices that operate IOIs. Once Janssen became expert regarding a business operation or practice management program topic presented by Xcenda, Lash, or other outside consultant, it often created a similar program that then became part of the catalogue of free business operations and practice management programs and services the Company's ABSs regularly provided to top accounts.

137. The consultative services provided by the outside business consultants were similar, and in many cases identical, to the services Janssen's ABSs regularly provided to top Remicade and Simponi ARIA accounts and accounts identified as having significant growth potential. That physicians voluntarily pay outside consultants significant fees to provide business advisory services similar to the services Janssen provided evidences both the value of the Janssen business services as well as physician demand for the services.

138. Moreover, although some of Janssen's accounts continued to engage outside consultants to advise them regarding various business operations and practice management issues, the services Janssen provided and paid outside consultants to provide significantly reduced or, in many cases, negated the need for many physicians to hire and pay for outside consultants to assist them in operating their infusion businesses.

3. *Janssen helped rheumatology and gastroenterology physician practices across America establish in-office infusion businesses*

139. When rheumatology and gastroenterology practices elected to follow Janssen's advice and open an in-office infusion suite, Janssen's ABSs, who were expert at opening infusion suites, assisted the physician practices with designing and setting-up the infusion suites and ensuring that the infusion suites opened quickly (within approximately six weeks) and with as little expense and burden on the stakeholder physicians as possible.

140. The free business advisory services and consultations that Janssen provided to promote the "Remicade business model" to prospective high-volume accounts and assist the accounts in establishing and opening infusion businesses included consultations and assistance with the following topics, among others:

(a) ***The economic benefits and advantages of opening and operating an in-office infusion business and infusing Remicade and Simponi ARIA rather than prescribing drugs that patients self-administer at home – the Remicade model.*** Janssen provided this business advisory service and consultation to physician practices, including the stakeholder physician(s), practice manager/administrator, and billing staff, in the following ways:

- Provided by ABSs as part of regular office visits
- Provided by ABSs in connection with formal presentations, including, among others, the presentation titled: "IV Therapy: An Important Option for Your Patients," a/k/a "Why IV"
- Provided by outside consultants, such as Lash and Xcenda, in connection with formal presentations

The physicians and their practices derived significant value from this business advisory service, which Janssen provided on multiple occasions or until the physicians agreed to open an IOI, for the following reasons, among others:

- The physicians received expert business advice and/or assistance regarding:
  (i) the economic benefits of infusing rather than prescribing drugs that patients self-administer at home
  (ii) the infusion/Remicade business model
  (iii) starting an infusion business

- The physicians did not need to pay other consultants for the business advice and assistance, reducing their start-up and operating costs

- It reduced the burdens on physicians and their staff as well as overhead costs

The "Why IV" presentation referenced above was designed to foster a discussion in which ABSs could explain to physicians and their staff the opportunity to earn a spread on each vial and service revenue on each infusion performed in an in-office infusion suite – *i.e.*, the infusion business model and Remicade model.

(b) ***The establishment of an IOI, including design and décor selection, selecting and acquiring furniture, equipment and supplies, and suite set-up.*** Janssen provided this business advisory service to physician practices, including the stakeholder physician(s), practice manager/administrator, infusion nurse(s), and billing staff, in the following ways:

- Provided by ABSs as part of regular office visits

- Provided by ABSs in connection with formal presentations, including, among others, the presentations titled:
  (i) Infusion Suite Modeler (a computer-generated layout plan)
  (ii) "Infusion Optimization Modeler," a/k/a "IOM"

- Provided by outside consultants, such as Lash and Xcenda, in connection with formal presentations, including, among others, the presentations titled: "Setting Up In-Office Infusions of Remicade"

The physicians and their practices derived significant value from this service, which Janssen provided to practices whenever the opportunity arose, for the following reasons, among others:

- The physicians received customized, expert business advice and/or assistance regarding:
  (i) starting an infusion business
  (ii) reducing IOI start-up costs

(iii) operating the infusion business more effectively, efficiently, and profitably
(iv) attracting and maintaining infusion patients
(v) making the IOI more aesthetically pleasing to patients

- The physicians did not need to pay other consultants for the business advice/assistance, reducing their start-up and operating costs

- It reduced the burdens on physicians and their staff as well as overhead costs

Janssen provided advice regarding the optimal design and organization of the infusion suites so as to fit in as many infusion chairs as possible and in turn optimize scheduling to maximize the infusion suites' profitability. The "Infusion Suite Modeler" program provided a blueprint for infusion suites' layout. The ABSs presented mock IOMs, which are described in more detail in paragraph 166(a) below, to show the accounts how many infusions could be performed each day in in the infusion suite. If patients find an infusion suite to be aesthetically pleasing and comfortable, they will pay more and travel further to receive their infusions there. Accordingly, Janssen assisted top customers by providing design and décor advice, often making infusion suites feel like a spa experience. This advice helped top customers ensure retention of their current infusion patients, most of whom received Remicade and/or Simponi ARIA infusions, as well as attract new patients.

141. The below "Efficiency Checklist," which Janssen first provided to ABSs in or around 2003, sets forth the various operational and practice management issues about which Janssen advised and educated physician practices (free of charge) leading up to and following the opening of an in-office infusion suite:

Account Name:	**Date:**	
EFFICIENCY CHECKLIST		
	Y/N	**Comments**
ACCESSONE		
Uses AccessOne		
BAA [business associate agreement] signed		
LOS [limitation of services] signed		
Aware of Site Coordinators name and extension		
Utilizes fax BIF [benefits investigation form]		
Utilizes e-BIF		
Maintains a BIF log or filing system		
Enrolled in Care Coordination		
Enrolled in Prior Authorization Monitoring		
Reviews Verification of Benefits when received		
Does someone discuss financial responsibility with patient		
Is there a signed financial agreement or patient contract in place		
Office aware of Patient Affordability Options		
Recertification process in place-who owns the process		
Tracking mechanism to obtain a prior authorization		
Prior auth form or prior auth monitoring checked on BIF		
Tracking mechanism for following when a PC [primary care] referral is required		
Accepts referrals from other practices		
Enrolled in 2infuse.com		
Requirements for referring patients-MD order, tests, documentation		
PATIENT AFFORDABILITY OPTIONS		
Office aware of Patient Affordability Options		
JJPAF, Foundations, Remistart		
Is office part of the Remistart Closed Network		
Does office provide Remistart enrollment form as needed		
Is office utilizing the Remistart Provider Report on e-bif		
Does office submit EOB's [explanation of benefits] for the patient or require the patient to complete		
SCHEDULING		
Who owns the schedule-Infusion Staff, Front Desk		
Patient scheduled timely after verification received		
Maintenance patients scheduled for multiple appointments		
Opportunity to run IOM [Infusion Optimization Modeler]		
Patient scheduled for next appointment prior to leaving		
Postcard/email/text appointment reminders		
Implement charges for no-shows		
INVENTORY MANAGEMENT		
Practice has recently evaluated purchase options		
Practice has recently evaluated purchase terms		
Practice has single individual responsible for ordering		
Practice has single individual responsible for receipt and storage of drug		
Drug counted and checked against invoice prior to storage		
Inventory tracking method in place and followed		
Practice orders timely to decrease inventory on hand		
Emergency drug procurement procedure established		

Practice has policy in place for SPP [specialty pharmacy] Patients		
Practice using SPP tools and resources		
Rider policy on Property Insurance for inventory		
Is the Rider policy reviewed prn and adjusted for growth		
Refrigerator is secure and of sufficient size-Location safe and locked		
Surge protector on refrigerator or connected to back up generator		
Temperatures monitored and log maintained		
Food stored in separate refrigerator		
ENVIRONMENTAL ISSUES		
Infusions occur in separate room		
Infusion chairs are appropriate for infusion-material able to be cleaned easily? Are larger chairs available for obese patients?		
Is there an area to move a patient if a reaction occurs? Curtains?		
Television/Reading material present for patients		
WiFi available		
Sharps containers are used for storage of waste		
Biohazardous waste management process is in place		
INFUSION/WORKFLOW		
Patient scheduling process is in place and followed		
Patient is called 24-48 hrs prior to infusions-assessment performed?		
Staff is trained		
Clinical competency is assessed routinely		
Capacity is sufficient for future growth:		
Number of trained staff		
Number of days		
Number of chairs		
Back-up staff identified and trained		
Cancellation process established		
Alternate sites established		
CHART/DOCUMENTATION		
Separate paper chart or EMR section (or chart section)		
HAQ/Rapid 3/DAS score incorporated into evaluation		
Infusion Documentation:		
Utilizing Janssen Biotech Infusion Flow Sheet or EMR [electronic medical record]		
Diagnosis code appropriate		
Physicians order in chart/Are orders updated PRN [whenever necessary]?		
Documentation as per Payer Policy-DMARD failure, MTX [methotrexate]		
Pre-screening questionnaire prior to each infusion		
Infusion flow chart present and contains the following:		
Wt		
Dose (is wastage documented) - JW Modifier		
Allergies		
Infection evaluation		
PPD testing / Hep B testing/ Quantaferon Gold		
Catheter Placement-Site/Gauge/Length of Catheter/# of Attempts/Removal		
Lot # / Exp Date		
Vital signs (initial and ongoing)		
Premeds		

Protocol Available		
Infusion Start and Stop Times		
S/E –ADR [side effect management and advanced directives]		
Check local/state licensure requirements-RN/LPN/MA		
Check state board of medicine for requirements-Does MD need to sign verifying correct reconstituted amount for LPN/MA?		
Clinical signature		
BILLING		
Remicade Tracking log in place		
Process in place and followed to capture all infusion charges		
Cross check infusion schedule with infusions billed		
Prior auth/Pre-cert process in place and followed		
Collection policy in place		
Patient copay collected up front		
Medicare non coverage policy signed-ABN [assignment of benefit notification] available?		
Current Price loaded for Remicade-Someone assigned to track changes?		
Electronic claims filed		
A/R [accounts receivable] aging report reviewed appropriately		
Separate cost center / Bank account established for Remicade		
Individual identified to follow up on outstanding claims		
Adequate computer software / alternate system		
Denied claims appeals process initiated timely		
Is office aware of AccessOne's Appeal Process-administrative appeals only		
Denied claims follow-up/responsibility		
CONTRACTS		
Yearly review of Contracts (does the contract address IOI [in-office infusion])		
Review reimbursements captured to ensure contracts are being honored		
Advocates in the local Market		
Insurer Policy Summary Sheet utilized		
Copies of Contracts on file		
MBPO PROCESS IN PLACE		
Routine MBPO [Managing Biologics in the Physician's Office presentation] scheduled		
PAYING INVOICE		
Terms of invoice followed		
Terms negotiated on a regular interval-discounts available? Longer terms?		
PATIENT EDUCATION		
Education Documented		
Patient provided Remicade information - informed consent		
Medication Guide shared		
Discharge information provided		
Patient provided education materials		

142. ABSs typically spent a consultative session or office visit covering each section of the checklist (a few sections were sometimes combined into one consultative session). As a

result of this and other close business support, ABSs usually became entrenched in the physician practices and ended up working side by side with the practice managers and office staff in completing many of the tasks on the checklist.

143. Relator estimates that Janssen's ABSs helped hundreds of rheumatology and gastroenterology practices across the country start an in-office infusion business.

144. By closely assisting physicians and their staff with establishing and opening an infusion suite business, Janssen ensured that physicians opened the infusion suite, prescribed and infused Janssen's products once it was open, and profited from infusing Remicade and Simponi ARIA. By providing these free services, Janssen also secured the physicians' reliance and loyalty, which in turn gave Janssen future access to the physicians and their staff. Janssen referred to the growth in Remicade patients and sales generated as a result of the consultative services ABSs provided as "pull through."

4. *After helping physician practices establish in-office infusion suites, Janssen regularly provided free business operations and practice management services to induce physicians to prescribe and infuse Remicade and Simponi ARIA*

145. Like any other health care services business, operating an infusion suite is complicated and requires good management to be successful and profitable. In fact, many physicians who have opened an infusion suite have subsequently closed the business because they lacked the time and expertise to operate the infusion suite efficiently, profitably, and/or in compliance with all federal and state legal requirements.

146. Regardless of the number of infusions administered, if a physician practice cannot operate its infusion suite profitably, then it will likely switch from prescribing and infusing Remicade and Simponi ARIA to predominantly prescribing the Self-Injectables or other biologics that come in tablet form, both of which are easier to prescribe since they are not subject

to the step therapy requirements imposed by commercial payers and involve no additional business expense and risk. As Janssen often tells physician practices to which it provides free business advisory services, "if you are upside down on the drug you will not use it."

147. The importance and value of Janssen's provision of free business operations and practice management services to increase the efficiency and profitability of in-office infusion suites grew over time because Medicare lowered the amount it reimbursed physician practices for Remicade vials while increasing the amount it paid for the infusion services.

148. In order to ensure that rheumatology and gastroenterology practices profited from their infusion suites, Janssen had ABSs provide ongoing, free practice management advice and services and made sure that the ABSs were always available to help address any business issues that these practices confronted.

149. Janssen's Business Specialists and Janssen-paid outside consultants regularly provided free business operations and practice management support to accounts that prescribed and infused large quantities of Remicade and/or Simponi ARIA. In this manner, Janssen and top physician practice accounts had a business support arrangement.

150. By ensuring that a rheumatology and gastroenterology practice's infusion suite became and continued to operate as a major profit center for the stakeholder physicians, Janssen created a powerful economic incentive for the practice to continue prescribing and infusing Remicade and/or Simponi ARIA rather than prescribing less profitable Self-Injectables or biologics taken orally.

151. And by becoming an integral part of the success of their infusion business, Janssen sought to secure physicians' loyalty and desire for continued business advisory and

support services so that the physicians would continue favoring Remicade and Simponi ARIA over competing biologic and non-biologic treatments administered via infusion.

152. Likewise, since these providers reaped substantial economic benefits from Janssen's ongoing free business advisory and support services, they wanted to maintain their partnership/business arrangement with Janssen so as to continue receiving the valuable free services. As a result, the practices also generally chose Remicade and Simponi ARIA over competing biologics and non-biologic treatments.

153. In fact, Janssen's strategy was to cause rheumatology and gastroenterology practices to become dependent on the revenue from the Remicade and Simponi ARIA spreads and infusions because the practices would then be more likely to continue buying and infusing these drugs. Janssen helped many of its top accounts grow and develop their infusion businesses exponentially, in many cases creating high volume in-office infusion suites, which Janssen sometimes internally referred to as "cash cows" and "Remicade mills."

154. Janssen's kickback scheme was highly effective at increasing sales of Remicade and Simponi Area while sustaining the infusion/Remicade business model. Most rheumatology and gastroenterology physician practices that received Janssen's free assistance in establishing and operating their infusion businesses strongly favored Remicade and/or Simponi ARIA over other biologics and drugs. By comparison, physician practices that did not have an infusion suite generally prescribed all of the biologics—Remicade, Simponi ARIA, other infusibles, Self-Injectables, and oral biologics—but substantially more Self-Injectables than infusibles. Notably, patients who are prescribed infusible medicines by a physician who does not operate an in-office infusion business have numerous options as to locations where they can receive an infusion:

local hospitals, infusion centers, home infusion providers, or other medical practices that have an infusion suite.

155. By offering the valuable business operations/practice management consultations and support for free and helping physicians succeed under the Remicade business model, Janssen captured the loyalty and achieved unrestricted access to physicians and their staff for its ABSs as well as its sales force.

156. Said differently, Janssen's kickback scheme influenced and corrupted—and continues to influence and corrupt—the treatment decisions of providers at the rheumatology and gastroenterology practices with infusion suites that are administering Remicade and/or Simponi ARIA to high volumes of unsuspecting patients, including Medicare and Medicaid beneficiaries. Congress enacted the AKS to prevent this very type of corrupting marketing practice.

157. Self-Injectables and biologics that come in tablet form can be administered far more quickly and conveniently, as patients can self-administer these drugs in their home. Remicade and Simponi ARIA, on the other hand, are delivered through lengthy infusions performed at medical facilities every eight weeks for long stretches of the patients' lives, or in some cases permanently. Additionally, infusion procedures can be difficult on the body. Patients often feel fatigued and weak afterwards, requiring them to rest to recover from the procedure.

158. Consequently, by influencing hundreds if not thousands of health care providers to prescribe Remicade and Simponi ARIA instead of equally effective Self-Injectables and biologics that are taken orally, Janssen has caused very sick patients, many of whom are immobile or struggle moving from place to place, substantial inconvenience and discomfort while also exposing them to the drugs' potential harmful side effects.

159. The patients are unaware that the physicians received free business advisory services and support from Janssen. These patients—and Medicare and Medicaid which are paying for the treatment—are entitled to receive uncompromised treatment plans and advice that are not influenced by a drug company's free business services and support.

160. Janssen attempted to disguise its long-running, pervasive business advisory services and support kickback scheme as merely a method of making sure that patients would have access to an infusion suite where they can receive Remicade and Simponi ARIA. However, as explained above, there is no shortage of health care facilities and providers who offer infusion services. In addition, Janssen not only helped open in-office infusion businesses, it also helped grow them. By helping grow these infusion businesses, or Remicade mills, Janssen completely disregarded patients' best interests, and indeed inconvenienced them and exposed them to potential harm, in order to increase sales of Remicade and Simponi ARIA by corrupting rheumatologists' and gastroenterologists' treatment decisions. Janssen caused physicians to become hooked on the significant passive income that can be made from infusing Remicade and Simponi ARIA so that whenever possible the practices prescribe these Janssen products instead of non-biologic therapy, competing Self-Injectables, such as Humira, Enbrel, and Cimzia, other infusibles, and competing biologics that can be taken orally. This is the infusion/Remicade business model.

161. Typically, Remicade's and Simponi ARIA's top accounts are physician practices that have developed, with Janssen's close assistance, infusion businesses that perform the highest volume of infusions in their respective region. To reward those accounts in each territory across the country that purchase and infuse the highest volume of Remicade and Simponi ARIA and to induce them to continue to grow their usage of the drugs, Janssen visited these physician

practices at least once a month—and in most cases multiple times a month—to provide free practice management services that helped the infusion businesses, increase the practices' reliance on Janssen's business support, and grow utilization of Janssen's products. The second tier of customers in terms of Remicade and Simponi ARIA sales were rewarded with at least one on-site practice management consultation a quarter. The third tier of customers received at least one on-site practice management consultation a year. Physician practices that did not prescribe and infuse Remicade or Simponi ARIA and accounts where the sales volume was relatively low did not receive any free business advisory services unless they expressed an interest in growing their infusion business and showed a commitment to prescribe and infuse Remicade and Simponi ARIA, in which case Janssen tried to help them develop and grow their infusion businesses.

162. Similarly, each quarter the ABSs selected several accounts in their territory that they believed they could induce to grow usage of Remicade and/or Simponi ARIA and provided these accounts free business advice and practice management services.

163. Given their close relationship with many top accounts, the ABSs often met with the physicians and/or their staff multiple times per month to provide operational support of their infusion business. Moreover, when accounts ran into business or operational problems, the ABSs and, when necessary, the Janssen-paid outside consultants assisted the accounts in addressing the problems. These accounts continued growing their use of Remicade and/or Simponi ARIA at least in part because of the business advice they received from Janssen and in order to continue receiving the valuable business advice, which they did not receive from other drug manufacturers that marketed their products lawfully.

164. Since Janssen had already helped many top rheumatology and gastroenterology practices build infusion profit centers and turn them into well-oiled machines and highly-

profitable enterprises, many of the top accounts had become fairly proficient in operating their infusion businesses. Janssen's ABSs, nevertheless, regularly provided these accounts with business operations and practice management advice and services to further grow the infusion businesses and address specific operational issues within the practices' infusion businesses or even their non-infusion businesses. Most, if not all, of the practices valued all of the assistance they received over the years from Janssen's ABSs and considered the ABSs to be practice management experts and silent business partners who were integral to the success of their infusion businesses.

165. Rheumatology and gastroenterology practices that are operating a new or fairly new in-office infusion business found the ABSs' free business advisory services and support to be extremely helpful to the operation and growth of their infusion businesses and thus likewise derived substantial value from the services.

166. The business advisory services and support that Janssen provided to top accounts to help them maintain and grow their infusion businesses, and correspondingly to induce them to use Remicade and/or Simponi ARIA, addressed the following business operations and practice management topics, among others:

(a) ***The economic benefits and advantages of maintaining and growing the IOI; review of the IOI's infusion volume and profitability; Remicade and Simponi Aria utilization and profitability***. Janssen provided business advisory services and support concerning these topics to physician practices, including the stakeholder physician(s) and practice manager/administrator, in the following ways:

- Provided by ABSs as part of regular office visits

- Provided by ABSs in connection with formal presentations, including, among others, the presentations titled:
  (i) "iBiz"
  (ii) "Infusion Optimization Modeler," a/k/a "IOM"
  (iii) "Optimizing patients scheduling and infusion capacity"
  (iv) "Managing Biologics in the Physician Office," a/k/a MBPO

- Provided by outside consultants, such as Lash and Xcenda, in connection with formal presentations, including, among others, presentations titled: "Managing Biologics in the Physician Office," a/k/a MBPO

The physicians and their practices derived significant value from this business advice and support, which Janssen provided to practices weekly, monthly, or quarterly, for the following reasons, among others:

- The physicians received customized, expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) expanding the capacity of the IOI and increasing infusion service volume
  (iv) the economic benefits of infusing rather than prescribing drugs patients self-administer at home
  (v) the economic opportunity offered by Remicade and Simponi Aria infusions
  (vi) taking advantage of Medicare's coverage standard (*i.e.*, no step therapy requirement)
  (vii) reducing nurse staffing costs

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

Using its analytical program called "IBiz" (short for "Infusion Business")[11], Janssen analyzed the practice's and each physician's prescribing patterns and showed how the practice could increase profitability by using infusible biologics—namely Remicade or Simponi ARIA—

[11] Janssen changed this core and influential consultative presentation's name multiple times over the years. Other names Janssen used include "Account Review," "Managing Biologics in the Physician Office" (a/k/a "MBPO"), and "Infusion Services Review." These iterations of the IBiz presentation are collectively referred to herein as the "IBiz".

instead of the Self-Injectables, such as Humira, Enbrel, or Cimzia, or other biologics taken orally, such as Xeljanz. In the customized analyses that Janssen performed for top accounts since before 2008, the Company started by having the practices provide prescribing data for the period. It then analyzed the data and showed the accounts how much infusion service revenue the top accounts missed out on by prescribing certain patients a Self-Injectable or oral biologic. As part of the IBiz, Janssen similarly reviewed each individual practitioner's biologic usage history so the practices and stakeholder physicians knew which individual physicians were costing it revenue by prescribing Self-Injectables or oral biologics rather than Remicade or Simponi ARIA. In addition, Janssen compared the practice's average usage of Remicade and Simponi ARIA to the national average for the drugs. If a practice was lower than the national average, Janssen advised the practice that it should be more aggressive in prescribing and infusing Remicade and Simponi ARIA.

The main objective of the IBiz consultation was to help accounts maximize the income and minimize the overhead cost of its in-office infusion suite, which in turn incentivized and induced the physicians to prescribe and infuse more Remicade and Simponi ARIA.

Starting before 2008, Janssen advised top accounts on how to maximize their profits by managing their infusion schedules more efficiently so as to perform all infusions in a shorter period of time while minimizing the practices' overhead costs, namely nurse coverage (physician practices that operate infusion suites typically pay a nurse an hourly fee to insert and remove the IVs and monitor that patients receiving infusions). Using its analytical program called the "Infusion Optimization Modeler," or "IOM," Janssen reviewed top accounts' infusion schedules and instructed them how to stagger infusion start times to perform all infusions during a set number of days and provided a schedule optimization plan. ABSs used the IOM to advise

accounts regarding how they could increase the in-office infusion businesses' profitability by increasing the number of infusions performed and performing the infusions over a fewer number of business hours or days. ABSs were trained to always prepare the IOM in a manner that would induce accounts to add chairs, schedule time, and staff to its infusion business, which in turn would influence accounts to expand and grow their infusion business. Similarly, Janssen directed ABSs to always advise accounts that they were running out of capacity in order to cause the account to expand the IOI, which then put pressure on them to infuse more Remicade and Simponi ARIA.

After providing the IBiz and IOM consultations, ABSs monitored and followed-up with accounts to make sure that they implemented the scheduling and capacity changes that the ABSs advised them to make.

Janssen determined that the IBiz and IOM consultations were the most effective way for ABSs to influence physician prescribing behavior so as to grow sales of Remicade and Simponi ARIA. That these consultations were the best tool for ABSs to increase physician utilization of the drugs was routinely emphasized internally by ABS management. On its business plan forms, Janssen directed ABSs to "effect change in accounts" using the IBiz and IOM consultations. As a result, ABSs were required to identify the top growing accounts and accounts with strong growth potential within their territory and provide the IBiz and IOM consultations to these accounts monthly, or at least quarterly. Janssen had ABSs provide the IBiz and IOM consultations to accounts that prescribed and infused a smaller volume of Remicade and Simponi ARIA semiannually or annually.

ABSs also utilized the IBiz and IOM consultative services to advise accounts on how they could achieve the year-over-year growth necessary to qualify for the highest price discounts

under Janssen's Contract Purchase Program discussed in Part V-A-3 above. ABSs likewise utilized the "CPP calculator" tool to convince accounts to increase utilization of Remicade and/or Simponi Aria so that they would qualify for the highest discounts under the CPP.

(b) ***Improving an IOI's efficiency and optimizing the infusion schedule in order to perform more infusions, maximize profits, and grow the infusion business.*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s), practice manager/administrator, practice biologic coordinator, infusion nurse(s), and billing staff, in the following ways:

- Provided by ABSs as part of regular office visits
- Provided by ABSs in connection with formal presentations, including, among others, the presentations titled:
  (i) "iBiz"
  (ii) "Infusion Optimization Modeler," a/k/a "IOM"
  (iii) "Efficiency Checklist"
  (iv) "Optimizing patients scheduling and infusion capacity"
  (v) "Managing Biologics in the Physician Office," a/k/a MBPO
- Provided by outside consultants, such as Lash and Xcenda, in connection with formal presentations, including, among others, the presentations titled: "Managing Biologics in the Physician Office," a/k/a MBPO

The physicians and their practices derived significant value from this business advice and support, which Janssen provided to practices weekly, monthly, or quarterly, for the following reasons, among others:

- The physicians received customized, expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) expanding the capacity of the IOI and increasing infusion service volume
  (iv) the economic benefits of infusing rather than prescribing drugs patients self-administer at home
  (v) the economic opportunity offered by Remicade and Simponi Aria infusions

(vi) reducing nurse staffing costs

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance
- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

On ABSs' business plans, Janssen specifically included "all operational efficiencies will be enhanced and optimized within high volume sites of care" and "infusion operations are maximized" as two strategies for growing Remicade and/or Simponi ARIA utilization by accounts with in-office infusion businesses.

(c) ***Proactively managing and growing the entire practice as well as the infusion business.*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s), practice manager/administrator, the practice's biologic coordinator, infusion nurse(s), and billing staff, in the following ways:

- Provided by ABSs as part of regular office visits
- Provided by ABSs in connection with formal presentations, including, among others, the presentation titled: "Considerations for Proactive Practice Management"
- Provided by outside consultants, such as Lash and Xcenda, in connection with formal presentations, including, among others, the presentation titled: "Considerations for Proactive Practice Management"

The physicians and their practices derived significant value from this business advice and support, which Janssen typically provided to practices monthly, for the following reasons, among others:

- The physicians received customized, expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) managing the infusion business proactively rather than reactively

(iv) managing the entire practice proactively rather than reactively
(v) strategies that ensured maximum reimbursement from government and commercial payers while avoiding audits

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

The objective of the Proactive Practice Management presentation was to help practices manage their operational issues more proactively, and the specific topics covered in the presentation included:

- Understanding the practice landscape and processes

- Identifying benchmarking and potential areas of improvement for practices

- Establishing operational Standard Operating Procedures (SOPs) for the continuum of care

- Understanding the importance of business office management planning

- Integrating new mandatory technologies in the infusing practice

(d) ***Analysis and renegotiation of reimbursement rates from commercial payers for practices' top services and drugs.*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s), practice manager/administrator, the practice's biologic coordinator, billing staff, and the practice's accountant, in the following ways:

- Provided by ABSs as part of regular office visits

- Provided by ABSs in connection with formal presentations, including, among others, the presentations titled:
  (i) "Payer Management"
  (ii) "Negotiating Payer Contracts"
  (iii) "Quality of Care (patient satisfaction scores)"
  (iv) "Raising the Infusion Suite Experience," a/k/a "RISE"
  (v) "Enhancing quality measures, patient experience, and satisfaction"
  (vi) "Contracting, acquiring drug, and managing payers"

(vii) "Payer Relationship Management"
(viii) Payer/Insurance Summary sheets

- Provided by outside consultants, such as Lash and Xcenda, in connection with formal presentations

The physicians and their practices derived significant value from this business advice and support, which Janssen provided whenever the opportunity arose or at least quarterly, for the following reasons, among others:

- The physicians received customized, expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) operating the entire practice more profitably
  (iv) negotiating higher reimbursement rates on infusions as well as other high-volume services
  (v) negotiating higher reimbursement rates on Remicade and Simponi Aria as well as other high-volume drugs

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

Janssen advised accounts on how to negotiate contracts with commercial payers to obtain the highest reimbursement for Remicade and Simponi ARIA, infusion services, as well as other top revenue-generating services (usually the top 20-30 services and drugs billed by a practice). This helped accounts maximize their reimbursement amounts and profits for Remicade and Simponi ARIA and the related infusion services as well as other frequently billed services and drugs. Janssen advised practices to terminate the auto-renew provision so they could negotiate higher reimbursement rates. As part of this service, Janssen provided the practice manager a payer summary sheet for each commercial payer with which the practice had a contract. The practice manager then contacted each commercial payer to determine the practice's current

contracted rates for Remicade and Simponi ARIA, the infusion services (codes 96413 and 96415), and other services and drugs. In addition, Janssen helped outline negotiation strategies that top accounts could use to obtain better rates from commercial payers. Janssen also helped the top accounts enhance their practice profile going into their negotiations by addressing items that the commercial payers often considered in setting rates, such as the practice's quality of care metrics, patient satisfaction scores, staff expertise, referral times, convenience, patient parking access, weekend hours, wait times, and efficiency of infusion procedures (total time in the infusion suite).

Janssen also helped top accounts survey patients to learn about their infusion experience. Janssen called this service "RISE," which stands for "Raising Infusion Suite Experience." Janssen's RISE program frequently helped top accounts negotiate higher reimbursements on Remicade and Simponi ARIA and infusion services. Similarly, ABSs conducted "time studies" in the waiting room to assess patient flow, another metric that was then used to bolster patient satisfaction scores. When accounts showed the commercial payers that their infusion patients gave them high satisfaction scores, the insurance companies often were more willing to increase the reimbursement rates on infusion services.

(e) ***Establishing and implementing standard operating procedures to improve the infusion business workflow – drug eligibility and benefit verification, pre-authorization, infusion, coding, billing, collection, and appeals.*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s), practice manager/ administrator, the practice's biologic coordinator, and infusion nurse(s), in the following ways:

- Provided by ABSs as part of regular office visits

- Provided by ABSs in connection with formal presentations, including, among others, the presentations titled:
  (i) "Instituting best practice SOPs and clinical protocols"
  (ii) "Optimizing your prior authorization/benefit investigations workflows"
  (iii) "Utilizing alternative approaches to mitigate risk with buy-and-bill"
  (iv) "Billing and Coding for Infusions"
  (v) "Preparing the total office for ICD-10"

- Provided by outside consultants, such as Lash and Xcenda, in connection with formal presentations

The physicians and their practices derived significant value from this business advice and support, which Janssen typically provided monthly, for the following reasons, among others:

- The physicians received customized, expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) setting and documenting staff members' roles and responsibilities for the infusion service line
  (iv) strategies that ensured maximum reimbursement from government and commercial payers while avoiding audits

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

(f) ***Tracking and management of accounts receivable from infusions to increase payment collections from insurers and patients.*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s), practice manager/administrator, the practice's biologic coordinator, infusion nurse(s), and billing staff, in the following ways:

- Provided by ABSs as part of regular office visits

- Provided by ABSs in connection with formal presentations, including, among others, the presentation titled: "Billing and Coding for Infusions"

The physicians and their practices derived significant value from this business advice and support, which Janssen typically provided monthly, for the following reasons, among others:

- The physicians received expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) increasing collections from insurers and patients

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

(g) ***Refurbishing or enhancing the IOI; moving the IOI to a new location.***

Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s), practice manager/administrator, the practice's biologic coordinator, and infusion nurse(s), in the following ways:

- Provided by ABSs as part of regular office visits

- Provided by ABSs in connection with formal presentations, including, among others, the presentations titled:
  (i) "Raising the Infusion Suite Experience," a/k/a "RISE"
  (ii) "Enhancing quality measures, patient experience, and satisfaction"
  (iii) Infusion Suite Modeler (a computer-generated layout plan)

The physicians and their practices derived significant value from this business advice and support, which Janssen provided whenever the opportunity arose, for the following reasons, among others:

- The physicians received customized, expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) making the IOI more aesthetically pleasing to patients
  (iv) making and promoting the IOI as an alternate site of care (ASOC) to which other physicians would refer patients for infusions

(v) increasing patient and infusion volume

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

(h) ***Continuing and/or expanding the account's infusion business by adding other infusion service lines and treatments (e.g., oncology treatments and treatments for blood and lymph conditions).*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s), practice manager/administrator, the practice's biologic coordinator, infusion nurse(s), and billing staff, in the following ways:

- Provided by ABSs as part of regular office visits

- Provided by ABSs in connection with formal presentations, including, among others, the presentation titled: "IV Therapy: An Important Option For Your Patients," a/k/a "Why IV"

- Provided by outside consultants, such as Lash and Xcenda, in connection with formal presentations, including, among others, the presentation titled: "An Overview of Biopharmaceutical Trends: Today and Tomorrow"

The physicians and their practices derived significant value from this business advice and support, which Janssen provided whenever the opportunity arose, for the following reasons, among others:

- The physicians received expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) the economic benefits of infusing rather than prescribing drugs patients self-administer at home
  (iv) making and promoting the IOI as an alternate site of care (ASOC) to which other physicians would refer patients for infusions

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

(i) ***Maximization of CMS meaningful use bonuses under Medicare's Electronic Health Record (EHR) Incentive Program.*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s), practice manager/administrator, the practice's biologic coordinator, infusion nurse(s), and billing staff, in the following ways:

- Provided by ABSs as part of regular office visits

- Provided by ABSs in connection with formal presentations, including, among others, the presentations titled:
  (i) "Electronic Medical Records and Meaningful Use"
  (ii) "Achieving Meaningful Use 2 with electronic health records"

- Provided by outside consultants, such as Lash and Xcenda, in connection with a formal presentation

The physicians and their practices derived significant value from this business advice and support, which Janssen typically provided quarterly, for the following reasons, among others:

- The physicians received customized, expert business advice and/or assistance regarding:
  (i) operational support of the practice and infusion business
  (ii) operating infusion business and entire practice business more effectively, efficiently, and profitably
  (iii) effective utilization of electronic medical records systems
  (iv) securing maximum meaningful use bonuses from CMS

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

In 2009, Congress enacted the Health Information Technology for Economic and Clinical Health Act (HITECH) to establish a variety of programs designed to improve healthcare delivery

and patient care through investment and adoption of health information technology. One such program was the Medicare Electronic Health Record (EHR) Incentive Program under which physicians, including rheumatologists and gastroenterologists, could receive $44,000 or more in Medicare Incentive Payments by demonstrating "meaningful use" of government certified EHR technology. Meaningful use requirements centered on electronically capturing health information, using that key information to track clinical conditions, and communicating that information for care coordination purposes. Moreover, beginning in 2015, physicians who did not successfully demonstrate meaningful use became subject to a negative payment adjustment for services provided to Medicare beneficiaries. The payment reduction starts at 1% and increases each year that an eligible professional does not demonstrate meaningful use, up to a maximum of 5%.

Janssen advised accounts regarding the meaningful use bonuses available from CMS and further advised accounts regarding how to satisfy the clinical quality measures (CQMs) that demonstrated "meaningful use" so the accounts could earn the maximum incentive payments from Medicare and avoid paying penalties.

(j) ***Maximizing Remicade and Simponi ARIA discounts under the Contract Purchase Program.*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s) and practice manager/administrator, in the following ways:

- Provided by ABSs as part of regular office visits
- Provided by ABSs in connection with formal presentations, including, among others, the presentations titled:
  (i) "CPP End of Quarter Contract Report"
  (ii) "Vial Trend Update"
  (iii) "CPP Calculator"

The physicians and their practices derived significant value from this business advice and support, which Janssen typically provided monthly, for the following reasons, among others:

- The physicians received customized, expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) obtaining maximum discounts Janssen offered on purchases of Remicade and Simponi Aria vials under the Contract Purchase Program
  (iv) increasing infusion volume and maximizing profits by starting new rheumatoid arthritis patients on Simponi Aria rather than Remicade

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

(k) ***Management of vial/drug inventory; tracking of vials acquired via buy and bill and specialty pharmacy.*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s), practice manager/administrator, and billing staff, in the following ways:

- Provided by ABSs as part of regular office visits

- Provided by ABSs in connection with formal presentations, including, among others, the presentations titled:
  (i) "Controlling and managing the infusible inventory"
  (ii) "Inventory and Supply Management"

The physicians and their practices derived significant value from this business advice and support, which Janssen typically provided quarterly, for the following reasons, among others:

- The physicians received customized, expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) managing the infusion business proactively rather than reactively

(iv) obtaining the maximum discounts Janssen offered on purchases of Remicade and Simponi Aria vials under the Contract Purchase Program

- Reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- Reduced operational and administrative burdens for physicians and their staff as well as overhead costs

(l) ***Facilitating referral arrangements between accounts with an IOI and physicians who do not provide infusion services.*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s), practice manager/administrator, and the practice's biologic coordinator, in the following ways:

- Provided by ABSs as part of regular office visits

- Provided by ABSs in connection with formal presentations, including, among others, the presentations titled:
  (i) "Infusion Referrals: Improving the Continuity of Care"
  (ii) "Enhancing the continuity of care with inbound and/or outbound referrals"
  (iii) "IV Therapy: An Important Option For Your Patients," a/k/a "Why IV"

- Janssen's IOI locator - 2infuse.com

- Provided by outside consultants, such as Lash and Xcenda, in connection with formal presentations

The physicians and their practices derived significant value from this business advice and support, which Janssen provided whenever the opportunity arose, for the following reasons, among others:

- The physicians received expert customized, business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) making and promoting the IOI as an alternate site of care (ASOC) to which other physicians would refer patients for infusions

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

- It reduced physicians' marketing expenditures and efforts

(m) ***Use of gastroenterology practices' ambulatory surgical centers (ASC) as in-office infusion suites by reclassifying the ASC space.*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s) and practice manager/administrator, in the following ways:

- Provided by ABSs as part of regular office visits

- Provided by ABSs in connection with formal presentations, including, among others, the presentation titled: "Ambulatory Surgical Centers and Infusion Services"

- Provided by outside consultants, such as The Resource Group, Lash, and Xcenda, in connection with formal presentations

The physicians and their practices derived significant value from this business advice and support, which Janssen provided whenever the opportunity arose, for the following reasons, among others:

- The physicians received expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) increasing patient and infusion volume
  (iv) reclassifying practice space from ASC to infusion suite

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

By law, only certain services are allowed to be performed in the ASC setting; infusions are not one of the services allowed. For approximately ten years, Janssen arranged and paid for outside consultant The Resource Group (specifically Christine Pierce), Lash, and Xcenda to advise top gastroenterology accounts how to reclassify their ASC space for periods so that they could provide lucrative infusions in the space during such periods. Starting in or around 2010, Janssen also had ABSs advise gastroenterology practices regarding utilization of their ASC space for infusions. Due to concerns over potential liability issues if the infusion services and ASC services were not properly segregated, Janssen stopped having ABSs provide advice on this topic in 2013 and only arranged and paid for The Resource Group to provide this advisory program to gastroenterology accounts.

(n) ***State clinical staff licensing/certification requirements for infusion administration and monitoring (i.e., nurse practitioners (NP), physician assistants (PA), registered nurses, and licensed practical nurses) and advising practices on Medicare's requirements for billing infusion services provided by NPs and PAs as "incident to" a physician's order so that the practice could receive higher Medicare reimbursements.*** Janssen provided business advisory services and support concerning this business operations and practice management topic to physician practices, including the stakeholder physician(s), practice manager/administrator, the practice's biologic coordinator, infusion nurse(s), and billing staff, in the following ways:

- Provided by ABSs as part of regular office visits
- Provided by ABSs in connection with formal presentations, including, among others, the presentations titled:
  (i) "Proactive Practice Management"
  (ii) "Efficiency Checklist"

- Provided by outside consultants, such as Lash and Xcenda and The Resource Group, in connection with a formal presentation

The physicians and their practices derived significant value from this business advice and support, which Janssen provided quarterly or whenever needed, for the following reasons, among others:

- The physicians received customized, expert business advice and/or assistance regarding:
  (i) operational support of the infusion business
  (ii) operating the infusion business more effectively, efficiently, and profitably
  (iii) regulatory compliance for nursing staff
  (iv) Medicare's "incident to" billing requirements
  (v) practice's educational protocols for infusion nurses

- It reduced operating costs because the physicians did not need to pay other consultants for the business advice/assistance

- It reduced operational and administrative burdens for physicians and their staff as well as overhead costs

(o) ***Switching from Remicade to Simponi ARIA (product hopping)***. Knowing that Remicade's exclusivity rights were set to expire soon, when Simponi ARIA was approved in July 2013, Janssen began advising top rheumatology accounts that they could increase their infusion revenue by administering Simponi ARIA instead of Remicade. Since the time of infusion for Simponi ARIA is 30 minutes compared to 120 minutes for Remicade, Janssen advised rheumatology practices that if they used Simponi ARIA rather than Remicade and appropriately scheduled the patients they could perform three times more infusions in a day. And since Medicare reimburses significantly more for the first hour of an infusion than the second hour, as illustrated by the chart below, the practices' infusion suites could earn more revenue per day by performing more 30-minute Simponi ARIA infusions than two-hour Remicade infusions.

Comparison of Infusion Service Reimbursement for Remicade vs. Simponi ARIA (2013 Physician Fee Schedule Rates for Mass. (Excluding Metropolitan Boston Area))			
	Daily Infusions Per Chair	**Infusion Service Reimbursement**	**Daily Infusion Service Revenue Per Chair**
Remicade (2 hr. infusion)	4	$183 (1st hr. $151+ 2nd hr. $32)	$732
Simponi ARIA (30 min. infusion)	12	$151	$1,812

To further incentivize physicians to use Simponi ARIA instead of Remicade, through its CPP program (*see* Part V-A-3 above), Janssen offered physician practices a larger discount on Simponi ARIA than Remicade.

This business advice illustrates how Janssen placed sales and infusion suite profitability over patient care.

The below "action items" from Relator's February 2015 monthly performance evaluation report written by Relator's manager[12] shows how Janssen was aggressively advising accounts to switch patients from Remicade to Simponi ARIA before Remicade's patent expired, a practice known as "product hopping":

> Get to [infusion nurse] we spoke to from [Account A] this week and have her see the value that Simpono aria [sic] makes to the infusion center[.]
>
> * * *
>
> [Physician I-1 from Account I] needs to hear more drive for Simponi ARIA…..Expalin [sic] and document for him the need to drive more Arai [sic] in his infusion center. Ask for more (2) new patients per week. Use you trigger report and ask for the business. … [G]rowth and advancement of SA will drive your overall performance[.]

In instructing Relator to "explain and document" to this rheumatologist "the need to drive more [Simponi ARIA] in his infusion center," the manager was directing Relator to use the IBiz and IOM presentations discussed in paragraph 166(a) above to show the physician how he could

[12] Relator's manager served as the manager for the ABSs assigned to territories in the "Mid-Atlantic Region," which included all of Pennsylvania except for Philadelphia, New York, Massachusetts, Connecticut, Rhode Island, New Hampshire, Vermont, and Maine.

generate more revenue by prescribing and infusing Simponi ARIA rather than Remicade or other competing biologics. Notably, Relator's manager's statement also shows how, at the same time that ABSs provided free business advisory services to top accounts, they sought to gain commitments from the accounts to increase their use of Remicade and/or Simponi ARIA.

Demonstrating the impact of Janssen's advice to top accounts about switching from Remicade to Simponi ARIA, the ratio of Simponi ARIA sales to Remicade sales is much higher among rheumatology accounts that received Janssen's free practice management services than among those that did not receive such services.

(p) ***Placement of practice managers and infusion nurses who would assist in opening an IOI and/or serving as a loyal infusion champion.*** Janssen recruited and placed infusion nurses, practice managers, and office staff for accounts. These individuals became highly loyal to the ABSs and Janssen's products and would willingly agree to implement Janssen's utilization growth and efficiency strategies. Notably, ABSs received points in their evaluations for placing an infusion nurse, practice manager, or other staff person with an account, which led to higher bonuses and compensation.

The physicians and their practices derived significant value from this business support, which Janssen provided whenever needed, for the following reasons, among others:

- Placement of practice managers/administrators and infusion nurses for practice
- Reduced operational and administrative burdens for physician(s) and staff as well as overhead costs

(q) ***Circumventing commercial payers' coverage requirements (step therapy) for Remicade, Simponi ARIA, and other infusion treatments.*** As explained in paragraph 107 above, many commercial insurers will only cover infusible biologics, including Remicade and Simponi ARIA, when the patient has tried and failed a self-injectable biologic or multiple self-

injectable biologics. To circumvent the step therapy requirements, Janssen, which wants patients to receive Remicade and Simponi ARIA first line before trying a self-injectable biologic, essentially encouraged accounts to lie to commercial insurers by having the ABSs advise accounts with a "wink, wink, nod, nod" that insurers often covered Remicade when prescribers reported that the patient was unable to self-inject Humira or Enbrel.[13]

(r) ***Other infusion suite business issues referenced on the Janssen checklist set forth at paragraph 141 above.***[14]

167. Most of the presentations and consultative programs referenced above were designed to provide practice management and business operations advice and assistance while simultaneously creating an opportunity for ABSs to play an integral role in the operations of the in-office infusion businesses so as to be able to influence the physicians to grow their use of Janssen's products. At the end of most consultative sessions, ABSs sought a commitment from the practice and physicians to grow the infusion suite (by adding chairs, hours, and/or staffing) and to prescribe and infuse Remicade and/or Simponi ARIA to more patients, including Medicare and Medicaid beneficiaries.

168. For many years, Janssen referred to the presentations it provided as part of the wide range of business advisory services as "SOC360 Programs" − "SOC" was short for "Site of Care" and 360 was a reference to 360° (or total) account support.

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[13] Although misrepresenting that patients were unable to self-inject worked for several years, many insurance companies eventually realized that a large percentage of "unable to self-inject" claims were false and, consequently, they have recently ceased accepting this as a valid reason to cover Remicade and Simponi Aria.

[14] Janssen provides accounts other free services, including assistance with obtaining prior authorizations and insurance coverage for Janssen's products and patient financial assistance, that Relator does not allege violate the Federal AKS, State AKS, and/or FCA in this action. In addition, Relator does not allege any claims based on free business advisory services Janssen provided to hospitals.

169. Accounts were always able to request that Janssen provide practice management/ business operations consultations and assistance that would help them improve the operation of their IOIs and/or practices as a whole. However, in or around September 2015, Janssen formalized accounts' ability to select specific consultative sessions. Under the "Hot Buttons" initiative, Janssen offered accounts a menu of practice management/business advisory programs, also referred to as "Practice Pearls," from which accounts could select programs that they felt would be helpful to their infusion businesses and/or would address an issue with which they sought assistance. Several of the presentations identified above were included on the list of SOC360 programs and Hot Buttons menu of consultative sessions.

170. Although Janssen's management led ABSs to believe that providing free business consulting services to physicians was legal, they went to great lengths to conceal the nature of the services ABSs provided to accounts. The Regional Directors and Regional Business Managers repeatedly warned ABSs not to leave a paper trail. They instructed ABSs to avoid putting their profitability and practice management discussions with accounts in writing and to never leave the IBiz, IOMs, and other individualized business analyses behind with accounts. Similarly, the Regional Directors and Regional Business Managers repeatedly instructed ABSs not to send them account updates, questions from customers, or anything business related via text message or email because "we do not want to leave a paper trail."

171. The various business advisory services and support were provided by Janssen's ABSs during consultative sessions with practice managers, practice stakeholders, and office staff that typically lasted approximately three hours. Before an ABS was permitted to present on a particular business operations or practice management topic, Janssen educated the ABS on the topic, trained the ABS on how to present the information to physician practice accounts to drive

Remicade and Simponi ARIA infusions, and required the ABS to pass a test to become certified on the presentation.

172. ABSs spent more time implementing strategies than presenting them. Once again, Janssen designed the ABSs' presentations to provide information to physicians and office staff that would give rise to more detailed discussions concerning the operations, efficiency, and profitability of the accounts' infusion businesses. Once ABSs identified an operational weakness or area for which they could assist and add value, the ABSs went into action and worked with the account to address the issue. In addition to helping to grow rheumatology and gastroenterology practices' infusion businesses by making them more efficient and profitable, ABSs and Janssen also gained the trust and loyalty of these accounts because the accounts greatly appreciated receiving the free practice management expertise and support. In fact, many rheumatology and gastroenterology practices viewed ABSs as practice management experts who were always available to assist with any business operations or practice management need.

173. All of the practice management consultative services that the rheumatology and gastroenterology practices received free of charge from their "business partner" Janssen helped them operate more profitably by growing the revenue generated by their in-office infusion suites while also helping the practices reduce their overhead costs. Notably, although Janssen provided the free business advisory services to induce utilization of its products, much of the business operations and practice management information and advice that Janssen provided applied equally to other infusible drugs and services, and even general administrative functions, and thus helped the practices more efficiently and profitably manage other aspects of their businesses far beyond the prescription and infusion of Remicade and Simponi ARIA.

174. Tellingly, many physicians did not want their staff to see them accept free practice management and advisory services, so they would request that the ABS meet with them in private, separate from the office staff, to advise them on how they could grow their infusion suite businesses and maximize their profits.

175. Relator met with many of her top physician practice accounts on a weekly basis. During many of these meetings she provided the business advisory support services detailed in paragraph 166 above. Over the course of several years, Janssen helped grow accounts' infusion suites into highly lucrative businesses, which led to significant growth in Remicade and Simponi ARIA utilization by the accounts.

176. A few specific examples of physician practices for which Relator, on behalf of and at the direction of Janssen, helped establish in-office infusion suites and helped grow the infusion businesses (and Remicade and Simponi ARIA purchases) by providing the regular free practice management and business advisory services detailed above, as well as other practice management and business support, include the following:

(a) Relator provided the business operations and practice management services and support discussed above to help Account A grow and enhance its six-chair infusion suite. Janssen helped Account A open its infusion business in or around 2000. At this multi-specialty practice, the rheumatology group prescribed and infused Remicade and Simponi ARIA, and the gastroenterology group referred patients to the rheumatology group for Remicade treatment; the gastroenterologists received financial credit for the Remicade and Simponi ARIA infusions that they referred to their rheumatology group. An example of other valuable business operations/practice management services that Relator provided at the request of Account A, in or around 2011, Relator assisted the practice with determining the source of financial shortfalls in

its infusion suite. Upon investigation, and using the Janssen efficiency checklist, it was discovered that:

- Different employees provided the back-office support for the rheumatology and gastroenterology groups, and these employees did not understand their role and responsibilities with regard to the infusion service line;
- The billing department was not using the appropriate infusion service and Remicade and Simponi ARIA codes;
- The practice was not collecting the 20% co-pay for infusions of biologics provided to Medicare beneficiaries;
- There was no internal audit system in place to ensure that the billing system was functioning properly and payers were paying the contracted rates for infusion services and drugs;
- The practice did not have infusion protocols in place;
- Encounter sheets had not been updated;
- The gastroenterology group sent patients to the rheumatology group, which purchased the biologics, for infusion services. The reimbursements for the biologics were divided equally between the gastroenterology and rheumatology groups, causing the rheumatology group to sustain a loss on each purchase; and
- The practice was not tracking biologics obtained from a specialty pharmacy to distinguish them from biologics acquired through buy-and-bill methodology, causing the practice to not bill for thousands of dollars' worth of biologics acquired through buy-and-bill methodology.

Relator helped the practice address all of these operational problems and return its infusion suite to profitability. In terms of sales volume growth, based on these and numerous other business advisory consultations from Janssen, Account A's rheumatology group became one of the top accounts in the region for Remicade and Simponi ARIA sales, and the practice's gastroenterology group became one of the top accounts in the region for Remicade sales. The free business advisory and practice management services Janssen provided to this practice induced a steady increase in prescriptions and infusions of Remicade and Simponi ARIA.

The following reference letter written by a stakeholder physician from Account A describes Janssen's and its ABSs' close involvement in the management of this top Remicade and Simponi ARIA account and the significant value of the free business advisory services and support that Janssen provided to the account:

> I am writing to you on behalf of [Relator]. I have had professional contact with [Relator] over the past 13 years. I am [a] Rheumatologist for [Account A] and have served in this capacity since July of 2002. Shortly after starting with my company I had the privilege to meet [Relator].
>
> Many representatives have crossed my path from many companies over the years. [Relator] has been a constant and has been critical to my ability to do my job effectively. **[Relator's] skill, knowledge, and professionalism has been an asset to my practice in many aspects. [Relator's] business knowledge and background in infusion helped streamline my center to be more cost effective, structured, and provided needed educational support for staff and patients.**
>
> If I had any questions no matter how big or small, [Relator] was always available and would follow through on all tasks requested. [Relator] maintained the highest level of professional deportment when interacting with myself and my staff. [Relator] always made [Relator's] goals clear, concise, and within industry standards of professionalism. [Relator] is held in the highest regard not just by me, but also my staff, and the administrators who have interacted with [Relator] as well.
>
> My only hardship would be losing [Relator] to another position within your company. My loss would certainly be your gain. [Relator] will be missed by many in the arena of Rheumatology and Infusion. I have no reservations for recommending [Relator] for your team.

(Emphasis added).

(b) When Account B relocated its office several years ago to a state-of-the-art office with a dedicated infusion suite, the stakeholder physicians asked Relator to train the new office manager on how to maximize the practice's infusion suite's efficiency and profitability. Relator helped this practice become more profitable and infuse more Remicade through the infusion optimization advice that Relator provided directly to the physicians and practice

manager in 2010 using the IOM and IBiz presentations. Pursuant to Janssen's advice, Account B added a half day to its infusion schedule so as to enable the practice to perform more Remicade infusions. The practice's office manager continued to rely heavily on Janssen's free practice management services. In 2010, Relator arranged for outside consultant Lash to meet with the practice manager and a stakeholder physician to advise them concerning renegotiating the reimbursement rates from commercial payers. The practice applied the free information and strategies they learned from Lash to successfully negotiate higher reimbursement rates on many of the services it provides and infusion drugs it administers, including Remicade.

(c) From 2003 until Relator left Janssen, Relator provided Account C weekly business advisory services and support in order to educate the practice concerning, among other operational and practice management issues, optimization of their infusion suite, successfully negotiating better reimbursement rates, having no coverage limitations for Remicade and Simponi ARIA, use of the electronic medical record system to satisfy Medicare's meaningful use requirements, negotiating a mixing fee into its contract with the region's dominant commercial payer, and development of infusion protocols. In addition, in February 2010, Relator helped Account C design a new infusion center and optimize its profitability by determining the number of infusion chairs it could manage. Afterwards, the practice added six additional infusion chairs based upon Janssen's IOM optimization analysis. In addition, Janssen arranged and paid for Lash consultant Alberto Vigo to assist the practice with negotiating higher reimbursement rates from commercial insurance companies.

Throughout the approximately 15 years that Relator worked as a Janssen ABS, she, and occasionally outside consultants arranged and paid for by Janssen, provided the services described in paragraph 166 above to Account C. Recognizing and benefiting from the value of

the free business operations and practice management advice and support Janssen provided, Account C's stakeholders and staff met with Relator on a regular basis. Over that span, Janssen helped Account C substantially grow the number of Remicade infusions it performed. Demonstrating the extent to which ABSs became enmeshed in the operation and management of Account C and other top accounts, when Account C's four different practice managers left and/or retired, the stakeholder physicians requested that Relator train the new practice managers regarding the operation and management of the in-office infusion business using all of the presentations and programming described in paragraph 166 above.

(d) In 2010, Account D, which had been receiving the free business advisory services and support referenced in paragraph 166 above for several years, requested that Janssen help it create an infusion suite at a second location. Because Account D had difficulty accommodating all Remicade patients at its new infusion suite, it considered instead prescribing Orencia, which only requires a 30-minute infusion compared to Remicade's two-hour infusion. Janssen analyzed the practice's Remicade and Orencia volume and created a schedule that allowed the practice to perform all infusions over two days each week, ensuring continued utilization of Remicade by the practice and preventing the practice from using Orencia instead of Remicade. Before that, relator along with an outside consultant from Xcenda whose fees were paid by Janssen, instructed the practice on negotiating payer contracts and ultimately helped it to obtain more favorable reimbursement rates.

(e) In 2015, Janssen identified a rheumatology practice, Account E, that had an in-office infusion suite but was not using it to perform very many infusions. Relator met regularly with Account E's practice manager to advise her on the operation and management of the infusion suite. Using the IBiz, IOM, and Proactive Practice Management presentations to

establish a business consultant and partner relationship with Account E, Relator advised the stakeholder physicians and their staff about the business opportunity of infusing biologics rather than prescribing Self-Injectables and growing the in-office infusion business. Following these business advisory services, Account E became more committed to the infusion/Remicade business model and steadily increased its use of Remicade and Simponi ARIA.

ABSs' managers, or "Regional Business Managers," periodically accompanied ABSs on office visits to evaluate their effectiveness in providing the business advisory services and support. In October 2015, Relator attended a lunch meeting with her manager, a Janssen sales representative, and Account E's stakeholder physicians. After advising the account on how and why it should ramp up its use of the in-office infusion suite, Relator and her manager "pushed hard" for Account E to commit to prescribing and infusing Simponi ARIA to three new patients, as reflected in the following excerpt from a Field Coaching Report prepared by Relator's manager:

> Observed Performance:
> Lunch ppt with new ISR [Immunology Specialist]
> Spoke about ICD 10
> IBIZ
> Simponi Aria and the need for more new patients in RA [rheumatoid arthritis]
> CMS update a[n]d how this values the infusion process – medical vs pharmacy benefit
> Uses of Access One
> Payer policies and perhaps the need for Proactive Practice Management for this office?
>
> * * *
>
> Coaching Points:
> Overall a stron[g] lunch appt. Both [stakeholder physicians] were present throughout entire lunch. Strong SA [Simponi ARIA] message
> [U]se more of the customer when talking and selling Aria 30 minute infusion and how this impact[s] RN time.
>
> * * *
>
> Closed hard for 3 new patietns [sic] by the close of this week.
> Continue to push hard and follow up and follow your reports for the data for above request.

(f) In or around 2013, Relator helped Account F undertake a financial analysis and feasibility study regarding the opening of an in-office infusion suite to perform Remicade infusions. Relator helped this practice open the infusion suite and train its employees on the operation of the suite and thereafter regularly provided the business operations and practice management programs and support discussed above. Inasmuch as many hospitals do not profit from Remicade infusions, Relator advised Hospital A to refer any Medicare and Medicaid beneficiaries who needed Remicade infusions to Account F, helping this customer grow its in-office infusion business.[15] Relator's work in advising Hospital A to refer its infusion patients to Account F resulted in a windfall for Account F's in-office infusion business and also helped Janssen by shifting business from a hospital to a loyal in-office infusion suite customer.

A June 2013 email from a Janssen sales representative (Immunology Specialist) to the district sales manager illustrates how Janssen's help in opening the in-office infusion suite at Account F induced sales of Remicade:

> [Account F] started to infuse today. [Relator] and I started this process last July when [Account F] was added to my territory. After countless hours of educational meetings, the IOI [in-office infusion suite] opened today without a flaw. We brought in Jane Clevenger from MCV[16] and she did a tremendous job with … the new infusion nurse in [Account F's] office. **For now, they are infusing all**

[15] As explained in paragraph 63 above, Janssen did not allow hospitals to participate in its discount program and historically set prices at levels that made it unattractive for hospitals to administer Remicade and Simponi ARIA infusions to Medicare and Medicaid beneficiaries. Janssen went further and advised hospitals to refer infusion cases to local gastroenterology or rheumatology practices, most of which were Janssen customers or "business partners," and to only provide infusion services to patients insured by commercial payers, because they pay higher reimbursements to hospitals than do Medicare and Medicaid. Many hospitals followed Janssen's advice and began referring Medicare and Medicaid infusion cases to local gastroenterology and rheumatology practices, which helped Janssen because, unlike physicians employed by a hospital, the physician practices have a financial incentive to ensure that these patients continue receiving Remicade or Simponi ARIA infusions.

[16] MCV is an outside consulting firm that Janssen paid to provide infusion training and information to rheumatology and gastroenterology practices that were opening in-office infusion businesses.

> **new patients with patients being infused in the hospital being added as time goes by. They currently have over 70 patients on Remicade, and so far [Account F] has added 7 new patients. With this current trend they should be adding 4-5 new patients a month.** There is great excitement within the practice and they are very proud of their IOI. The IOI has two chairs now and within the next 6 months they will be adding a third, and they have room to add a fourth when it is needed. They will be infusing every Monday and Thursday and hope to be at four days a week very soon. **Their first order was for 24 vials and they should be ordering weekly as they go forward.**
>
> After talking with the office at the end of the day their patients were really impressed with the facility and were very happy with the care they received during their infusion. **[Account F's] office coordinator could not thank Janssen enough. She said that they could not have opened this IOI without us.** I will be monitoring this account very closely and making sure that all their questions and concerns are answered in a timely manner. **The addition of this IOI will definitely help the … district rise to the top and help us finish number one in the Region.**
>
> I want to thank [Relator] for all [Relator's] efforts in getting this account on line with all their billing needs and making sure this IOI went off without a hitch.

(Emphasis added). Due In part to these and other business operations/practice management services and support provided by Janssen, the volume of Remicade prescriptions and infusions by Account F increased exponentially from 2013 to 2015 after Janssen helped the practice establish and grow its in-office infusion business.

(g) In or around 2008, Relator helped Account G open an infusion suite at a centralized location, train its employees on the operation of the infusion business, hire an infusion nurse director, and improve its reimbursement rates from commercial insurers. Account G's practice administrator relied heavily on Janssen's free practice management services to enhance and grow the practice's in-office infusion business. Afterwards, the practice's sales of Remicade steadily grew approximately 20% annually despite many local commercial payers imposing single step therapy and prior authorization requirements. In addition, after Relator provided the IBiz and IOM presentations to the physicians at Account G, the gastroenterology

practice placed an additional chair in the infusion center as well as a new nurse to improve the efficiency of its infusion business and substantially increased the volume of Remicade infusions performed.

Illustrating that one of Janssen's primary objectives in providing the free business advisory services was to induce/grow utilization of its products, following a visit to Account G with Relator in February, 2015, Relator's manager noted the following coaching point about this account with a mature in-office infusion business: "[e]xtra days and chairs will require IOM IBiz to help drive more new patients."

(h) In or around 2012, Relator started regularly providing free business advisory services and support to Account H. Another ABS had previously assisted Account H with opening and growing its in-office infusion business. Account H requested Relator to consult the practice on specific operational issues to assist the practice, regularly selecting from the Hot Buttons menu programs that the account felt would be helpful to its infusion business. Account H implemented the advice provided during these practice management programs. And apparently influenced by Janssen's regular provision of free business advisory services and support, Account H's prescriptions and infusions of Remicade grew substantially during the period relator provided the free business services to the account. In addition, Account H also prescribed and infused a significant and growing volume of Simponi ARIA while Relator provided it free business advisory services and support.

5. ***The free business advisory services and support Janssen regularly provided to rheumatology and gastroenterology practices had significant value***

177. As detailed above, accounts and their stakeholder physicians and staff derived significant value from Janssen's free business advisory services and support.

178. In addition to the value described above, other facts demonstrate that the business advisory services and support that Janssen provided to physician practices were valuable to those practices including:

(a) Accounts repeatedly accepted, and indeed requested, Janssen's assistance and applied its advice and strategies to grow their infusion businesses and make them more efficient and profitable; and

(b) Stakeholder physicians and practice managers from top Remicade and Simponi ARIA accounts regularly created time in their full schedules to consult with their Janssen ABSs and the outside consultants arranged and paid for by Janssen.

179. The services' significant value is also evidenced by the fact that health care providers pay significant fees to consultants to receive similar business advisory services.

180. The value of the services that Janssen provided to accounts is demonstrated by the fact that Janssen paid outside consultants, such as Xcenda, Lash, and MCV, significant fees (often over $1,200 per consultative session) to provide the same and other similar services to top accounts.

181. In addition to the letter referenced in paragraph 176(a) above, an October 2015 letter of reference from a Janssen sales manager highlights the significant value of the ABS services:

> [Relator] and I have developed a professional relationship at Janssen for over eight years in [Relator's] Area Business Specialist role. During this time, we have also established a personal friendship, as well as a professional business partnership with our common customers. [Relator's] territory success has come largely in part to [Relator's] strong business acumen and work ethic. [Relator's] strongest attribute, that I've witnessed, is [Relator's] commitment to the customer approach to business. **Customers trust [Relator] to get their problems resolved.** This is the core to [Relator's] success. **[Relator] is able to combine selling skills with providing value to her customers** and her crossover teams. [Relator's] customers have developed strong bonds with [Relator], recognizing

> that [Relator] has integrity and provides them with more than what is in [Relator's] best interest. [Relator's] colleagues, including myself, routinely call on [Relator] to provide insight, clarification, and help when solving issues for difficult customers and situations. [Relator] manages this with professionalism and never misses a stride with [Relator's] own customers, both internally and in the field. …

(Emphasis added).

182. Janssen paid significant sums to provide top accounts with ABS services and outside consulting services for years. Janssen would not have expended these significant sums year after year for over a more than 15-year period unless the accounts, and particularly their stakeholder physicians, found the services valuable and unless the strategy helped grow utilization and sales. The substantial profits that Janssen earned from the increases in sales of Remicade and Simponi ARIA generated by the free business advisory services scheme more than paid for the significant cost Janssen incurred to provide the valuable services.

183. While the rheumatologists and gastroenterologists constituting Janssen's top accounts were loyal to Janssen and typically strongly favored Remicade and/or Simponi ARIA, nearly all of these physicians also prescribed and infused other biologic DMARDs (*e.g.*, Orencia, Rituxan, Tysabri, Actemra, Entyvio, and Benlysta (lupus treatment)) as well as other drugs (*e.g.*, IVIG (intravenous immunoglobulin), Reclast (zoledronic acid), Prednisone, Solu Medrol (methylprednisolone sodium succinate), Boniva (ibandronate), Injectafer, and saline) for a wide variety of medical conditions. Accordingly, the free business advisory services and support that Janssen bestowed upon these accounts to help them establish infusion businesses and, afterwards, to operate them profitably, not only helped the accounts earn enormous profits on Remicade and Simponi ARIA, but also had a spillover effect and helped the accounts increase the profits they earned on many other drugs and services.

184. In fact, because it was in Janssen's business interest for accounts to profit from and therefore continue operating and growing their infusion services businesses, ABSs advised the accounts that the information and assistance that they provided was applicable to other infusion service lines or treatments and the accounts' infusion businesses as a whole.

185. Further illustrating the value of the practice management services Janssen provides, multiple accounts asked Relator, while employed as an ABS, whether she should sign an IRS Form 1099 from the practice.

6. One of Janssen's principal objectives in providing free business operations and practice management services was to induce physicians to prescribe and infuse Remicade and Simponi ARIA in patients, including Medicare and Medicaid beneficiaries

186. By promoting and helping physician practices implement and execute the infusion/Remicade business model, which involves increasing utilization of its products, Janssen intentionally used free business services to secure physician access and loyalty and to influence these physicians' treatment decisions and induce them to prescribe and infuse Remicade and/or Simponi ARIA instead of other treatments for rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriatic arthritis, ankylosing spondylitis, and other conditions.

187. Janssen's ABS training materials, business plan forms, manager evaluations, and other internal materials discussing ABSs' responsibilities directed ABSs to provide the business advisory services described in this Complaint to prescribers for the purpose of growing the infusion/Remicade business model and correspondingly growing sales of Remicade and Simponi ARIA by physician practices with an in-office infusion business or by physicians who showed an interest in establishing or growing an infusion business.

188. The following facts, among others, make clear that at least one purpose—likely the primary purpose—of Janssen providing free business consulting services was to induce

physicians to prescribe and infuse Remicade and Simponi ARIA in patients, including those covered by the government health insurance programs:

(a) Janssen ABSs and the consultants paid for by Janssen promoted and assisted with the establishment and expansion of in-office infusion suites and advised physician practices to increase Remicade and Simponi ARIA infusion volume to increase the profitability of their infusion businesses.

(b) Janssen only provided the free services to accounts that prescribed and infused a significant volume of Remicade and/or Simponi ARIA, or to accounts identified as having a high potential for substantial growth in utilization of the Janssen infusible drugs.

(c) The volume and frequency of the free business advisory services and support that Janssen provided to accounts was determined by how much Remicade and/or Simponi ARIA the accounts prescribed and infused – *i.e.*, accounts that purchased the most Remicade and Simponi ARIA usually received the highest volume of free services.

(d) Janssen compensated ABSs based, in part, on the number of in-office infusion businesses they helped open and their accounts' growth in utilization of Remicade and Simponi ARIA.

(e) Janssen closely monitored the influence and impact that the ABSs' and outside consultants' services had on sales of Remicade and Simponi ARIA.

(f) The free services were a critical component of Janssen's strategy to grow Remicade's and Simponi ARIA's usage and revenues.

7. *Physicians who received Janssen's free services infused Remicade and Simponi ARIA in Medicare and Medicaid beneficiaries and falsely certified to the government health care programs that the related claims for payment complied with the Federal AKS and State AKS*

189. The claims for reimbursement for Remicade, Simponi ARIA, and related infusion services submitted to Medicare and Medicaid by physicians who received free business advisory services and support from Janssen falsely represented that the drugs were prescribed and infused in compliance with the AKS.

190. These on-going claims for reimbursement tainted by Janssen's bribes in the form of free valuable business services were not eligible for payment by Medicare or Medicaid.

191. For example, from approximately August 2015 to mid-2017, Account B (Physician B-2 and/or Physician B-3) submitted to Medicare Part B claims for reimbursement related to Remicade vials and infusion services provided approximately every eight weeks to Medicare Beneficiary B-1 to treat psoriatic arthritis.[17] As part of those claims for reimbursement, the Account B physician certified to Medicare that the claim "complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute." Those certifications were false because well before August 2015 through when Relator departed Janssen in February 2016 (and on information and belief after Relator departed Janssen), Account B regularly accepted Janssen's offer to provide many of the free business advisory services described in this Complaint, tainting the Account B physicians' decisions to prescribe and administer Remicade to Medicare

[17] Physicians from Account B prescribed and administered Remicade to Medicare Beneficiary B-1 for multiple years before Medicare Beneficiary B-1 became Medicare eligible in August 2015. Physician B-2 was Medicare Beneficiary B-1's original treating physician at Account B before Physician B-3 took over as the treating physician.

Beneficiary B-1 (and other Medicare and Medicaid beneficiaries) and rendering the related claims ineligible for reimbursement.

192. Stakeholder physicians from Accounts A through I referenced above and other accounts that received free business advisory services and support from Janssen billed Medicare for a significant volume of tainted Remicade infusions while they were receiving the kickbacks from Janssen. For example, CMS reported that the physicians from Accounts A, B, C, D, H, and I identified in the table below prescribed and infused significant volumes of Remicade between 2012 and 2017 while Janssen, through Relator and outside business consultants, regularly provided them with valuable business advisory services and support for no charge. CMS has not made available Remicade infusion service data for providers from Accounts E, F, or G or all providers from Account B.

Remicade Infusions (10mg) Administered to Medicare Beneficiaries and Billed to Medicare						
	2012	**2013**	**2014**	**2015**	**2016**	**2017**
Physician A-1	4,470	6,670	7,860	8,452	8,400	7,060
Physician B-1	4,550	4,480	4,000	4,240	4,070	3,955
Physician B-2	2,370	2,930	2,651	2,910	2,660	2,480
Physician C-1	10,750	12,030	10,290	7,460	6,930	5,970
Physician C-2	7,470	8,470	8,610	6,850	7,680	6,890
Physician D-1	4,380	4,610	4,900	5,500	15,460	12,660
Physician D-2	9,190	10,265	10,231	11,000	Retired	Retired
Physician H-1	13,780	15,320	16,820	19,760	19,170	19,150
Physician I-1	3,600	4,780	5,420	3,830	3,580	1,990

(Source: CMS's Medicare Provider Utilization and Payment Data (avail. at https://data.cms.gov/Medicare-Physician-Supplier/Medicare-Provider-Utilization-and-Payment-Data-Phy/fs4p-t5eq/data)).

193. Similarly, a physician from Account H referenced above billed Medicare for a significant volume of Simponi ARIA infusions while regularly receiving free business advisory services and support from Janssen. CMS has not made available Simponi ARIA infusion service data for providers from Accounts A, B, C, D, E, F, G, or I.

Simponi ARIA Infusions (1mg) Administered to Medicare Beneficiaries and Billed to Medicare				
	2014	**2015**	**2016**	**2017**
Physician H-1	-	12,151	16,650	22,623

(Source: CMS's Medicare Provider Utilization and Payment Data (avail. at https://data.cms.gov/Medicare-Physician-Supplier/Medicare-Provider-Utilization-and-Payment-Data-Phy/fs4p-t5eq/data)).

8. ***Janssen knew that providing free business advisory services and support to induce sales of Remicade and Simponi ARIA violated the Federal AKS and FCA and State AKS and FCAs***

194. Janssen's management, including, but not limited to, former Regional Business Directors and Regional Business Managers, closely monitored whether the strategy of providing physician practices with free business advisory services and support concerning a wide range of business operations and practice management topics had a positive impact on inducing physicians to increase their use of Remicade and Simponi ARIA. In other words, Janssen's management closely monitored the return on its large, strategic investment in providing the free services and determined that it made business sense to incur that significant expense.

195. Janssen closely monitored the costs incurred in furnishing the free practice management services to physician practices. The costs included (a) employing the large team of ABSs, (b) paying several outside consulting firms to provide business advisory and practice management consultations to accounts, (c) meals and drinks served to physicians and their staff during the consultative sessions, and (d) development of programs and presentations that ABSs

utilized to become valued partners to accounts in opening, growing, maintaining, and operating the accounts' infusion businesses.

196. Janssen formally tracked each time an ABS provided the IBiz and/or IOM consultations to an account, as these business consultations were considered by management to be highly effective in influencing and inducing accounts to grow the volume of Remicade and Simponi Aria they prescribed and infused.

197. ABSs were required to record many of the practice management consultations and services that they provided to accounts on their business plans and self-evaluations provided to managers.

198. For example, in a report titled Manager Based Objectives Results, ABSs provided significant detail about their account activities, the specific accounts to which they provided the various practice management programs, the strategies for growing utilization of Remicade and/or Simponi ARIA at specific accounts, the specific accounts that they assisted with opening an infusion suite, Remicade and Simponi ARIA sales volume, as well as specific account issues the ABSs helped to address.

199. Janssen maintained computer applications and systems that stored information regarding each account, including information about the practice management services that each account received and the account's Remicade and Simponi ARIA utilization, as well as each account's utilization of competing drugs.

200. Janssen closely monitored how many new IOIs the ABSs helped open and the level of sales growth that the ABSs helped generate by providing the free consultative services.

201. Moreover, Janssen was aware that a large percentage of its rheumatology and gastroenterology accounts' patients were Medicare and Medicaid beneficiaries and that the

government health care programs were key payers for the Remicade and Simponi ARIA vials and related infusion services that these patients received. Indeed, Janssen advised the practices that these were the most desirable patients because, unlike many commercial insurers, Medicare and many of the state Medicaid programs do not have any prior authorization or step therapy requirements.

202. Janssen knew that by providing the free business advisory services that it was inducing accounts to prescribe and infuse Remicade and/or Simponi ARIA in Medicare and Medicaid beneficiaries, which in turn would result in the accounts submitting claims for reimbursement to the Medicare and Medicaid programs that were false because the providers had falsely certified in connection with each claim for payment that the underlying treatment decision was not compromised or influenced in any way because the provider had not accepted any kickbacks from Janssen.

203. Janssen acknowledged in internal compliance documents and training sessions that providing these types of practice management and business consulting services to physician practices free of charge could violate the Federal AKS and FCA as well as the State AKS and FCAs.

204. For example, in an internal document from 2014 prepared by Janssen's compliance department titled "Health Care Compliance – Site of Care ABS Speaker Training," Janssen recognized that the Federal AKS **"[m]akes it illegal for pharmaceutical manufacturers to give [health care providers] anything of value to induce them to prescribe or purchase products that are reimbursed in whole or part by a federal health care program."** (Emphasis added).

205. In that same document, Janssen also recognized that "[o]rders for prescription drugs that were induced by improper incentives or kickbacks, and later reimbursed by a federal program" violate the False Claims Act, and that "[c]ompanies/individuals have also been held liable for claims made by [health care providers] if their conduct 'caused' a false claim to be submitted."

206. Janssen openly admitted in a policy statement set forth in the document, which it neither followed nor enforced, that the very services that Janssen regularly provided to rheumatology and gastroenterology practices constituted kickbacks:

> **[E]mployees may not offer consulting services that relate to the management of customers' business practices** because the customer is ultimately responsible for seeking that advice and in many cases paying for the service.
>
> **If a company were to provide advice, it could be considered a kickback because it could offset the normal overhead expenses for the practice as well as expose our company to potential legal liability.**

(Emphasis added).

207. In that document, Janssen also essentially acknowledged that some of the very types of business advisory services and support that it had ABSs and outside consultants provide to physician practices, such as assisting with negotiating higher reimbursement rates from health insurers for high volume services and drugs and advice about growing their infusion businesses (and infusions of Remicade and Simponi ARIA) to maximize profits, could violate the AKS.

208. Given the inconsistency with their job function and the directives they were given by their managers (who ensured that ABSs effectively carried out the directives), many ABSs found these occasional hollow warnings from compliance strange and somewhat confusing, Notwithstanding, ABSs continued to provide the free business advisory services to accounts

because that was their job, and they trusted (wrongly) that Janssen believed it was legal to provide the services.

209. Janssen's parent JNJ has also acknowledged that providing practice management services to induce sales of its products is inappropriate and unethical when it agreed to abide by the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Health Care Professionals, which includes the following provisions among others:

> Providing items for health care professionals' use that do not advance disease or treatment education — even if they are practice-related items of minimal value (such as pens, note pads, mugs and similar "reminder" items with company or product logos) — may foster misperceptions that company interactions with health care professionals are not based on informing them about medical and scientific issues. **Such non-educational items should not be offered to health care professionals or members of their staff, even if they are accompanied by patient or physician educational materials.**
>
> * * *
>
> **No … support, consulting contracts, or educational or practice related items should be provided or offered to a health care professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a health care professional's prescribing practices.**

Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals (Jan. 2009) at §§ 10, 11 & 13.[18]

210. Despite its agreement to adopt the PhRMA Code, Janssen's management and legal department at all times relevant to this action knew that Janssen's ABSs were not only dispensing kickbacks contrary to law but could themselves reasonably be characterized as kickbacks personified.

[18] The Pharmaceutical Research and Manufacturers of America, also known as "PhRMA," is a trade group that is operated by pharmaceutical companies, including JNJ.

VI. COUNTS

Count I
Federal False Claims Act
31 U.S.C. § 3729(a)(1) (*Before May 20, 2009*)
31 U.S.C. § 3729(a)(1)(A) (*On or After May 20, 2009*)

211. This is a claim for treble damages and civil penalties against Janssen under the Federal FCA, 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*), for knowingly presenting, or causing to be presented, false or fraudulent claims for payment or approval to the United States and/or, pursuant to 31 U.S.C. § 3729(b)(2)(A)(ii) (*May 20, 2009 and beyond*), to any state Medicaid program.

212. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

213. As a result of its offering and paying kickbacks to induce health care providers to purchase, order, or recommend the purchasing or ordering of Remicade and Simponi ARIA as well as infusion services to administer the drugs in violation of the Federal AKS, 42 U.S.C. § 1320a-7b(b), and State AKS, Janssen caused the health care providers to present claims for reimbursement to Medicare and the state Medicaid programs that were false or fraudulent because the providers violated the Federal AKS and State AKS by accepting the kickbacks from Janssen.

214. Janssen violated 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and/or 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*) because through these acts it knowingly caused health care providers who accepted Janssen's kickbacks to present false or fraudulent claims to Medicare for reimbursement for Remicade and Simponi ARIA as well as infusion services provided to Medicare beneficiaries.

215. Janssen also violated 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and/or 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*) because through these acts it knowingly caused healthcare providers who accepted Janssen's kickbacks to present false or fraudulent claims to the state Medicaid programs for reimbursement for Remicade and Simponi ARIA as well as infusion services provided to Medicaid beneficiaries. Accordingly, Janssen also caused the state Medicaid programs to submit false claims to the United States for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(1) (*pre-May 20, 2009*) and/or 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*).

216. And Janssen violated 31 U.S.C. § 3729(a)(1)(A) (*May 20, 2009 and beyond*) because through these acts it knowingly caused others to present, under 31 U.S.C. § 3729(b)(2)(A)(ii), false or fraudulent claims to the state Medicaid programs (grantees and/or recipients of United States funds) for reimbursement for Remicade and Simponi ARIA as well as infusion services provided to Medicaid beneficiaries.

217. The United States, unaware of the foregoing circumstances and conduct, and in reliance on the truth and accuracy of the claims for payment, paid or authorized payment of those claims and has been damaged in an amount to be proven at trial.

Count II
Federal False Claims Act
31 U.S.C. § 3729(a)(2) (*Before June 7, 2008*)
31 U.S.C. § 3729(a)(1)(B) (*On or After June 7, 2008*)

218. This is a claim for treble damages and civil penalties against Janssen under the Federal FCA, 31 U.S.C. § 3729(a)(2) (*pre-June 7, 2008*) and 31 U.S.C. § 3729(a)(1)(B) (*June 7, 2008 and beyond*), for knowingly making, using, or causing to be made or used, a false record or statement to get—or that was material to—false or fraudulent claims paid or approved by the

United States and/or, pursuant to 31 U.S.C. § 3729(b)(2)(A)(ii) (*May 20, 2009 and beyond*), to any state Medicaid program.

219. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

220. As a result of its offering and paying kickbacks to induce health care providers to purchase, order, or recommend the purchasing or ordering of Remicade and Simponi ARIA as well as infusion services to administer the drugs in violation of the Federal AKS, 42 U.S.C. § 1320a-7b(b), and State AKS, Janssen caused health care providers to make false records or statements that were material to getting false or fraudulent claims paid by Medicare and Medicaid.

221. More specifically, the health care providers falsely certified, stated, and/or represented that the reimbursements they sought for Remicade and Simponi ARIA as well as infusion services to administer the drugs were in full compliance with applicable federal and state laws prohibiting fraudulent and false reporting, including, but not limited to, the Federal AKS and State AKS. The health care providers' false certifications, statements, or representations caused Medicare and Medicaid to pay out sums that would not have been paid if those programs had been made aware of the falsity of the health care providers' certifications, statements, or representations.

222. Accordingly, Janssen knowingly caused the making or use of false records or statements (a) to get paid (*pre-June 7, 2008*), and/or (b) that were material to (*June 7, 2008 and beyond*) the false or fraudulent claims submitted to the United States for reimbursement for Remicade and Simponi ARIA as well as infusion services to administer the drugs that were provided to Medicare beneficiaries.

223. Janssen also violated 31 U.S.C. § 3729(a)(2) (*pre-June 7, 2008*) and/or 31 U.S.C. § 3729(a)(1)(B) (*June 7, 2008 and beyond*) because through these acts it knowingly caused the making or use of false records or statements (a) to get paid (*pre-June 7, 2008*), and/or (b) that were material to (*June 7, 2008 and beyond*) the false or fraudulent claims health care providers submitted to the state Medicaid programs for reimbursement for Remicade and Simponi ARIA as well as infusion services to administer the drugs that were provided to Medicaid beneficiaries. Accordingly, Janssen also caused the state Medicaid programs to submit false or fraudulent submissions to the United States for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(2) (*pre-June 7, 2008*) and/or 31 U.S.C. § 3729(a)(1)(B) (*June 7, 2008 and beyond*).

224. Janssen also violated 31 U.S.C. § 3729(a)(1)(B) (*June 7, 2008 and beyond*) because through these acts it knowingly made, used, or caused to be made or used, a false record or statement material to false or fraudulent claims under 31 U.S.C. § 3729(b)(2)(A)(ii) submitted by health care providers to the state Medicaid programs (grantees and/or recipients of United States funds) for reimbursement for Remicade and Simponi ARIA as well as infusion services to administer the drugs that were provided to Medicaid beneficiaries.

225. The United States, unaware of the foregoing circumstances and conduct, and in reliance on the truth and accuracy of the claims for payment, paid or authorized payment of those claims and has been damaged in an amount to be proven at trial.

Count III
California False Claims Act
Cal. Gov't Code §§ 12651(a)(1) & (2)

226. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

227. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Cal. Gov't Code § 12651(a)(1).

228. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Cal. Gov't Code § 12651(a)(2).

229. The State of California, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

230. By reason of Janssen's acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Cal. Gov't Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count IV
Colorado Medicaid False Claims Act
Colo. Rev. Stat. §§ 25.5-4-305(1)(a) & (b)

231. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

232. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Colo. Rev. Stat. § 25.5-4-305(1)(a).

233. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Colo. Rev. Stat. § 25.5-4-305(1)(b).

234. The State of Colorado, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

235. By reason of Janssen's acts, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Colo. Rev. Stat. § 25.5-4-305(1), the State of Colorado is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count V
Connecticut False Claims Act
Conn. Gen. Stat. §§ 4-275(a)(1) & (2)

236. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

237. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval …" in violation of Conn. Gen. Stat. § 4-275(a)(1).

238. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d] or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim …" in violation of Conn. Gen. Stat. § 4-275(a)(2).

239. The State of Connecticut, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and

continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

240. By reason of Janssen's acts, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Conn. Gen. Stat. § 4-275(b), the State of Connecticut is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count VI
Delaware False Claims and Reporting Act
Del. Code tit. 6, §§ 1201(a)(1) & (2)

241. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

242. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Del. Code tit. 6, § 1201(a)(1).

243. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Del. Code tit. 6, § 1201(a)(2).

244. The State of Delaware, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

245. By reason of Janssen's acts, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Del. Code

tit. 6, § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count VII
District of Columbia False Claims Act
D.C. Code §§ 2-381.02(a)(1) & (2)

246. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

247. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of D.C. Code § 2-381.02(a)(1).

248. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of D.C. Code § 2-381.02(a)(2).

249. The District of Columbia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

250. By reason of Janssen's acts, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to D.C. Code § 2-381.02(a), the District of Columbia is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count VIII
Florida False Claims Act
Fla. Stat. §§ 68.082(2)(a) & (b)

251. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

252. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Fla. Stat. § 68.082(2)(a).

253. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d] or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Fla. Stat. § 68.082(2)(b).

254. The State of Florida, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

255. By reason of Janssen's acts, the State of Florida has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Fla. Stat. § 68.082(2), the State of Florida is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count IX
Georgia State False Medicaid Claims Act
Ga. Code §§ 49-4-168.1(a)(1) & (2)

256. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

257. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval" in violation of Ga. Code § 49-4-168.1(a)(1).

258. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Ga. Code § 49-4-168.1(a)(2).

259. The State of Georgia, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

260. By reason of Janssen's acts, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Ga. Code § 49-4-168.1(a), the State of Georgia is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count X
Hawaii False Claims Act
Haw. Rev. Stat. §§ 661-21(a)(1) & (2)

261. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

262. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Haw. Rev. Stat. § 661-21(a)(1).

263. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Haw. Rev. Stat. § 661-21(a)(2).

264. The State of Hawaii, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for the acts and conduct of Janssen alleged herein.

265. By reason of Janssen's acts, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Haw. Rev. Stat. § 661-21(a), the State of Hawaii is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XI
Illinois False Claims Act
740 Ill. Comp. Stat. 175/3(a)(1)(A) & (B)

266. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

267. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(A).

268. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of 740 Ill. Comp. Stat. 175/3(a)(1)(B).

269. The State of Illinois, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

270. By reason of Janssen's acts, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to 740 Ill. Comp. Stat.

175/3(a)(1), the State of Illinois is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XII
Indiana False Claims & Whistleblower Protection Act
Ind. Code §§ 5-11-5.5-2(a)(1), (2), & (8) (*Before and On June 30, 2014*)
Ind. Code §§ 5-11-5.5-2(b)(1), (2), & (8) (*After June 30, 2014*)

271. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

272. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Ind. Code §§ 5-11-5.5-2(a)(1) & (8) (*before and on June 30, 2014*).

273. By virtue of the acts described above, Janssen "knowingly or intentionally … present[ed] ['or cause[d] or induce[d] another person' to present] a false claim to the state for payment or approval" in violation of Ind. Code §§ 5-11-5.5-2(b)(1) & (8) (*after June 30, 2014*).

274. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Ind. Code §§ 5-11-5.5-2(a)(2) & (8) (*before and on June 30, 2014*).

275. By virtue of the acts described above, Janssen "knowingly or intentionally … ma[de] or use[d] ['or cause[d] or induce[d] another person' to make or use] a false record or statement to obtain payment or approval of a false claim from the state" in violation of Ind. Code §§ 5-11-5.5-2(b)(2) & (8) (*after June 30, 2014*).

276. The State of Indiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

277. By reason of Janssen's acts, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Ind. Code § 5-11-5.5-2(b), the State of Indiana is entitled to three times the amount of actual damages plus a penalty of at least $5,000.

Count XIII
Iowa False Claims Act
Iowa Code §§ 685.2(1)(a) & (b)

278. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

279. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Iowa Code § 685.2(1)(a).

280. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Iowa Code § 685.2(1)(b).

281. The State of Iowa, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

282. By reason of Janssen's acts, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Iowa Code § 685.2(1), the State of Iowa is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XIV
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. §§ 46:438.3(A) & (B)

283. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

284. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim" in violation of La. Rev. Stat. § 46:438.3(A).

285. By virtue of the acts described above, Janssen "[k]nowingly engage[d] in misrepresentation or ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of La. Rev. Stat. § 46:438.3(B).

286. The State of Louisiana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

287. By reason of Janssen's acts, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to La. Rev. Stat. § 46:438.6, the State of Louisiana is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XV
Massachusetts False Claims Law
Mass. Laws. Ch. 12, §§ 5B(a)(1) & (2)

288. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

289. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Mass. Laws. Ch. 12, § 5B(a)(1).

290. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Mass. Laws. Ch. 12, § 5B(a)(2).

291. 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 Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

292. By reason of Janssen's acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Mass. Laws. Ch. 12, § 5B(a), the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XVI
Michigan Medicaid False Claims Act
Mich. Comp. Laws §§ 400.607(1)

293. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

294. By virtue of the acts described above, Janssen "ma[de] or present[ed] or cause[d] to be made or presented to an employee or officer of this state a claim under the social welfare act … upon or against the state, knowing the claim to be false" in violation of Mich. Comp. Laws § 400.607(1).

295. The State of Michigan, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

296. By reason of Janssen's acts, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Mich. Comp. Laws § 400.612, the State of Michigan is entitled to three times the amount of actual damages plus a penalty of $5,000 to $10,000 per violation.

Count XVII
Minnesota False Claims Act
Minn. Stat. §§ 15C.02(a)(1) & (2)

297. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

298. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Minn. Stat. § 15C.02(a)(1).

299. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Minn. Stat. § 15C.02(a)(2).

300. The State of Minnesota, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

301. By reason of Janssen's acts, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Minn. Stat. § 15C.02(a), the State of Minnesota is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XVIII
Montana False Claims Act
Mont. Code §§ 17-8-403(1)(a) & (b)

302. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

303. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Mont. Code § 17-8-403(1)(a).

304. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement material to a false or fraudulent claim" in violation of Mont. Code § 17-8-403(1)(b).

305. The State of Montana, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

306. By reason of Janssen's acts, the State of Montana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Mont. Code § 17-8-403, the State of Montana is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XIX
Nevada False Claims Act
Nev. Rev. Stat. §§ 357.040(1)(a) & (b)

307. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

308. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of Nev. Rev. Stat. § 357.040(1)(a).

309. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Nev. Rev. Stat. § 357.040(1)(b).

310. The State of Nevada, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

311. By reason of Janssen's acts, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Nev. Rev. Stat. § 357.040(2), the State of Nevada is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XX
New Jersey False Claims Act
N.J. Stat. §§ 2A:32C-3(a) & (b)

312. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

313. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented to an employee, officer or agent of the State, or to any contractor,

grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval" in violation of N.J. Stat. § 2A:32C-3(a).

314. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State" in violation of N.J. Stat. § 2A:32C-3(b).

315. The State of New Jersey, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

316. By reason of Janssen's acts, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to N.J. Stat. § 2A:32C-3, the State of New Jersey is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XXI
New York False Claims Act
N.Y. State Fin. Law §§ 189(1)(a) & (b)

317. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

318. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of N.Y. State Fin. Law § 189(1)(a).

319. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of N.Y. State Fin. Law § 189(1)(b).

320. The State of New York, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

321. By reason of Janssen's acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to N.Y. State Fin. Law § 189(1), the State of New York is entitled to three times the amount of actual damages plus a penalty of $6,000 to $12,000 per violation.

Count XXII
North Carolina False Claims Act
N.C. Gen. Stat. §§ 1-607(a)(1) & (2)

322. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

323. By virtue of the acts described above, Janssen "[k]nowingly present[ed] or cause[d] to be presented a false or fraudulent claim for payment or approval" in violation of N.C. Gen. Stat. § 1-607(a)(1).

324. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of N.C. Gen. Stat. § 1-607(a)(2).

325. The State of North Carolina, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

326. By reason of Janssen's acts, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to N.C. Gen. Stat. § 1-607(a), the State of North Carolina is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XXIII
Oklahoma Medicaid False Claims Act
63 Okl. St. §§ 5053.1(B)(1) & (2)

327. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

328. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval" in violation of 63 Okl. St. § 5053.1(B)(1).

329. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim paid or approved the state" in violation of 63 Okl. St. § 5053.1(B)(2).

330. The State of Oklahoma, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

331. By reason of Janssen's acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to 63 Okl. St. § 5053.1(B), the State of Oklahoma is entitled to three times the amount of actual damages plus a penalty of $5,000 to $10,000 per violation.

Count XXIV
Rhode Island False Claims Act
R.I. Gen. Laws §§ 9-1.1-3(a)(1) & (2)

332. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

333. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of R.I. Gen. Laws § 9-1.1-3(a)(1).

334. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of R.I. Gen. Laws § 9-1.1-3(a)(2).

335. The State of Rhode Island, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

336. By reason of Janssen's acts, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to R.I. Gen. Laws § 9-1.1-3(a), the State of Rhode Island is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XXV
Tennessee Medicaid False Claims Act
Tenn. Code §§ 71-5-182(a)(1)(A) & (B)

337. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

338. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval under the medicaid program" in violation of Tenn. Code § 71-5-182(a)(1)(A).

339. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim under the medicaid program" in violation of Tenn. Code § 71-5-182(a)(1)(B).

340. The State of Tennessee, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

341. By reason of Janssen's acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Tenn. Code §§71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus a penalty of $5,000 to $25,000 per violation.

Count XXVI
Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code §§ 36.002(1), (5) & (13)

342. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

343. By virtue of the acts described above, Janssen "knowingly ma[de] or cause[d] to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized" in violation of Tex. Hum. Res. Code § 36.002(1).

344. By virtue of the acts described above, Janssen "knowingly pa[id], … solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, … or other consideration as a condition to the provision of a service or product or the continued provision of a service or product if the cost of the service or product is paid for, in whole or in part, under the Medicaid program" in violation of Tex. Hum. Res. Code § 36.002(5).

345. By virtue of the acts described above, Janssen "knowingly engage[d] in conduct that constitutes a violation under Section 32.039(b) [prohibiting kickbacks]" in violation of Tex. Hum. Res. Code § 36.002(13).

346. The State of Texas, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

347. By reason of Janssen's acts, the State of Texas has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Tex. Hum. Res. Code § 36.052(a)(3), the State of Texas is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XXVII
Vermont False Claims Act
32 V.S.A. §§ 631(a)(1) & (2)

348. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

349. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of 32 V.S.A. § 631(a)(1).

350. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of 32 V.S.A. § 631(a)(2).

351. The State of Vermont, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

352. By reason of Janssen's acts, the State of Vermont has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to 32 V.S.A. §§ 631(b)(1) & (2), the State of Vermont is entitled to three times the amount of actual damages plus a penalty of $5,500 to $21,563 per violation.

Count XXVIII
Virginia Fraud Against Taxpayers Act
Va. Code §§ 8.01-216.3(A)(1) & (2)

353. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

354. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Va. Code § 8.01-216.3(A)(l).

355. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Va. Code § 8.01-216.3(A)(2).

356. 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 Janssen, paid and

continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

357. By reason of Janssen's acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Va. Code § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

Count XXIX
Washington Medicaid Fraud False Claims Act
Wash. Rev. Code §§ 74.66.020(1)(a) & (b)

358. Relator re-alleges and incorporates each allegation in each of the preceding paragraphs as if fully set forth herein and further alleges as follows:

359. By virtue of the acts described above, Janssen "[k]nowingly present[ed], or cause[d] to be presented, a false or fraudulent claim for payment or approval" in violation of Wash. Rev. Code § 74.66.020(1)(a).

360. By virtue of the acts described above, Janssen "[k]nowingly ma[de], use[d], or cause[d] to be made or used, a false record or statement material to a false or fraudulent claim" in violation of Wash. Rev. Code § 74.66.020(1)(b).

361. The State of Washington, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Janssen, paid and continues to pay the claims that would not be paid but for Janssen's acts and conduct alleged herein.

362. By reason of Janssen's acts, the State of Washington has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Pursuant to Wash.

Rev. Code § 74.66.020(1), the State of Washington is entitled to three times the amount of actual damages plus a penalty of $5,500 to $11,000 per violation.

PRAYER FOR RELIEF

WHEREFORE, Relator demands that judgment be entered in favor of the United States and the Plaintiff States and against Janssen for the maximum amount of damages and such other relief as the Court may deem appropriate on each Count. This request includes, with respect to the Federal FCA, three times the amount of damages to the United States, plus civil penalties of no more than $11,000 and no less than $5,500 for each false claim submitted on or before November 2, 2015 and civil penalties of no more than $22,363 and no less than $11,181 for each false claim submitted on or after November 3, 2015, and any other recoveries or relief provided for under the Federal FCA. This Request also includes, with respect to the Plaintiff States' false claims statutes, the maximum damages, the maximum fines or penalties, and any other recoveries or relief provided for or permitted by those state statutes.

Further, Relator requests that she receive the maximum amount permitted by law from the proceeds or settlement of this action as well as from any alternative remedies collected by the United States and the Plaintiff States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs. Relator requests that her award be based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities who are not parties to this action.

DEMAND FOR JURY TRIAL

A jury trial is demanded in this case.

DATED: February 11, 2020

Respectfully submitted,

By: /s/ Casey M. Preston

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Counsel for Plaintiff Relator Julie Long

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing. Paper copies will be sent to those indicated as non-registered participants.

DATED: February 11, 2020

/s/ Casey M. Preston
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