UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

BOSTON RETIREMENT SYSTEM, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

vs.

ALEXION PHARMACEUTICALS, INC., LEONARD BELL, DAVID L. HALLAL, VIKAS SINHA, DAVID BRENNAN, DAVID J. ANDERSON, LUDWIG HANTSON, and CARSTEN THIEL

Defendants.

Civ. No. 3:16-cv-2127 (AWT)

CLASS ACTION

AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

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Co-Lead Counsel for Lead Plaintiffs and the Class

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Lead Plaintiffs the Public Employee Retirement System of Idaho and Erste Asset Management GmbH ("Lead Plaintiffs"), by their undersigned attorneys, bring this action under Sections 10(b) and 20(a) of the U.S. Securities Exchange Act of 1934 (the "Exchange Act"), and Securities and Exchange Commission (the "SEC") Rule 10b-5 promulgated thereunder, on behalf of themselves and all others similarly situated who purchased or otherwise acquired the publicly traded common stock of Alexion Pharmaceuticals, Inc. ("Alexion" or the "Company") between January 30, 2014 and May 26, 2017, inclusive (the "Class Period"), subject to certain exclusions described in ¶ 348 below.

Lead Plaintiffs allege the following upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters. Lead Plaintiffs' information and belief are based on, among other things, the independent investigation of Court-appointed Co-Lead Counsel Labaton Sucharow LLP and Motley Rice LLC. This investigation has included, among other things, a review and analysis of: (i) public filings by Alexion with the SEC; (ii) public reports and news articles; (iii) research reports by securities and financial analysts; (iv) economic analyses of securities movement and pricing data; (v) transcripts of investor calls with Alexion senior management; (vi) publicly available legal proceedings; (vii) an investigation conducted by and through Lead Plaintiffs' attorneys and their investigators, including but not limited to interviews and discussions with former Alexion employees; and (viii) other publicly available material and data identified herein. In addition, Lead Plaintiffs have consulted with an industry expert with knowledge of the applicable pharmaceutical regulations, laws, and industry standards, and more than 25 years of experience in pharmaceutical sales and marketing.

Co-Lead Counsel's investigation regarding the factual allegations contained herein is ongoing, and many of the facts supporting the allegations contained herein are known only to the Defendants (as defined herein) or are exclusively within their custody or control. Lead Plaintiffs believe that further substantial evidentiary support will exist for the allegations contained herein after a reasonable opportunity for discovery.

I. INTRODUCTION – NATURE OF THE ACTION

1. Throughout the Class Period, Alexion and the Individual Defendants (defined below) consistently misled the investing public by falsely attributing the source of the Company's meteoric success to its ability to identify new patients for the Company's only money-making drug, Soliris. Investors were left holding the bag, however, to the tune of billions in market losses when Alexion management admitted to a "tone at the top" problem that improperly boosted sales of Soliris through illegal practices that violated federal laws, industry standards, and ethical regulations.

2. Indeed, throughout the Class Period, Defendants stated repeatedly that Soliris's strong sales were due to the Company's presumably lawful efforts to educate doctors and the public about the drug's benefits and to fund various diagnostic initiatives. Moreover, to substantiate these assertions, Defendants also affirmatively touted Alexion's strict compliance program and adherence to industry ethical codes.

3. But these statements and assurances were materially false and misleading when made. As revealed to the investing public through a May 24, 2017 exposé in Bloomberg News, and as corroborated and further detailed by five former employees who spoke to Lead Plaintiffs' investigators, Alexion's management, including the Individual Defendants, fostered an anything-goes atmosphere when it came to selling Soliris, and they directed employees to engage in sales tactics they knew were illegal, unethical, and outside of industry standards.

4. For example, Company founder and former chairman Dr. Leonard Bell ("Bell"), former CEO David Hallal ("Hallal"), and other executives directed Alexion in-house nurses to pressure physicians and patients to start Soliris treatments or stay on the drug, even if not in the best interests of the patient. Defendants also schemed with partner diagnostic labs to illegally obtain private, confidential patient information for marketing purposes. Moreover, Defendants illegally funded kickbacks to charitable organizations to have government agencies such as Medicare pay for Soliris. Because Defendants repeatedly and affirmatively touted the supposed lawful sources of Alexion's success, they commensurately had an affirmative duty to disclose to the investing public ***the actual*** illegal and unethical practices that were sustaining the Company's sales and revenue growth.

5. Yet, investors were unaware of these illicit activities until November 2016, when—facing allegations from a former employee—Alexion announced it was investigating whether its employees engaged in sales practices that violated the Company's policies and procedures. As a result of that investigation, Hallal and then-CFO Vikas Sinha ("Sinha") were forced to resign without warning or explanation, and Alexion admitted that senior management encouraged and/or allowed employees to engage in sales practices that violated Company policy.

6. Notwithstanding these admissions, instead of coming clean and telling investors the full extent of their illegal and unethical sales tactics, Defendants continued their fraud by telling investors that the Company's troubles related only to so-called "pull-in" transactions, which they conveniently claimed were inconsequential. Indeed, it took several more months for the full truth to finally emerge. Investors did not learn the full scope of the problems until May 24, 2017, when Bloomberg published its exposé. Because of Defendants' fraudulent conduct,

Alexion's stock lost ***more than 30%*** of its market value, wiping out nearly $10 billion in shareholder wealth.

A. Defendants Misled Investors Throughout the Class Period About the Source of Their Successful Financial Results

7. Alexion is a pharmaceutical drug company that generates nearly all of its revenue from selling Soliris. Worldwide, only approximately 11,000 patients use Soliris, which treats patients suffering from one of two ultra-rare diseases, paroxysmal nocturnal hemoglobinuria ("PNH") and atypical hemolytic uremic syndrome ("aHUS"). Despite the rarity of the disorders its drug treats, the Company can generate substantial revenue from Soliris because Alexion has a monopoly on the treatment and charges patients and insurers an exorbitant price for the drug. On an annual basis, each patient is charged between $500,000 and $700,000 for the drug.

8. Soliris's exceedingly high unit price, and the fact that Alexion is effectively a "one drug" company, means that a relatively small change in the number of prescriptions written worldwide has an extraordinary impact on the Company's bottom line. Indeed, sales of Soliris generated more than 99% of the Company's revenue in 2015 and more than 90% in 2016. Therefore, to keep revenues growing, the Company resorted to ever more improper sales tactics that flouted legal and ethical codes governing pharmaceutical sales. But of course Defendants could not—and did not—tell the market that reality. Rather, to convince analysts and investors that the Company's future prospects were bright, Defendants painted for the market the woefully incomplete picture that Alexion had the ability to continually identify new patients for its treatments.

9. Indeed, throughout the Class Period, Defendants repeatedly misled investors by claiming that the source of their impressive financial results was the Company's ability to "identify new patients" through presumably lawful means such as Alexion's "disease awareness

and diagnostic programs." For instance, on January 30, 2014, Defendant Hallal attributed Alexion's record full-year 2013 financial results to "***strong rates of patient identification and rapid treatment initiation with Soliris . . . as our disease awareness and diagnostic programs continue to support optimal patient care***." Defendants made similar statements about their financial success an additional eighteen times during the Class Period. Of course, Defendants always failed to make any mention of the Company's rampant illegal and unethical sales practices.

10. Analysts covering Alexion accepted (and were impressed by) these misleading omissions. For instance, on January 30, 2014, Leerink Partners LLC ("Leerink") increased its valuation of Alexion, specifically linked the "growth of Soliris" with Alexion's "continued identification of new patients," and further noted that "[Alexion's] diagnostic pathway initiative has led to more flow cytometry tests for PNH and an increase in newly diagnosed patients."

B. Alexion's Sales Practices Violated Applicable Industry Ethical Standards and Federal Law

11. Unbeknownst to investors, however, the ***stated source*** of Alexion's continued success—its supposed ability to identify new patients—differed tremendously from the ***actual*** source of that success—pressuring patients and physicians through in-house nurses, harvesting confidential patient data from partner labs, and funneling kickbacks through charitable organizations. Moreover, based on these undisclosed behaviors, Alexion's statements about its supposed adherence to applicable ethical standards and laws were also highly misleading.

12. Five confidential witnesses ("CWs"), all former employees of Alexion, have corroborated that during the Class Period the Company relied on undisclosed illegal and unethical sales tactics that included, *inter alia*: (i) relying on a team of in-house nurses, who worked under the Company's sales organization, to pressure patients and doctors to use Soliris,

even if not in the patients' best interests; (ii) encouraging doctors to send patients' tests to "partner labs," which, in turn, would inappropriately share with Alexion the results of these tests so that Alexion could identify patients diagnosed with PNH and aHUS (*i.e.*, potential customers); and (iii) funneling illegal kickbacks to Medicare and Medicaid patients through charitable organizations to cover co-pays and other costs for Soliris.

13. Alexion's improper sales tactics violated mandatory industry ethical guidelines set forth in federal guidance; the Code on Interactions with Healthcare Professionals (the "PhRMA Code" or "Code"), which is issued by the Pharmaceutical Research and Manufacturers of America; as well as federal laws including the Health Insurance Portability and Accountability Act of 1966 ("HIPAA"); and the Medicare-Medicaid Anti-Fraud and Abuse Act, 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute"), all of which govern Alexion's business. Furthermore, the Office of Inspector General for the Department of Health and Human Services ("OIG") disallows healthcare providers such as Alexion's in-house nurses, who were actually acting as sales representatives, from engaging in so-called "white coat marketing" or recommending to patients courses of treatment to make sales of a company's drugs.

14. Importantly, the PhRMA Code restricts pharmaceutical representatives from providing medical advice to patients and treating physicians, and demands that company representatives limit the information they provide to scientific and educational materials and steer clear of exerting any undue influence on doctors or interfering with the doctor-patient relationship. Moreover, the applicable Code of Ethics for Nurses required Alexion's nurses to, *inter alia*, set forth all treatment options in an unbiased manner and to avoid and fully disclose any conflicts of interest.

15. Instead of adhering to these applicable federal laws and ethical standards, Alexion used a platoon of in-house nurses in its commercial business organization to put inappropriate pressure on physicians and patients to start or continue taking Soliris. Two former Alexion in-house nurses and a former Alexion Senior Director stated that Defendants Bell and Hallal ***personally*** instructed and directed sales representatives and nurses to pressure physicians to start Soliris treatments even when the treating physician did not believe Soliris was an appropriate option.

16. These same nurses and a third former nurse also stated Hallal and other executives conducted regular sales meetings where they pressured each nurse to convince patients to stay on Soliris and provided scripts telling patients that "you're going to die." Nurses were further instructed to tell patients to switch doctors if their existing physicians were not prescribing Soliris.

17. In addition, Defendants' undisclosed partnerships with diagnostic labs that allowed Alexion to easily identify potential new customers blatantly violated HIPAA, which requires appropriate safeguards to protect the privacy of patients' personal health information.

18. According to two former in-house nurses, Alexion partnered with certain diagnostic labs and agreed to provide a valuable chemical reagent used in testing for PNH and aHUS. With Hallal's and Bell's knowledge and blessing, Alexion nurses and sales representatives steered patients and doctors to these partner labs. In turn, the labs provided Alexion with copies of the patients' test results. In clear violation of HIPAA, the results included identifying and personal details about the patient, such as the patient's age, gender, zip code, the hospital and doctor ordering the test, and a summary of the patient's test results. With

this information, sales representatives were able to easily locate patients (*i.e.*, potential customers) who would have otherwise been extremely difficult to find.

19. Defendants also brazenly violated the Anti-Kickback Statute by funneling money through certain charitable patient advocacy groups to pay for Medicare and Medicaid patients' co-pays and other costs for taking Soliris. According to a former in-house nurse, Alexion made conditioned donations to Patient Services, Inc. ("PSI") and National Organization for Rare Disorders ("NORD") that could only be used to help patients pay for Soliris. This witness attended meetings during which Defendants Hallal and Bell oversaw discussions that Alexion employees coordinated and matched whatever donations were needed for NORD and PSI to facilitate Medicare and Medicaid co-pays for Soliris.

C. The Truth About Alexion's Illegal and Unethical Sales Practices Was Slowly Revealed Through a Series of Partial Disclosures

20. On November 4, 2016, Alexion abruptly cancelled an appearance at the Credit Suisse Healthcare Conference. On this news, Alexion's share price fell ***nearly 7%***. Later, on November 9, 2016, Defendants issued a press release revealing that the Company would not file its forthcoming Form 10-Q on time and was investigating allegations by a former employee about "***whether Company personnel have engaged in sales practices that were inconsistent with Company policies and procedures***." Over the next two trading days, Alexion's share price fell ***more than 10%***.

21. Then, on December 12, 2016, Alexion announced that Defendant Hallal had resigned as CEO and Defendant Sinha had resigned as CFO, but failed to provide any reason for the abrupt departures. Analysts covering Alexion linked the sudden departures to the Company's investigation into its improper sales tactics, and on the news, Alexion's stock price experienced a one-day decline of ***almost 13%***.

22. On January 4, 2017, Alexion issued a press release in which it announced that, after investigating allegations of improper sales tactics, the Company had identified a material weakness in its internal controls, which was caused by senior management not setting an appropriate "tone at the top." However, rather than reveal the full truth, the Company concealed the full extent of Alexion's unethical and illegal conduct, and informed investors that the only improper sales practices it had discovered related to "pull-in" sales that occurred in the fourth quarter of December 2015. Further downplaying the extent of Alexion's illegal and unethical sales practices, the Company explained that the pull-ins represented less than 1% of total revenue for 2015 and did not require the Company to issue a restatement.

23. Despite Alexion's efforts to cover up the Company's misconduct, however, the truth continued to slowly reveal itself. For instance, on March 6, 2017, Defendant David Brennan ("Brennan"), the then-interim CEO, admitted that "[a]s a Board, we are disappointed" with Alexion's "tone at the top," which had created "pressure to do some things that were not in accordance with our policies and procedures." However, Brennan continued to conceal the full extent of Alexion's illicit sales practices and mentioned only pull-ins.

24. Then on May 23, 2017, Alexion announced another significant shake-up of its executive leadership with the departure of Alexion's CFO (Defendant David J. Anderson ("Anderson")), CCO (Defendant Carsten Thiel ("Thiel")), and two other executive vice presidents. On each of these announcements on March 6, 2017 and May 23, 2017, the Company's shares fell sharply.

25. On May 24, 2017, the market finally gained a fuller picture of the scope of Alexion's illegal and unethical sales practices. Relying on interviews with more than 20 current and former employees and a review of more than 2,000 pages of internal documents, Bloomberg

released an in-depth exposé (the "May Bloomberg Article") disclosing for the first time many of Alexion's illicit and unethical sales practices. The May Bloomberg Article revealed Alexion's use of in-house nurses, its unlawful relationships with partner labs, and grants that it had made to charitable organizations, similar to PSI and NORD, that improperly tried to get the Brazilian government to pay for Soliris. On the news, Alexion's stock experienced a two-day slide of ***more than 6%***. In all, Alexion's stock fell ***more than 30%*** as the fraud was revealed, wiping out nearly $10 billion in shareholder value.

II. JURISDICTION AND VENUE

26. The claims asserted herein arise pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

27. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

28. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act, 15 U.S.C. § 78aa. Many of the acts and transactions that constitute violations of law complained of herein, including the dissemination to the public of untrue statements of material facts, occurred in this District.

29. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the mails, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

A. Lead Plaintiffs

30. Lead Plaintiff Public Employee Retirement System of Idaho ("PERSI") is a public pension fund that provides retirement, disability, survivor, and other benefits to more than

155,000 members in the state of Idaho. PERSI has approximately $17.7 billion assets under management. On April 12, 2017, the Court appointed PERSI as Lead Plaintiff for this litigation. As set forth in the certification filed with this Court (ECF No. 69), PERSI purchased Alexion common stock during the Class Period, and suffered damages as a result of Defendants' fraud.

31. Lead Plaintiff Erste Asset Management GmbH ("Erste Asset") is an investment company based in Vienna, Austria.[1] As part of Erste Asset's asset management services, it is responsible for managing mutual funds, private funds, and institutional funds. On April 12, 2017, the Court appointed Erste Asset as Lead Plaintiff for this litigation. As set forth in the certification filed with this Court (ECF No. 70), Erste Asset, on behalf of its funds, purchased Alexion common stock during the Class Period, and suffered damages as a result of Defendants' fraud.

B. The Defendants

32. Defendant Alexion is a biopharmaceutical company that develops and commercializes products to treat patients with ultra-rare disorders. Based in New Haven, Connecticut, the Company was incorporated in 1992. Until the fourth quarter of 2015, Soliris, a drug designed to treat rare blood disorders, was Alexion's only marketed product, and it remained the Company's principal source of revenue throughout the remainder of the Class Period. Alexion went public in 1996 and its stock trades on the NASDAQ stock exchange, which is an efficient market, under ticker symbol "ALXN." As of April 23, 2019, Alexion had over 224 million shares of stock outstanding, owned by thousands of investors, including Lead Plaintiffs and other members of the proposed Class.

[1] Erste Asset entered this action under its former name Erste-Sparinvest Kapitalanlagegesellschaft mbH, and on November 14, 2018 filed a Notice of Name Change with the Court. *See* ECF No. 105.

33. Defendant Leonard Bell was the principal founder of Alexion and served as the Chief Executive Officer ("CEO") of the Company from January 1992 to March 31, 2015. Bell served as Chairman of Alexion's Board of Directors (the "Board") from October 2014 to May 10, 2017. As CEO, Bell reviewed, approved, and signed Alexion's false and misleading SEC filings. Bell also participated in conference calls with securities analysts, during which Alexion's false and misleading statements filed with the SEC and included in press releases were presented and discussed.

34. Defendant David L. Hallal served as Alexion's Chief Executive Officer ("CEO") from April 1, 2015, until his resignation on December 12, 2016. From November 2012 through March 2015, Hallal served as Alexion's Chief Commercial Officer ("CCO"). From May 2010 to October 2012, Hallal was Senior Vice President, Global Commercial Operations. From November 2008 to May 2010, Hallal was Senior Vice President, Commercial Operations Americas. From June 2006 until November 2008, Hallal was Senior Vice President, US Commercial Operations. As CEO, Hallal reviewed, approved, and signed Alexion's false and misleading SEC filings. Hallal also participated in conference calls with securities analysts, during which Alexion's false and misleading statements filed with the SEC and included in press releases were presented and discussed.

35. Defendant Vikas Sinha served at all relevant times as Alexion's Chief Financial Officer ("CFO") and Executive Vice President, until his resignation on December 12, 2016. As CFO, Sinha reviewed, approved, and signed Alexion's false and misleading SEC filings. Sinha also participated in conference calls with securities analysts, during which Alexion's false and misleading statements filed with the SEC and included in press releases were presented and discussed.

36. Defendant David Brennan served as Alexion's interim CEO from December 12, 2016, until March 27, 2017, when he was replaced by Defendant Hantson. As interim CEO, Brennan reviewed, approved, and signed Alexion's false and misleading SEC filings.

37. Defendant David J. Anderson served as Alexion's CFO beginning on December 12, 2016. As detailed below, on May 23, 2017, the Company announced that Anderson would resign as CFO. On June 13, 2017, the Company announced that Anderson would serve as CFO until July 31, 2017, when he was replaced by Paul J. Clancy. As CFO, Anderson reviewed, approved, and signed Alexion's false and misleading SEC filings.

38. Defendant Ludwig N. Hantson ("Hantson") has served as Alexion's CEO since March 27, 2017, when the Board approved him to replace interim CEO Brennan. Defendant Hantson directed the management and policies of Defendant Alexion. As CEO, Hantson reviewed, approved, and signed Alexion's false and misleading SEC filings.

39. Defendant Carsten Thiel served as Alexion's CCO from September 2015 until June 1, 2017. Defendant Thiel participated in conference calls with securities analysts, during which Alexion's false and misleading statements filed with the SEC and included in press releases were presented and discussed.

40. Defendants Bell, Hallal, Sinha, Brennan, Anderson, Hantson, and Thiel are collectively referred to as the "Individual Defendants" and, together with Alexion, as the "Defendants." The Individual Defendants directly participated in the management of Alexion's operations, including its accounting and reporting functions, had the ability to and did control Alexion's financial reporting, and were privy to confidential information concerning Alexion and its business, operations, and financial statements, as alleged herein. They were also involved in drafting, reviewing, publishing, and/or disseminating the false and misleading financial

statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements were being issued, and approved or ratified these misstatements in violation of the federal securities laws.

C. Relevant Non-Parties

Former Employees

41. CW 1 was employed by Alexion from 2008 to 2015 as a Nurse in Alexion's commercial sales organization. CW 1's responsibilities included communicating with prescribing physicians and interacting with patients to market Soliris. CW 1 had direct experience with Defendants' unethical and illegal sales and marketing tactics at Alexion during the Class Period. CW 1 had repeated meetings with Defendants Bell, Hallal, and other members of Alexion's C-Suite wherein the executives would go through CW 1's entire caseload, patient by patient, wanting to discuss any patient that decided to stop taking Soliris and demanding to know what CW 1 was doing to pressure patients to continue treatment.

42. CW 2 was employed by Alexion from 2015 to 2018 as a Nurse and Case Manager in Alexion's commercial division. CW 2's responsibilities included making sure that patients had access to Soliris and that they could stay on the drug. CW 2 was directly involved in Alexion's relationship with patient assistance programs and assisted patients with contacting PSI or NORD. CW 2 attended regular meetings with Company executives, to review each patient's starts, stops, and restarts with Soliris.

43. CW 3 was employed by Alexion from 2009 to 2017 as a Senior Director. CW 3's responsibilities included the development and management of business relationships and company strategies. CW 3 had direct personal experience and knowledge of the improper sales and marketing tactics in place at Alexion during the Class Period. CW 3 attended regular meetings headed by Defendants Bell, Hallal, and other Company executives (including

commercial and medical affairs executives) during which Country Managers were pressured on a patient-by-patient basis to have treating physicians start or continue Soliris treatments.

44. CW 4 was employed by Alexion during the entirety of the Class Period as a Nurse and was responsible for disease and diagnostic education and marketing of Soliris. Although CW 4 was a nurse, CW 4 reported to Alexion's commercial organization and ultimately reported to the head of Alexion's commercial organization. CW 4 had direct experience with Alexion's unethical and illegal sales and marketing tactics during the Class Period. CW 4 attended regular meetings with Defendants Bell and Hallal and other Company executives where they pressured nurses and other staff to convince physicians and patients to start or continue Soliris treatments.

45. CW 5 was employed by Alexion from 2016 to 2017 as a Regional Clinical Specialist ("RCS") in the commercial organization and then from 2017 to 2018 as a Medical Science Liaison ("MSL") in the medical affairs unit. As an RCS, CW 5 was involved in interacting with physicians that had experience treating PNH and aHUS known as "Key Opinion Leaders." CW 5 also interacted directly with community physicians to provide education on the use of Soliris. CW 5 had direct personal experience and knowledge of Alexion's sales and marketing tactics during the Class Period. In particular, CW 5 attended regular meetings with case managers, other RCSs, Regional Account Managers, and diagnostic specialists, where they discussed patient information and ways to convince physicians to start their patients on Soliris.

Partner Diagnostic Laboratories

46. Dahl-Chase Diagnostic Services ("Dahl-Chase") is a regional medical laboratory that provides diagnostic services, including specialty flow cytometry testing, to hospitals and physician offices across the United States. Dahl-Chase had an agreement with Alexion to provide the Company with copies of patients' test results that indicated a condition for which

Soliris could be useful. Those test results contained a number of identifying and personal details, such as the patient's age, gender, zip code, the hospital and doctor ordering the test, and a summary of the results. Dahl-Chase is located at 417 State St., Suite 540, Bangor, Maine 04401.

47. Machaon Diagnostics, Inc. ("Machaon Diagnostics") is a regional clinical reference laboratory that specializes in the diagnosis of hemostatic and thrombotic conditions, including aHUS. Machaon Diagnostics had an agreement with Alexion to provide the Company with copies of patients' test results that indicated a condition for which Soliris could be useful. Those test results contained a number of identifying and personal details, such as the patient's age, gender, zip code, the hospital and doctor ordering the test, and a summary of the results. Machaon Diagnostics is located at 3023 Summit St., Oakland, California 94609.

48. Laboratory Corporation of America Holdings ("LabCorp") operates one of the largest clinical laboratory networks in the world, including 36 primary laboratories in the United States. LabCorp had an agreement with Alexion to provide the Company with copies of patients' test results that indicated a condition for which Soliris could be useful. Those test results contained a number of identifying and personal details, such as the patient's age, gender, zip code, the hospital and doctor ordering the test, and a summary of the results. LabCorp is headquartered in Burlington, North Carolina, which is where it performs its largest volume of specialty testing.

49. Quest Diagnostics Inc. ("Quest") is an American clinical laboratory which offers diagnostic testing services for cancer, cardiovascular disease, infection disease, and neurological disorders, among others. Quest had an agreement with Alexion to provide the Company with copies of patients' test results that indicated a condition for which Soliris could be useful. Those test results contained a number of identifying and personal details, such as the patient's age,

gender, zip code, the hospital and doctor ordering the test, and a summary of the results. Quest is headquartered at 500 Plaza Drive, Secaucus, New Jersey 07094.

50. Mayo Clinic Laboratories, f/k/a Mayo Medical Laboratories ("Mayo Labs"), is a global reference laboratory that offers testing services for a variety of diseases, including aHUS and PNH. Mayo Labs had an agreement with Alexion to provide the Company with copies of patients' test results that indicated a condition for which Soliris could be useful. Those test results contained a number of identifying and personal details, such as the patient's age, gender, zip code, the hospital and doctor ordering the test, and a summary of the results. Mayo Labs is located in Rochester, Minnesota and Jacksonville, Florida.

51. Dahl-Chase, Machaon Diagnostics, LabCorp, Quest, and Mayo Labs are collectively referred to as the "Partner Labs."

IV. RELEVANT COMPANY AND INDUSTRY BACKGROUND

A. Alexion's Founding and Discovery of Soliris

52. Alexion, a biopharmaceutical company that focuses on developing and commercializing drugs for patients with severe and ultra-rare disorders, was founded in 1992 by Defendant Bell, then a 33-year-old cardiologist.

53. At the time Alexion was founded, Defendant Bell was focused on developing drugs that harnessed the power of a part of the body's own immune response, known as the complement cascade, which helps the blood stream eliminate damaged cells and bacteria. Because sometimes this protective immune response can cause harm to the body, such as when a body rejects a transplanted organ, Defendant Bell reasoned that if he could ascertain how to limit the complement cascade in certain situations, he could develop drugs that use complement blockers to solve a variety of medical problems, including rheumatoid arthritis, skin disease, kidney disease, and the heart inflammation that occurs during heart attacks—ailments that affect

a large segment of the population. With this business strategy in mind, Defendant Bell launched Alexion.

54. Funding this new venture proved challenging. Worse yet, it became increasingly clear that the complement blockers in the body could not be harnessed in a way that Defendant Bell had initially planned, and therefore would not make good drugs for wide use.

55. But then, in 1995, as the Company was on the verge of closure, Alexion discovered a seemingly breakthrough technology. At the time, other pharmaceutical companies were working to develop pig organs that could be implanted into humans, but were having trouble determining how to prevent the body's complement system from destroying the implanted organs. While working with another company on an effort to create pig organs that could resist human complement blockers, Alexion developed a new technology—a complement-blocking antibody that later became known as Soliris.

56. This technological breakthrough helped Alexion attract investors, and, in 1996, Alexion went public. Investors were attracted to the prospect that the antibody Alexion had developed (*i.e.*, Soliris) would be able to treat a wide range of ailments and diseases (and, thus, a large number of patients).

57. However, after Soliris went into production in 1997, tests to determine whether Soliris would effectively treat these different diseases all failed. Ultimately, Defendant Bell's vision of harnessing the complement cascade to create drugs that treat a multitude of diseases proved unachievable. The problem, as Defendant Bell later explained, was that he was looking

for big markets for Soliris, rather than the right markets, and he "kind of went with the crowd thinking as to how to build a business."[2]

58. But then, in 2002, Alexion stumbled upon a new market for its drug, albeit an extremely small one: a British researcher discovered that Soliris helped patients suffering from the extremely rare blood disorder known as paroxysmal nocturnal hemoglobinuria ("PNH"), which occurs when a patient's complement system attacks red blood cells. Aware that they may have unwittingly discovered a treatment for this ultra-rare disease, Defendant Bell and his researchers spent months designing studies to get Soliris approved to treat PNH.

59. In March 2007, after years of research and clinical trials, the FDA granted marketing approval for Soliris to treat PNH, and, in April 2007, Alexion began to sell Soliris commercially in the United States. Soliris was later approved to treat PNH in Europe, Japan, and Canada.

60. Years later, in September 2011, Soliris was approved by the FDA to treat patients suffering from another ultra-rare blood disorder: atypical hemolytic uremic syndrome ("aHUS"), a disease characterized by the destruction of red blood cells, low platelet count, and an inability of the kidneys to process waste product from the blood. Soliris was later approved to treat aHUS in Europe and Japan.

61. Soliris is the only drug approved to treat patients suffering from PNH and aHUS.

B. Soliris Was Critically Important to Alexion's Business Prospects

62. Once Alexion was granted approval for Soliris, the Company had to determine how to generate enough revenue off a drug that, as of May 2017, treated only approximately 11,000 patients worldwide. Indeed, Defendant Hallal acknowledged as much during an

[2] Matthew Herper, *How a $440,000 Drug Is Turning Alexion Into Biotech's New Innovation Powerhouse*, FORBES (Sept. 24, 2012).

interview in 2015, explaining: "Back in 2007, the bear story on Alexion was, how do you even make a business in this? Aren't there just a few hundred people in the world living with PNH?"[3]

63. To successfully generate revenue, despite this obvious hurdle, Alexion embarked on a two-pronged strategy: exorbitant pricing and "do-whatever-it-takes" sales tactics—including, as detailed below, conduct that was improper and illegal.

64. Soliris is one of the most expensive drugs in the world, costing approximately ***$500,000 to $700,000 per patient per year***. Because Soliris is the only drug approved to treat PNH and aHUS, Alexion has substantial pricing power over the drug. The hefty price tag also reflects the impact of the Orphan Drug Act, passed in 1983, which gives drug makers significant financial and competition-reducing incentives to develop drugs that treat rare diseases, like PNH and aHUS.

65. Because Soliris is so expensive, the drug has been tremendously profitable for the Company, notwithstanding Soliris's limited customer base. Buoyed by the Company's improper sales tactics, as detailed herein, net product sales for Soliris were $2.23 billion for the year ended 2014, $2.59 billion for the year ended 2015, and $2.84 billion for the year ended 2016.

66. Sales of Soliris have also increased every year since the drug was approved in 2007, and have done so at an astounding rate: In 2008, the first full year in which Soliris was sold, net product sales were approximately $259 million, rising to nearly $541 million in 2010, $1.1 billion in 2012, $2.23 billion in 2014, and $2.84 billion in 2016.

67. Because Soliris has been so profitable for the Company, Alexion has for years been able to rely solely on sales of Soliris to generate revenue. From the Company's founding in 1992 until late 2015, Soliris was the only drug the Company sold. In short, Alexion has largely

[3] Benjamin Elgin, Doni Bloomfield & Caroline Chen, *When the Patient is a Gold Mine: The Trouble With Rare-Disease Drugs*, BLOOMBERG (May 24, 2017).

been a "one-drug" company. And even after the addition of two new drugs to its portfolio through a corporate acquisition in 2015, Soliris still amounted to over 90% of Alexion's net product sales in 2015 and 2016.

C. Defendants' Incomplete Public Disclosures Addressed Only Presumably Lawful Sales And Marketing Tactics

68. Because Soliris is an orphan drug used to treat rare diseases, Alexion needed to educate physicians about the drug and the diseases that it treated to market and sell the drug to patients with a need for it. To do so, the Company disclosed to its investors that it was engaged in certain sales and marketing tactics, all of which were, at least theoretically (given the lack of specificity and detail), legally and ethically permissible. This included initiatives focused on "disease awareness," "diagnostic initiatives," and "patient support."

69. In support of their focus on "disease awareness," Defendants told investors during a Class Period investor presentation that they educated doctors on how to identify patients that fall into "high risk groups" for PNH and aHUS, and on the impacts of those diseases and the success of Soliris in treating them. Defendants also stated in their 2013 Annual Report that they were "sponsoring a multinational registry to gather information regarding the natural history of patients with PNH and the longer term outcomes during Soliris treatment." Defendants did not provide any further details regarding how they were educating doctors, nor did they explain what their multinational registry would entail. However, on a theoretical basis, such conduct as outlined by Defendants was an entirely permissible method of marketing Soliris.

70. Defendants also claimed during a Class Period investor conference that they had instituted various "diagnostic initiatives" to aid in patient identification and testing, including presenting doctors with various "pathways" to assist them in diagnosing PNH and aHUS and recommending which tests should be run for these diseases. Defendants further disclosed that

the Company had "[d]eveloped lab partnerships" to further enhance its diagnostic capabilities, although it provided no details as to what those lab partnerships entailed. Like their disease awareness program, however, this conduct, notwithstanding its lack of specificity, was theoretically permissible conduct to market and sell Soliris.

71. Further, in support of their focus on "patient support," Defendants stated that they had established a program which utilized the services of registered nurses to provide education, assistance with access to Soliris, and treatment support for PNH and aHUS patients. Soliris was also part of a Risk Evaluation and Mitigation Strategy ("REMS") program mandated by the FDA, under which physicians prescribing Soliris were required to certify that they were aware of potential risks associated with the administration of the drug and that they would inform patients of these risks using educational materials approved by the FDA.

72. Finally, Defendants disclosed to their investors in their 2013 Annual Report that they "financially supported non-profit organizations which assist patients in accessing treatment for PNH and aHUS," including "patients whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations."

73. Once again, all of the sales and marketing-related conduct that Defendants disclosed to investors and the public, while lacking any concrete details, could theoretically be lawful and permissible ways for a pharmaceutical company to promote and market its products, and Defendants gave no indication to the investing public that this was not, in fact, the case.

D. Relevant Industry Codes and Regulatory Framework Governing Pharmaceutical Companies

74. Notwithstanding Defendants' vague descriptions and breezy assurances about their patient identification initiatives, the activities on which Alexion embarked are regulated by rigid industry codes and federal laws that limit what pharmaceutical companies and their sales

representatives can do to market and sell their products. Indeed, all pharmaceutical manufacturing companies in the United States, such as Alexion, are subject to various laws, regulations, and industry codes that dictate what sales and marketing conduct is appropriate.

75. Alexion's conduct in marketing and selling its drug to physicians and patients went well beyond the permissible activities that the Company repeatedly outlined in its public statements and filings. Alexion and the Individual Defendants routinely and systematically engaged in various illegal and unethical sales and marketing tactics that were not disclosed to investors. In engaging in, and directing Company employees to engage in, such illegal and unethical sales and marketing practices, Alexion and the Individual Defendants acted in violation of these laws, regulations, and codes. In relevant part, these regulations include (i) the OIG Guidelines, (ii) the PhRMA Code, (iii) the Code of Ethics for Nurses, (iv) HIPAA laws, and (v) the federal Anti-Kickback Statute.

1. OIG Guidelines Prohibiting "White Coat Marketing"

76. The OIG has issued relevant guidance on pharmaceutical company sales and marketing, specifically as it relates to what the OIG has termed "white coat marketing." White coat marketing refers to the practice of healthcare professionals (like registered nurses) advertising and marketing pharmaceutical products, while in a position of trust, whereby they may exert influence when recommending drugs or services. The OIG is particularly concerned about such practices because patients may have difficulty distinguishing between professional medical advice and commercial sales activities.

77. Indeed, the OIG's guidance regarding "white coat marketing" is directly related to Alexion's business practice of using nurses to educate patients and market Soliris. The OIG's guidance discusses the propriety of white coat marketing practices in similar contexts, noting that it has "long been concerned about aggressive marketing," including marketing practices such as

"[i]n-person sales pitches or 'informational' sessions," which "are highly susceptible to fraud and abuse." That risk of fraud and abuse is compounded where "a physician or other health care professional is involved in the marketing activity," because "physicians and other health care professionals are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services—especially when marketing to their patients." "Given the nature of these relationships, when physicians or other health care professionals market items and services to their patients, patients may have difficulty distinguishing between professional medical advice and a commercial sales pitch." Under these conditions, the OIG concluded that white coat marketing should be avoided. OIG Advisory Opinion No. 11-08.

78. In its *Compliance Program Guidance for Pharmaceutical Manufacturers*, the OIG has further expressed concern regarding the relationship between pharmaceutical manufacturers and their sales agents, noting that sales agents "are paid to recommend and arrange for the purchase of the items or services they offer for sale on behalf of the pharmaceutical manufacturer they represent." The guidance recommends that manufacturers "should carefully review their compensation arrangements with sales agents" through reference to several factors including "the identity of the sales agent engaged in the marketing or promotional activity (*e.g.*, is the agent a 'white coat' marketer or otherwise in a position of exceptional influence) . . . ."[4]

2. PhRMA Code

79. In 2002, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), a voluntary association of leading research-based pharmaceutical and

[4] https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf.

biotechnology companies, adopted the PhRMA Code. The PhRMA Code governs the pharmaceutical industry's relationships with physicians and other health care professionals. An updated version of the Code was implemented in January 2009.[5]

80. Pursuant to Connecticut General Statutes, Section 21a-70e, pharmaceutical manufacturing companies such as Alexion are required to adopt and implement a code "that is consistent with, and minimally contains all of the requirements prescribed in, the [PhRMA Code]." Conn. Gen. Stat. § 21a-70e(a).

81. Pursuant to Connecticut General Statutes, Section 21a-70e, pharmaceutical manufacturing companies including Alexion are required to adopt and implement a "comprehensive compliance program in accordance with the guidelines provided in the 'Compliance Program Guidance for Pharmaceutical Manufacturers' dated April, 2003 and issued by the United States Department of Health and Human Services Office of Inspector General." Conn. Gen. Stat. § 21a-70e(b). Throughout the Class Period, in purported compliance with this law, Alexion informed the public that it had voluntarily adopted the PhRMA code without exception and implemented the required compliance program.

82. The Code has also been endorsed by the OIG, which, as noted above, has issued a *Compliance Program Guidance for Pharmaceutical Manufacturers* to reinforce the PhRMA Code. This endorsement establishes the Code as a measure for compliance with the legal requirements that govern health care marketing.

83. The PhRMA Code requires that pharmaceutical and biotechnology companies pursue policies and practices that best serve the needs of patients and the healthcare community.

[5] The current version of the PhRMA Code is available at http://phrmadocs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf.

Importantly, the PhRMA Code requires that pharmaceutical marketing practices comply with the highest ethical standards.

84. The first tenet of the PhRMA Code is that interactions with physicians "should be focused on informing health care professionals about products, providing scientific and educational information, and supporting medical education." To that end, the Code provides a series of rules that cover pharmaceutical marketing practices.

85. In relevant part, the PhRMA Code provides direction on the relationship between pharmaceutical companies and prescribing physicians, noting that "[Pharmaceutical company] representatives often serve as the primary point of contact between the companies who research, develop, manufacture and market life-saving and life-enhancing medicines and the healthcare professionals who prescribe them." As such, the PhRMA Code mandates that "***the company representatives must act with the highest degree of professionalism and integrity***." PhRMA Code § 14.

86. In turn, the pharmaceutical companies must "ensure that all representatives who are employed by or [are] acting on behalf of the companies and who visit healthcare professionals receive training about the applicable laws, regulations and industry codes of practice, including this Code, that govern the representatives' interactions with healthcare professionals." Additionally, pharmaceutical companies are required to "assess their representatives periodically to ensure that they comply with relevant company polices and standards of conduct," and "should take appropriate conduct when representatives fail to comply." *Id.*

3. The Code of Ethics for Nurses

87. Alexion's use of in-house nurses implicates the Code of Ethics for Nurses promulgated by the American Nurses Association ("ANA"), the largest professional association

of nurses in the United States. Their mission is to promulgate practice and ethical standards for all registered nurses. As stated, Alexion deployed nurses to educate doctors and patients about Soliris, including providing treatment support for patients with PNH and aHUS. Again, the PhRMA code required Alexion to ensure that its employees followed all "applicable laws, regulations and industry codes of practice," which would include the Code of Ethics for Nurses, adopted in 2001 and most recently updated in January of 2015.

88. The pertinent provisions of the ANA's Code of Ethics for Nurses include the following requirements:

a) "The nurse's primary commitment is to the . . . patient" and "[h]onest discussions about available resources, treatment options, and capacity for self-care are essential" (Provision 2.1);

b) "Nurses . . . must identify and, whenever possible, avoid conflicts of interest . . . [and] [a]ny perceived or actual conflict of interest should be disclosed to all relevant parties and, if indicated, nurses should withdraw, without prejudice, from further participation" (Provision 2.2);

c) "The nurse has a duty to maintain confidentiality of all patient information, both personal and clinical in the work setting . . . [and] [i]nformation used for purposes of continuity of care, education, peer review, [etc.] may be disclosed only under defined policies, mandates, or protocols" (Provision 3.1); and

d) "Nurses must be alert to and must take appropriate action in all instances of incompetent, unethical, illegal, or impaired practice that place the rights or best interests of the patient in jeopardy" (Provision 3.5).

4. HIPAA Regulations

89. Alexion's sales and marketing practices also implicated HIPAA, which establishes national standards to protect individuals' medical records and other personal health information. The law requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such health information without patient authorization.

90. Specifically, HIPAA prohibits all individuals and entities from "obtain[ing] individually identifiable health information relating to an individual" from any covered entity. 42 U.S.C. § 1320d-6(a)(2).

91. Among others, a "covered entity" under HIPAA includes "health care provider[s]" who "transmit[] any health information in electronic form in connection with a transaction covered by [HIPAA]." 45 C.F.R. § 160.103. A health care provider is defined as "a provider of services . . . , a provider of medical or health services . . . , and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business." *Id.*

92. These covered entities are prohibited from transmitting "protected health information" ("PHI") without the consent of the individual patient. Specifically, in relevant part, HIPAA requires that "a covered entity must obtain an authorization for any use ***or disclosure of protected health information for marketing . . . .***" 45 C.F.R. § 164.508(a)(3). In this regard, "marketing means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service." 45 C.F.R. § 164.501.

93. PHI includes not only individuals' names, but also geographic subdivisions smaller than a state; all elements of dates (except year) related to an individual (including admission and discharge dates, birthdate, date of death, all ages over 89 years old, and elements of dates (including year) that are indicative of age); telephone, cellphone, and fax numbers; email

addresses; IP addresses; social security numbers; medical record numbers; health plan beneficiary numbers; device identifiers and serial numbers; certificate/license numbers; account numbers; vehicle identifiers and serial numbers; website URLs; full face photos and comparable images; biometric identifiers; and any unique identifying numbers, characteristics or codes.

94. The Partner Labs with which Alexion maintains agreements to provide positive aHUS and PNH testing results are considered "covered entities" and are required to abide by HIPAA regulations.

95. For example, on its website, Quest specifically states that it "is required by law to maintain the privacy of your PHI," and that, except in specifically enumerated situations, Quest needs each patient's written authorization to use or disclose their health information.[6] However, Quest makes no mention of the disclosure of PHI to pharmaceutical companies for marketing purposes, but rather specifically states that it "will not . . . use or disclose your PHI for marketing purposes or sell your PHI, unless you have signed an authorization."

96. Similarly, Dahl-Chase provides a Notice of Privacy Practices on its website which states how it may use and disclose patient PHI.[7] While Dahl-Chase notes that it may use PHI to manage patients' healthcare by sharing it with the provider who ordered the tests or other persons involved in the patients' care, it states that any "[o]ther uses and disclosures will be made only with your written authorization," including "generally before sharing your health information in a way that is considered a sale under the law." There is no indication on its privacy notice that Dahl-Chase is providing patient PHI to pharmaceutical companies for manufacturing purposes.

[6] https://www.questdiagnostics.com/home/privacy-policy/notice-privacy-practices.html.

[7] https://www.dahlchase.com/pdf/privacy-notice-2015.pdf.

97. LabCorp also discloses on its website that it is subject to HIPAA regulations, and further lists the permissible purposes for disclosure of any patient PHI.[8] These permissible purposes do not include disclosure to pharmaceutical companies for marketing and sales. In particular, LabCorp states that for any "disclosures of PHI for marketing purposes . . . LabCorp will ask for patient authorization before using or disclosing PHI."

98. And while Alexion claims in its Annual Reports on Form 10-K for the years ended 2013 through 2017 that it is "neither a 'covered entity' nor a 'business associate' under HIPAA," the Company has acknowledged from 2014 onward that "the regulations may affect our interactions with healthcare providers, health plans, and research institutions from whom we obtain patient health information. Further, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA."

99. The Annual Reports for 2014-2017 further state that "[i]f we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by [HIPAA] or for aiding and abetting the violation of HIPAA."

5. Anti-Kickback Statute

100. Alexion is also required to comply with the Anti-Kickback Statute, which is a federal law that prohibits providing or receiving anything of value to induce a person to use a product if that product will be paid for in whole or in part by a federal insurance program. The

[8] https://www.labcorp.com/hipaa-privacy/hipaa-information.

Anti-Kickback Statute is intended to guard against increased costs through higher utilization of services or substitution of higher-cost products and to preserve the integrity of health care programs by prohibiting inducements that could bias treatment.

101. Specifically, the statute on its face prohibits the offering of remuneration for the purposes of "arranging for or recommending the purchasing, leasing, or ordering any . . . 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)(1)(B). The Anti-Kickback Statute applies if at least one purpose of the remuneration is to induce referrals even if there may be other legitimate purposes.

V. DEFENDANTS' FRAUDULENT SCHEME

102. As set forth above, *see* Section IV.C, Defendants disclosed to Alexion's investors that they were engaging in various legally permissible programs to educate physicians and market Soliris. Moreover, throughout the Class Period, Defendants consistently attributed their stellar year-over-year revenue and earnings growth to these supposedly lawful practices that allowed Alexion to identify new patients eligible for Soliris treatment. However, contrary to these representations, Defendants were not simply focused on the disease awareness, diagnostic initiatives, and patient support techniques that they disclosed to investors. Rather, they fostered an "anything-goes" culture at Alexion that was focused on sales of Soliris regardless of the legality and ethics of the tactics employed and to the exclusion of all other considerations and, in fact, required Alexion employees to participate in unethical and illegal conduct to generate sales. This culture commenced shortly after Soliris was approved for the treatment of PNH, as early as 2010, and continued throughout the duration of the Class Period.

103. According to CW 1, during the early years that Alexion was selling Soliris, the sales organization got "all the low hanging fruit" because doctors were eager to get their patients on Soliris and for the nurses to educate them so that they could get the right people on the drug.

Thus, while the sales tactics described above were in use during this time, Defendants had little need to push them aggressively because sales were already continually improving.

104. But after several years, the "low hanging fruit" began to dry up, and to maintain profits, the Company had to more actively search for patients that could use Soliris. These practices intensified with the promotion of Defendant Hallal to CCO in 2012 and, at that time, Defendants began pushing the Company's illegal sales tactics with even greater consistency, placing increasingly more pressure on Company personnel to continue to hit ever-increasing sales projections.

105. This culture included a series of illegal sales practices designed solely to increase sales of Soliris, including (i) requiring in-house nursing staff to scare and pressure patients and physicians into taking or prescribing Soliris, and persuading patients to switch doctors when their prescribing physician would not prescribe Soliris; (ii) partnering with various laboratories to obtain confidential and protected patient health information for patients with PNH and aHUS prior to the patient and ordering physician receiving those test results; and (iii) directing donations to patient advocacy groups to be used to provide financial assistance solely to patients receiving Soliris, and demanding that the donation not be used for any patient who had elected to go off of Soliris.

A. Fear Tactics and Company-Paid Healthcare Personnel to Drive Sales of Soliris

106. In particular, one of the illegal and unethical sales practices that Alexion employed was the use of in-house nursing staff to scare patients into taking or staying on Soliris, persuading patients to switch doctors when their prescribing physician would not prescribe Soliris, and pressuring physicians to prescribe Soliris to their patients. While Defendants disclosed to their investors that their employees were involved in educating physicians on how to

identify and diagnose PNH and aHUS, Defendants failed to disclose any information about these unethical and unlawful practices.

Alexion Failed to Firewall Its Medical and Commercial Operations

107. Given the strict rules regarding patient privacy, patient primacy, and the avoidance of conflicts of interest embedded within the PhRMA Code and other applicable guidelines and laws, it is standard industry practice for a pharmaceutical company to maintain a medical affairs department separate and apart from its commercial sales organization. The medical affairs department consists of all in-house healthcare personnel, including nurses, doctors, and MSLs, whose jobs it is to have peer-to-peer relationships with physicians and educate them about the pharmaceutical products and the diseases that they treat. These professionals should be within that medical affairs department, rather than part of the commercial organization. Indeed, as licensed practitioners, in-house nurses and physicians are supposed to prioritize their patients' interests over their employers' profits, which is why most drug companies, to avoid conflicts, maintain a firewall between their medical affairs and sales units. As CW 3 explained, medical affairs provide the science, not the sales.

108. At Alexion, however, ***nurses and certain MSLs reported directly to sales***, and often faced intense pressure from the sales department and directly from executive management to secure and keep customers. As detailed below, these practices were explicit violations of the OIG's guidance against "white coat marketing," the PhRMA Code, and the Code of Ethics for Nurses.

109. According to CW 1, a nurse who was employed in Alexion's commercial organization, during the early years of Soliris, when the nurses and sales personnel were still gathering the "low hanging fruit," it felt more as though they were intended to be there for

patients—most of whom were longtime hematology patients with regular blood transfusions that were thankful for Soliris. That is, because doctors were eager to get the right patients on Soliris, and many had already been diagnosed with the diseases that Soliris was approved to treat, the nurses and sales staff could market Soliris by educating physicians about the existence of the drug and getting the right people on it.

110. According to CW 1, at this time, the nurses were also involved in getting insurance companies up to speed on Soliris (so that they would approve the drug for coverage). It took about three to four years to get most of the insurance companies onboard and to get a lot of the patients that needed the drug on it.

111. However, according to CW 1, in or around 2012, and directly related to Defendant Hallal's promotion and Hendric Bjarke, VP of Global Metabolic Disorders Franchise, joining the commercial organization, there was a "pivotal shift" at Alexion where the nurses began to experience extreme "pressure from sales."

112. CW 3 added that Alexion initially maintained a group of MSLs in the medical affairs department under the Director of Medical Affairs. According to CW 3, Hallal was dissatisfied with the MSLs and replaced them with pseudo-MSLs known internally as Regional Clinical Specialists ("RCSs"), who, unlike the MSLs, reported to Senior Vice President Keith Woods in the commercial organization. Like MSLs, RCSs engaged in relationships with physicians (similar to peer-to-peer discussions) providing medical advice, but in reality they had commercial practices, and not medical practices. CW 3, who had decades of experience in the industry at major pharmaceutical companies, said this practice was not typical in that the role of medical affairs is guided by medical concerns. CW 3 believed that the practice was against regulations because MSLs traditionally report to medical affairs and not commercial, as

commercial employees are incentivized to increase sales, not provide medical advice. CW 3 further explained that by having the commercial organization at every contact with physicians through the use of RCSs, Alexion was able to emphasize or de-emphasize any aspect of Soliris that made it more marketable.

113. CW 5, a former Alexion RCS corroborated much of CW 3's account and confirmed the existence of RCSs that were doing the same job as MSLs but in the commercial organization. For instance, despite being in the commercial organization, RCSs were allowed to do roundtables, take physicians out to dinner, and do other similar tasks that were analogous with what MSLs were doing on the medical side of the business. CW 5 did not appreciate the problem until the Spring of 2017 when the RCSs were dissolved and moved over to the medical side. According to CW 5, the MSLs and former RCSs did not get along, and it was then that CW 5 appreciated the overlap and questioned the practice. When CW 5 asked why the RCSs were dissolved, CW 5 was told that they would be "safer on the medical side" following Hallal's termination. Further CW 5 was told that things they were doing on the commercial side—blurring the line between medical and commercial practices—were questionable and the move was made for compliance reasons.

114. According to CW 3, the hiring of the RCS team by Hallal created tension between the commercial and medical affairs organization, and MSLs complained that RCSs were doing their job with a commercial practice that conflicted with the role of MSLs as peer-to-peer contact. CW 3 knew that complaints reached senior managers Thomas Bock, Keith Woods, Marrgaret Olinger and Jeroen van Beek. According to CW 3, senior managers had to be aware of the complaints given the acuteness of the issue and it was common practice for such managers to make Hallal aware of such issues.

The Commercial Organization Pressured Physicians and Patients

115. Notably, even after Defendant Hallal was promoted to CEO, according to CW 3, patient directives (particularly PNH physician-patient activities) were also "driven by [Defendant] Bell," who was extremely hands-on and directed Alexion's commercial activities even though he had officially stepped back from running the day-to-day management of the Company. Defendant Bell continued to push an initiative program known internally as "POM to POT," or "Patients on Management" to "Patients on Therapy," which was an initiative designed to get as many patients as possible on Soliris, and his overarching instruction to the sales team was to get patients transferred onto Soliris treatment as soon as possible.

116. According to CW 3, the POM to POT initiative was carried out on regular early-morning calls led by Defendant Bell, and held at least once per quarter, prior to and during the Class Period. Defendant Hallal attended the POM to POT calls, as did Alexion's Country Managers and Case Managers, but according to CW 3 they were "Lenny's meeting." CW 3 recalled that the POM to POT calls involved ***Alexion's commercial organization*** reviewing various patients' clinical profiles and discussing how Alexion could motivate physicians and patients to get on Soliris. Led by Bell, the participants would discuss particular patients by referring to their physician's name and specific lab results related to that patient. CW 3 further stated that the discussions centered around characteristics related to the approved indications for Soliris and that Alexion's Case Management team had access to the lab data for specific patients that were discussed.

117. Around this time, the Company also began to push the slogan "More Faster!" which is something CW 1 heard Defendant Bell say repeatedly. CW 4 corroborated CW 3's and CW 1's accounts. CW 4 attended numerous sales meetings held by Defendants Hallal and Bell

in which they instructed everyone (including nurses) to use improper sales tactics and repeated the mantra "More Faster!"

118. CW 4 also was aware of the POM to POT initiative and recounted how CW 4 had information on patients with PNH and aHUS that were not currently on Soliris therapy. CW 4 recalled that there were patients that tested positive, but their physicians were hesitant to put them on Soliris for various reasons. According to CW 4, physicians often felt that the patients with PNH did not need to go on Soliris—for instance, if they had a blood clot, or if their hemolysis (biomarker of red blood cell destruction) was not very high. CW 4 recalled how during the relevant time period Alexion executives wanted all of the patients with a PNH clone greater than 10% to be on Soliris treatment, and instructed sales personnel to "push" physicians who had "a good clinical reason" for not putting their patients on Soliris to start treatment.

119. Alexion's sales tactics of pressuring physicians to put patients on Soliris through POM to POT programs violated PhRMA Code §§ 1 and 14, which instruct pharmaceutical representatives to focus on providing physicians with educational and scientific information about the products rather than intervening in decisions about particular patient treatments. These sales tactics also violated the OIG Guidelines against "white coat marketing."

120. CW 4 stated that throughout the Class Period, Hallal was very aggressive and pressured Regional Sales Managers who, in turn, pressured individuals throughout the commercial organization. CW 4 stated that the sales pressure was not "fun to watch" and sales personnel tried to push back on Hallal's demands. CW 4 recalled a particular National Sales Meeting in 2014 in Utah, during which Defendant Hallal stated that employees could leave if they did not like Alexion's sales culture. CW 4 recognized that the unlawful tactics put CW 4's name, reputation, and nursing license on the line. As a result, CW 4 tried to avoid engaging in

these practices, but CW 4 stated that many sales personnel at Alexion did engage in pressure sales tactics.

121. Indeed, according to CW 1, Alexion's nurses were faced with quotas, and they were required to justify to the entire C-Suite, including Hallal, Bell, and others, each time any of their patients came off Soliris. Nurses were required to meet with Company executives, including Defendants Hallal and Bell, on multiple occasions "and literally justify every single patient that stopped" taking Soliris. Each nurse would be called into the meetings one at a time and would have to go through their "entire caseload." At these meetings, CW 1, along with the other nurses, would be required to discuss any stop (*i.e.*, if the patient missed one dose) and all patients that discontinued treatment altogether.

122. CW 2, another nurse and case manager in Alexion's commercial division, confirmed this practice, noting that prior to Q1 2017 the nurses and case managers met regularly with Alexion executives, to review patient stops, restarts, possible starts, and other patient specific situations. CW 2 further stated that the regular meetings also included the POM to POT initiative and stated that they would discuss patients of a specific physician that was not on Soliris and how to convert them to therapy. CW 2 recounted that the pressure tactics that the sales team wanted to be used to convert patients to Soliris treatment were "ridiculous" and that CW 2 pushed back because CW 2 had a nursing license to defend. CW 2 also stated that these conversations with the sales team made people feel uncomfortable. CW 2 also explained that the purpose behind the directives to use pressure tactics was to meet monthly forecasts of Soliris sales set by C-Suite executives and specifically Defendant Hallal.

123. CW 3 similarly recounted that Bell used to say how he wanted Alexion to "own every PNH patient in the world." According to CW 3, Alexion's executives were aware of the

questionable sales practices and knew that physicians should have been the ones making treatment determinations for their patients based on the patients' clinical profile rather than Alexion's desire to make more sales.

124. CW 1 further stated that if a patient had stopped taking Soliris, Hallal and other executives would then question the nurses about what they were doing to keep the patient on Soliris, asking questions such as "have you educated them?" and "do they know their life is at risk?" The nurses were given scripts which contained strong language intended to coerce the patients to continue with Soliris. For example, the script contained the directive to call the patients and tell them "you're going to die" if they stopped taking Soliris.

125. CW 4 confirmed that Regional Sales Directors met with Hallal at Regional Sales Meetings at least quarterly and Hallal put pressure on the directors to execute orders "no questions asked." In particular, CW 4 stated that Hallal felt that any patient that started Soliris treatment needed to be on the "therapy for life" even if the patient's physicians recommended stopping treatment. Hallal instructed nurses and other commercial sales personnel to convince physicians to keep patients on Soliris because "it's a genetic disease."

126. In 2016, CW 5, a former Alexion RCS, participated in regularly scheduled calls with Case Managers, other RCSs and Regional Account Managers to discuss specific patients that had stopped or were planning to stop treatment and how the sales team should "strongly encourage" the physician not to stop the patient's treatment. CW 5 recounted how patient information was "broadcast" on those calls, and that the calls stopped after Hallal and others were terminated in late 2016. CW 5 found these regular calls odd given CW 5's prior employment at Novartis where they never had these kinds of meetings. CW 5 added that these

calls occurred throughout Alexion and that each Regional Account Manager would hold them regularly.

127. These practices of frightening patients and doctors to prescribe or maintain Soliris treatments clearly violated PhRMA Code §§ 1 and 14 instructing pharmaceutical representatives to focus on providing physicians with educational and scientific information about the products rather than intervening in decisions about particular patient treatments. They also violated the OIG Guidelines against "white coat marketing."

128. Notably, as licensed healthcare representatives, the nurses were in a particular position of public trust and had the ability—which they exercised—to exert undue influence when recommending that patients purchase and use Soliris. In addition, because these practices were often carried out by Alexion's nurses they violated the Code of Ethics for Nurses Provision 1.2 (establish patient trust); Provision 2.1 (put patient first); Provision 2.2 (identify and avoid conflicts of interest); and Provision 3.5 (report unethical or illegal conduct).

129. According to CW 1, the improper sales tactics worsened once Alexion was approved for aHUS. CW 1 explained that Alexion's executives then wanted the nurses to use "scary language," especially with the parents of children who were aHUS patients, even though many of the nurses were very uncomfortable with this directive. CW 1 stated that these patient interactions were scripted and carefully crafted by Alexion's marketing department. CW 1 further explained that the scripts to use with patients came from corporate executives and every word CW 1 was permitted to say to a doctor or patient was "carefully crafted."

130. Further, according to CW 1, the nurses were instructed to call patients to suggest that they change physicians if their doctor would not give them Soliris. The goal was to direct the patients to doctors that they knew would prescribe Soliris. To that end, the nurses were

instructed to "plant a seed that maybe your doctor isn't doing the best thing for you" by not prescribing Soliris. The nurses were also very uncomfortable with this directive, which came from executives, and CW 1 stated that as a nurse at a pharmaceutical company it was inappropriate to tell patients what doctor they should use just so that Alexion could sell more Soliris.

131. CW 5 described encountering similar conduct at a medical conference in 2016. At the conference a group of physicians approached CW 5 because they were upset about an email exchange from Alexion's sales team to those physicians. According to CW 5, the emails showed that Alexion's sales personnel had tried to get a patient to switch hematologists because he would not prescribe Soliris, which CW 5 understood was not appropriate and "fully not compliant." When the physicians got wind of other questionable sales tactics used by Alexion, they approached CW 5 at the conference and asked to speak with Alexion's highest ranking official in attendance.

132. Again, this conduct of trying to get patients to switch physicians clearly violated PhRMA Code §§ 1, 14; the OIG Guidelines; and the Code of Ethics for Nurses Provisions 1.2, 2.1, 2.2, and 3.5.

The May Bloomberg Article Corroborated Alexion's Pressure Tactics

133. The allegations by former employees that Company management instructed them to pressure patients and doctors is fully consistent with and corroborated by the May Bloomberg Article that detailed many of these same practices. In particular, according to the May Bloomberg Article, which itself was based on interviews of more than 20 current and former Alexion employees, managers stressed that sales staff needed to question doctors, many of whom had not seen patients with rare diseases, and to "transform no to yes." If doctors did not think

patients were sick enough to warrant a drug that is as expensive as Soliris, Alexion officers instructed sales staff to warn the doctor that his/her patient could die. The nurses were further directed to steer the patient to another doctor who would resume the treatment. As one former longtime Company nurse quoted in the May Bloomberg Article explained, "It was your feet to the fire, sweat pouring down your back."

134. The May Bloomberg Article chronicled a particular case of one patient, named Stacey, who was diagnosed with PNH in 2004. Her blood results showed little improvement when she tried Soliris. When she told her Alexion nurse that she and her doctor were going to stop treatment, the Alexion nurse started calling Stacey, urging her to continue the treatment. Stacey explained: "I felt like they were scaring me, saying 'Oh my gosh, you really shouldn't stop. You could get a clot and die.'"

135. The May Bloomberg Article also described how the Company closely tracked key details, such as the number of tests ordered by each physician in their core markets. To this end, sales staff maintained detailed spreadsheets that included a wide range of information about potential patients, including dates of birth, information about symptoms, doctors, and hospitals, and patients in some cases were identified by their initials. This was corroborated by CW 3 who stated that during the internal POM to POT calls involving Defendants Bell and Hallal, the commercial organization had patient information including specific lab results and the name of the treating physician. CW 5 stated that during regular commercial sales meetings particular patient information was "broadcasted." Because patient information was provided to sales staff outside of medical affairs organization and maintained for marketing and sales purposes, these practices violated HIPAA as well as the Code of Ethics for Nurses Provision 3.1 (maintain patient confidential information).

B. Improper Use of Partner Labs to Identify Potential Customers

136. Alexion also consistently took extreme and unlawful steps to locate patients suffering from these extremely rare diseases and to steer doctors to prescribe them Soliris. Alexion worked to persuade doctors to test more frequently for PNH and aHUS, and took unethical and illegal steps to view the results of these tests, which traditionally are only shared amongst the doctor, the patient, and the lab that performs the test. While Defendants disclosed in their 2013 Annual Report that they had "[d]eveloped lab partnerships," which theoretically could have been permissible and legal partnerships, they failed to disclose the specifics of their agreements with those labs and the fact that they were obtaining patient lab test results from their Partner Labs in violation of HIPAA laws.

137. According to CW 1, the reagent[9] that was originally needed to diagnose PNH patients was "very unstable," and once the bottle was opened the reagent had a shelf life of only six months, so labs did not want to store it for testing. For this reason, Alexion had trouble finding a lab to send patients' tests, even if the prescribing physician was on board and wanted to test the patient. As a result, Alexion partnered with Dahl-Chase to buy the reagent. Subsequently, Alexion perfected it with a longer shelf life and began to give it away for free. Because Alexion provided the reagent for free to Partner Labs which provided diagnostic tests for patients on Medicare and Medicaid, this practice violated the Anti-Kickback Statute.

138. According to the May Bloomberg Article, sales representatives were instructed to urge doctors to send all tests to these preferred "Partner Labs," which later included not only Dahl-Chase in Maine, but also Machaon Diagnostics Inc. in Oakland, California, as well as

[9] A reagent is a substance or mixture for use in a chemical analysis.

national labs such as LabCorp, Quest, and Mayo Labs. In fact, because these labs were the only ones with access to the reagent, it made sense for doctors to send all PNH tests there.

139. Unbeknownst to patients and many of the doctors, several of these Partner Labs had agreements with Alexion to provide the Company with copies of the patients' test results, which included confidential patient information that, pursuant to HIPAA, could not be shared without express patient authorization. Obtaining such information was a clear violation of HIPAA. According to CW 1, Defendants Bell and Hallal were involved in making deals with Partner Labs.

140. Although patient names were often removed from the test results shared with Alexion, the Partner Labs provided a number of other identifying and personal details, such as the patient's age, gender, zip code, the hospital and doctor ordering the test, and a summary of the results. With this information, sales representatives were able to easily locate patients (*i.e.*, potential customers) who would have otherwise been extremely difficult to find.

141. When a result for PNH or aHUS was reported by a lab to Alexion, the diagnostic team at the Company passed the information to the sales team, which descended on the doctor listed in the lab result. A former account representative of the Company quoted in the May Bloomberg Article explained, "[i]t was like Normandy." These agreements and Alexion's conduct after receiving the test results were in violation of HIPAA laws, which prevent companies from obtaining protected patient health information from covered entities—*i.e.*, the Partner Labs—for marketing purposes.

142. According to CW 1, Alexion's field people suddenly knew of positive PNH patients before the doctors did. They began receiving positive PNH tests results by fax, from which they could easily identify the patients. Alexion's sales personnel were then showing up

"on the doctors' doorsteps" before the doctors even received their patients' results. Alexion sales personnel would even know the "clone size" or percentage of red blood cells that came up in those tests—indications of PNH—because the labs were giving them the information right away.

143. CW 1 further explained that the nurses were directed by Company executives that patients' tests should only be done by the Partner Labs, rather than at hospitals, because Alexion was not able to get results from the hospitals allowing them to target specific doctors and patients, unlike the relationship that Alexion had with those labs.

144. CW 4, a nurse in Alexion's commercial division corroborated much of CW 1's account of Alexion's unlawful relationship with its Partner Labs. CW 4 stated that the sales organization became aware of new patients for Soliris because Alexion's Partner Labs testing for PNH would tell them if the patient tested positive for the clone. CW 4 advised that if they had the profile of a patient, Alexion would encourage the physician to test them for PNH. On some occasions, CW 4 would be told when test results came back with the clone, and on other occasions CW 4 was shown the results personally. CW 4 clarified that Alexion could figure out patient identities from information provided in the results if, for example, the results indicated the area where the patient had been tested. In that case, a salesperson could simply visit the limited number of hematologists in the given area and figure out who the patient was.

145. CW 4 further stated that there was a group at Alexion called the Diagnostic Lab Specialists who worked with the Partner Labs and would get the reports from them. CW 4 further explained that a group within Alexion called One Source, which was composed of Nurse/Case Managers, like CW 1, had the "patient protected" information from Partner Labs. According to CW 4, certain labs would provide all of the patient's information to the diagnostics

team at Alexion, making new patients readily identifiable. Other Partner Labs (including the Mayo Clinic), provided the last 3 digits of the patient's zip code, which nevertheless allowed Alexion to figure out where the patient was located and zero in on the patient and physician. And according to CW 4, Defendants Bell and Hallal knew of all of the patients who had tested positive for PNH through information provided from Partner Labs.

146. According to CW 5, a former Alexion RCS, Alexion received lab results from Partner Labs, including clone sizes and other specific details, which were entered into Alexion's Salesforce.com database. Salesforce.com allowed Regional Account Managers to know patient results and target certain physicians. CW 5 learned of this practice because if sales people were trying to reach out to a physician and the physician did not answer, they would reach out to CW 5 and other RCSs to see if they had a relationship with that physician so that they could "gain some access."

147. Improper sharing of identifiable patient health information for marketing purposes, without authorization by the patient, as occurred here, constitutes a serious violation of HIPAA. Indeed, in May 2017, after investigative reporters began asking Alexion questions about its data gathering practices and scrutinizing these so-called "partner lab" relationships, the Company halted these practices and explained that it was reviewing its relationship with these labs. Notably, while the Company later resumed its relationships with the labs, it did so only after "clarifying in their contracts with lab companies what exactly they were doing with the data," further calling into question the legality of their agreements during the Class Period.

C. Funding of Patient Advocacy Organizations and Related Unethical and Illegal Business Practices

1. Alexion's Relationship with PSI and NORD

148. Alexion also had relationships with patient assistance programs in the United States, including Patient Services, Inc. ("PSI") and National Organization for Rare Disorders ("NORD"). These organizations, which are 501(c)(3) organizations, provide assistance to patients in order to obtain medication that they otherwise could not afford. In order to do so, the organizations provide financial assistance for insurance premiums and co-pays, among other expenses. Alexion disclosed that it "financially supported non-profit organizations which assist patients in accessing treatment for PNH and aHUS," including "patients whose insurance coverage leaves them with prohibitive co-payment amounts or other expensive financial obligations." Notably, it is perfectly legal to donate to organizations for this purpose. However, Alexion failed to disclose that its donations to these groups came with strings attached, which violated the Anti-Kickback Statute. In particular, Alexion conditioned that its donations to PSI and NORD could only be spent on co-pays and other costs for patients, including Medicare patients, who were taking Soliris, in contravention of federal Anti-Kickback laws.

149. According to CW 1, these were "generous donations" that were always "perfectly coordinated": Alexion's nurses, including CW 1, would tell Alexion staff in charge of coordinating donations the amount that specific patients were paying (in co-pays, premiums, etc.), and then "magically" a donation was made to NORD or PSI to cover those costs. In fact, CW 1 was directly involved in a quarterly staff meeting with the Company executives, including Defendants Bell and Hallal, in which it was discussed that Alexion was matching whatever the patient needed through their donations to NORD and PSI.

150. According to CW 1, however, NORD "would not touch aHUS," but instead only provided financial assistance to PNH patients. CW 3 explained that with aHUS, once a patient was on therapy, there is some question as to whether patients can discontinue treatment and wait for the next event. Moreover, according to CW 1, NORD would give Alexion "a lot of pushback" on some of Alexion's practices, and eventually "drew the line." As a result, Alexion began to focus on PSI because, according to CW 1, PSI was willing to "do more," including agreeing to provide financial assistance to both PNH and aHUS patients, and agreeing to pay more patient expenses, including transportation for patients to and from their treatments and doctor's visits.

151. After Alexion provided its donations to PSI and NORD, those organizations would pay for the premiums, deductibles, and co-pays of patients taking Soliris. According to CW 1, it was as if Alexion was paying money to overcome any barrier so that the patient would obtain Soliris. Specifically, according to a later settlement with the Department of Justice ("DOJ"), because "Alexion knew that the price for Soliris could pose a barrier to patients' purchases of it," the Company had approached PSI to create a fund—the Complement Mediated Diseases Fund ("CMD Fund")—to provide financial assistance to Soliris patients in order to induce those patients to purchase Soliris. Alexion and PSI had discussed the parameters of Alexion's donations, and Alexion had explicitly made PSI aware of its "desire that PSI 'not support a patient with any of these [Complement Mediated Diseases] diagnoses ***for other reasons tha[n] Soliris therapy***." That is, any financial assistance provided by PSI to patients from the CMD Fund was contingent upon that patient taking Soliris.

152. At the same time, Alexion "had a general practice of not permitting Medicare patients to participate in its free drug program, which was open to other financially needy

patients," but instead "referred Medicare patients prescribed Soliris to PSI" so that it could "generate revenue from Medicare and induce purchases of Soliris."

153. Nurses were in charge of transferring the patient over to the patient assistance programs, including PSI and NORD, and, at the beginning of CW 2's tenure with Alexion in 2015, they were permitted to remain on the phone with the patient and the PSI or NORD representative in order to help the patient with any issues, including just walking them through the process. However, this changed towards the end of CW 2's tenure in 2017, after Defendants Hallal and Sinha were terminated and new executive management installed at Alexion "overhaul[ed] the entire thing." Management then directed that nurses were no longer allowed to be on calls with patients and patient assistance program representatives, but were instead "completely firewalled," further confirming the illegal nature of Alexion's prior interactions with these organizations.

154. Alexion's provision of monetary donations in exchange for PSI and NORD's agreement to use that money solely for the expenses of patients currently taking Soliris, including patients on Medicare, violated the federal Anti-Kickback Statute, and Alexion has since settled claims with the U.S. Department of Justice regarding this illegal conduct.

2. Alexion's Relationship with AFAG

155. Alexion also has a particularly close relationship with a patient advocacy group in Brazil called Associacao dos Familiares, Amigos e Portadores de Doenças Graves ("AFAG").[10]

156. For drugmakers to be reimbursed for drugs sold in Brazil, companies are supposed to negotiate with the government on price. However, Alexion avoided this step and delayed registering Soliris in Brazil for years. Because the Brazilian constitution guarantees

[10] All allegations in this section are based upon the May Bloomberg Article and an article published in Brazilian newspaper *Exame* on May 8, 2017.

healthcare for each citizen and because Alexion has not negotiated with the government on price, the only way Brazilian citizens can get access to Soliris is to sue the government. If the citizen's lawsuit is successful, the government must pay for the drug without the usual price negotiations, meaning Alexion receives the full price of Soliris.

157. Because most patients in Brazil cannot afford to pursue such a lawsuit, which is known as "judicialization," Alexion began funding patient groups. One such patient group's primary lawyers, who worked on these lawsuits on behalf of patients, initially came from a law firm owned by the sister of Alexion's local manager, according to a December 2014 confidential analysis prepared by an outside law firm that Alexion commissioned to review its business practices in Brazil.

158. In 2012, Alexion began funding AFAG. Although AFAG works with other drug companies, much of its funding comes from Alexion: In 2014 and 2015, Alexion contributed 1.672 million Brazilian reais (approximately $500,000) to AFAG, which represented roughly 30% of the group's budget. In 2016 the donation increased to 2.675 reais (approximately $817,000).

159. Because of these significant contributions, Alexion was granted special access, and each week an Alexion manager would review patient files at the AFAG office. The Alexion manager told AFAG which cases to pursue and brought all relevant patient information back to Alexion. AFAG would then commence lawsuits on behalf of patients seeking government reimbursement for Soliris.

160. In reality, however, some of the lawsuits funded by Alexion through its donations to AFAG appear to have been fraudulent and used inaccurate diagnoses to generate patients. That is, in at least ten examples, the patients suing the government for access to Soliris have

reported being induced by AFAG to file lawsuits to treat diseases they did not have. In another case, armed guards regularly delivered far more Soliris to a woman who was incorrectly diagnosed with aHUS. After years of excessive shipments, the patient had stockpiled about 2.2 million reais of the drug in her refrigerator, and she ultimately reported the situation to Brazilian authorities, which issued a search warrant for Alexion's offices.

161. Alexion's outside law firm, hired to review the Company's business practices in Brazil, concluded in its December 2014 confidential report that these operations were "***unethical***." But these unethical business practices have been lucrative for the Company. Since 2010, more than 900 lawsuits for access to Soliris have been filed in Brazil by AFAG and other patient advocacy organizations. Brazil's health ministry has paid more than 1.29 billion reais (or approximately $400 million) to grant access to Soliris through these lawsuits. By the end of 2016, Alexion projected that 600 Brazilians would be taking Soliris, which would produce revenue of more than $200 million. Strikingly, while Soliris treats just 0.0003% of Brazil's population, the drug accounted for ***30%*** of the country's judicialization budget in 2013 and 2014.

162. Alexion is currently under an ongoing investigation in Brazil for its relationship with AFAG.

D. Defendants Materially Misled Investors About the Source of Alexion's Success, Its Compliance with Industry Codes of Ethics, and Its Internal Controls

163. Despite this ongoing illegal, unethical and improper conduct, throughout the Class Period, Defendants repeatedly misled investors by claiming that the source of their impressive financial results was due to Alexion's ability to "identify new patients" through presumably lawful means such as the Company's "disease awareness and diagnostic programs."

164. For instance, at the start of the Class Period, on January 30, 2014, in announcing record financial results for fourth-quarter and full-year 2013, Defendant Hallal attributed those

results to legal business practices without disclosing the material illegal business practices that actually drove the Company's sales:

> During 2013 we achieved strong Soliris revenue growth of 37%, reflecting continued steady growth in PNH and our ongoing strong launch in aHUS in initial countries. . . . ***Importantly, throughout 2013 we continued to identify new patients with PNH each quarter even in our longest established territories.*** Looking specifically at Q4, ***strong rates of patient identification and rapid treatment initiation with Soliris continued as in prior quarters, as our disease awareness and diagnostic programs continue to support optimal patient care.***

165. That statement was clearly misleading since it omitted the key information that Alexion had achieved its results by illegally pressuring doctors and patients to start or continue Soliris treatments, obtaining confidential patient information from its illicit arrangements with Partner Labs, and funneling kickbacks to Medicare and Medicaid patients to cover co-pays and other costs, all at the behest of and with the knowledge of Hallal and Alexion's senior management.

166. Indeed, analysts covering the Company were duped and credited Alexion's supposedly lawful business practices and were unaware that Alexion's continued strong growth and success hinged on unlawful sales tactics. For example, analyst Jefferies & Co. ("Jefferies") issued a favorable report on January 30, 2014, citing Alexion's "strong Soliris sales." Indeed, that next day, analyst Leerink increased its valuation of Alexion and specifically linked the "growth of Soliris" with Alexion's "continued identification of new patients." Leerink had even relied on the fact that "[Alexion's] diagnostic pathway initiative has led to more flow cytometry tests for PNH and an increase in newly diagnosed patients."

167. As more fully set forth in Section VII, *infra*, throughout the Class Period, Defendants made 18 additional similar statements about the presumably lawful source of Alexion's continued quarter-over-quarter and year-over-year growth, without ever hinting at the

fact that those results were made possible by the use of illegal and unethical sales practices. In addition, Defendants twice misled investors about the Company's adoption and compliance with the PhRMA Code in its annual reports. They also falsely certified and signed a dozen SOX Certifications attesting to the sufficiency of Alexion's internal controls.

VI. THE TRUTH EMERGED THROUGH A SERIES OF PARTIAL DISCLOSURES

168. Alexion's reliance on exorbitant pricing and unethical and illegal sales tactics to generate significant sales of Soliris worked quite well for a time: net product sales of Soliris have more than doubled every two years between 2008 (the first full year Soliris was sold) and 2014, and continued to rise each year throughout the Class Period.

169. However, beginning in November 2016 and continuing through April 2019, the market began to learn that the Company had been relying on illegal conduct to generate this revenue.

A. Alexion Delayed the Filing of Its Form 10-Q

170. On November 4, 2016, before the market closed, Alexion abruptly cancelled an appearance at the Credit Suisse Healthcare Conference, which was scheduled for November 6-8, 2016. Analysts at Leerink spoke to the Company about its decision to withdraw from the conference and revealed that Alexion evasively explained only that "something came up."

171. Following the announcement that the Company would not attend the conference, analysts also discovered that Alexion's Form 10-Q filing was delayed, as compared to the Company's usual timing for filing its quarterly reports. Analysts at Leerink explained:

> In the past the company typically files their 'Q' within one day of reporting their quarterly results. Even its 10-K's are filed within 7 days of reporting Q4 and full year results. This year, their results were disclosed on October 27 [2016], and 8 days later the filing has still not occurred. In discussions with the company they acknowledged the delay compared to their usual practice, and

> indicated that they were 'working hard' to make the filing by the statutory due date, which is Wednesday 11.9.2016."

172. On news that Alexion would not attend the conference and that it would not be able to timely file its Form 10-Q, foreseeable risks of the Company's unlawful sales tactics, Alexion's stock price dropped $8.95 per share, or 6.94%, to close at $120.05 on November 7, 2016.

B. Alexion Revealed That the Company Began Investigating Its Sales Practices

173. The next day, analysts at Leerink also identified suspicious insider selling, explaining as follows in a report published on November 8, 2016:

> As we have been carefully monitoring for SEC filings by Alexion, we noticed yesterday that the company did post an unfortunately timed notification of a significant stock sale by former CEO and current chairman Leonard Bell. ***On Friday [November 4, 2016] Mr. Bell exercised 36,649 options at prices between $136 and $145, for a total sale of $5.23mm and a profit of $4.4mm. Unsurprisingly these options were exercised as part of a Rule 10b5 sale program, but that will be cold comfort to longstanding investors who would not have been able to take advantage of the unusual volatility.*** That this volatility was associated with cancelled investor conference appearances, (giving the impression of a possible acquisition) but in reality was more likely to have been connected with [an administrative] issue, will only add insult to injury.
>
> ***
>
> ***[W]e believe that the company's board of directors must necessarily be aware of the events, whatever they are***.

174. Then, on November 9, 2016, after the close of trading, Alexion issued a press release in which it announced that it would not be able to timely file its Form 10-Q for the third quarter ended September 30, 2016, ambiguously revealing that the Company was investigating allegations made by a former employee about sales practices of Soliris and whether those practices violated Company policy:

> Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced that it has filed with the U.S. Securities and Exchange Commission (SEC) a Form 12b-25 Notification of Late Filing with regard to its Quarterly Report on Form 10-Q for the quarter ended September 30, 2016.
>
> The Audit and Finance Committee of the Board of Directors is conducting an investigation into allegations that recently have been made by a former employee with respect to the Company's sales practices of Soliris® (eculizumab). ***Specifically, the Audit and Finance Committee is investigating whether Company personnel have engaged in sales practices that were inconsistent with Company policies and procedures and the related disclosure and other considerations raised by such practices.*** The Audit and Finance Committee has retained outside counsel to assist it in the investigation.
>
> At this point in time, the Audit and Finance Committee's investigation has not identified instances where Soliris orders were not placed by customers for patients or any facts that require the Company to update its previously reported historical results. The Audit and Finance Committee and its counsel are working diligently to complete the investigation but at this time it is uncertain when the investigation will be complete and what the results of such investigation will be.

175. Alexion failed to provide any more specific information about what these "sales practices" were, how they "were inconsistent with Company policies and procedures," or what "other considerations" were "raised by such practices"—leaving investors and analysts to speculate about the underlying conduct and the future of the Company.

176. Numerous analysts immediately reported on the situation. For example, on November 9, 2016, Cowen and Company ("Cowen") published a report, which stated: "We believe the situation is serious, and will take weeks to resolve . . . ." The report further noted:

> The News: Last week it became clear that Alexion's 10-Q was delayed, causing much consternation in the investment community regarding the circumstances behind the delay. This afternoon, the company filed for an open-ended extension on its 10-Q citing the need to complete an ongoing investigation relating to accusations made by a former employee.

***

> In the meantime, ALXN shares have underperformed the biotech sectors since last Friday as ***investors have feared the worst*** . . . .

177. On November 10, 2016, Leerink issued a report that discussed the delayed Form 10-Q and management's investigation of "fraudulent sales practices" and explained that: "[f]rom our conversation last night with management, it indeed seems likely that the resolution of this investigation, and the clarification of the company's re-statements, if needed, will take potentially weeks rather than days."

178. Leerink also appeared to predict that sales of Soliris would suffer now that Defendants' fraud, including the Company's reliance on improper and illegal sales tactics to boost revenue, had begun to come to light. Indeed, the report stated that "increased scrutiny and tighter control of selling practices" would result in an "inevitable slowing in patient accrual"; that "increased oversight" would put "pressure" on "new patient accruals"; and that "increased disclosure requirements from commercial staff, and tighter controls on when revenue is recognized" would "slow the wheels of the organization and bring down the rate of new patient identification and initiation to treatment."

179. On November 10, 2016, in response to this news, Alexion's stock price dropped $0.28 per share, or 0.22%, to close at $126.88 per share. As the market continued to make sense of these announcements, Alexion's stock price dropped an additional $13.26 per share, or 10.45%, to close at $113.62 on November 11, 2016.

180. Indeed, as analyst Piper Jaffray reported on November 13, 2016, "ALXN shares have underperformed considerably since the company disclosed on Wednesday that it delayed its

10Q filing as a result of ongoing investigations by its Audit and Finance Committee about an allegation made by a former employee regarding sales practices of Soliris."

181. Furthermore, despite the announcement of Alexion's internal investigation, analyst reports concluded that the full truth was not yet revealed. For example, on November 9, 2016, Piper Jaffray acknowledged that it was unaware of the underlying reasons for the investigations: "Hard to speculate on the possible whistleblower items-- off-label marketing? kickbacks? something else?" Furthermore, on November 10, 2016, J.P. Morgan, after speaking with Alexion, noted that Alexion "did not provide many details (*i.e.*, nature of sales practice in question, potential geography or geographies in question, time period, etc) or timelines." Notably, Alexion downplayed the allegations to J.P. Morgan when it "reiterated that this is a singular company employee allegation." Credit Suisse's report that same day similarly stated that "[w]e had a lot of questions but the company is staying relatively quiet during this ongoing investigation." In fact, Credit Suisse at that time was still "slightly encouraged that 1) no restatement of revenue needed so far and 2) haven't identified any points where orders weren't placed by customers and 3) day to day operations remain unaffected."

182. Analyst RBC Capital Markets on November 11, 2016 further confirmed the materiality of these prior two partial corrective disclosures: "What investors really care about is the 10Q filing and the investigation."

C. Defendants Hallal and Sinha Abruptly Resign as the Company Conducts the Internal Investigation

183. While the Company's internal investigation was ongoing, on December 12, 2016, before the market opened, Alexion issued a press release and announced that Defendant Hallal had resigned as CEO and Defendant Sinha had resigned as CFO. Defendant Brennan took over as interim CEO and Defendant Anderson took over as CFO, both effective immediately.

184. Alexion attempted to downplay these resignations, claiming that Defendant Hallal had resigned "for personal reasons" and that Defendant Sinha had resigned "to pursue other opportunities," but failed to give investors any substantive explanation of the reason for the immediate departures of these two high-ranking executives *on the exact same day* and in the midst of the internal investigation into Alexion's "sales practices."

185. Notwithstanding Defendants' lack of transparency, analysts specifically tied the resignations to the findings of the Company's investigation. For example, on December 12, 2016, Cowen published a report describing the announcement as "An Unwelcome Surprise" and stating:

> We are surprised and saddened at today's news as we had expected fairly quick resolution of the investigation into marketing practices without any fallout in senior management. ***We now believe the Board lost confidence in its senior leadership team, perhaps due to findings of unprofessional activity that were uncovered during the investigation, and decided that a change needed to be made now.***

186. Similarly, also on December 12, 2016, Bloomberg reported that Alexion's "board lost confidence in its top two executives because of information that was uncovered during an internal investigation, according to a person familiar with the matter who asked not to be identified."

187. Also on December 12, 2016, RBC Capital Markets published a report that stated: "The 'Where there's smoke . . .' proverb appears to be true in the case of [Alexion's] delay of 10Q filing: CEO and CFO gone, filing to be completed (*i.e.*, more news to come) 'in January 2017 or earlier.'" The report also stated: "What started as an innocuous delay in filing of 3Q16 financials has ***turned out to be a serious problem for Alexion, costing the jobs of its CEO and CFO, for starters***." Indeed, despite any attempt to suggest that the investigation and the

resignations are unrelated, on December 13, 2016, an analyst with Leerink noted that "comments from the company's former CEO suggest that these changes were partly a response to his frustration with the progress and operational execution at the company, and partly a result of the need to bolster the company's compliance, risk management, and financial oversight." A Piper Jaffray report on February 22, 2017, also linked the two: "CEO and CFO abruptly departed for peculiar circumstances related to 'internal controls' and 'tone at the top.'" Similarly, with respect to Defendant Sinha, on December 22, 2016, Leerink described his resignation as a "forced resignation."

188. On news of these high-level resignations, Alexion's stock price dropped from a closing price of $132.07 per share on December 9, 2016, to a closing price of $115.08 per share on December 12, 2016, or almost 13%. On December 13, 2016, as analysts and investors continued to react to the volatile situation, the price of Alexion dropped a further 4.4% from closing at $115.08 per share on December 12, 2016, to closing at $110.01 per share on December 13, 2016.

189. Unknown to investors, Alexion's new management took steps to try and correct the illegal sales tactics that had been previously deployed to boost Alexion's sales. CW 4, a nurse in the commercial organization, reported that after Hallal's and Sinha's abrupt departures, nurse case managers and the One Source group were finally firewalled from the sales organization, as is customary in the industry. *See* Section V.A. Because Alexion was under a microscope, communications between the sales organization and the nurse case managers were completely cut off. Further, case managers no longer reported to the commercial organization but now reported to the medical affairs team. CW 4 described it as going from a "really crazy Animal House" to a "buttoned up military academy."

D. Alexion Reveals It Used Improper Sales Tactics and That Senior Management Set an Inappropriate "Tone at the Top"

190. On January 4, 2017, Alexion issued a press release in which it announced that, after investigating allegations of improper sales tactics, the Company had identified a material weakness in its internal controls, which was caused by senior management not setting an appropriate "tone at the top." The press release stated, in relevant part, that "the Company concluded there was a material weakness in its internal controls over financial reporting that existed as of December 31, 2015 and subsequent quarters, caused by senior management not setting an appropriate tone at the top for an effective control environment."

191. Yet, rather than explain to investors the full extent of Alexion's unethical and illegal conduct, as discussed above, Alexion informed investors that the only improper sales practices it had discovered related to "pull-in" sales that occurred in the fourth quarter of 2015. Pull-in sales occur when a customer is encouraged by a Company sales representative to place an order earlier than it needs to so that the Company can record the sale in an early financial quarter. According to Alexion, these pull-in sales, which were ostensibly the only "inappropriate business conduct" that Alexion had uncovered in its investigation, "represented less than 1% of total revenue for 2015," amounting to between $10 and $17 million, and did not require the Company to restate its financial results for the 2015 fiscal year.

192. Alexion made no mention of the other unethical and illegal sales practices in which it was engaging, including its relationships with "Partner Labs" from which it obtained personal medical information for potential patients, or its relationship with patient advocacy organizations such as PSI and AFAG, among others. Thus, Alexion's acknowledgement of the pull-in sales that had purportedly occurred only in one quarter of 2015 was nothing more than a

red herring meant to mislead investors into believing that the Company was not committing more serious, illegal conduct.

193. Analysts similarly noted Alexion's lack of transparency. On January 5, 2017, RBC Capital Markets published a report that stated:

> We believe that the company has missed out on a great opportunity to come out on top of a bad situation by being a lot more open and much more transparent with investors and having the chance to regain much needed trust. The very carefully worded press release left us (as believers in the company and the value of the Soliris franchise) perplexed and in the end disappointed in the management team and the Board: if there was wrongdoing (including material weakness in internal controls over financial reporting), as it appears it has, why not discuss it a lot more openly and talk about the parties responsible? Right now investors are supposed to accept today's facts (of corporate inappropriate behavior), along with the fact that the company's two most senior leaders left a few weeks ago to pursue other opportunities etc. . . . We have a very difficult time recalling when a major biotech had its CEO and CFO gone on the same day (other than a major restructuring). Why not be more open with investors and discuss exactly what happened, with specific numbers, quarters etc., especially if the impact on sales is only <1%? Hold a conference call and take questions (unlike last time). *Why not?* The investigation is now concluded, correct? This should put investors' minds at ease and allow them to focus on what the value of Soliris and the two metabolic products is going forward.

194. On January 19, 2017, Alexion filed an Amended Form 10-K for the fiscal year ended December 31, 2015 (which had initially been filed on February 8, 2016) to reflect that the Company's disclosure controls and procedures were not effective as of December 31, 2015, and that a material weakness existed at the time that 10-K was filed.

195. On February 16, 2017, Alexion filed its Form 10-K for the fiscal year ended December 31, 2016, which reiterated that the investigation found that senior management failed to set an appropriate "tone at the top" for internal controls and senior management failed to reinforce the need for compliance with the Company's policies and procedures, which

contributed to the inappropriate sales practices that were the subject of the investigation. In doing so, the Company continued to reference only its conduct in pulling in sales in the fourth quarter of 2015, failing yet again to disclose the full extent of its improper and illegal sales and marketing conduct.

E. Alexion Again Acknowledges That Senior Management Set an Inappropriate "Tone at the Top"

196. On March 6, 2017, Interim CEO Brennan attended the Cowen Healthcare Conference with analysts and investors. During the conference, held before the close of trading, Brennan once again admitted that "[a]s a [B]oard, we were disappointed" with Alexion's "tone at the top," which had created "pressure to do some things that were not in accordance with our policies and procedures."

197. Specifically, Mr. Brennan stated:

> I think on the disappointing side, I mean, the biggest issue has been the management transition, the very quick – the abrupt change in December, and I would say that I think ***we were disappointed with the idea that tone at the top was a material weakness for the Company. As a Board, we were disappointed.*** And I think stepping – when the Board (technical difficulty) recognizing that that was going to be an issue, then trying to deal directly with the issue of tone at the top with the people in the organization to help them understand in areas where ***we might have had some pressure to do some things that were not in accordance with our policies and procedures*** that we weren't going to do that going forward, and we wanted to create a more open, honest environment and a culture around that, and ***that's probably the biggest disappointment I think I've had as a Board member***. Certainly, I've stepped in and doing everything I can to kind of stabilize things as we look for a new CEO, but I think we were disappointed and I think the organization has responded well to the messages that I've tried to bring to it.

198. Following these admissions, the price of Alexion stock fell from closing at $133.33 on March 6, 2017, to closing at $129.18 on March 7, 2017—a decline of approximately 3.1%.

199. Notably, however, in so admitting, Defendant Brennan indicated that the conduct already disclosed—the pull-in sales—was the extent of Alexion's improper conduct, once again failing to disclose to investors the myriad of other improper and illegal sales practices that Alexion was employing and misleadingly suggesting that such conduct was in the past.

200. Specifically, by relying solely on pull-in sales as an excuse for the previously disclosed employee complaint, Defendant Brennan failed to disclose how Defendants directed their employees, including the nurses, to engage in fear tactics to scare patients into using Soliris, how the Company maintained agreements with Partner Labs to obtain protected patient health information in violation of HIPAA, and how Alexion was involved in illegal kickback schemes with patient advocacy groups. Had the full truth emerged, Alexion's stock price would have fallen lower than it did. Because full disclosure had not been made, however, investors continued to be misled about the ongoing illegal sales practices that Alexion and its employees were engaging in.

201. That the investing public was unaware of the scope of the Company's pervasive misconduct is evidenced by a March 8, 2017 report from RBC Capital Markets that stated that: "[W]e believe that Alexion has endured through the worse [*sic*] and is moving to a period without many/any serious overhangs. We view the remainder of 2017 as simply an opportunity to execute and we believe that Brennan, Anderson and their team have more than enough experience and expertise to excel there." This could not have been further from the truth.

F. Brazilian Authorities Raid Alexion's Offices in São Paulo

202. Additional details about Alexion's improper sales tactics came to light before the close of trading on May 8, 2017, when reports emerged that the Company's São Paulo, Brazil offices were raided by Brazilian authorities as part of "Operation Serpent's Chalice"—a multi-year coordinated federal investigation regarding healthcare fraud in the pharmaceutical industry.

203. Specifically, Brazilian news magazine *Exame* reported that the Brazilian Federal Police and Federal Attorney General's Office were investigating the criminal scheme involving AFAG's filing of fraudulent lawsuits for the purpose of transferring large amounts of public funds from Brazil's national health system to Alexion for Soliris. As part of the investigation, AFAG's offices were also raided on May 8, 2017. The investigation has focused on the allegedly fraudulent filing of lawsuits aimed at obtaining government reimbursement for sales of Soliris in circumstances involving inconclusive and fake diagnoses of PNH and aHUS.

204. According to *Exame*, the Brazilian authorities' investigation began when a patient reported being induced by AFAG to file a lawsuit for access to Soliris in order to treat aHUS—a disease she did not have. In the federal warrant application to search and seize documents from Alexion's São Paulo office, the Brazilian Federal Police alleged that a representative of Alexion facilitated contact between the misdiagnosed patient and AFAG. The patient reported being misdiagnosed by two doctors and giving power of attorney to AFAG—which Brazilian authorities alleged did not charge legal fees—to file an action on her behalf.

205. *Exame* further reported that the Brazilian Federal Attorney General's Office is aware of at least ten similar lawsuits filed by AFAG involving Soliris. These lawsuits were supported by diagnoses from the same group of physicians and were filed by the same group of attorneys, according to the Brazilian newspaper *O Globo*. The medical reports were also suspiciously similar. After these suspicious details emerged, a Brazilian judge ordered independent medical reevaluations for patients who filed lawsuits involving aHUS diagnoses. According to Brazilian authorities, several actions involving diagnoses by the same doctors were abruptly withdrawn shortly after the judge's order.

206. According to *Exame*, Brazilian authorities were also investigating Alexion's financial contributions to AFAG. Alexion disclosed to investors that it gave more than $500,000 to AFAG in 2015. The average payment in 2015 was approximately $26,000 per entity. Indeed, AFAG received more in 2015 than any of the 115 other foreign Patient Advocacy Organizations in 18 countries that received financial support from Alexion that year.

207. On news of the details of Alexion's relationship with AFAG and the raid of Alexion's offices in Brazil, Alexion's stock price fell from an opening price on May 8, 2017 of $129.12 per share, to close that same day at $124.70 per share, or 3.4%.

G. Alexion Announces Additional Resignations by Senior Management

208. Just over two weeks after Alexion's Brazilian offices were raided, Alexion announced another significant shakeup of its executive leadership team, ***including the departure of the Company's second CFO in just six months***.

209. Indeed, on May 23, 2017, before the market opened, Alexion issued a press release in which it announced that Defendant Anderson would resign as CFO at the end of August, after having been named CFO just months earlier, on December 12, 2016. Notably, Defendant Anderson had not been named as an interim CFO on December 12, 2016, but was appointed to a ***permanent*** position, which made his departure, announced just five months later, that much more surprising to the market.

210. Alexion also announced in the May 23, 2017 press release that its Chief Commercial Officer, Defendant Carsten Thiel was departing the company, effective June 1, 2017, to be replaced by Brian Goff, and that two executive vice presidents (Martin Mackay, Head of Research & Development and Clare Carmichael, Chief Human Resources Officer) were also leaving the Company.

211. The management departures announced on May 23, 2017 were not the only changes to Alexion's leadership that the Company made in 2017. Just months earlier, on March 2, 2017, Alexion announced that Defendant Bell, the Company's founder and the Chairman of its Board, would leave the Company. In addition, Alexion also announced in March 2017 that its Chief Compliance Officer, Edward Miller, was leaving the Company.

212. This means that between December 2016 and May 2017, Alexion announced the departure of (i) its CEO, (ii) two different CFOs, (iii) its founder and Chairman of the Board, (iv) its Chief Compliance Officer, (v) its Chief Commercial Officer, and (vi) two executive vice presidents.

213. Analysts were unsurprisingly disturbed by this new announcement of high-level resignations. For example, on May 23, 2017, Jefferies issued a report stating that "the scale of changes in such a short period seems highly unusual (CEO, 2x for CFO, COO, head of R&D, Chief HR since 12/16)." The same day, analysts at UBS issued a report explaining that they were "surprised" at the "timing" of the "sweeping changes." Also that day, J.P. Morgan downgraded Alexion stock, stating that "with ongoing management changes and recent events (including a raid of a Brazilian facility), we cannot keep our Overweight rating . . . ."

214. On news of this new management shakeup, occurring within six months of such other high-profile resignations, Alexion's stock price dropped from a closing price of $115.42 per share on May 22, 2017 to close at $104.64 per share on May 23, 2017, or 9.3%, on heavy trading volume.

215. Not only does the above stock drop evidence that the full truth was not fully revealed at an earlier time, but analysts confirm as such. For example Morgan Stanley reported on May 25, 2017, "[w]hile many investors had believed that underlying concerns to the business

were over when the sales practices investigation ended, the recent Brazil raid and new CEO Hantson's shake-up of the top ranks has re-ignited those concerns."

216. Yet, Defendants continued to mislead investors by failing to disclose the totality of the Company's unlawful sales practices. Indeed, analysts confirm that investors continued to be misled. For instance, on May 24, 2017, at 12:15 am EDT, J.P Morgan noted that they "do not think" that "there is something more meaningful behind recent [management changes]" because the "company swiftly worked through the sales practice allegation YE17/1Q18 and our sense is new/existing management, as well as the board, have been extremely diligent on the compliance front."

H. Additional Details About Alexion's Illegal Sales Tactics Come to Light

217. On May 24, 2017, at 4:00 am EDT, the day after Alexion's management shakeup, Bloomberg released an in-depth exposé disclosing for the first time many of Alexion's unlawful sales practices. The May Bloomberg Article provided specifics about the wide range of tactics Alexion used to encourage patients to purchase Soliris at times when they did not need it.

218. Relying on interviews with more than twenty current and former employees and a review of more than 2,000 pages of internal documents, the May Bloomberg Article provides details to the public for the first time about a number of Alexion's improper sales tactics as discussed above, *see* Section V, including:

(a) Its reliance on in-house nurses who worked with the Company's sales team and their use of a variety of scare tactics to pressure patients and doctors to use Soliris, even if not in the patients' best interest;

(b) Its relationships with "Partner Labs," which would inappropriately share with Alexion the results of these tests so that Alexion could identify patients diagnosed with PNH and aHUS (*i.e.*, potential customers); and

(c) Its grants to patient advocacy groups so that Alexion could have greater access to patient populations, and the Company's related use of certain of these groups to obtain illegal reimbursement for Soliris from foreign governments.

219. Following the release of the article (which occurred before the market opened on May 24, 2017), Alexion's stock price fell from an opening price on May 24, 2017 of $104.50 per share, to close that same day at $101.08 per share, or a decline of 3.27%. Over the next two days, as the market continued to absorb this information, Alexion's stock price slid further. On May 25, 2017, Alexion's stock price fell from an opening price of $104.36 to close at $98.50, a decline of approximately 5.62%, and then closed on May 26, 2017 at a price of $97.70, a decline of over 6.5% from the May 24, 2017 opening price.

220. Indeed, analyst UBS in a May 29, 2017 report attributed Alexion's May 26, 2017 stock drop in part specifically to "an article in Bloomberg [], which cast a negative light on Alexion's orphan drug business model."

I. Discouraging Projections About Alexion's Long-Term Prospects Emerged

221. On June 15, 2017, at 2:00 pm EDT, Bloomberg released another article detailing gloomy projections for the future of Alexion in light of the controversy regarding its sales practices of Soliris and noting that the Company's market capitalization had declined to $27 billion, a decline of approximately 33% from a peak of more than $40 billion in July 2015.[11]

222. The article further discussed what the disclosure of those improper sales tactics—"Soliris's current difficulties"—was likely to mean for the company and its prospects going forward: "The aggressive tactics that Alexion has used to sell [Soliris]—documented extensively in a report from Bloomberg Businessweek—cost the Company its previous leadership and leave

[11] Max Nisen, *Alexion Has A Savior Complex*, BLOOMBERG (June 15, 2017).

it with legal risk. ***Toning those tactics down could hurt sales significantly***; Soliris can cost as much as $700,000 a year, meaning every new patient really matters."

J. Alexion Settled with the Department of Justice Over Kickback Scheme

223. On July 6, 2017, Bloomberg reported that Alexion was under investigation by the U.S. Department of Health and Human Services' Office of Inspector General, related to the Company's support for charities that aid Medicare patients. The U.S. Attorney's Office for the District of Massachusetts was conducting a similar investigation of the Company for the same alleged misconduct, and Alexion announced on January 4, 2017 that it had received a subpoena in December 2016 in connection with that investigation.

224. In its Form 10-K filing on February 6, 2019, Alexion disclosed that it had settled with the U.S. Attorney's Office for the District of Massachusetts "relating generally to our support of Patient Services, Inc. (PSI) and National Organization for Rare Disorders (NORD), 501(c)(3) organizations that provide financial assistance to Medicare patients taking drugs sold by Alexion (among other matters)" in the amount of "approximately $13.0 [million]."

225. That settlement agreement (the "Settlement Agreement") was made public on April 4, 2019 by the DOJ. It revealed that Alexion had settled claims by the DOJ pertaining to the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, which "prohibits pharmaceutical companies from paying remuneration to induce Medicare beneficiaries to purchase, or their physicians to prescribe, drugs that are reimbursed by Medicare."

226. The Settlement Agreement exposed Alexion's agreements with one patient advocacy group, PSI, a 501(c)(3) organization that pays various expenses for patients, including Medicare patients. According to the DOJ, since January 2010, Alexion had been making directed donations to PSI so that PSI would provide financial assistance solely to Soliris patients, including by paying patients' Soliris Medicare co-pays and other medical expenses.

227. Specifically, because "Alexion knew that the price for Soliris could pose a barrier to patients' purchases of it," the Company had approached PSI to create a fund—the Complement Mediated Diseases Fund ("CMD Fund")—to provide financial assistance to Soliris patients in order to induce those patients to purchase Soliris. Alexion and PSI had discussed the parameters of Alexion's donations, and Alexion had explicitly made PSI aware of its "desire that PSI 'not support a patient with any of these [Complement Mediated Diseases] diagnoses ***for other reasons tha[n] Soliris therapy***.'" That is, any financial assistance provided by PSI to patients from the CMD Fund was contingent upon that patient taking Soliris.

228. At the same time, the DOJ revealed that Alexion "had a general practice of not permitting Medicare patients to participate in its free drug program, which was open to other financially needy patients," but instead "referred Medicare patients prescribed Soliris to PSI" so that it could "generate revenue from Medicare and induce purchases of Soliris."

229. This obviously illegal behavior, which was designed to increase Alexion's sales of Soliris and which had been ongoing for at least seven years—since January 2010— was contrary to the Company's statements throughout the Class Period, which had misleadingly indicated that the Company's ever-increasing product sales were the result of lawful business conduct.

230. Pursuant to the terms of the Settlement Agreement, Alexion agreed to pay $13 million to the United States, of which $7,020,000 was in restitution.

VII. DEFENDANTS' FALSE AND MISLEADING STATEMENTS

231. Lead Plaintiffs allege that the statements highlighted in bold and italics within this section were materially false and misleading because, among other reasons, they omitted to disclose material information of which Defendants were aware or were reckless in not knowing. As alleged herein, such statements artificially inflated or artificially maintained the price of

Alexion's publicly traded common stock and operated as a fraud or deceit on all persons and entities who purchased or otherwise acquired that common stock during the Class Period. Because Defendants chose to speak on the issues described below, it was important that they not mislead investors or withhold material information. As described below, Defendants created an impression of a state of affairs at Alexion that differed in a material way from the one that actually existed.

232. Throughout the Class Period, Defendants made three broad categories of materially false and misleading statements and omissions. First, Defendants made a series of misrepresentations concerning sales of Soliris, in which they misled investors concerning the Company's strategy for marketing its lifeblood drug, while intentionally omitting crucial details about the illegal practices that were artificially propping up those sales.

233. Second, during the same time period and further compounding the false impression made by the misrepresentations and omissions about Soliris sales, Defendants also repeatedly touted to investors their continual compliance with the PhRMA Code regulations, even though Defendants were fully aware when those statements were made of the Company's gross violations of the PhRMA Code.

234. Finally, Defendants signed SOX Certifications throughout the Class Period and certified that they had designed and evaluated effective internal and disclosure controls over financial reporting, even though the Company had failed to put in place adequate measures to prevent rampant illegal practices with respect to the Company's sales.

A. False and Misleading Statements About the Source of Alexion's Revenue

Misstatement 1:

235. On January 30, 2014, Alexion issued a press release in which it announced its fourth-quarter and full-year 2013 financial results, disclosing that net product sales of Soliris

were $441.9 million for the quarter and $1.551 billion for the full year. The sales figure for the fourth quarter of 2013 exceeded analysts' consensus estimates of $431 million.

236. On an earnings conference call discussing the fourth-quarter and full-year financial results (the "January 30, 2014 Earnings Call") Defendant Hallal attributed those results to presumably lawful business practices, including the Company's ability to "identify new patients," through their "disease awareness and diagnostic programs":

> During 2013 we achieved strong Soliris revenue growth of 37%, reflecting continued steady growth in PNH and our ongoing strong launch in aHUS in initial countries. . . . Importantly, throughout 2013 we continued to identify new patients with PNH each quarter even in our longest established territories. Looking specifically at Q4, ***strong rates of patient identification and rapid treatment initiation with Soliris continued as in prior quarters, as our disease awareness and diagnostic programs continued to support optimal patient care.***

237. Defendant Hallal's statement on the January 30, 2014 Earnings Call attributing Alexion's net product sales of Soliris to lawful business factors materially misled investors because Defendants failed to disclose that the key drivers of those results were instead attributable to Alexion's use of illegal sales tactics, caused by senior management's failure to set an appropriate "tone at the top." Because Hallal raised the issue of the cause of the Company's success, Defendants had a duty to disclose information concerning the source of its success and reasonable investors would find that Alexion's reliance on illegal tactics to drive sales would significantly alter the mix of available information about the Company. As alleged elsewhere herein, the illegal sales tactics included:

a) Alexion's failure to maintain a firewall between registered nurse case managers, RCSs, and the sales organization, contrary to standard industry practice;

b) Alexion's practice, which according to former Company employees, *see* ¶¶ 115-18, 135, was directed by Bell and Hallal, of pressuring physicians through the POM to POT program to place patients on Soliris, in violation of PhRMA Code §§ 1, 14, and the OIG Guidance against white coat marketing;

c) Alexion's practice, which according to former Company employees, *see* ¶¶ 116-18, 120-26, and the May Bloomberg Article was directed by Bell, Hallal, and other executives, of pressuring Alexion's registered nurses to intervene in patient care and scare patients and doctors into prescribing or continuing Soliris treatment, in violation of PhRMA Code §§ 1, 14, the OIG Guidance against white coat marketing, and Code of Ethics for Nurses Provisions 1.2, 2.1, 2.2, and 3.5;

d) Alexion's practice, which according to former Company employees, *see* ¶¶ 130-31, was directed by corporate executives, of pressuring patients to switch to a doctor who would prescribe Soliris, in violation of PhRMA Code §§ 1, 14, the OIG Guidance against white coat marketing, and Code of Ethics for Nurses Provisions 1.2, 2.1, 2.2, and 3.5;

e) Alexion's practice, according to the May Bloomberg Article, of maintaining confidential patient information for sales and marketing purposes, in violation of HIPAA and Code of Ethics for Nurses Provision 3.1;

f) Alexion's practice, according to former Company employees, *see* ¶ 137, of providing Partner Labs with free testing reagent to use to test patients potentially eligible for Soliris treatment, in violation of the federal Anti-Kickback Statute;

g) Alexion's practice, which according to former Company employees, *see* ¶¶ 139, 142-46, was known by Bell, Hallal and other executives, of obtaining private

patient information including confidential test results before patients or doctors were even aware of the results, in violation of HIPAA and Code of Ethics for Nurses Provision 3.4;

h) Alexion's practice, which according to former Company employees, *see* ¶¶ 149-51, was known by Hallal and Bell of paying co-pays for patients on Medicare, Medicaid, and other government funded insurance programs, through coordinated donations to charitable organizations, in violation of the federal Anti-Kickback Statute; and

i) Alexion's practice, according to the May Bloomberg Article, of funding Brazilian charitable organizations to file fraudulent lawsuits on behalf of patients seeking reimbursement from the Brazilian government for Soliris treatments, in violation of Brazilian law.

238. Analysts reacted positively to the press release and earnings call referenced in ¶¶ 236 and 237 above. For example, analyst Jefferies issued a favorable report on January 30, 2014, citing Alexion's "strong Soliris sales." Indeed, that next day, analyst Leerink increased its valuation of Alexion and specifically linked the "growth of Soliris" with Alexion's "continued identification of new patients." Leerink had even relied on the fact that "[Alexion's] diagnostic pathway initiative has led to more flow cytometry tests for PNH and an increase in newly diagnosed patients."

Misstatement 2:

239. On February 10, 2014, Defendants filed their Annual Report on Form 10-K for the year ended December 31, 2013 (the "2013 10-K"), which was signed by Defendants Bell and Sinha. In discussing the Company's revenue increase from the previous year, Defendants stated

that the increase in revenue of 37% for the year ended December 31, 2013 "***was largely due to physicians globally requesting Soliris therapy for additional patients***."

240. Defendants further stated that the increase in revenue for the previous year ended December 31, 2012 "***was largely due to physicians globally requesting Soliris therapy for additional patients, as well as reimbursement and price approvals in additional territories and reimbursement for aHUS in the United States.***"

241. These statements attributing Alexion's increase in revenue to lawful business factors and conditions were materially false and misleading for the same reasons set forth in paragraph 237, herein.

Misstatement 3:

242. On April 24, 2014, Alexion issued a press release in which it announced its first-quarter 2014 financial results, disclosing that net product sales of Soliris were $566.6 million. This sales figure beat analysts' consensus estimate of approximately $561 million.

243. On an earnings conference call discussing the first-quarter 2014 financial results (the "April 24, 2014 Earnings Call"), Defendant Hallal attributed the Soliris sales results to lawful business factors and conditions, such as Alexion's "disease education and diagnostic initiatives":

> During Q1, we achieved strong Soliris in-quarter revenue growth of 41% over the year-ago quarter. This reflects continued steady growth in PNH and our ongoing launch in aHUS now further supported the recent reimbursement progress in Europe. . . . In all territories, including those where we have operated the longest, we continue to observe that the majority of patients with PNH newly starting on Soliris were also newly diagnosed. ***The consistent number of newly diagnosed patients and continuing uptake of Soliris in PNH reflects the ongoing positive impact of our disease awareness and diagnostic initiatives***.
>
> ***

> In the U.S., ***our aHUS disease education and diagnostic initiatives again resulted in a steady increase in the number of new patients commencing Soliris therapy***.

244. Defendant Hallal's statements on the April 24, 2014 Earnings Call attributing Alexion's sales of Soliris to lawful business factors and conditions materially misled investors for the same reasons set forth in paragraph 237, herein.

245. Analysts again reacted favorably to Defendants' positive statements regarding Soliris sales. For example, on April 24, 2014, analyst Cowen and Company stated that "[Alexion] represents one of the industry's cleanest growth stories, with Soliris driving highly visible and likely durable long-term earnings growth." Similarly, that same day, analyst Wells Fargo noted that Alexion's positive announcement was "driven by continued strong demand growth." Analyst William Blair that same day in fact cited Alexion's "effective patient identification" as a reason for the "[s]teady growth of Soliris in the quarter."

Misstatement 4:

246. On April 25, 2014, Defendants filed Alexion's Report on Form 10-Q for the quarter ended March 31, 2014 ("1Q 2014 10-Q"), which was signed by Defendants Bell and Sinha. In discussing the Company's increase in revenue as compared to the same quarter during the previous year, Defendants stated that the increase in revenue of 41.3% "***was due to an increase in unit volumes of 36.8%***" which, in turn "***was largely due to physicians globally requesting Soliris therapy for additional patients***."

247. This statement attributing Alexion's increase in revenue to lawful business factors and conditions was materially false and misleading for the same reasons set forth in paragraph 237, herein.

248. Analysts were misled as to the true cause of the Company's success. For instance, analyst Wells Fargo on April 25, 2014 raised its valuation of Alexion, noting that "strong Soliris sales" in part was "supported by continuing strength in Soliris's underlying demand." Furthermore, on May 1, 2014, analyst Morgan Stanley was further misled and reported that "Soliris has significant growth left in PNH as geographic expansion continues and new diagnostic algorithms increase diagnosis rates."

Misstatement 5:

249. On July 24, 2014, Alexion issued a press release in which it announced its second-quarter 2014 financial results, disclosing that net product sales of Soliris were $512.5 million. This sales figure beat analysts' consensus estimate of approximately $510 million.

250. On an earnings conference call discussing the second-quarter 2014 financial results (the "July 24, 2014 Earnings Call"), Defendant Hallal attributed those Soliris sales results to presumably lawful business practices, including Alexion's "disease awareness and diagnostic initiative":

> During Q2, we achieved strong Soliris in-quarter revenue growth of 38% over the year-ago quarter. This reflects continued steady growth in PNH globally and the early progress of our ongoing aHUS launch. . . . In all territories, including those where we have operated the longest, we consistently observe that the majority of patients with PNH newly starting on Soliris were also newly diagnosed. ***The steady identification of newly diagnosed patients and the ongoing uptake of Soliris in PNH reflect the ongoing positive impact of our disease awareness and diagnostic initiative.***

251. Defendant Hallal's statement on the July 24, 2014 Earnings Call attributing Alexion's net product sales of Soliris to lawful business factors and conditions materially misled investors for the same reasons set forth in paragraph 237, herein.

252. Analysts again believed Defendants' positive misstatements. For instance, on July 24, 2014, in maintaining its "Outperform" rating on Alexion, analyst William Blair highlighted Alexion's "Steady growth of Soliris" and its "effective patient identification." That same day, analyst Janney Capital Markets noted that Alexion's "[t]op-line growth was primarily driven by the increase in the number of new patients with PNH and aHUS." Analyst Piper Jaffray that same day likewise cited to Alexion's "ability to identify new patients" as a reason for reiterating its "Overweight" rating.

Misstatement 6:

253. On July 25, 2014, Defendants filed Alexion's Report on Form 10-Q for the quarter ended June 30, 2014 ("2Q 2014 10-Q"), which was signed by Defendants Bell and Sinha. In discussing the Company's increase in revenue for the three and six months ended June 30, 2014 as compared to the same periods during the previous year, Defendants stated that the increase in revenue of 38.5% and 40% "***was due to an increase in unit volumes of 34.4% and 35.6%***" which, in turn "***was largely due to physicians globally requesting Soliris therapy for additional patients***."

254. This statement attributing Alexion's increase in revenue to lawful business factors and conditions was materially false and misleading for the same reasons set forth in paragraph 237, herein.

255. On September 4, 2014, analyst SunTrust Robinson Humphrey ("SunTrust") initiated a "Buy" rating on Alexion stock, explaining that "[p]hysician education, diagnostic testing and a patient-centric approach should continue to drive growth." Significantly, this buy recommendation was made without the knowledge that Alexion's success depended on illegal sales practices.

Misstatement 7:

256. On October 24, 2014, Defendants filed Alexion's Report on Form 10-Q for the quarter ended September 30, 2014 ("3Q 2014 10-Q"), which was signed by Defendants Bell and Sinha. In discussing the Company's increase in net product sales for the three and nine months ended September 30, 2014 as compared to the same periods during the previous year, Defendants stated that the increase in net product sales "***was primarily due to an increase in unit volumes of 31.9% and 34.2%, due to increased physician demand globally for Soliris therapy for patients with PNH or aHUS during the respectively [sic] periods.***"

257. This statement attributing Alexion's increase in revenue to lawful business factors and conditions was materially false and misleading for the same reasons set forth in paragraph 237, herein.

258. Analysts again attributed Alexion's positive results to the increasing demand for Soliris, without knowing that the Company also relied on illegal sales tactics to drive its results. For instance, analyst Acquisdata reported on October 29, 2014 that Alexion's quarter performance "reflected steady additions of new patients with [PNH] and [aHUS] commencing Soliris treatment." On November 12, 2014, analyst J.P. Morgan was similarly "encouraged with Alexion's disease awareness initiatives."

Misstatement 8:

259. On January 29, 2015, Alexion issued a press release in which it announced its fourth-quarter and full-year 2014 financial results, disclosing that net product sales were $599 million for the quarter and $2.234 billion for the full year. The sales figure for the fourth-quarter 2014 beat analysts' consensus estimates of $591 million.

260. On an earnings conference call discussing the fourth-quarter and full-year 2014 financial results (the "January 29, 2015 Earnings Call"), Defendant Sinha attributed those results to lawful business factors and conditions:

> ***In Q4 the steady increase in uptake of Soliris among PNH and aHUS patients in our core territories and newer markets resulted in strong revenue and EPS growth during the quarter and for the year***. Revenue in Q4 increased 36% year-on-year to $599 million despite the early signs of weakness in key ex-U.S. currencies late in the quarter.

261. Defendant Sinha's statement on the January 29, 2015 Earnings Call attributing Alexion's net product sales of Soliris to lawful business factors and conditions materially misled investors for the same reasons set forth in paragraph 237, herein.

262. Analysts continued to be misled. That same day, analyst Brean Capital, LLC issued a report reiterating its "Buy" status, basing it in part on the fact that "Alexion continued to add aHUS patients in the US and EU," and that "Alexion will continue to educate physicians on the signs and symptoms of PNH and aHUS to appropriately diagnose and treat patients." The next day, Morningstar linked Alexion's revenue growth to the addition of "new patients." Similarly, on January 29, 2015, analyst Barclays credited Defendants' statements by acknowledging that the "strong performance [in Soliris sales] was driven by the steady and consistent identification of new PNH and aHUS patients."

Misstatement 9:

263. On February 6, 2015, Defendants filed their Annual Report on Form 10-K for the year ended December 31, 2014 (the "2014 10-K"), which was signed by Defendants Bell and Sinha. In discussing the Company's increase in net product sales from the previous year, Defendants stated it was "***primarily due to an increase in unit volumes of 34% due to increased***

physician demand globally for Soliris therapy for patients with PNH or aHUS during the respective periods."

264. Defendants further stated that the increase in revenue for the previous year ended December 31, 2013 "***was largely due to physicians globally requesting Soliris therapy for additional patients,*** as well as reimbursement and price approvals in additional territories and reimbursement for aHUS in the United States."

265. These statements attributing Alexion's increase in revenue and net product sales to lawful business factors and conditions were materially false and misleading for the same reasons set forth in paragraph 237, herein.

Misstatement 10:

266. On April 23, 2015, Alexion issued a press release in which it announced its first-quarter 2015 financial results, disclosing that net product sales of Soliris were $600.3 million. This sales figure beat analysts' consensus estimate of $591 million.

267. On an earnings conference call discussing the first-quarter 2015 financial results (the "April 23, 2015 Earnings Call"), Defendant Hallal attributed those results to lawful business factors and conditions, including the ability of Alexion's "commercial organization" to identify "newly diagnosed patients" through "diagnostic initiatives":

> During the quarter, our commercial organization delivered, leveraging our world-class expertise in rare diseases to serve more patients with both PNH and aHUS. This resulted in a 25% increase in revenues and a 31% increase in volume year-on-year.
>
> ***
>
> Looking more closely at our PNH franchise, in Q1 as in all prior quarters since 2007, we identified a consistently high number of newly diagnosed patients with PNH in the U.S., Europe and Japan, the three territories in which we have operated the longest, as well as in other key markets such as Turkey and Brazil.

***

> ***The success of our PNH diagnostic initiatives drives our steady growth***, as we continue to see that the majority of patients newly starting on Soliris are also newly diagnosed.

***

> ***Our performance in Q1 reflects the strength of our underlying business, as well as the buildout of our metabolic franchise, the advancement of our development opportunities and the broadening of our pipelines***.

268. Defendant Hallal's statements on the April 23, 2015 Earnings Call attributing Alexion's net product sales of Soliris to lawful business factors and conditions materially misled investors for the same reasons set forth in paragraph 237, herein.

269. Defendants' failure to disclose the full truth continued to mislead analysts. That same day, analyst Barclays reiterated its "Overweight" rating and noted that Alexion "continued to emphasize the growth opportunity for Soliris in established markets – highlighting [] consistently high numbers of newly diagnosed patients . . . ." Also on April 23, 2015, Cowen similarly understood that Soliris's "impressive" sales growth was because Alexion "continue[d] to identify and treat a steady number of PNH patients."

Misstatement 11:

270. On April 24, 2015, Defendants filed Alexion's Report on Form 10-Q for the quarter ended March 31, 2015 ("1Q 2015 10-Q"), which was signed by Defendants Hallal and Sinha. In discussing the Company's increase in net product sales from the same quarter during the previous year, Defendants stated that the increase in net product sales "***was primarily due to an increase in unit volumes of 31.0%, due to increased physician demand globally for Soliris therapy for patients with PNH or aHUS during the respectively [sic] periods.***"

271. This statement attributing Alexion's increase in revenue to lawful business factors and conditions was materially false and misleading for the same reasons set forth in paragraph 237, herein.

Misstatement 12:

272. On July 31, 2015, Defendants filed Alexion's Report on Form 10-Q for the quarter ended June 30, 2015 ("2Q 2015 10-Q"), which was signed by Defendants Hallal and Sinha. In discussing the Company's increase in net product sales for the three and six months ended June 30, 2015 as compared to the same periods during the previous year, Defendants stated that the increase "***was primarily due to an increase in unit volumes of 31.0% due to increased physician demand globally for Soliris therapy for patients with PNH or aHUS during the respective periods***."

273. This statement attributing Alexion's increase in revenue to lawful business factors and conditions was materially false and misleading for the same reasons set forth in paragraph 237, herein.

274. Analysts continued to focus on the fact that Soliris's growth was being "[d]riven by identification of new patients for Soliris treatment at a fairly consistent rate," as analyst Guggenheim reported on August 3, 2015.

Misstatement 13:

275. On October 29, 2015, Alexion issued a press release in which it announced its third-quarter 2015 financial results, disclosing that net product sales of Soliris were $665.4 million. This sales figure was slightly below analysts' consensus estimate of $666 million.

276. On an earnings conference call discussing the third-quarter 2015 financial results (the "October 29, 2015 Earnings Call"), Defendant Thiel, Alexion's CCO, attributed the "strong

29% volume growth" of Soliris sales during the third quarter of 2015 to "the ongoing success of our diagnostic initiatives" and "our disease awareness programs":

> Our global commercial operations delivered a strong 29% volume growth year-on-year, reflecting the underlying strength of our core Soliris business. Starting with PNH, ***the ongoing success of our diagnostic initiatives drove steady growth.***

277. Defendant Thiel's statement on the October 29, 2015 Earnings Call attributing Alexion's net product sales of Soliris to lawful business factors and conditions materially misled investors for the same reasons set forth in paragraph 237, herein.

278. Analysts again believed Defendants' misstatements. For example, on October 29, 2015, analyst Guggenheim referred to Soliris as a "commercial workhorse" and noted that the "[C]ompany continues to identify new patients." Analysts Cowen and UBS expressed similar sentiments that same day by, respectively, citing to Alexion's "new patient identifications/starts" and Alexion's ability to "identify a consistent number of new patients with PNH."

Misstatement 14:

279. On November 2, 2015, Defendants filed Alexion's Report on Form 10-Q for the quarter ended September 30, 2015 ("3Q 2015 10-Q"), which was signed by Defendants Hallal and Sinha. In discussing the Company's increase in net product sales for the three and nine months ended September 30, 2015 as compared to the same periods during the previous year, Defendants stated that the increase "***was primarily due to an increase in unit volumes of 29.0% due to increased physician demand globally for Soliris therapy for patients with PNH or aHUS during the respective periods***."

280. This statement attributing Alexion's increase in revenue to lawful business factors and conditions was materially false and misleading for the same reasons set forth in paragraph 237, herein.

Misstatement 15:

281. On February 3, 2016, Alexion issued a press release in which it announced its fourth-quarter and full-year 2015 financial results, disclosing that net product sales were $701 million for the quarter and $2.604 billion for the full year.

282. On an earnings conference call discussing the fourth-quarter and full-year 2015 financial results (the "February 3, 2016 Earnings Call"), Defendant Thiel attributed the strong volume growth with the "ongoing success of [their] diagnostic initiatives":

> In 2015, our global commercial operations continued to serve more patients with Soliris as we delivered a strong 28% volume growth year-on-year, reflecting the underlying strength of our core Soliris business while also initiating the launches of Strensiq and Kanuma for patients with HPP and LAL-D. Starting with Soliris and PNH. ***The ongoing success of our diagnostic initiatives is driving a steady addition of new patients. In 2015 as in prior years, we consistently identified a high number of newly diagnosed patients with PNH across our 50-country platform.***

283. Defendant Thiel's statement on the February 3, 2016 Earnings Call attributing Alexion's net product sales of Soliris to lawful business factors and conditions materially misled investors for the same reasons set forth in paragraph 237, herein.

284. Defendants continued to persuade analysts that their success was premised on Alexion's ability to identify new patients without disclosing that the Company's success was based on illegal conduct. For example, a SunTrust report from February 3, 2016 found that "Soliris Volume Growth Remains Robust," explaining that "Management notes that volume growth continues to be strong as the company consistently identifies a steady number of PNH patients and reiterates that the aHUS opportunity is larger than PNH."

Misstatement 16:

285. On February 8, 2016, Defendants filed their Annual Report on Form 10-K for the year ended December 31, 2015 (the "2015 10-K"), which was signed by Defendants Hallal and Sinha. In discussing the Company's increase in net product sales from the previous year, Defendants stated that it "***was primarily due to an increase in unit volumes of 29% due to increase demand globally for Soliris therapy for patients with PNH or aHUS during the respective periods***."

286. Defendants further stated that the increase in net product sales for the year ended December 31, 2014 "***was primarily due to an increase in unit volumes of 34% due to increased physician demand globally for Soliris therapy for patients with PNH or aHUS during the respective periods***."

287. These statements attributing Alexion's increase in net product sales to lawful business factors and conditions were materially false and misleading for the same reasons set forth in paragraph 237, herein.

Misstatement 17:

288. On March 16, 2016, Defendant Hallal attended the Barclays Global Health Care Conference with analysts and investors. During the conference, Defendant Hallal attributed Alexion's ability to "continue on an annual basis to identify a similar number of new patients with PNH" to the Company's "disease awareness and diagnostic initiatives . . . across our 50-country operating platform":

> When we look at PNH, really the durability of this franchise stands out on the slide, and what you see on the slide on the left-hand side is that, in our core territories of the U.S., Europe and Japan, the territories where we have been operating the longest, we continue on an annual basis to identify a similar number of new patients with PNH. This makes up the majority of new patients who

> commence Soliris treatment in any given year. ***And this continued trend is really driven by our disease awareness and diagnostic initiatives which we run across our 50-country operating platform***.

289. Defendant Hallal's statement during the March 16, 2016 Barclays Global Health Care Conference attributing Alexion's sales of Soliris to lawful business factors and conditions materially misled investors for the same reasons set forth in paragraph 237, herein.

290. Analysts interpreted Defendants' positive statements to mean that the "significant growth" that Soliris was experiencing was caused by "new diagnostic algorithms that increase diagnosis rates," as Morgan Stanley reported on April 29, 2016.

Misstatement 18:

291. On July 28, 2016, Alexion issued a press release in which it announced its second-quarter 2016 financial results, disclosing that net product sales of Soliris were $701 million. This sales figure beat analysts' consensus estimates of $697 million.

292. On an earnings conference call discussing the second-quarter 2016 financial results (the "July 28, 2016 Earnings Call"), Defendant Hallal attributed those results to lawful business factors and conditions, including the ability of Alexion's "commercial team" to "identify and serve a consistently high number of newly-diagnosed patients globally by executing [the Company's] . . . diagnostic initiatives":

> In Q2, the Alexion team extended our global leadership in rare diseases as we continued to provide life-transforming therapies to more patients with rare and devastating disorders. ***As our commercial team reached more patients during the quarter, we delivered strong revenue growth*** and improved our operating margins while also progressing our robust R&D pipeline. Our commercial organization delivered total year-over-year revenue growth of 18% and volume growth of 23% driven by the strength of our three highly-innovative marketed therapies.
>
> ***

> Now, for a closer look at our commercial performance, starting with Soliris in PNH. In Q2, ***we continued to identify and serve a consistently high number of newly-diagnosed patients globally by executing our PNH diagnostic initiatives with urgency.***

293. Defendant Hallal's statements on the July 28, 2016 Earnings Call attributing Alexion's sales of Soliris to lawful business factors and conditions materially misled investors for the same reasons set forth in paragraph 237, herein.

Misstatement 19:

294. On October 27, 2016, Alexion issued a press release in which it announced its third-quarter 2016 financial results, disclosing that net product sales of Soliris were $729 million. This sales figure beat analysts' consensus estimates of $727 million.

295. On an earnings conference call discussing the third-quarter 2016 financial results (the "October 27, 2016 Earnings Call"), Defendant Hallal attributed those results to lawful business factors and conditions, including the Company's "diagnostic initiatives":

> In Q3, the global Alexion team delivered on our patient-centered objectives. Our commercial organization achieved total year-over-year revenue growth of 20% and volume growth of 23%, driven by the strength of our three highly innovative marketed therapies. First, ***Soliris continued to grow with a steady number of new patients with PNH and aHUS treated globally.***
>
> ***
>
> Taking a closer look at our commercial performance, starting with Soliris. ***In Q3, we continued to identify and treat a consistently high number of newly diagnosed patients with PNH globally by executing our diagnostic initiatives with urgency.***

296. Defendant Hallal's statements during the October 27, 2016 Earnings Call attributing Alexion's sales of Soliris to lawful business factors and conditions materially misled investors for the same reasons set forth in paragraph 237, herein.

Misstatement 20:

297. On January 4, 2017, Defendants filed Alexion's Report on Form 10-Q for the quarter ended September 30, 2016 ("3Q 2016 10-Q"), which was signed by Defendants Brennan and Anderson. In discussing the allegations of Alexion's improper sales tactics made by a former employee against the Company, Defendants stated that "***The Audit Committee Investigation found that senior management applied pressure on personnel to use pull-in sales to meet targets***," and that "***certain Company personnel engaged in inappropriate business conduct to realize pull-in sales, as a result of pressure from senior management***."

298. Defendants described "pull-in sales" as sales transactions that "increase revenue recognized in an earlier fiscal quarter than the one in which a sale otherwise would have occurred and result in a corresponding decrease in the revenue that will be realized in the subsequent fiscal quarter."

299. According to Defendants, these pull-in sales "represented less than 1% of total revenue for 2015," amounting to only between $10 and $17 million.

300. This statement attributing the allegations of improper sales tactics solely to pull-in sales amounting to less than 1% of Alexion's total sales for only one year, materially misled investors because Defendants failed to disclose the other illegal sales practices in which they were engaging, as set forth in paragraph 237, herein.

B. False and Misleading Statements About Alexion's Compliance with the PhRMA Code

301. The misleading nature of Defendants' statements concerning revenue and sales practices during the Class Period was compounded by additional contemporaneous misrepresentations regarding the Company's adherence to the PhRMA Code.

Misstatement 21:

302. As of July 1, 2014, Alexion published on its website an "Alexion Pharmaceuticals, Inc. Code of Ethics and Business Conduct" (the "2014 Code of Ethics"), which touted Alexion's adoption of and compliance with the PhRMA Code:

> In addition to healthcare laws and regulations governing our conduct, a number of trade groups have issued standards addressing a range of activities including pharmaceutical promotional and educational practices. In the United States, the Pharmaceutical Research and Manufacturers Association ("PhRMA") has issued the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code"), with which the member companies of PhRMA have voluntarily undertaken to comply. ***Alexion*** has voluntarily adopted and ***complies with the PhRMA Code***.

303. This statement made in the 2014 Code of Ethics was materially false and misleading when made because it led the market to believe that Alexion was currently in compliance with the PhRMA Code, when in fact the Company routinely and systematically violated those standards through its illegal sales tactics, caused by senior management's failure to set an appropriate tone at the top.

304. Specifically, Alexion was in violation of PhRMA Code § 14, which requires that pharmaceutical company representatives act with the highest degree of professionalism and integrity, by paying "[a] team of nurses" who "reported directly to sales" and on whom "pressure to lock in and keep customers was often heaped." At "sales meetings" attended by "sales staff and nurses," Alexion managers would ask nurses whose patients had "stopped taking Soliris" to "keep the patient on the drug," tell the patient "he could get a potentially fatal blood clot if he stops," and "steer the patient to a different doctor who might resume treatment." If a patient's doctor did not think the patient was sick enough to warrant a drug that is as expensive as Soliris,

sales staff and in-house nurses were instructed to warn the doctor that the doctor's patient could die.

Misstatement 22:

305. On March 31, 2016, Alexion filed a Proxy Statement on Schedule 14A referring investors to the Company's "new code of ethics, the Alexion Pharmaceuticals, Inc. Code of Ethics and Business Conduct" (the "2015 Code of Ethics"), which repeated the same representations concerning Alexion's compliance with the PhRMA Code:

> In the United States, the Pharmaceutical Research and Manufacturers Association ("PhRMA") has issued the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code"), with which the member companies of PhRMA have voluntarily undertaken to comply. ***Alexion*** has voluntarily adopted and ***complies with the PhRMA Code***.

306. This statement made in the 2015 Code of Ethics was materially false and misleading when made because it led the market to believe that Alexion was currently in compliance with the PhRMA Code, when in fact Alexion routinely and systematically violated those standards through its illegal sales tactics, caused by senior management's failure to set an appropriate tone at the top.

307. Specifically, Alexion was in violation of PhRMA Code § 14, which requires that pharmaceutical company representatives act with the highest degree of professionalism and integrity, by paying "[a] team of nurses" who "reported directly to sales" and on whom "pressure to lock in and keep customers was often heaped." At "sales meetings" attended by "sales staff and nurses," Alexion managers would ask nurses whose patients had "stopped taking Soliris" to "keep the patient on the drug," tell the patient "he could get a potentially fatal blood clot if he stops," and "steer the patient to a different doctor who might resume treatment." If a patient's doctor did not think the patient was sick enough to warrant a drug that is as expensive as Soliris,

sales staff and in-house nurses were instructed to warn the doctor that the doctor's patient could die.

C. Defendants Executed Fraudulent SOX Certifications Concerning the Company's Internal Controls

Misstatements 23-34:

308. In connection with each quarterly and annual report Alexion filed with the SEC during the Class Period, Defendants Bell, Hallal, Sinha, Brennan, Anderson, and Hantson signed SOX Certifications. Pursuant to Section 302 of SOX, and also covered by Sections 304 and 906 of SOX, Bell, Hallal, Sinha, Brennan, Anderson, and Hantson certified that they had designed and evaluated effective internal and disclosure controls over financial reporting, which assured the reliability of financial reporting, and also that the financial statements fairly and accurately presented the financial condition of the Company.

309. For example, in connection with Alexion's Forms 10-K filed on February 10, 2014 and February 6, 2015, Defendants Bell and Sinha each certified, *inter alia*, as follows:

> ***Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report***; . . .
>
> ***Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report***; . . .
>
> ***The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):***
>
> ***(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and***

> ***(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting***.

310. Defendants Bell and Sinha also signed identical SOX Certifications in connection with the Company's Form 10-Qs filed on April 25, 2014; July 25, 2014; and October 24, 2014.

311. Defendants Hallal and Sinha also signed identical SOX Certifications in connection with the Company's Form 10-K filed on February 8, 2016, and the Company's Forms 10-Q filed on April 24, 2015; July 31, 2015; November 2, 2015; April 29, 2016; and July 29, 2016.

312. Defendants Brennan and Anderson also signed identical SOX Certifications in connection with the Company's Form 10-K filed on February 16, 2017, and Form 10-Q filed on January 4, 2017.

313. Defendants Hantson and Anderson also signed identical SOX Certifications in connection with the Company's Form 10-Q filed on April 27, 2017.

314. The SOX Certifications signed by Defendants Bell, Hallal, Sinha, Brennan, Anderson, and Hantson during the Class Period were materially false and misleading when made because, as the Company has admitted, "there was a material weakness in the Company's internal controls over financial reporting because senior management did not set an appropriate 'tone at the top' for an effective control environment and such failure resulted in inappropriate business conduct, including conduct that was inconsistent with, and in violation of, the Company's policies and procedures."

315. The SOX Certifications signed by Defendants Bell, Hallal, Sinha, Brennan, Anderson, and Hantson during the Class Period were materially false and misleading when made because, as Interim CEO David Brennan admitted on March 6, 2017, "tone at the top was a

material weakness for the Company"; "[a]s a Board, we were disappointed"; and "that's probably the biggest disappointment I think I've had as a Board member."

316. The SOX Certifications were also materially false and misleading because, as new CEO Ludwig Hantson admitted on an April 27, 2017 earnings call and at a May 16, 2017 Bank of America Merrill Lynch Healthcare Conference, Alexion's "systems and processes did not keep up pace" as the Company grew resulting in the Company's "ma[king] changes in leadership positions in key countries" and making "significant changes" on "the processes, marketing and sales practices" including having "stopped supporting physicians traveling to medical conferences" and "pausing and reflecting on how we deal with lab data in the U.S., and so on and so on" in order "to be a business model that is compliant."

317. Further, the SOX Certifications were materially false and misleading when made because, contrary to the representation that the Company's SEC filings did "not contain any untrue statement of a material fact" or any material omission, the SEC filings to which these certifications were appended contained numerous materially false and misleading statements and omissions, as set forth elsewhere herein.

VIII. ADDITIONAL INDICIA OF SCIENTER

318. Numerous additional facts give rise to the strong inference of scienter that, throughout the Class Period, Defendants were not only aware of the Company's improper and illegal business practices, but in fact were directly responsible for the improper "tone at the top" that resulted in these practices.[12]

[12] The cumulative knowledge of all members of the Company's management team, including, but not limited to, the Individual Defendants, is properly imputed to Alexion.

A. The Company Has Admitted Scienter

319. *First*, the Company itself has already admitted its scienter. The Company explained in its January 2017 SEC filings that its illegal marketing and sales practices were the result of a lack of "tone at the top."

320. The Company's own finding regarding an inappropriate "tone at the top" is noteworthy. "The tone at the top is the ethical environment fostered by organizational leadership and ***the single most important factor in determining the organization's resistance to bribery and corruption***."[13]

321. As explained by the Association of Certified Fraud Examiners:

> Tone at the top refers to the ethical atmosphere that is created in the workplace by the organization's leadership. Whatever tone management sets will have a trickle-down effect on employees of the company. If the tone set by managers upholds ethics and integrity, employees will be more inclined to uphold those same values. ***However, if upper management appears unconcerned with ethics and focuses solely on the bottom line, employees will be more prone to commit fraud because they feel that ethical conduct is not a focus or priority within the organization. Employees pay close attention to the behavior and actions of their bosses, and they follow their lead. In short, employees will do what they witness their bosses doing.***[14]

322. At its core, "tone at the top" means that a company (i) has a corporate culture that requires ethical behavior; (ii) adopts a code of conduct; and (iii) employs senior management officials who actively monitor the state of affairs within the organization to ensure that employees are behaving in compliance with the applicable code. Not only did the Individual Defendants fail to adequately monitor the illegal and unethical activities of the Company's sales organization (as evidenced by the pervasive nature of the malfeasance in question – *see* Section

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[13] Deloitte LLP, *Tone at the Top: The critical and misunderstood trickle down anti-corruption control* (April 2016) (emphasis added), http://afptoronto.org/wp-content/uploads/2016/04/Tone-at-the-Top_Final_April_16.pdf.

[14] Ass'n of Certified Fraud Examiners, *Tone at the Top: How Management Can Prevent Fraud in the Workplace*, J. of Bus. Ethics (Jan. 2014) (emphasis added), https://www.acfe.com/uploadedFiles/ACFE_Website/Content/documents/tone-at-the-top-research.pdf.

V, *supra*), but in numerous instances they themselves (including Defendants Bell and Hallal) personally directed that wrongdoing occur. *Id.* at ¶¶ 115-18, 120-25.

B. The Illegal Sales Culture Was Directed By Defendants Bell and Hallal

323. *Second*, as CW 1 made clear, the improper sales culture, including the unlawful conduct of the nurses and relationships with "Partner Labs," as well as the illegal donations to PSI and NORD, were directed by Defendants Bell and Hallal. And according to CW 1, it was Defendant Bell that began pushing the slogan "More Faster!"

324. Moreover, CW 1 recounted how Defendants Bell and Hallal required the nurses employed by Alexion to attend meetings where they were required to review their entire caseload with the Company executives, and to justify each patient that had stopped taking Soliris. Defendants would then grill the nurses on what they were doing to keep the patients on Soliris and whether they had made clear to the patients that their lives were at risk if they stopped using the drug. Defendants further directed the nurses to use strong and frightening language to coerce patients and doctors to continue with Soliris.

325. And according to CW 3, any "patient directives" were "definitely driven by [Defendant] Bell," who focused exclusively on "maximizing" the use of Soliris for PNH patients.

326. According to CW 2, nurse case managers met with executives and other members of the sales team on a regular basis to review patient stops, restarts, and possible starts. At these meetings the sales team asked employees, including nurses, to use "ridiculous" pressure tactics to increase sales of Soliris, specifically by having patients start Soliris treatments (*i.e.*, POM to POT). The purpose of these directives was to meet monthly sales forecasts created by C-Suite executives, specifically Hallal.

C. Defendants Bell and Hallal Were in Charge of the Relationships With Partner Labs

327. *Third*, according to CW 1, Defendants Bell and Hallal were responsible for making the deals with "Partner Labs," like Dahl-Chase and Quest. CW 1 explained that through these agreements, the Partner Labs provided Alexion with private patient test results before the patients' doctors had even received those results so that Alexion's sales staff was able to pitch Soliris to those patients and their doctors. Defendants also gave the orders to nurses to ensure that patients' PNH tests should be done only by those labs so that Alexion was sure to receive the results. According to the May Bloomberg Article, Alexion had similar arrangements with Machaon, LabCorp, and Mayo Labs.

D. Defendants Bell and Hallal Were Responsible for the Illegal Conduct with PSI

328. *Fourth*, according to CW 1, Defendants Bell and Hallal attended quarterly staff meetings that included discussions about donations to patient assistance programs including PSI and NORD. Specifically, they discussed matching whatever the patient needed through their donations in order to overcome any barrier to the patient receiving Soliris.

329. Moreover, according to CW 2, although the nurses were initially permitted to be on the phone calls between patients and PSI or NORD representatives, starting in the first quarter of 2017 they were firewalled from such activity and were no longer allowed to be involved in these calls. This suggests that prior to Q1 2017, such conduct had been permitted, but was then disallowed by the new members of the executive management team.

E. Outside Legal Counsel Informed Alexion That Its Practices Were "Unethical" and Illegal

330. *Fifth*, Defendants knew as early as late 2014 that the Company's Brazil operations were "***unethical***," and violated Brazilian law. Indeed, this was the conclusion of the outside law

firm that Alexion hired to review the Company's business practices in Brazil, and which informed Alexion of its conclusions in a December 2014 confidential report.

F. Eight Executives Resigned Within Six Months

331. *Sixth*, the large number of resignations by key executives of the Company during the Class Period supports an inference that the Defendants acted with scienter. In this case, the number of resignations in a short period of time is particularly striking. Between December 2016 and May 2017, Alexion announced the departure of (i) its CEO, (ii) two different CFOs, (iii) its founder and Chairman of the Board, (iv) its Chief Compliance Officer, (v) its Chief Commercial Officer, and (vi) two executive vice presidents.

332. Moreover, these resignations are temporally connected to disclosures of the Company's fraud, which further supports an inference of scienter. Indeed, Defendants Hallal and Sinha resigned on December 12, 2016, as a result of the Company's investigation regarding allegations made by a former employee that Company personnel had engaged in sales practices that were inconsistent with corporate policies and procedures. Just weeks after these resignations, on January 4, 2017, Alexion began to disclose some of its fraudulent behavior, announcing that through its investigation the Company had identified a material weakness in its internal controls, caused by senior management not setting an appropriate "tone at the top."

333. Moreover, on May 23, 2017, just two weeks after the Company's stock price plummeted on news that its offices in Brazil were raided by government authorities, Alexion announced a major change to its executive leadership team, which included the departure of Defendant Anderson—the second CFO to resign in just six months. The proximity of this management shakeup to news of the Brazil office raid strongly indicates that the two developments were related and therefore further supports an inference of scienter.

G. The Sale of Soliris Is Critical to Alexion's Core Operations

334. *Seventh*, The Individual Defendants' knowledge of these practices with respect to the sales of Soliris can be inferred because these facts are critical to Alexion's core operations. Alexion is a "one-drug" company that relied on sales of Soliris to generate substantially all of the Company's sales. Knowledge of Alexion's sales practices with respect to Soliris—the Company's most important product—can therefore be imputed to the Individual Defendants. This is particularly true for Defendant Hallal, who was Alexion's Chief Commercial Officer (*i.e.*, the head of sales) before becoming CEO. According to a January 29, 2015 Cowen analyst report, "Hallal . . . built and has headed up Alexion's commercial team since 2006 . . . ."

IX. LOSS CAUSATION AND ECONOMIC LOSS

335. During the Class Period, as detailed herein, Defendants engaged in a course of conduct that artificially inflated the price of Alexion common stock and operated as a fraud or deceit on Class Period purchasers of Alexion common stock by failing to disclose and misrepresenting the inappropriate sales practices detailed herein. As Defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the price of Alexion common stock declined significantly as the prior artificial inflation came out of the Company's stock price.

336. As a result of their purchases of Alexion common stock during the Class Period, Lead Plaintiffs and the other Class members suffered economic loss (*i.e.*, damages) under the federal securities laws. Defendants' materially false and misleading statements had the intended effect and caused Alexion common stock to trade at artificially inflated levels throughout the Class Period, reaching as high as $208.88 per share on July 23, 2015.

337. By concealing from investors the adverse facts detailed herein, Defendants presented a misleading picture of Alexion's business and prospects. As the truth about the

Company was revealed to the market, the price of Alexion common stock fell significantly. These declines removed the inflation from the price of Alexion common stock, causing real economic loss to investors who had purchased Alexion common stock during the Class Period.

338. The declines in the price of Alexion common stock after the corrective disclosures came to light were a direct result of the nature and extent of Defendants' fraudulent misrepresentations being revealed to investors and the market. The timing and magnitude of the price declines in Alexion common stock negate any inference that the loss suffered by Lead Plaintiffs and the other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to Defendants' fraudulent conduct.

339. During the Class Period, the price of Alexion stock declined as the true state of Alexion's operations was revealed to the investing public. In that regard, from Alexion's November 4, 2016 announcement that it had cancelled its appearance at the Credit Suisse Healthcare Conference because "something came up," to the May 24, 2017 Bloomberg article reporting that "[e]thical lines were routinely crossed" by Alexion's "sales staff," the Company's stock declined more than 30% (from an intraday high of $145.41 on November 4, 2016 to close at $101.08 on May 24, 2017)—wiping out nearly $10 billion in shareholder value.

340. The economic loss, *i.e.*, damages, suffered by Lead Plaintiffs and the other Class members was a direct result of Defendants' fraudulent scheme to artificially inflate the price of Alexion common stock and the subsequent significant decline in the value of Alexion common stock when Defendants' prior misrepresentations and other fraudulent conduct were revealed.

X. PRESUMPTION OF RELIANCE

341. At all relevant times, the market for Alexion's common stock was efficient for the following reasons, among others:

(a) Alexion's stock met the requirements for listing, and was listed and actively traded on the NASDAQ stock exchange, a highly efficient and automated market;

(b) As a regulated issuer, Alexion filed periodic reports with the SEC and NASDAQ;

(c) Alexion regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Alexion was followed by numerous securities analysts employed by major brokerage firms who wrote reports which were distributed to those brokerage firms' sales force and certain customers. Each of these reports was publicly available and entered the public market place.

342. As a result of the foregoing, the market for Alexion stock reasonably promptly digested current information regarding Alexion from all publicly available sources and reflected such information in Alexion's stock price. Under these circumstances, all purchasers of Alexion common stock during the Class Period suffered similar injury through their purchase of Alexion common stock at artificially inflated prices, and a presumption of reliance applies.

343. Further, to the extent that the Defendants concealed or improperly failed to disclose material facts with regard to the Company, Lead Plaintiffs are entitled to a presumption of reliance in accordance with *Affiliated Ute Citizens v. United States*, 406 U.S. 128, 153 (1972).

XI. NO SAFE HARBOR; BESPEAKS CAUTION IS NOT APPLICABLE

344. The statutory safe harbor and/or bespeaks caution doctrine applicable to forward-looking statements under certain circumstances does not apply to any of the material

misrepresentations and omissions alleged in this Amended Consolidated Class Action Complaint.

345. Defendants acted with scienter because at the time they issued public documents and other statements in the Company's name they knew, or with extreme recklessness disregarded, the fact that such statements were materially false and misleading or omitted material facts. Moreover, Defendants knew such documents and statements would be issued or disseminated to the investing public, knew that persons were likely to rely upon those misrepresentations and omissions, and knowingly and recklessly participated in the issuance and dissemination of such statements and documents as primary violators of the federal securities laws.

346. As set forth in detail throughout this Amended Consolidated Class Action Complaint, Defendants, by virtue of their control over, and/or receipt of, the Company's materially misleading statements and their positions with the Company that made them privy to confidential proprietary information, used such information to artificially inflate the Company's financial results. Defendants were informed of, participated in, and knew of the improprieties and unlawful conduct alleged herein and understood their material effect on the Company's business and future prospects. With respect to non-forward-looking statements and omissions, Defendants knew and recklessly disregarded the falsity and misleading nature of that information, which they caused to be disseminated to the investing public.

347. Alternatively, to the extent that the statutory safe harbor applies to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because, at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false and/or the

forward-looking statement was authorized and/or approved by an executive officer of the Company who knew that those statements were false when made. Moreover, to the extent that Defendants issued any disclosures designed to "warn" or "caution" investors of certain "risks," those disclosures were also false and misleading because they did not disclose that Defendants were actually engaging in the very actions about which they purportedly warned and/or had actual knowledge of material adverse facts undermining such disclosures.

XII. CLASS ACTION ALLEGATIONS

348. Lead Plaintiffs bring this action on their own behalf and as a class action pursuant to Rules 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a class consisting of all persons and entities who purchased or otherwise acquired the publicly traded common stock of Alexion from January 30, 2014 to May 26, 2017 (the "Class"). Excluded from the Class are: Defendants; members of the immediate families of the Individual Defendants; Alexion's subsidiaries and affiliates; any person who is or was an officer or director of Alexion or any of the Company's subsidiaries or affiliates during the Class Period; any entity in which any Defendant has a controlling interest; and the legal representatives, heirs, successors, and assigns of any such excluded person or entity.

349. The members of the Class are so numerous that joinder of all members is impracticable. During the Class Period, Alexion had between approximately 197 and 224 million shares of common stock outstanding and actively trading on the NASDAQ. While the exact number of Class members is unknown to Lead Plaintiffs at this time and can only be ascertained through appropriate discovery, Lead Plaintiffs believe that the proposed Class numbers in the thousands and is geographically widely dispersed. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer

agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

350. Lead Plaintiffs' claims are typical of the claims of the members of the Class. All members of the Class were similarly affected by Defendants' allegedly wrongful conduct in violation of the Exchange Act as complained of herein.

351. Lead Plaintiffs will fairly and adequately protect the interests of the members of the Class. Lead Plaintiffs have retained counsel competent and experienced in class and securities litigation.

352. Common questions of law and fact exist as to all members of the Class, and predominate over any questions solely affecting individual members of the Class. The questions of law and fact common to the Class include:

(a) whether the federal securities laws were violated by Defendants' acts and omissions as alleged herein;

(b) whether the statements made to the investing public during the Class Period contained material misrepresentations or omitted to state material information;

(c) whether and to what extent the market price of Alexion's common stock was artificially inflated during the Class Period because of the material misstatements alleged herein;

(d) whether Defendants acted with the requisite level of scienter;

(e) whether the Individual Defendants were controlling persons of the Company;

(f) whether reliance may be presumed; and

(g) whether the members of the Class have sustained damages as a result of the conduct complained of herein and, if so, the proper measure of damages.

353. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy because, among other things, joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

XIII. CAUSES OF ACTION

COUNT I

FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND SEC RULE 10b-5 PROMULGATED THEREUNDER (Against Defendant Alexion and the Individual Defendants)

354. Lead Plaintiffs repeat and re-allege every allegation set forth above as if fully set forth herein.

355. This Count is asserted on behalf of all members of the Class against Defendant Alexion and the Individual Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder, 17 C.F.R. § 240.10b-5.

356. During the Class Period, Defendants disseminated or approved the false statements specified herein, among others, which they knew or deliberately disregarded were materially misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

357. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of

material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Lead Plaintiffs and others similarly situated in connection with their purchases of Alexion common stock during the Class Period. As detailed herein, the misrepresentations contained in, or the material facts omitted from, those statements included, but were not limited to the following:

(a) Defendants reported strong and growing sales of Soliris, and attributed those results to presumably lawful business practices and operational factors, but failed to disclose that the key drivers of those results were the Company's use of illegal and improper sales and marketing tactics, which Defendants had an obligation to disclose.

(b) Defendants repeatedly assured the market that it was complying with the PhRMA Code but failed to disclose that it had actually been relying on illegal and improper sales and marketing practices to sell Soliris in contravention of that Code.

358. Defendants, individually and in concert, directly and indirectly, by the use of the means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Lead Plaintiffs and the Class; made various untrue and/or misleading statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; made the above statements intentionally or with a severely reckless disregard for the truth; and employed devices and artifices to defraud in connection with the purchase and sale of Alexion common stock, which were intended to, and did: (a) deceive the investing public, including Lead Plaintiffs and the Class, regarding, among other things, the tactics used to generate sales of Soliris; (b) artificially inflate and maintain the

market price of Alexion's securities; and (c) cause Lead Plaintiffs and other members of the Class to purchase Alexion common stock at artificially inflated prices and suffer losses when the true facts become known.

359. Defendant Alexion is liable for all materially false and misleading statements made during the Class Period, as alleged above.

360. The Individual Defendants are liable for the false and misleading statements they made and for which they were responsible, as alleged above.

361. As described above, the Defendants acted with scienter throughout the Class Period, in that they acted either with intent to deceive, manipulate, or defraud, or with severe recklessness. The misrepresentations and omissions of material facts set forth herein, which presented a danger of misleading buyers or sellers of Alexion stock, were either known to the Defendants or were so obvious that the Defendants should have been aware of them.

362. The above allegations, as well as the allegations pertaining to the overall scope and breadth of the fraud at Alexion, establish a strong inference that Defendants acted with scienter in making the materially false and misleading statements set forth above during the Class Period.

363. Lead Plaintiffs and the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for Alexion common stock, which inflation was removed from the price when the true facts became known. Lead Plaintiffs and the Class would not have purchased Alexion common stock at the prices they paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by the Defendants' misleading statements.

364. As a direct and proximate result of these Defendants' wrongful conduct, Lead Plaintiffs and the other members of the Class suffered damages attributable to the fraud alleged herein in connection with their purchases of Alexion common stock during the Class Period.

COUNT II

FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND SEC RULE 10b-5(a) AND (c) PROMULGATED THEREUNDER (Against Defendant Alexion and the Individual Defendants)

365. Lead Plaintiffs repeat and re-allege every allegation set forth above as if fully set forth herein.

366. This Count is brought solely and exclusively under the provisions of Rule 10b-5(a) and (c). Accordingly, Lead Plaintiffs need not allege in this Court nor prove in this case that any of the Defendants made any misrepresentations or omissions of material fact for which they may also be liable under Rule 10b-5(b) and/or any other provisions of law.

367. During the Class Period, Defendants carried out a common plan, scheme, and unlawful course of conduct that was intended to, and did: (i) deceive the investing public, including Lead Plaintiffs and the Class; (ii) artificially inflate the price of Alexion common stock; and (iii) cause Lead Plaintiffs to purchase Alexion common stock at artificially inflated prices.

368. In furtherance of this unlawful plan, scheme and course of conduct, Defendants employed devices, schemes and artifices to defraud, and knowingly and/or recklessly engaged in acts, transactions, practices, and courses of business that operated as a fraud and deceit upon Lead Plaintiffs and the Class in connection with their purchases of Alexion common stock, in violation of Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) promulgated thereunder.

369. Defendants' fraudulent devices, schemes, artifices and deceptive acts, practices, and course of business included the knowing and/or reckless suppression and concealment of information regarding Alexion's illegal and improper sales and marketing tactics.

370. Lead Plaintiffs and the Class reasonably relied upon the integrity of the market in which Alexion's common stock traded.

371. During the Class Period, Lead Plaintiffs and the Class were unaware of Defendants' fraudulent scheme and unlawful course of conduct and/or the impact of the fraudulent scheme. Had Lead Plaintiffs and the Class known the true extent of Defendants' unlawful scheme and unlawful course of conduct, they would not have purchased Alexion's common stock, or if they had, would not have done so at the artificially inflated prices paid for such securities.

372. As a direct and proximate result of Defendants' scheme to defraud and such unlawful course of conduct, Lead Plaintiffs and the Class suffered damages in connection with their purchases of Alexion common stock during the Class Period.

373. By reason of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) promulgated thereunder, and are liable to Lead Plaintiffs and the Class for damages suffered in connection with their purchases of Alexion common stock during the Class Period.

COUNT III

FOR VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT (Against Defendants Bell, Hallal, Sinha, Brennan, Anderson, Hantson, and Thiel)

374. Lead Plaintiffs repeat and re-allege every allegation set forth above as if fully set forth herein.

375. This Count is asserted on behalf of all members of the Class against each of the Individual Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

376. During their tenures as officers and/or directors of Alexion, each of these Defendants was a controlling person of the Company within the meaning of Section 20(a) of the Exchange Act. By reason of their positions of control and authority as officers and/or directors of Alexion, these Defendants had the power and authority to direct the management and activities of the Company and its employees, and to cause the Company to engage in the wrongful conduct complained of herein. These Defendants were able to and did control, directly and indirectly, the content of the public statements made by Alexion during the Class Period, including its materially misleading financial statements, thereby causing the dissemination of the false and misleading statements and omissions of material facts as alleged herein.

377. In their capacities as senior corporate officers of the Company, and as more fully described above, the Individual Defendants had direct involvement in the day-to-day operations of the Company, in reviewing and managing its regulatory and legal compliance, and in its accounting and reporting functions. Defendants Bell, Hallal, Sinha, Brennan, Anderson, and Hantson signed the Company's SEC filings during the Class Period, and were directly involved in providing false information and certifying and/or approving the false statements disseminated by Alexion during the Class Period. Defendant Thiel participated in conference calls with securities analysts, during which Alexion's false and misleading statements filed with the SEC and included in press releases were presented and discussed. As a result of the foregoing, the Individual Defendants, as a group and individually, were controlling persons of Alexion within the meaning of Section 20(a) of the Exchange Act.

378. As set forth above, Alexion violated Section 10(b) of the Exchange Act by its acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons of Alexion and as a result of their own aforementioned conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as, the Company is liable under Section 10(b) of the Exchange Act and rule 10b-5 promulgated thereunder, to Lead Plaintiffs and the other members of the Class who purchased or otherwise acquired Alexion common stock. Moreover, during the respective times these Defendants served as officers and/or directors of Alexion, each of these Defendants was culpable for the material misstatements and omissions made by Alexion, as set forth above.

XIV. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs pray relief and judgment as follows:

(a) Declaring the action to be a proper class action pursuant to Fed. R. Civ. P. 23;

(b) Awarding compensatory damages in favor of Lead Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Lead Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

(d) Awarding such equitable, injunctive, and other relief as the Court may deem just and proper.

XV. DEMAND FOR TRIAL BY JURY

Lead Plaintiffs hereby demand a trial by jury of all issues so triable.

DATED: May 31, 2019

LABATON SUCHAROW LLP

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CERTIFICATE OF SERVICE

I hereby certify that on June 2, 2019, the foregoing was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing. Parties may access this filing through the Court's system.

/s/ Michael H. Rogers
Michael H. Rogers