

PREET BHARARA
United States Attorney for the
Southern District of New York
By: LAWRENCE H. FOGELMAN
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
Tel.: (212) 637-2719
Fax: (212) 637-2686
Email: Lawrence.Fogelman@usdoj.gov

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

UNITED STATES OF AMERICA,

Plaintiff,

v.

INSPIRE PHARMACEUTICALS, INC.,

Defendant.

ECF Case

10 Civ. 7450 (LAP)

**COMPLAINT-IN-
INTERVENTION OF THE
UNITED STATES OF AMERICA**

Jury Trial Demanded

Plaintiff the United States of America (the “United States” or the “Government”), by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, alleges upon information and belief as follows:

INTRODUCTION

1. The United States seeks damages and penalties in this civil fraud lawsuit from Inspire Pharmaceuticals, Inc. (“Inspire” or “Defendant”) under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, arising from Defendant’s fraudulent scheme to promote its drug AzaSite to healthcare providers for uses that were not approved as safe and effective by the Food and Drug Administration (“FDA”) from January 1, 2008, until its acquisition by Merck & Co., Inc., in or around May 2011. Specifically, although the FDA had only approved AzaSite for the treatment

of bacterial conjunctivitis (also known as pink eye), Defendant, soon after launching its product AzaSite, shifted its marketing campaign to drive prescriptions for the non-FDA approved treatment of blepharitis, a type of lid margin disease characterized by an inflammation of the eyelids. The standard of care for the treatment of blepharitis is good hygiene and the use of eyelid scrubs, and not prescription medication. Moreover, in April 2011, the FDA found that the purported anti-inflammatory effects of AzaSite that Inspire asserted in its then-current advertisement had “not been demonstrated by substantial evidence or substantial clinical experience.” The FDA advised Inspire that the advertisement was “false or misleading because it broadens the indication, makes unsubstantiated claims, and omits and minimizes important risks associated with the use of AzaSite.” Inspire knowingly and actively promoted AzaSite as a safe and effective treatment for non-FDA approved uses in order to induce doctors to write prescriptions for non-FDA approved uses, causing Medicare, Medicaid and other federal healthcare programs to pay millions of dollars for uncovered claims.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over the claims brought under the False Claims Act pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345.

3. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant transacted business in this District and engaged in wrongful actions pertinent to the Government’s claims in this District.

4. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b)-(c) because Defendant transacted business in this District and committed acts proscribed by 31 U.S.C. § 3729 in this District.

PARTIES

5. Plaintiff is the United States of America.

6. Defendant Inspire is a Delaware corporation with its current principal place of business at 1925 West Field Court, Lake Forest, IL 60045. Prior to its acquisition by Merck & Co., Inc., in May 2011, Inspire had its principal place of business in Durham, North Carolina, and engaged in the development, distribution, and sale of pharmaceutical and health care products, including its drug AzaSite, throughout the United States, including in New York.

THE FEDERAL HEALTH CARE PROGRAMS

A. Medicaid

7. Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. The federal portion of each state's Medicaid payments varies by state and is generally between 50 and 83 percent, depending on the state's per capita income. 42 U.S.C. § 1396d(b).

8. The Medicaid programs of all states and the District of Columbia reimburse for prescription drugs. Before the beginning of each calendar quarter, each state submits to the Centers for Medicare & Medicaid Services ("CMS") an estimate of its Medicaid federal funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, determines the amount of federal funding needs for the quarter, and determines the amount of federal

funding each state will be permitted to draw down as it actually incurs expenditures during the quarter. The state then draws down federal funding as actual provider claims are presented for payment. At the end of each quarter, the state submits to CMS a final expenditure report, which provides the basis for adjustment to the quarterly federal funding amount to reconcile the estimated expenditures to actual expenditures. 42 C.F.R. § 430.30.

9. The Medicaid Drug Rebate Program (the “Rebate Program”) is a partnership between CMS, state Medicaid agencies, and participating drug manufacturers that helps to offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. The Rebate Program requires, among other things, that a drug manufacturer enter into, and have in effect, a national rebate agreement with the Secretary of the Department of Health and Human Services in exchange for state Medicaid coverage of most of the manufacturer’s drugs. Manufacturers are then responsible for paying rebates to states for those drugs based in part on utilization by Medicaid patients. These rebates are paid by drug manufacturers on a quarterly basis and are generally shared between the states and the federal government to offset the overall cost of the prescription drugs under Medicaid.

10. A “covered outpatient drug” is defined in the federal Medicaid Drug Rebate Statute, 42 U.S.C. § 1396r-8(k)(2). Once the manufacturer enters into a Rebate Agreement, a state is generally required to cover that manufacturer’s covered outpatient drugs under the state plan (with certain limited exceptions) unless the “prescribed use is not for a medically accepted indication.” 42 U.S.C. § 1396r-8(d)(1)(B).

11. The Medicaid Drug Rebate Statute defines “medically accepted indication” as any FDA approved use or a use that is “supported by one or more citations included or approved for inclusion in any of the compendia” set forth in the statute. 42 U.S.C. § 1396r-8(k)(6).

12. A drug does not generally meet the definition of a “covered outpatient drug” if it is prescribed for a use that is neither FDA-approved nor supported by a citation included or approved for inclusion in the compendia. 42 U.S.C. § 1396r-8(k)(2), (k)(3). Thus, even if a drug is FDA-approved for a particular use, Medicaid ordinarily does not cover uses of the drug for other, non-FDA approved uses that are not supported by one or more citations included in the specified compendia.

B. Medicare Part D

13. The Medicare program pays for the costs of certain healthcare services and items for eligible beneficiaries based on age, disability, or affliction with end-stage renal disease.

14. In 2003, Congress amended the relevant statutes to create Medicare Part D, which provides additional optional drug coverage for Medicare beneficiaries. Under the Part D benefit, a “covered part D drug” means, in relevant part, a drug that is approved by the FDA and is used for a “medically accepted indication.” 42 U.S.C. § 1395w-102(d)(1) & (e)(4)(A)(ii) (citing 42 U.S.C. § 1396r-8(k)(6)). A “medically accepted indication” is defined as any use which is FDA-approved or which is supported by one or more citations included or approved for inclusion in one of three specified drug compendia. Generally, Part D coverage is provided by sponsors who contract with CMS to provide such coverage and are responsible for making coverage determinations in accordance with the statutes and regulations.

C. The TRICARE Program

15. TRICARE is a managed health care program established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

16. The regulatory authority establishing the TRICARE program does not cover drugs not approved by the FDA. *See* 32 C.F.R. § 199.4(g)(15)(i)(A).

17. TRICARE does not cover drugs used for non-FDA approved indications unless such use is proven medically necessary and safe and effective by the medical literature, national organizations, or technology assessment bodies. *See* 32 C.F.R. § 199.4(g)(15)(i)(A)(Note).

D. The Federal Employee Health Benefits Program

18. The Federal Employee Health Benefits Program (“FEHBP”) is a federally-funded health care program established by Congress in 1959, pursuant to the Federal Employees Health Benefits Act. 5 U.S.C. §§ 8901 *et seq.*

19. The United States Office of Personnel Management (“OPM”) administers the FEHBP and contracts with various health insurance carriers to provide services to FEHBP members. *Id.* §§ 8902, 8909(a).

20. Funds for the FEHBP are maintained in the Employees Benefits Fund, which OPM administers. *Id.* § 8909(a). This Fund, which the United States Treasury holds and invests, is the source of all relevant payments to the insurance carriers for services rendered to members. *Id.* § 8909.

E. The Veterans Administration

21. The Veterans Administration maintains a system of medical facilities from which all pharmaceutical supplies, including prescription drugs, are purchased directly or indirectly by the Veterans Administration and dispensed to beneficiaries. It also supports a mail service prescription program as part of the outpatient drug benefit. The system serves approximately four million veterans.

INSPIRE'S FRAUDULENT PROMOTIONAL SCHEME

22. AzaSite is an ophthalmic solution of azithromycin indicated for the treatment of bacterial conjunctivitis caused by susceptible isolates of the following microorganisms: CDC coryneform group G, *Haemophilus influenza*, *Staphylococcus aureus*, *Streptococcus mitis* group, and *Streptococcus pneumoniae*.

23. The FDA has approved the sale of a 5 mL size bottle of AzaSite filled with 2.5 mL of a 1% sterile topical ophthalmic solution.

24. The FDA-approved dosage and administration for AzaSite is to instill one drop in the affected eye twice daily, eight to twelve hours apart, for the first two days, and then to instill one drop in the affected eye once daily for the next five days, for a total of nine drops per affected eye over seven days.

25. The FDA approved AzaSite for the aforementioned indication, dosage, and administration on April 27, 2007.

26. As discussed in detail below, by no later than the beginning of 2008, in an effort to generate profits, Inspire began a promotional effort to encourage physicians to prescribe

AzaSite for the treatment of blepharitis, a type of lid margin disease characterized by an inflammation of the eyelids. Blepharitis can occur on the outside front of the eyelid where the eyelashes attach, as well as on the inner eyelid. The standard of care for the treatment of blepharitis is good hygiene and the use of eyelid scrubs, and not prescription medication. Blepharitis is distinct from bacterial conjunctivitis. Bacterial conjunctivitis, or pink eye, is an infection of the mucous membrane (the conjunctiva) that covers the eyelids and the surface of the eye. Inspire intentionally focused its marketing efforts on the purported anti-inflammatory characteristics of AzaSite in an effort to cause doctors to prescribe AzaSite for blepharitis, even though, as the FDA advised Inspire in 2011, the purported anti-inflammatory effects of AzaSite “had not been demonstrated by substantial evidence or substantial clinical experience.” The FDA told Inspire that its then-current advertisement for AzaSite was “false or misleading because it broadens the indication, makes unsubstantiated claims, and omits and minimizes important risks associated with the use of AzaSite.” Inspire’s promotional efforts had their intended effect: they caused doctors to prescribe AzaSite for uses not covered by federal healthcare programs, and resulted in federal healthcare programs paying millions of dollars in false claims.

27. The FDA has never approved AzaSite as safe and effective for the treatment of blepharitis.

A. Inspire’s Advertisements Shifted from a Focus on Bacterial Conjunctivitis to a Focus on Blepharitis

28. Following the launch of AzaSite in 2007, Inspire focused its marketing efforts on bacterial conjunctivitis, or pink eye. Pink eye is a common eye infection among kids, and

Inspire's advertisements prominently featured kids and emphasized the ease of administering AzaSite with only 9 drops.

29. The early marketing strategy for AzaSite indicated that "AzaSite will be presented to our customers based on the approved indication and labeled attributes of" the product.

30. Early marketing materials prominently featured a picture of a child dressed up as a superhero. The advertisement says, "SUPERHERO," with "HERO" scribbled out and the word "easy" written in its place to emphasize the ease of administering AzaSite. The marketing materials prominently addressed the "effective resolution of bacterial conjunctivitis with just 9 drops," and stated that AzaSite is "[e]asy to take, easy to remember." The early advertisements boasted of AzaSite's "unparalleled dosing convenience." Inspire referred to AzaSite as the "9-Drop Revolution."

31. Inspire thus initially focused its marketing campaign on the ease of dosing in treating bacterial conjunctivitis, while targeting doctors including primary care and pediatric physicians.

32. By early 2008, however, recognizing that it had not achieved its financial expectations following the launch of AzaSite, Inspire shifted its marketing strategy to target non-FDA approved uses to generate more profit. A Launch Update from October 30, 2007 recognized that "[w]e are off to a slower than expected start," and noted difficulties in marketing AzaSite to pediatricians and ophthalmologists to treat bacterial conjunctivitis.

33. Accordingly, Inspire shifted its marketing strategy away from bacterial conjunctivitis and instead focused on blepharitis. Specifically, Inspire's advertisements and

outreach to doctors focused on emphasizing AzaSite's alleged anti-inflammatory benefits because inflammation of the eyelid is the hallmark of blepharitis. Advertisements from February of 2008 depicting an adult climbing a rock emphasized AzaSite's "Anti-inflammatory and immunomodulatory effects," and the "High and sustained concentrations in ocular tissue."

34. An internal powerpoint from November 2008 observed that "[d]espite the [g]rowth," the company had "[n]ot [a]chieved [e]xpectations" with respect to revenues earned from AzaSite. The document explained "[w]hat lead us to focus on lid margin disease," and noted in bullet points, among other reasons, the "Potential Large Market Opportunity" and the "Unmet Need." The powerpoint explained that the "combination of anti-inflammatory and anti-microbial activity makes AzaSite a logical treatment choice for ocular surface disease and lid margin disease."

35. Inspire emphasized this message not just through print advertisements, but also through outreach by phone. Inspire observed in the November 2008 powerpoint:

"3 Message points that needs to be delivered on every call:

- **Concentration** and penetration into the ocular surface and the eyelids

- **Anti-inflammatory properties of azithromycin**

- **Anti-infective activity**, particularly against the prevalent pathogens in ocular surface/lid margin disease." (emphasis in original)

36. A Board of Directors Commercial Review from January 2009 noted agreement with a recommendation to "abandon BC" and likewise noted agreement "with [the] decision to focus efforts on LMD and pursue indication."

37. In or around 2010 and through part of 2011, Inspire developed a new advertisement campaign referred to as “Metal Man” that likewise barely mentioned pink eye and instead focused on symptoms of blepharitis such as inflammation. The advertisement depicted a partial metallic face with an eye that has an ocular surface condition. The next page depicted the same partial face, but the ocular surface condition had completely resolved. The advertisement claimed: “An ocular surface condition causes damage . . . AzaSite Can Restore a Healthy Ocular Surface By Delivering Significant Anti-Inflammatory and Antimicrobial Effects Directly to the Site of the Problem.” The advertisement also asserted that “AzaSite achieved therapeutic concentrations in ocular surface tissues and maintained them for at least five days after the *last* dose (day 7).” This marketing campaign was an effort to induce prescriptions for non-FDA approved use of AzaSite to treat blepharitis.

38. On April 14, 2011, the Division of Drug Marketing, Advertising, and Communications (“DDMAC”) of the FDA (now the Office of Prescription Drug Promotion) sent a letter to Inspire informing the company that a four-page journal advertisement for AzaSite was “false or misleading because it broadens the indication, makes substantial unsubstantiated claims, and omits and minimizes important risks associated with the use of AzaSite,” thereby violating the Federal Food, Drug, and Cosmetic Act and FDA’s implementing regulations.

39. Specifically, DDMAC faulted the journal advertisement for suggesting “that AzaSite is indicated to treat any condition that causes ocular surface damage” and implying “that AzaSite delivers anti-inflammatory effects,” even though these purported anti-inflammatory effects had “not been demonstrated by substantial evidence or substantial clinical experience.”

DDMAC likewise found that the advertisement implied “that AzaSite has been shown to maintain therapeutic concentrations in ocular surface tissues for at least five days after the last dose (i.e., days 8-12)” even though “this has not been demonstrated by substantial evidence or substantial clinical experience.” The advertisement, DDMAC found, had additional deficiencies in that it “omit[ted] information about serious risks associated with” AzaSite, and “fail[ed] to present risk information with a prominence and readability reasonably comparable to the presentation of efficacy claims.”

40. DDMAC requested in its April 14, 2011 letter that Inspire “immediately cease the dissemination of violative promotional materials for AzaSite” and noted that it “is [Inspire’s] responsibility to ensure that [its] promotional materials for AzaSite comply with each applicable requirement of [the Federal Food, Drug, and Cosmetic] Act and FDA implementing regulations.”

B. Inspire Targeted Doctors Likely To Write Prescriptions for Blepharitis

41. Inspire recognized early on that pediatricians treated the most cases of bacterial conjunctivitis, followed by primary care doctors, and described pediatricians as “the most prolific prescribers.” Inspire initially devoted resources toward targeting pediatric doctors and primary care physicians, but by approximately one year after the launch of AzaSite in 2007, Inspire had substantially reduced its efforts to target those doctors and instead was emphasizing outreach to eye care doctors more likely to write prescriptions for blepharitis. Whereas Inspire initially had an approximately 70/30 split of eye care doctors and other types of doctors versus pediatric or primary care doctors, that ratio changed by September 2008 to an almost exclusive focus on eye care doctors (nearly 95%) rather than pediatricians and primary care physicians.

Inspire observed in an internal powerpoint that “Lid margin disease was commonly seen by ophthalmologists,” and that “[a]pproximately one out of five patients managed by an ophthalmologist had lid margin disease.” Inspire also stated in an internal powerpoint: “Product basket established to identify highest potential treaters of eyelid and eye surface disease.”

42. By January 2009, Inspire recognized that “[i]n large measure, we have already exited pediatrics and primary care,” and told its national sales team that it would shortly “exit the pediatric/primary care space **entirely** and focus on Ophthalmology, Optometry and select Allergy (Elestat® only).”

43. By September 2009, Inspire based 55% of its incentive compensation to its sales staff only on AzaSite prescriptions written by eye care doctors, while disregarding any AzaSite prescriptions that its sales team procured from pediatricians and primary care physicians. Specifically, Inspire stated in its “Trimester 3 2009 Incentive Plan – Territory Managers” that “performance measurement will be based on all AzaSite Rx except those written by Primary Care or Pediatric prescribers.”

C. Inspire Trained Its Sales Force on the Purported Anti-Inflammatory Effects of AzaSite and Encouraged Its Sales Force to Focus on Blepharitis

44. Inspire emphasized to its sales force the benefits of treating blepharitis with AzaSite. For example, in a March 3, 2008 email to the National Sales Team, a Clinical Research Scientist from Inspire wrote: “In short, bacteria and inflammation really play a role in both anterior and posterior blepharitis (MGD). AzaSite offers well-established coverage against staph and an additional anti-inflammatory/immunomodulatory effect.”

45. As part of an “OPERATION: Inflection” meeting for the territory managers who marketed AzaSite in July 2008, Inspire presented speakers addressing “Lid Margin Disease” and “Identifying Meibomian Gland Disease.” Meibomian Gland Disease, also referred to as posterior blepharitis, is a type of lid margin disease. A document provided to territory managers had the title “AzaSite Scientific Update [--] Lid Margin Disease,” and included “[t]alking points” addressing blepharitis. The document provided information regarding the definitions of lid margin disease broken down between “Anterior Blepharitis” and “Meibomian gland disease (MGD; posterior [blepharitis]),” as well as information on “Azthromycin [sp] anti-inflammatory effects.”

46. Inspire touted to its National Sale Team by email dated September 30, 2008 the success of an Optometry Summit Meeting that the Inspire sales team pulled together which had “an amazing display of the potential Inspire and Optometry has in making AzaSite a first line treatment for Lid Margin Disease!” The Summit included presentations by one doctor “reviewing his independent study of AzaSite for Anterior Blepharitis” and another presentation “updating 2 studies using AzaSite for Posterior Blepharitis and Mixed Blepharitis (Posterior/Anterior).”

D. Inspire Prepared and Distributed Promotional Materials for AzaSite Aimed At Generating Prescriptions to Treat Blepharitis

47. As part of its effort to drive prescriptions for AzaSite, Inspire provided its sales team with marketing materials to be provided to doctors that touted the use of AzaSite for blepharitis in order to generate prescriptions from doctors to treat blepharitis.

48. For example, a March 17, 2008 email to the Inspire national sales team included as an attachment a “Lid Margin Disease medical information letter” for distribution to physicians. The letter to the doctor attached an information sheet with the prominent heading “AzaSite® -- LID MARGIN DISEASE.” The information sheet advised the doctor that “[l]id margin disease, more generally referred to as blepharitis, is a common chronic disease of the eyelids and lid margins which is inflammatory (posterior blepharitis or meibomian gland dysfunction) and/or infectious (anterior blepharitis) in nature,” while touting how azithromycin, the active ingredient in AzaSite, “possesses both anti-inflammatory and anti-infective properties.” The information sheet claimed that the “anti-inflammatory/immunomodulatory properties and favorable pharmacokinetic profile associated with azithromycin may offer additional utility in treating the posterior blepharitis/MGD disease process.”

49. In 2008, Dr. Jodi Luchs published a medical study entitled “Efficacy of Topical Azithromycin Ophthalmic Solution 1% in the Treatment of Posterior Blepharitis,” which “compared the efficacy of topical azithromycin ophthalmic solution 1% (AzaSite®; Inspire Pharmaceuticals, Inc, NC, USA) combined with warm compresses (azithromycin group) to warm compresses alone (compress group) in patients with posterior blepharitis.” 25 *Advances in Therapy* 858 (2008).

50. Inspire recognized that this study could support its promotional efforts to drive prescriptions of AzaSite for the non-FDA approved use of treating blepharitis and provided copies of the article to physicians to convince them to prescribe AzaSite for such use.

51. A March 17, 2009 email to the national Inspire sales team included as an attachment a draft proof of the Luchs article and instructed that “each territory manager will receive 100 reprints of the Jodi Luchs study” Also attached to this email was a powerpoint noting that “[a] territory manager can give a doctor the Luchs reprint whether it’s requested or not.” Territory managers were advised that “[e]ach Luchs reprint should be delivered with an AzaSite® package insert.”

52. Inspire likewise sought to capitalize on the March 15, 2008 edition of the Ophthalmology Times that contained an article addressing the Luchs study and another study by Dr. Stanley Bykov concerning the use of AzaSite to treat blepharitis. Inspire sent an April 2, 2008 email to a regional sales team that described this article as a “gem” and instructed the sales force to “[p]rint it, memorize it, speak to it, sell it, love it!”

E. Inspire Adopted a Speakers Program to Promote AzaSite as a Treatment for Blepharitis

53. Inspire had a nationwide speaker program that employed eye doctors to make presentations to healthcare providers, with the purpose of generating prescriptions of AzaSite to treat blepharitis.

54. The 2009 Optometry Speaker’s Training was touted to the national sales team as “the best speaker training meeting we have ever had,” with the statement that “[a] big part of that is due to all the data we have accumulated over the past year. We have an **incredible data set that supports the anti-inflammatory, anti-infective and high concentrations message of AzaSite.**” The speaker training program, like AzaSite’s marketing campaign, thus focused on

the attributes of AzaSite geared toward inflammation that is characteristic of blepharitis, instead of focusing on how AzaSite could be used to treat bacterial conjunctivitis.

55. Inspire selected speakers to attend speaker training programs, at which time Inspire provided speakers with powerpoint presentations to facilitate discussions on uses of AzaSite.

56. Inspire had slides prepared for its presenters to address non-FDA approved uses of AzaSite. Indeed, Inspire specifically denoted which slides addressed “off-label indications” by placing a “symbol in [the] lower left corner” of the slide that looks like the section (“§”) symbol, contained within a triangle. Inspire advised: “If you are asked an off-label question, you may use these slides to answer the question. However, you must state that the use in question is not approved by the FDA.”

57. An example of a slide containing the “§” symbol contained the heading “AzaSite® is disease modifying therapy for Blepharitis,” and featured bullet points promoting various attributes of AzaSite including its alleged “[s]ignificant anti-inflammatory activity w/o side effects of steroids.”

58. A “2010 Fall Speaker Update” contained a section on “Key Messages” that included the message: “Delivers significant anti-inflammatory and antimicrobial effects to the site of the problem.”

59. Inspire lauded its speakers who effectively addressed blepharitis. For example, in a November 17, 2008 email addressing the use of a particular speaker in Florida, the physician is identified as “do[ing] an awesome job talking bleph[aritis] and [A]zasite.”

F. Submission of False Claims to Federal Healthcare Programs

60. Inspire's marketing of AzaSite for the treatment of blepharitis, a use not approved by the FDA or covered by federal health care programs, was misleading by, among other things, making unsubstantiated claims about the purported anti-inflammatory effects of AzaSite, and resulted in the submission of false claims to federal healthcare programs. These claims were not reimbursable because they stemmed from the use of AzaSite for indications not approved by the FDA or supported by any of the compendia referenced in the Medicaid Drug Rebate Statute. Inspire's promotion of AzaSite to treat blepharitis was intended to cause -- and in fact caused -- doctors to prescribe AzaSite for uses not covered by federal healthcare programs, and resulted in federal healthcare programs paying millions of dollars in false claims.

FIRST CLAIM

**(Violations of the False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1)(2006), and as amended, 31 U.S.C. § 3729(a)(1)(A))**

61. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

62. Inspire knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for AzaSite prescriptions that were not covered by federal healthcare programs.

63. By virtue of the false or fraudulent claims that Inspire caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than \$5,500 and up to \$11,000 for each violation.

SECOND CLAIM

**(Violations of the False Claims Act: False Statements)
(31 U.S.C. § 3729(a)(2)(2006), and as amended, 31 U.S.C. § 3729(a)(1)(B))**

64. The Government incorporates by reference paragraphs 1 through 60 as if fully set forth herein.

65. Inspire knowingly made, used, or caused to be made or used, false records or statements material to a false or fraudulent claim.

66. By virtue of the false records or statements that Inspire made, used, or caused to be made or used, the United States is entitled to treble damages to be determined at trial, and civil penalties of not less than \$5,500 and up to \$11,000 for each such false record or statement.

THIRD CLAIM

(Unjust Enrichment)

67. The Government incorporates by reference paragraphs 1 through 60 as if fully set forth herein.

68. As a consequence of the acts set forth above, Inspire was unjustly enriched at the expense of the United States in an amount to be determined at trial which, under the circumstances, in equity and in good conscience, should be returned to the United States.

69. The United States claims the recovery of all monies by which Inspire has been unjustly enriched.

PRAYER FOR RELIEF


WHEREFORE, the Government demands and prays that judgment be entered in its favor against Inspire as follows:

1. On Counts One and Two under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.
2. On Count Three for unjust enrichment, for the damages sustained and/or amounts by which Inspire was unjustly enriched, plus interest, costs, and expenses, and all such further relief as may be just and proper.

Dated: June 12, 2015
New York, New York

Respectfully submitted,

PREET BHARARA
United States Attorney for the
Southern District of New York

By: 
LAWRENCE H. FOGELMAN
Assistant United States Attorney
86 Chambers Street, Third Floor
New York, New York 10007
Tel.: (212) 637-2719
Fax: (212) 637-2686
Email: Lawrence.Fogelman@usdoj.gov