

IN THE CIRCUIT COURT OF THE  
FOURTH JUDICIAL CIRCUIT, IN AND  
FOR DUVAL COUNTY, FLORIDA

DIVISION \_\_\_\_\_

CASE NO. \_\_\_\_\_

10X-MA

CAROLYN A. GLEASON,

Plaintiff,

**DIVISION CV-6**

vs.

ROCHE LABORATORIES, INC.,

Defendant.

\_\_\_\_\_ /

**COMPLAINT FOR RELIEF AND DEMAND FOR JURY TRIAL**

Plaintiff, CAROLYN GLEASON (hereinafter "Plaintiff" or "Gleason"), sues the Defendant, ROCHE LABORATORIES, INC. (hereinafter "Defendant" or "Roche") and alleges:

**NATURE OF ACTION**

1. This is an action for damages caused by Roche's discharge of Gleason from employment in violation of the Florida Private Sector Whistle-Blower Act ("Whistle-Blower Act"), §§ 448.101, *et seq.*, Florida Statutes, and the Florida Civil Rights Act ("FCRA"), §§ 760.01, *et seq.*, Florida Statutes. This action seeks to correct unlawful employment practices taken against Gleason and to make Gleason whole.

**PARTIES, JURISDICTION AND VENUE**

2. Plaintiff, CAROLYN GLEASON, is a resident of Duval County, Florida.

3. Defendant, ROCHE LABORATORIES, INC., is a corporation authorized to transact business in Florida, incorporated under the laws of Delaware, with its principal place of business in Nutley, New Jersey.

4. Defendant Roche is engaged in the business of manufacturing, marketing and selling pharmaceutical products.

5. This is an action for damages in excess of the court's minimum jurisdiction of \$15,000 exclusive of costs, interest, and attorneys' fees.

6. Roche transacts business in Duval County, Florida by marketing and selling its pharmaceutical products to health care providers.

7. The actions alleged in this Complaint took place within Duval County, Florida.

8. Venue is therefore proper in this Court.

#### **FACTS**

9. In 1997, Roche hired Gleason, a former registered nurse, as a Virology Specialist assigned to the Norfolk, Virginia area.

10. In 2000, after Gleason transferred to Florida, Roche assigned her to its Southeast Region based out of Tampa, Florida (hereinafter "Tampa Regional").

11. At Tampa Regional, after being promoted twice during a six-year period, Gleason's last position with Roche was a Medical Center Representative.

12. Gleason's primary duties as a Medical Center Representative were to market and sell Roche's pharmaceutical products to hospitals and other large-scale medical institutions.

13. Roche assigned Gleason to a sales territory encompassing Northeast Florida, including Jacksonville/Duval County, Nassau County, St. Augustine, Gainesville and Ocala.

14. During the course of her employment with Roche, Gleason, who received Roche's Special Achievement Award six times during a ten-year period, never received any negative performance reviews nor was she ever disciplined for any infraction.

15. In September 2006, Tom Long became Gleason's supervisor.

16. Until approximately June 2007, Gleason enjoyed a good working relationship with Mr. Long and he gave her excellent performance reviews, including a superior performance rating in December 2006.

17. Under federal law, it is illegal for a pharmaceutical manufacturer to promote a drug that has not been approved by the Food and Drug Administration ("FDA") for a particular medical use or indication (hereinafter "off-label use").

18. FDA rules require that any scientific data or studies regarding off-label use may not be presented or offered by a pharmaceutical company's sales representatives directly to health care providers or other potential customers.

19. FDA rules further require that any scientific data or studies regarding off-label use must be entirely unsolicited by potential customers, sent out directly from a pharmaceutical company's corporate office, and labeled "For Response Only" (FRO).

20. Under federal law, it is illegal for a pharmaceutical manufacturer to disseminate false or misleading information concerning its products, or to state that a drug is safe or effective for a particular use or indication for which it is being investigated by the FDA.

21. In or about mid-2007, Bill Sweeney, Tampa Regional's Manager, was ranked third out of six national regions in sales of Mycamine, an anti-fungal drug Roche co-markets with Astellas Pharma US, Inc., when he had previously ranked first in the country.

22. As a result, Mr. Sweeney began to pressure his managers, including Tom Long, to increase Mycamine's sales.

23. In order to boost Mycamine's regional sales, Mr. Sweeney's goal was 100% conversion of hospital accounts on Mycamine.

24. In order to obtain 100% conversion, Mr. Sweeney and Mr. Long instructed Gleason and Tampa Regional's other pharmaceutical sales representatives to aggressively market Mycamine to hospitals for "all purposes" and as the exclusive anti-fungal drug in its class.

25. In order to obtain the conversion, Mr. Sweeney and other members of Roche's management also decided to primarily market Mycamine in the 100 mg. dose, which was more cost competitive than other anti-fungal drugs in its class.

26. During the time in question, Roche had not yet received FDA approval for Mycamine in the United States for any indication requiring the lower-priced 100 mg. dose, thus limiting Roche's ability to market the drug to hospitals for "all purposes."

27. During the time in question, despite clinical trials and studies over a two-year period, Roche had also not yet received FDA approval of Mycamine for Candidemia, a common fungal infection in the blood, which was the primary use for this class of drugs in hospitals.

28. Gleason's supervisors, Mr. Sweeney and Mr. Long, instructed her to market Mycamine in the 100 mg. dose by falsely representing to potential customers that Roche had received FDA approval for Candidemia, an off-label use.

29. Gleason objected to Mr. Sweeney, Mr. Long and to other members of Roche's management that making false representations to potential customers that Mycamine had received FDA approval for Candidemia in the 100 mg. dose was unlawful.

30. Gleason refused to represent to health care providers and other potential customers that Mycamine had received FDA approval for Candidemia in the 100 mg. dose or for any other off-label use.

31. Gleason also refused to offer any scientific data or studies to health care providers and other customers pertaining to any off-label uses of Mycamine, including for Candidemia in the 100 mg. dose, which would violate federal law.

32. On June 13, 2007, Gleason delivered a marketing presentation on Mycamine to physicians attending a journal club luncheon.

33. During the luncheon, Mr. Long opened an unapproved clinical article, which offered data on Mycamine in unapproved uses, and placed it on the table for Gleason to use in her presentation.

34. Gleason refused to use the unapproved clinical article in her presentation.

35. In violation of FDA rules, Mr. Long represented to the physicians who were present at the luncheon that Mycamine 100 mg. is being used at Tampa General Hospital and Jackson Memorial, two large hospitals in Tampa Regional's sales territory.

36. Mr. Long falsely told the physicians present at the luncheon that, with regard to Mycamine, "no one questions the 100 mg. anymore, it's a given."

37. Gleason informed Mr. Long and other members of Roche's management, as she had before, that this promotion was "over the line" and that she would "not operate illegally."

38. After Gleason made it clear to her supervisors that she would not engage in illegal behavior to increase Mycamine sales, Mr. Long began to harass Gleason in various ways, although her excellent job performance had not changed.

39. In particular, after Gleason refused to market and sell Mycamine illegally, Mr. Long began harassing Gleason about submitting her expense reports.

40. During Gleason's nearly eleven years with Roche, she had never been disciplined for falsifying or submitting delinquent expense reports or any other necessary work documentation.

41. In early September 2007, Gleason attended a Roche sales meeting in Las Vegas, Nevada.

42. At a meeting in Mr. Long's hotel suite with other Medical Center Representatives, after Gleason reached out her hand to shake Mr. Long's hand, he pulled her into a hug and kissed her.

43. Later, after the meeting broke up, Gleason again extended her hand for Mr. Long to shake, but he pulled her into another hug and whispered in Gleason's ear, "I'll call you next week."

44. Mr. Long had never physically touched Gleason in this way before, and his sudden actions made her feel extremely uncomfortable.

45. Due to Mr. Long's position as Gleason's immediate supervisor, his recently expressed dissatisfaction with her job performance, and his unwarranted harassment towards her with regard to her expense reports, Gleason reasonably perceived Mr. Long's behavior as sexually harassing.

46. On September 10, 2007, Gleason telephoned Tampa Regional's Human Resources Department and reported Mr. Long's conduct by first leaving multiple voice mail messages, and later by sending an email detailing her sexual harassment complaint.

47. On September 14, 2007, Gleason spoke by telephone with Kristina Koptchev, Tampa Regional's Human Resources Manager, regarding her sexual harassment complaint.

48. On September 27, 2007, 17 days after Gleason first reported her sexual harassment complaint to Roche's representatives, and within three months of her refusal to violate the law by promoting any off-label uses of Mycamine or communicating false or misleading information concerning the drug, Roche terminated her employment.

**COUNT I**

**RETALIATION IN VIOLATION OF THE FLORIDA  
PRIVATE WHISTLE-BLOWER ACT (§§ 448.101, *et seq.*, Fla. Stat.)**

49. Gleason readopts and realleges Paragraphs 1 through 48 above as though fully set forth herein.

50. At all times material, Gleason was an “employee,” as that term is defined by the Whistle-Blower Act.

51. Roche is a private corporation that employs ten or more persons, and thus is an “employer” as that term is defined under the Whistle-Blower Act.

52. The federal statutes and FDA rules concerning off-label use and prohibiting the dissemination of false and misleading pharmaceutical information, which may be found in the Food, Drug and Cosmetic Act, §§ 301, *et seq.*, and 21 C.F.R. §§ 312, *et seq.*, are “laws, rules or regulations” applicable to Roche as an employer.

53. The federal statutes and FDA rules concerning off-label use and prohibiting the dissemination of false and misleading pharmaceutical information pertain to Roche’s business as a company that manufactures, markets and sells pharmaceutical products.

54. Due to her clinical background as a critical care registered nurse for over 20 years, and her 11 years of experience as a pharmaceutical sales representative, Gleason was very familiar with the use of prescription drugs in the hospital setting and the federal laws applicable to pharmaceutical sales.

55. Based on her education, training, knowledge and experience, Gleason objectively and reasonably believed that Roche was engaging in unlawful activity by promoting Mycamine for off-label use.

56. Gleason objectively and reasonably believed that Roche was violating the law by illegally offering scientific data or studies to customers regarding off-label uses of Mycamine.

57. Gleason objectively and reasonably believed that Roche was violating the law by disseminating false or misleading information concerning Mycamine.

58. Gleason objected to Roche's unlawful representations and to its illegal presentation of scientific data or studies directly to customers regarding off-label uses of Mycamine.

59. Gleason refused to participate in Roche's unlawful representations and the illegal presentation of scientific data or studies directly to customers regarding off-label uses of Mycamine.

60. Due to Gleason's objection and refusal to participate in the unlawful conduct of Defendant's representatives, Roche took "retaliatory personnel action" against her, as defined in the Whistle-Blower Act, by terminating her on September 27, 2007.

61. Roche's representatives unlawfully terminated Gleason based on her refusal to participate in and objection to actions which she reasonably believed to be illegal.

62. Roche's representatives also unlawfully terminated Gleason for complaining of sexual harassment, made illegal by Title VII of the 1964 Civil Rights Act and the FCRA.

63. Roche intentionally retaliated against Gleason by discharging her for complaining of its unlawful actions, in violation of the Whistle-Blower Act.

64. As a direct and proximate result of Roche's violation of the Whistle-Blower Act, Gleason has suffered lost wages and benefits, severe emotional distress, emotional pain, suffering, inconvenience, mental anguish and non-pecuniary losses.

65. WHEREFORE, Gleason prays that the Court:

- (a) enter judgment against Roche and for Gleason;
- (b) award Gleason actual damages for loss of wages and benefits caused her due to Roche's violations of law enumerated herein;
- (c) award Gleason compensatory damages;
- (d) award Gleason pre- and post-judgment interest;
- (e) award Gleason all reasonable attorneys' fees and costs incurred in this action as provided in the Whistle-Blower Act; and
- (f) grant Gleason such other and further relief as may be equitable and just.

## COUNT II

### **RETALIATION IN VIOLATION OF THE FLORIDA CIVIL RIGHTS ACT (§§ 760.01, *et seq.*, Fla. Stat.)**

66. Gleason readopts and realleges Paragraphs 1 through 48 above as though fully set forth herein.

67. At all times material, Roche employed 15 or more employees for each working day in each of 20 or more calendar weeks in the current or preceding calendar year, and was an “employer” pursuant to the FCRA.

68. Roche was Gleason’s “employer,” within the meaning of the FCRA, at all times relevant to this action.

69. On September 17, 2007, Gleason reported a complaint of sexual harassment against her supervisor to Defendant’s Human Resource representatives.

70. By making a complaint of sexual harassment, Gleason opposed the unlawful practices of Roche.

71. Gleason had a good faith and reasonable belief that her supervisor’s behavior towards her was sexually harassing, and thus in violation of the law.

72. Roche intentionally retaliated against Gleason by discharging her for complaining of its unlawful actions, in violation of the FCRA.

73. As a direct and proximate result of Roche’s violation of the FCRA, Gleason has suffered lost wages and benefits, severe emotional distress, emotional pain, suffering, inconvenience, mental anguish, loss of dignity, and non-pecuniary losses.

74. WHEREFORE, Gleason prays that the Court:

- (a) enter judgment against Roche and for Gleason;
- (b) award Gleason actual damages for loss of wages and benefits caused her by Roche’s violations of law enumerated herein;
- (c) award Gleason compensatory damages;
- (d) award Gleason punitive damages;

- (e) award Gleason pre- and post-judgment interest;
- (f) award Gleason all reasonable attorneys' fees and costs incurred in this action as provided in the FCRA; and
- (g) grant Gleason such other and further relief as may be equitable and just.

**JURY DEMAND**

Gleason demands trial by jury on all issues so triable.

Dated: October \_\_\_\_, 2008

Respectfully submitted,

**DELEGAL LAW OFFICES, P.A.**



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T.A. DELEGAL, III, ESQ.

Fla. Bar No. 0892701

WENDY E. BYNDLOSS, ESQ.

Fla. Bar No. 0048718

424 East Monroe Street

Jacksonville, FL 32202

Telephone: (904) 633-5000

Attorneys for Plaintiff