

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

UNITED STATES OF AMERICA)	
ex rel. PAUL P. McDERMOTT,)	
)	
Plaintiff,)	
)	
vs.)	No. 05-CV-0147-GC
)	
GENENTECH, INC. and)	
BIOGEN-IDEC, INC.,)	
)	
Defendants.)	Plaintiff Demands Trial
)	By Jury

CORRECTED SECOND AMENDED COMPLAINT

The Relator, Paul P. McDermott, by his attorneys, Jensen Baird Gardner & Henry, Korein Tillery LLC, Myron M. Cherry & Associates, LLC, Robert L. King, and McTeague Higbee, Case, Cohen, Whitney & Toker, P.A., for his Complaint against Defendants Genentech, Inc. and Biogen-Idec, Inc., states as follows:

The Parties

1. Relator Paul P. McDermott is a resident of Cumberland County in the State of Maine and is a former employee of Defendant, Genentech, Inc. While employed by Genentech, his office was located in Falmouth, Maine.
2. Defendant, Genentech, Inc. (“Genentech”) is a Delaware corporation with its principal place of business in South San Francisco, California. Genentech is a leading biotechnology company engaged in the development, manufacturing, commercialization and marketing of various pharmaceutical products, including *Rituxan*, a chemotherapeutic agent.

3. Defendant Biogen Idec, Inc., (“Biogen”), formerly known as Idec Pharmaceuticals Corporation, is a Delaware corporation with its principal place of business in Cambridge, Massachusetts. Defendant Biogen is engaged in the development, manufacturing, and commercialization of pharmaceuticals, including *Rituxan*.

Jurisdiction

4. Jurisdiction is based upon 31 U.S.C. § 3732. This action is not based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the government is already a party nor upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media. Moreover, Relator has direct and independent knowledge of the information on which the allegations of this lawsuit are based, and Relator voluntarily provided that information to the Government before filing this action. Relator is thus an original source of the information on which the allegations of this lawsuit are based. Jurisdiction over Plaintiff’s claims for violation of Maine’s Whistleblower Protection Act (“the WPA”), 29 M.R.S.A. § 831 *et seq.*, is based upon the doctrine of supplemental jurisdiction and upon diversity jurisdiction. The amount in controversy, exclusive of interest and costs, exceeds the sum specified by 28 U.S.C. § 1332.

Administrative Procedure

5. Plaintiff McDermott filed charges of violation of the WPA with the Maine Human Rights Commission (“MHRC”) on October 28, 2005. A copy of the charge is attached hereto as Exhibit 1.

6. By letter dated April 19, 2007, the MHRC issued its Statement of Finding that reasonable grounds exist to believe that Genentech discriminated against Plaintiff. A copy of the MHRC's Statement of Finding is attached hereto as Exhibit 2.

7. By letter dated April 24, 2007, the MHRC issued Plaintiff McDermott a letter stating that conciliation had been unsuccessful and authorizing suit. A copy of the MHRC's letter is attached hereto as Exhibit 3.

Background

8. Defendants Genentech and Biogen jointly developed *Rituxan*.

9. Defendant Genentech licenses *Rituxan* from Defendant Biogen.

10. At all times relevant to this Complaint, Defendant Genentech had a sales and marketing staff dedicated to sales and promotion of *Rituxan*.

11. Beginning in 2004, Defendant Biogen established a sales and marketing staff dedicated to sales and promotion of *Rituxan*.

12. Defendants Genentech and Biogen market and sell *Rituxan* in the United States in collaboration with one another.

13. Defendants' activities relating to the manufacture, marketing and sale of prescription pharmaceuticals such as *Rituxan* are regulated by the United States Food and Drug Administration as alleged below.

The FDA Approves *Rituxan* for the Treatment of non-Hodgkin's Lymphoma

14. *Rituxan*, an anti-CD20 antibody, is a "biological product" or "biologic" originally developed for the treatment of relapsed or refractory, low-grade or follicular, CD20-positive, non-Hodgkin's lymphoma (hereinafter simply "non-Hodgkin's lymphoma"), a cancer of the immune system.

15. In 1997, the United States Food and Drug Administration (“FDA”) approved *Rituxan*, and the appropriate dosages thereof, for the treatment of patients with non-Hodgkin’s lymphoma.

16. At that time, the FDA did not approve the use of *Rituxan* for any other purpose or in any other dosage.

The Government Pays Claims, such as Medicare or Medicaid Claims, for Prescription Drugs or Biologics Like *Rituxan* When Used to Treat A “Medically Accepted Indication”

17. Pharmaceutical products that are expensive are only widely prescribed when governmental medical expense reimbursement systems, such as Medicare or Medicaid, pay for such products.

18. Consequently, pharmaceutical manufacturers like Defendants Genentech and Biogen depend upon governmental medical expense reimbursement systems, such as Medicare or Medicaid, to pay for expensive pharmaceutical products such as *Rituxan* sold in the United States.

19. During all times relevant to this Complaint, Defendants Genentech and Biogen believed or knew the allegations set forth in the two preceding paragraphs, 14 and 15, to be true as a result of their experience in the pharmaceutical industry.

20. Federally funded medical reimbursement systems, such as Medicare or Medicaid, rely upon the informed and impartial judgment of rheumatologists and other medical professionals to allocate increasingly scarce financial resources to provide necessary and appropriate care to the elderly and poor residents of the United States.

21. Pursuant to governmental medical reimbursement systems such as Medicare or Medicaid, the U.S. government only pays claims for the use of pharmaceutical drugs or biologics when a rendering healthcare provider submits a claim for reimbursement on an appropriate claim form,

if the claim form is completed and the information provided on the form, if true, would make the claim eligible for reimbursement.

22. To obtain such payments, the healthcare provider must certify that the services it rendered to a patient “were medically indicated and necessary.”

23. The signature of the healthcare provider on government claim forms, such as Medicare or Medicaid claim forms, constitutes the provider’s certification that the services rendered “were medically indicated and necessary.”

24. The healthcare provider’s certification that the services rendered “were medically indicated and necessary” in turn constitutes its certification that the claim is eligible for reimbursement under federal law.

25. To be eligible for reimbursement under governmental medical reimbursement systems such as Medicare or Medicaid, a drug or biologic must be used for a “medically accepted indication.”

26. A “medically accepted indication” is one that is either approved by the FDA or listed in certain medical compendia. For simplicity’s sake, use of a drug or biologic for any condition that is not a “medically accepted indication” is referred to hereinafter as an “off-label” use.

27. Thus, governmental medical reimbursement systems such as Medicare or Medicaid rely upon the flow of accurate information and the unbiased professional medical judgment of physicians and pharmacists in providing payment for the drugs or biologics.

28. It is illegal for any party or entity to submit claims for reimbursement to governmental medical reimbursement systems such as Medicare or Medicaid for drugs or biologics used for off-label treatments.

29. During all times relevant to this Complaint, non-Hodgkin's lymphoma was the sole "medically accepted indication" for the prescription of *Rituxan*.

The Natural and Probable Consequence of a Pharmaceutical Manufacturer's Promotion of a Drug or Biologic for Off-Label Use is the Submission of Ineligible Claims for Reimbursement to the Government

30. Typically when a pharmaceutical manufacturer promotes a drug or biologic to treat a particular medical condition, some doctors begin using the drug or biologic to treat that medical condition.

31. Although physicians may prescribe a drug or biologic for purposes or in dosages other than those approved by the FDA, U.S. law strictly prohibits drug manufacturers from promoting or marketing to physicians FDA-regulated prescription drugs or biologics such as *Rituxan* for purposes or in dosages other than those approved by the FDA. 21 U.S.C. § 331(d).

32. Any increase in the incidence of off-label usage of a drug or biologic increases the likelihood that a healthcare provider will submit an ineligible claim for payment to a governmental medical reimbursement system such as Medicare or Medicaid for the off-label use.

33. Any increase in the incidence of off-label usage of an expensive drug or biologic to treat a medical condition common among elderly patients substantially increases the likelihood that a healthcare provider will submit an ineligible claim for payment to a governmental medical reimbursement system such as Medicare or Medicaid for the off-label use.

34. Thus, when a pharmaceutical manufacturer extensively promotes an off-label use of a drug or biologic, the natural and probable consequence of such illegal, off-label promotion is that some healthcare providers will submit ineligible claims for payment to a governmental medical reimbursement system such as Medicare or Medicaid for the off-label use.

35. It is common knowledge in the pharmaceutical industry that upon a manufacturer's promotion of an off-label use of a drug or biologic, that the natural and probable consequence of such illegal, off-label promotion is that some healthcare providers will inevitably submit ineligible claims for payment to a governmental medical reimbursement system such as Medicare or Medicaid for the off-label use.

36. Similarly, it is common knowledge in the pharmaceutical industry that a manufacturer's off-label promotion of a drug or biologic is a species of fraud against the U.S. Government because the natural and probable consequence of such illegal, off-label promotion is that some healthcare providers will inevitably submit ineligible claims for payment to a governmental medical reimbursement system such as Medicare or Medicaid for the off-label use.

37. Drug manufacturers, including Genentech and Biogen, are therefore sensitive to any suggestion that any of their marketing activities might constitute such off-label promotion of drug or biologic.

38. During all times relevant to this Complaint, Defendants Genentech and Biogen believed or knew each of the allegations set forth in paragraphs 27 through 34 to be true as a result of their experience in the pharmaceutical industry.

39. Thus, during all times relevant to this Complaint, Defendants Genentech and Biogen knew and/or intended that their extensive, off-label promotion of *Rituxan* for the treatment of rheumatoid arthritis (as alleged below) would result in the increased incidence of the off-label use of *Rituxan* for the treatment of rheumatoid arthritis.

40. Likewise during all times relevant to this Complaint, Defendants Genentech and Biogen knew and/or intended that their extensive, off-label promotion of *Rituxan* for the treatment of rheumatoid arthritis (as alleged below) would result in the increased submission of ineligible

claims for payment to governmental medical reimbursement systems such as Medicare or Medicaid for the off-label use of *Rituxan* for the treatment of rheumatoid arthritis.

**Defendants Unlawfully and Extensively Promoted
Rituxan for the Off-Label Treatment of Rheumatoid Arthritis**

41. In the 1990's, Defendants Genentech and Biogen began investigating the use of *Rituxan* for treatment of rheumatoid arthritis ("RA"). RA is a disease that most frequently afflicts older patients.

42. The FDA, however, did not approve use of *Rituxan* for treatment of RA until February 28, 2006.

43. Nevertheless, after the FDA approved *Rituxan* for treatment of non-Hodgkin's lymphoma in 1997, Genentech and Biogen began an extensive promotional campaign (the specific timing of which being within the exclusive knowledge of Defendants) for the off-label use of *Rituxan* to treat RA.

44. Defendant Genentech's and Biogen's unlawful promotion campaign consisted of, among other things, the illegal solicitation of physicians, illegal kickback schemes with physicians promoting *Rituxan* for off-label treatment of RA, and training their employees in methods of avoiding the detection of their off-label promotion activities, as alleged in detail below.

A. The Illegal Direct Solicitation of Physicians for Off-Label Uses of *Rituxan*

45. Genentech and Biogen directly solicited physicians and their medical professional staff members to illegally market off-label uses of *Rituxan* for treating RA. For example, on or about January 25, 2005 Relator McDermott learned of a prior visit by Genentech BioOncology sales representatives to a rheumatology practice, Rheumatology Associates, at 49 Seekonk Street, in Providence, Rhode Island. During this direct in-office promotion, the Genentech

BioOncology sales representatives discussed, among other things, dosing schedules and techniques for administering *Rituxan* to RA patients through intravenous infusion techniques. The Genentech BioOncology sales representatives promised the Rheumatology Associates Office Manager, Pam Nalette, that they would supplement their in-office promotion by forwarding to staff written instructions and materials demonstrating the ease with which they could administer *Rituxan* to RA patients through intravenous injections.

46. At all times relevant to this Complaint, Defendants Genentech and Biogen did not offer for sale any drugs or biologics that were FDA-approved for treating rheumatic diseases, including rheumatoid arthritis or related disorders of joints, muscles and bones. The only purpose for Genentech BioOncology or Biogen sales representatives to conduct in-office visits to rheumatologist offices was to engage in the illegal promotion of the off-label use of *Rituxan* for treating RA.

B. The Formation of a Nationwide Network of Employees Assigned to the Promotion of Off-Label Sales and Marketing

47. Genentech and Biogen created a nationwide network of employees falsely referred to as “Professional Educations Liaison’s” (“PEL’s”) and “Clinical Education Liaisons” (“CEL’s”) whose assigned duties involved the promotion of off-label sales and marketing activities regarding the use of *Rituxan* in treating RA, rather than legitimate educational activity (as alleged more fully below).

C. The Illegal Kickbacks of Monies and Consideration to Physicians Who, Under the Guise of “Consultants,” Promoted Off-Label Uses of *Rituxan*

48. Genentech and Biogen provided illegal kickbacks of monies and other consideration to physicians through the use of “sham” consulting agreements to illegally market *Rituxan* for off-label uses. Defendants Genentech and Biogen used sham consulting agreements

as a key tool to subvert the independent decision making process of physicians upon which both patients and medical reimbursement systems such as Medicare or Medicaid rely.

49. Defendant Genentech employed Professional Educations Liaisons (“PEL’s”) and Defendant Biogen employed “Clinical Education Liaisons” (“CEL’s”) who were responsible for identifying and selecting rheumatologists as Key Opinion Leaders (“KOL’s”). Once a KOL was identified, it was the PEL’s responsibility to persuade the KOL to enter into a “Synergy Consulting Agreement” with Defendants Genentech or Biogen.

50. Some KOL “consultants” included Dr. Joseph Markenson, Hospital for Special Surgery, 535 E. 70th Street, NY, NY 10021; Dr. Alan Gibofsky, M.D. J.D, Hospital for Special Surgery, 535 E. 70th Street, NY, NY 10021; Dr. Eric M. Ruderman, Division of Rheumatology, Northwestern University School of Medicine, 675 North St. Clair St. Suite 14-10, Chicago, IL 60611; and Dr. Marc Cohen, Mayo Clinic Jacksonville, 4500 San Pablo Road, Jacksonville, FL.

51. Once a rheumatologist was signed to a “Synergy Consulting Agreement,” he received payments for sham services. Defendants’ purpose in having KOL’s sign sham “Synergy Consulting Agreements” was to convert rheumatologists into active promoters for the off-label use of *Rituxan* for treating RA. With the execution of a “Synergy Consulting Agreement,” Defendants Genentech and Biogen attempted to transform a KOL from a practicing rheumatologist (with whom a PEL could not legally discuss or disseminate information regarding off-label uses of *Rituxan*) into a consultant (with whom the PEL could ostensibly promote off-label uses of *Rituxan* for RA).

52. Once Defendants transformed a rheumatologist into a consultant, Defendants could leverage the physician’s credibility in his or her professional community to identify additional target rheumatologists and to expand Defendants’ promotion of off-label uses of

Rituxan to treat RA. Materials promoting *Rituxan* for off-label treatment of RA are more fully accepted and integrated into physicians' professional belief systems when they are presented as educational in nature, in contrast to material that is clearly identified as promotional.

53. Using these sham consulting agreements, Defendants Genentech and Biogen were able influence and control the content of presentations consulting rheumatologists made to their peers at purportedly educational presentations, without disclosing the payments and consideration provided to such "consulting" speakers.

**D. The Illegal Kickbacks of Monies and Consideration
to Physicians Who, Under the Guise of Acting as Moderators
of Roundtable Dinners, Promoted Off-Label Uses of *Rituxan***

54. Once a physician is signed to a sham "Synergy Consulting Agreement," the next step in Genentech's and Biogen's illegal scheme is to further leverage such a physician through a series of dinner meetings known as "RA Roundtable Dinners." The "consulting" rheumatologist was paid a fee, typically \$2,000 to \$2,500, to "moderate" a RA Roundtable Dinner. The purpose of such dinners was to use the rheumatologist "moderator" as an advocate to promote the sales of *Rituxan* for off-label treatment of RA.

55. Pharmaceutical company sales and marketing research demonstrate that the use of physicians to pitch and promote drugs or biologics in a peer-to-peer context is much more effective than the use of pharmaceutical company salesman. A Genentech PEL or Biogen CEL would obtain from the "consulting" rheumatologist his physician letterhead and with his assistance prepare a targeted list of at least fifteen area rheumatologists. Using the "consulting" rheumatologist's professional letterhead, invitations were forwarded to area rheumatologists under his signature. Defendants Genentech and Biogen contracted with a third party

pharmaceutical sales promotion firm, Health Answers Education, to assist in organizing and holding the dinners.

56. Health Answers Education was utilized as a sham and front for the dinners. Defendants Genentech and Biogen exploited Health Answers Education as a façade in order to present the RA Roundtable off-label promotional dinners under the guise of an educational event produced by an independent continuing medical education organization. Health Answers Education maintained a website, www.RARoundtables.healthanswers.com, for meeting information and materials.

57. Defendants Genentech and Biogen and their sales and marketing staffs controlled and dictated all decision-making regarding the substance of RA Roundtable dinners. In addition to jointly planning the RA Roundtable Dinners, each Roundtable Dinner would have at least two attendees, typically one from defendant Genentech and one from defendant Biogen. Defendant Biogen employees who attended Roundtable Dinners included William Reiss, Trista King and Henry Leher. A standard topic for the RA Roundtable dinner series was “*Pathogenesis of Rheumatoid Arthritis: An in-depth look at B-cells.*” The venues for RA Roundtable dinners were usually up-scale area restaurants or dining facilities.

58. The following is a list of RA Roundtable Dinners, including the date, location, the “moderator,” the attending personnel from Defendants Genentech and Biogen, and attending personnel from the third-party pharmaceutical sales training firm Health Answers Education held in 2004: (a) August 4, 2004 RA Roundtable Dinner at Morton’s, 551 Fifth Avenue, New York, NY moderated by Dr. Arthur L. Weaver, attended by Dan Yip of Genentech and P. Evans of Health-Answers; (b) August 5, 2004 RA Roundtable Dinner at Ruth Chris, 431 North Dearborn, Chicago, IL moderated by Dr. Eric M. Ruderman, attended by Dan Yip of Genentech, Margaret

Masterson of Genentech and J. Thompson of Health Answers; (c) August 18, 2004 RA Roundtable Dinner at Morton's, 699 Boylston Street, Boston, MA moderated by Dr. James Morgan, attended by Paul McDermott of Genentech, Bill Reiss of Biogen and J. Thompson of Health Answers; (d) September 8, 2004 RA Roundtable Dinner at Morton's, 1411 Walnut Street, Philadelphia, PA moderated by Dr. Joseph Markenson, attended by Lisa Kruse of Genentech, Bill Reiss of Biogen, Larry Grogan (affiliation), and M.J. Holden of Health Answers; (e) September 8, 2004 RA Roundtable at Ruth Chris, 2525 N. Federal Highway, Ft. Lauderdale, FL, moderated by Dr. Marc Cohen, attended by J. Thompson of Health Answers; (f) September 9, 2004 RA Roundtable at Fleming Steakhouse, 103 Summit Blvd., Birmingham, AL moderated by Dr. Stanley Cohen, attended by Dan Yip of Genentech, J. Thompson of Health Answers; (g) September 15, 2004 RA Roundtable at Morton's, 501 Elm Street, Dallas, TX moderated by Dr. John Cush, attended by Margie Murdock of Genentech, Henry Leher of Biogen, and M.J. Holden of Health Answers; (h) September 22, 2004 RA Roundtable at Morton's, 1050 Connecticut Ave. NW, Washington, D.C. moderated by Dr. Allan Gibofsky, attended by Dan Yip of Genentech and J. Thompson of Health Answers; (i) September 28, 2004 RA Roundtable at Ruth Chris, 800 Fifth Avenue, Seattle, WA, moderated by Dr. Phillip Mease, attended by Tina Chang of Genentech, Susan Peper of Genentech, Bill Reiss of Biogen, and R. Trovinger of Health Answers; (j) September 29, 2004 RA Roundtable at Morton's, 30 State House Square, Hartford, CT, moderated by Dr. James Morgan, attended by Karen Dittrich of Genentech, Trista King of Biogen, and J. Thompson of Health Answers; (k) October 7, 2004 RA Roundtable at Maize, 50 Park Place, Newark NJ moderated by Dr. Allan Gibofsky, attended by Dave Metzger of Genentech, Henry Leher of Biogen, and M.J. Holden of Health Answers; (l) October 12, 2004 RA Roundtable at Morton's, 7822 Bonhomme Avenue, Clayton MO, moderated by Dr. Alvin

Wells, attended by Margie Murdock of Genentech and J. Thompson of Health Answers; (m) October 13, 2004 RA Roundtable at Morton's, One Towne Square, Southfield, MI, moderated by Dr. Eric H. Ruderman, attended by Henry Leher of Biogen, Margaret Masterson of Genentech and J. Thompson of Health Answers; and (n) October 27, 2004 RA Roundtable Dinner at Morton's, 300 South Charles St., Baltimore, Maryland, moderated by Dr. Lee Simon, attended by Dave Metzger of Genentech, Bill Reiss of Biogen, Larry Grogan of Genentech, and Renee Trovinger of Health Answers.

59. The following RA Roundtable dinners were also scheduled to be held in 2004 and, upon information and belief (based upon Defendant Genentech's practices during Relator McDermott's employment), were held on the following dates and with the following "moderators" and Genentech, Biogen and Health Answers attendees: (a) October 28, 2004 RA Roundtable Dinner at Morton's, 435 South La Cienega, Beverly Hills, CA moderated by Dr. James O'Dell, attended by Darlene Fujimoto from Genentech, Bill Reiss from Biogen, and P. Evans from Health Answers; (b) October 28, 2004 RA Roundtable Dinner at Morton's, 400 Post Street, San Francisco, CA moderated by Dr. Phillip Mease, attended by Kerri Ford of Genentech, Trista King of Biogen, and J. Thompson of Health Answers; (c) November 4, 2004 RA Roundtable Dinner at Third Street Pier, 1110 N. Old World 3rd Street, Milwaukee, WI moderated by Dr. James O'Dell, attended by Margaret Masterson of Genentech, Trista King of Biogen, Elizabeth Haney of Genentech and J. Thompson of Health Answers; (d) November 4, 2004 RA Roundtable Dinner at Morton's, 1710 Wynkoop Street, Denver CO moderated by Dr. Roy Fleichman, attended by P. Evans of Health Answers; (e) November 10, 2004 RA Roundtable Dinner at Morton's, 1200 Brickell Avenue, Suite 100, Miami FL, moderated by Dr. Joseph Markenson, attended by Margie Murdock of Genentech and J. Thompson of Health Answers; (f)

November 11, 2004 RA Roundtable Dinner at Ruth Chris, 1700 Westshore Blvd, Tampa FL, moderated by Dr. John Cush, attended by S. D. Doolan of Genentech, Henry Leher of Biogen and P. Evans of Health Answers; (g) November 16, 2004 RA Roundtable Dinner in Cincinnati, OH moderated by Dr. Alvin Wells, attended by Margaret Masterson of Genentech and M.J. Holden of Health Answers; (h) November 17, 2004 RA Roundtable Dinner at Morton's, 1600 West Second Street, Cleveland OH, moderated by Dr. Leonard Calabrese, and attended by Margaret Masterson of Genentech and M.J. Holden of Health Answers.

60. Although RA Roundtable dinners were structured to give the appearance that the information being provided had been developed, at least in part, by the "consulting" rheumatologist moderator as a practicing rheumatologist, in fact, the moderator was presenting information and materials prepared and packaged by Defendant Genentech's and Biogen's marketing personnel and consultants, including Dr. Alvin Wells, Kerri Ford, and William Reiss. Reiss was originally employed by Biogen and was later employed by Genentech. Ford was a Genentech employee. Wells was a rheumatologist who consulted with Genentech and Biogen and was previously employed by Abbott Laboratories. Genentech and Biogen did not allow moderators to make any additions, deletions or edits to the materials Genentech and Biogen gave to them for presentation.

61. The presentation materials Genentech and Biogen prepared did not fairly balance the available information on B-cell therapy and the efficacy of available medications. In some instances, prospective moderators refused to "moderate" such RA Roundtable dinners after reviewing the packaged materials because the materials failed to present independent, fair and balanced information and data. As an example, Dr. Ted Lally of Providence, Rhode Island, who had agreed to serve as a KOL rheumatologist and to moderate an RA Roundtable dinner, decided

not to proceed with the planned dinner after Genentech and Biogen advised him on or about October 29, 2004, that he could not make any changes to, and was required to present, the Genentech and Biogen slide decks as prepared.

62. Dr. Lally recognized the role that Genentech and Biogen intended for him was a sham, namely, a promoter of *Rituxan* off-label uses to treat RA under the guise of a disinterested medical educational instructor or peer skilled in the treatment of RA. In fact, Genentech and Biogen used these RA Roundtable dinners to promote *Rituxan*'s off-label use to treat RA and to disseminate data to generate off-label *Rituxan* use in treating RA. Genentech and Biogen were very successful in their off-label promotion as evidenced by the tremendous growth of *Rituxan* sales in the United States in the last several years, along with its correspondingly high percentage of off-label use to treat RA.

**E. The Illegal Kickbacks of Monies and Consideration
to Physicians Who, Under the Guise of Participating in
Regional Advisory Boards, Promoted Off-Label Uses of *Rituxan***

63. The next level in Genentech's and Biogen's scheme to promote off-label uses of *Rituxan*, involves the use of "Rituxan in Rheumatoid Arthritis Regional Advisory Board" meetings. Unlike the RA Roundtable promotional dinners held locally in the community of each "consulting" rheumatologist moderator, the Regional Advisory Board meetings were two day events held regionally at exclusive hotels in major cities throughout the United States. For example, the Regional Advisory Board meeting on March 25-26, 2004 was held at The Carlyle Hotel in New York City.

64. Genentech and Biogen again leveraged "consulting" rheumatologists under contract to promote off-label use of *Rituxan* to treat RA under the guise of acting as a "chair" for a Regional Advisory Board Meeting. Genentech and Biogen created stock agendas for Regional

Advisory Board meetings, and Genentech and Biogen did not allow the sham “chair” to make any additions, deletions, or edits to the packaged materials provided.

65. Genentech and Biogen marketing personnel also attended and presented at these meetings. Genentech and Biogen used these meetings to promote *Rituxan*’s off-label use to treat RA and to disseminate data to generate off-label *Rituxan* use in treating RA. Genentech and Biogen used the sham “chair” as a vehicle to present this information which included an unbalanced presentation of information regarding the inadequate responses of other RA therapies.

F. The Illegal Kickback of Monies and Consideration to Physicians Who, Under the Guise of Publishing Independent Articles and Case Studies, Promoted Off-Label Uses of *Rituxan*

66. As an additional prong to their illegal strategy, Genentech and Biogen identified and persuaded rheumatologists to participate in the publication of articles promoting *Rituxan*’s use in off-label treatments of RA. As part of his PEL job responsibilities, Relator McDermott worked with rheumatologists who had been identified as persons willing to work with Genentech staffers in the writing of such articles in exchange for the payment of money or other consideration. Genentech marketing staffers would select the subject of any such articles promoting *Rituxan*’s off-label use to treat RA.

67. Genentech staffers wrote the articles but Genentech and Biogen would list the “consulting” rheumatologists as the authors. Genentech and Biogen used the articles purportedly authored by rheumatologist peers to induce other physicians both to prescribe *Rituxan* for off-label treatment of RA and to recommend its use to others. Examples of physicians assigned to Relator McDermott for recruitment include Dr. Jonathan Kay, Boston, Massachusetts, Dr. Alna Kaell, Port Jefferson Station, N.Y., and Dr. Gregory Rihaceck, Old Bridge, N.J.

**G. Genentech and Biogen Trained Employees
To Avoid the Detection of Their Off-Label
Sales and Marketing Activities Regarding *Rituxan***

68. In order to implement their illegal scheme to market *Rituxan* for off-label uses, Genentech and Biogen trained their employees in methods of concealing and avoiding detection of their off-label sales and marketing activities. For example, upon reporting to Genentech management his knowledge of the existence of direct, in-office promotion and marketing of *Rituxan* for off-label treatment of RA by Genentech BioOncology sales representatives, Genentech management warned Relator McDermott to avoid creating any record of these discussions by fax, e-mail or voicemail. This advice to avoid creating any permanent record of Genentech's illegal promotion and marketing scheme for the off-label use of *Rituxan* in treating RA was consistent with Genentech's business practices with respect to PEL's, as alleged below.

69. Upon hiring, the job title Genentech assigned to Relator McDermott was "Professional Educational Liaison Rituxan RA," and Genentech printed that title on Relator McDermott's business cards and stationary which it provided to him. More than six months after his hiring, Genentech deleted the "Rituxan RA" language from Relator McDermott's business cards and stationary, thereafter identifying him instead only as a Genentech Professional Education Liaison. Relator McDermott understood that Genentech's Legal Department ordered the "Rituxan RA" deletion when it discovered that his real, but illegal, job responsibility was printed on Relator McDermott's business cards and stationary. Genentech made no substantive changes in Relator McDermott's job responsibilities or the techniques described previously, other than deleting this language from his business card and stationary so as to avoid the detection of PEL off-label sales and marketing activities regarding the use of *Rituxan* in treating RA.

70. In November, 2004, Relator McDermott was asked to attend a meeting at Genentech World Headquarters in South San Francisco, California hosted by Douglas Love, a member of Genentech's Legal Department. At that meeting, Genentech presenters cautioned Relator McDermott and other *Rituxan* RA PEL's to make sure that their business communications in promoting *Rituxan* for off-label treatment of RA did not adversely effect Genentech's position in any investigation or litigation.

71. Genentech presenters also counseled the PEL's to avoid communicating in writing unless necessary and to confer with the Legal Department before putting any sensitive material relating to their promotional work in writing. Genentech presenters cautioned the PEL's that if anything was required to be put into a permanent writing or e-mail, it must be written in such a way that it could be published in the *New York Times* without any negative impact on Genentech.

72. Genentech presenters also cautioned the PEL's that conduct in connection with the off-label promotion of *Rituxan* which they personally deemed to be unethical or immoral was not necessarily improper or unlawful, and that they should therefore avoid describing it as such.

73. During the meeting, Legal Department attorney Love characterized United States Government investigations of the pharmaceutical industry as nothing more than improper efforts to extort monies from pharmaceutical companies. The meeting ended with a reminder from Love for PEL's to comply with Genentech's record retention policy. Genentech never provided any such policy to Relator McDermott.

**Defendants Knew and Intended that their Unlawful,
Off-Label Promotion of *Rituxan* Would Result in the
Submission of Ineligible Claims for Reimbursement to the Government**

74. Because RA was not a “medically accepted indication” for the use of *Rituxan* nor listed in any of the applicable compendia during all times relevant to this Complaint, any use of *Rituxan* for the treatment of RA was not eligible for reimbursement pursuant to governmental medical reimbursement systems such as Medicare or Medicaid.

75. During all times relevant to this Complaint, Defendants Genentech and Biogen knew that the FDA had approved *Rituxan* in 1997 for the exclusive treatment of non-Hodgkin’s lymphoma.

76. During all times relevant to this Complaint, Defendants Genentech and Biogen knew that RA was not a “medically accepted indication” for the use of *Rituxan* nor listed in any of the applicable compendia.

77. Thus, during all times relevant to this Complaint, Defendants Genentech and Biogen knew that any use of *Rituxan* to treat RA would be an off-label use ineligible for reimbursement pursuant to governmental medical reimbursement systems such as Medicare or Medicaid.

78. During all times relevant to this Complaint, Defendants Genentech and Biogen charged thousands of dollars, at times over \$15,000, for one treatment of *Rituxan* for an RA patient.

79. Thus, during all times relevant to this Complaint, Defendants knew that *Rituxan* treatments would only be widely prescribed for treating RA if governmental medical reimbursement systems such as Medicare or Medicaid reimbursed claims for the use of *Rituxan* to treat RA, due to the high cost of *Rituxan* treatments.

80. As part of Relator McDermott’s training to promote *Rituxan* for the treatment of RA at Genentech, Defendant Genentech instructed Relator McDermott to counsel rheumatologists how

they should discuss with their Medicare patients afflicted with RA the financial ramifications of commencing *Rituxan* treatment.

81. Specifically, Defendant Genentech instructed Relator McDermott to counsel rheumatologists that the Medicare co-payments (20%) are higher than those of many private insurers and about the difficulties such patients might have making the co- payments because of the high cost of *Rituxan* per treatment compared to their prior medications.

82. Thus, during all times relevant to this Complaint, Defendants knew or intended that their extensive, off-label promotion of *Rituxan* for the treatment of RA would result in the submission of claims for reimbursement, pursuant to governmental medical reimbursement systems such as Medicare or Medicaid, for the off-label use of *Rituxan* to treat RA.

Defendants' Unlawful, Off-Label Promotion of *Rituxan* In Fact Caused the Submission of Ineligible Claims for Reimbursement to the Government

83. Annual U.S. sales exceeding \$1.8 billion for an expensive drug or biologic like *Rituxan* can occur only if a governmental medical reimbursement system such as Medicare or Medicaid reimburses claims for widespread use of the drug or biologic.

84. Over the five year period between 2000 and 2005, Defendant Genentech's and Biogen's annual sales of *Rituxan* increased from \$424 million to \$1.8 billion.

85. A significant amount of *Rituxan* sales, and the rapid growth in the sales volume of *Rituxan* in recent years, was a direct result of the off-label use of *Rituxan* to treat RA.

86. The reason Defendant Genentech and Biogen employed dedicated personnel just to respond to clinicians' inquiries regarding *Rituxan*'s off-label use to treat RA was the substantial volume of *Rituxan* sales for the treatment of RA.

87. Due to the high cost of *Rituxan*, the substantial volume of *Rituxan* sales to treat RA could occur only if a governmental medical reimbursement system such as Medicare or Medicaid reimbursed large numbers of claims for the off-label use of *Rituxan* to treat RA.

88. Defendant Genentech trained its sales representatives like Relator McDermott to counsel rheumatologists how they should discuss with their Medicare patients afflicted with RA the financial ramifications of commencing *Rituxan* treatment because such healthcare providers were submitting claims for reimbursement to governmental medical reimbursement systems such as Medicare or Medicaid for use of *Rituxan* to treat RA.

89. Defendant Genentech's and Biogen's unlawful promotion of the off-label use of *Rituxan* to treat RA caused a substantial number of rheumatologists to prescribe *Rituxan* for the off-label treatment of RA who would not have otherwise done so.

90. Consequently, Defendant Genentech's and Biogen's unlawful promotion of the off-label use of *Rituxan* to treat RA caused a substantial number of healthcare providers to submit claims for reimbursement to governmental medical reimbursement systems such as Medicare or Medicaid for use of *Rituxan* to treat RA which, but for Defendants' off-label promotion campaign, would not have otherwise done so.

**All Claims For Payment For *Rituxan* Used To Treat RA
During Relevant Times Were Necessarily False Or Fraudulent,
And Genentech And Biogen Knew That Such Claims Were False Or Fraudulent.**

91. Because treatment of RA, during all times relevant to this Complaint, was not a "medically accepted indication" for the use of *Rituxan*, the off-label use of *Rituxan* to treat RA was not eligible for reimbursement pursuant to governmental medical reimbursement systems such as Medicare or Medicaid.

92. Because every claim submitted for reimbursement pursuant to a governmental medical reimbursement system such as Medicare or Medicaid is paid only if the rendering healthcare provider has certified that the services rendered are eligible for reimbursement under federal law, every claim submitted to and paid by a governmental medical reimbursement system for reimbursement for the off-label use of *Rituxan* to treat RA was necessarily a false or fraudulent claim for payment, during all times relevant to this Complaint.

**Defendants' Multiyear, Nationwide Off-Label Promotion Campaign
Resulted In The Submission Of Massive Numbers Of False Or Fraudulent Claims
Submitted To The Government For Reimbursement Of *Rituxan* Treatments For RA**

93. The false or fraudulent claims that healthcare providers submitted to governmental medical reimbursement systems including Medicare and Medicaid for payment for prescriptions of *Rituxan* to treat RA are confidential patient medical records and may not be legally disclosed to third parties such as Relator McDermott.

94. Genentech and Biogen promoted the use of *Rituxan* for the treatment of RA on a nationwide basis.

95. During the eight year period that Genentech and Biogen illegally promoted the off-label use of *Rituxan*, there were approximately 3,200 practicing rheumatologists in the United States.

96. During that approximate eight year period, Genentech had approximately 50 representatives for the promotion of *Rituxan* for the treatment of RA scattered across the United States. The cost and expense of some of the Genentech employees involved in the promotion of *Rituxan* for RA was split by Genentech and Biogen.

97. As a result of the lengthy period during which Genentech and Biogen illegally promoted *Rituxan* for the treatment of RA and during which healthcare providers submitted the false or fraudulent claims; as a result of the massive number of such claims submitted throughout the

entire United States during that span of years; and as a result of the secret and confidential nature of the reimbursement claims the disclosure of which is prohibited by law, no one (including Defendants, the Government and Relator) knows which specific *Rituxan* reimbursement claims among the thousands submitted to the Government were false or fraudulent as alleged above, and it would be impossible for anyone to identify them without formal discovery and court assistance. The existence, submission and Government payment of numerous such false claims are a fact beyond doubt, however.

COUNT ONE

31 U.S.C. § 3729(a)(1):

Causing False or Fraudulent Claims for Payment to be Presented to the Government

98. Relator McDermott realleges and reincorporates paragraphs 1-4 and 8-97 of the Complaint as the initial paragraph of this Count I.

99. The False Claims Act, 31 U.S.C. § 3729 *et seq.*, the primary tool of the United States against fraud upon the Government, prohibits anyone from, among other things, causing a false or fraudulent claim for payment to be presented to the United States Government.

100. A significant number of patients who used *Rituxan* for off-label treatment of RA were persons whose prescriptions were paid for in whole or in part by federally funded medical reimbursement systems such as Medicare or Medicaid.

101. Defendants Genentech and Biogen knowingly caused healthcare providers to submit claims for payment to the U.S. Government which were false or fraudulent because they were for *Rituxan* treatments that were not eligible for reimbursement under federal law.

102. Defendant Genentech's and Biogen's illegal scheme caused the U.S. Government to pay such false or fraudulent claims.

103. Relator communicated the information upon which he bases his allegations as set forth herein to the United States Government on May 9, 2005, June 2, 2005, June 21, 2005 and July 25, 2005.

WHEREFORE, Relator Paul P. McDermott, prays for the entry of judgment against Defendants Genentech and Biogen and in favor of the United States of America in an amount to be proved at trial and then trebled, and for an award to Relator pursuant to 31 U.S.C. § 3730, together with all costs, expenses, attorneys' fees, interest and such further relief as is appropriate under the circumstances.

COUNT TWO

31 U.S.C. § 3729 (a)(3):
Conspiracy

104. Relator McDermott realleges and reincorporates paragraphs 1-4 and 8-103 of the Complaint as the initial paragraph of this Count II.

105. Defendants Genentech and Biogen agreed and conspired to defraud the U.S. Government by getting such false or fraudulent claims paid.

106. Defendant Genentech's and Biogen's illegal conspiracy caused the U.S. Government to pay such false or fraudulent claims.

WHEREFORE, Relator Paul P. McDermott, prays for the entry of judgment against Defendants Genentech and Biogen and in favor of the United States of America in an amount to be proved at trial and then trebled, and for an award to Relator pursuant to 31 U.S.C. § 3730, together with all costs, expenses, attorneys' fees, interest and such further relief as is appropriate under the circumstances.

COUNT THREE

31 U.S.C. 3730 (h):
Retaliatory Discharge

107. Relator McDermott realleges and reincorporates paragraphs 1-4 and 8-106 of the Complaint as the initial paragraph of this Count III.

108. The False Claims Act, 31 U.S.C. § 3729 *et seq.*, prohibits the discharge of an employee in retaliation for his lawful acts in furtherance of a False Claims Act action. In or about mid-January 2005, Relator McDermott reported to his supervisor, Genentech Associate Director Robert Rice, and advised him of his knowledge that Genentech BioOncology sales representatives were illegally engaging in the promotion of Rituxan for off-label treatment of RA during visits to rheumatology offices. Rice was based at Genentech World Headquarters in South San Francisco, California. McDermott questioned Rice what Genentech was going to do about it.

109. On or about February 1, 2005, during a meeting at the Genentech National Sales Meeting in Orlando, Florida, Relator McDermott met with Rice, reiterated his concerns that Genentech BioOncology sales representatives were illegally engaging in the promotion of Rituxan for off-label treatment of RA during visits to rheumatology offices, and questioned whether Genentech had done anything about it since his initial complaint several weeks earlier.

110. As a member of Defendant Genentech's management team, Rice had a responsibility to advise Genentech management of illegal sales or marketing activities including the off-label activities reported to him by Relator McDermott. Rice expressed no interest in taking any action to stop the illegal sales or marketing activities reported by Relator McDermott.

111. On February 2, 2005, during an evening social event at the Genentech National Sales Meeting hotel, Relator McDermott met with Genentech Vice President Martin Babler and

advised him of his knowledge that Genentech BioOncology sales representatives were engaging in the promotion of *Rituxan* for off-label treatment of RA during visits to rheumatologist offices. Babler, as Genentech's Vice President of Immunology Sales and Marketing, was responsible for *Rituxan* sales and marketing activities.

112. During the February 2, 2005 conversation, Babler indicated that he would be "taking care" of the situation reported by Relator McDermott. Babler warned Relator McDermott not to send any communication about promotional activities for *Rituxan* off-label treatments for RA to him by facsimile, e-mail or voicemail.

113. Three weeks later, on February 23, 2005, Relator McDermott spoke with Rice by telephone after McDermott missed a flight to Chicago where he was scheduled to meet with Rice to discuss collaboration plans. During the call, Relator McDermott again expressed his disappointment to Rice about his unwillingness to investigate the illegal off-label promotion activities previously brought to his attention. Rice advised Relator McDermott to find a different position at Genentech within sixty days.

114. On March 4, 2005, Relator McDermott participated in a telephone conference call with Genentech Senior Director Fred Logan and Genentech Senior Manager of Human Resources David Hooper. During the call, Relator McDermott was offered a separation agreement and a payment of \$20,900.00 which he declined. Relator McDermott advised that he was seeking a position with Genentech's Managed Care Group.

115. On April 29, 2005, at 9:00 p.m., Relator McDermott received by e-mail a letter from Robert Rice falsely stating that Relator McDermott had resigned effective immediately.

116. Genentech terminated Relator McDermott's health insurance coverage, and that of his wife and four young children, three hours after receipt of the e-mail.

117. That same night, Relator McDermott responded by e-mail to Rice and stated that he had not resigned contrary to Rice's false statement in his letter. Rice did not reply to Relator McDermott's response.

118. Prior to reporting his knowledge of illegal promotions of *Rituxan* off-label treatments of RA by Genentech sales representatives to Rice and asking him to investigate and stop such practices, Relator McDermott had received no indication from anyone of any dissatisfaction with his job performance.

119. As alleged above in paragraphs 27 through 34, Defendant Genentech knew that off-label promotion of *Rituxan* would result in the submission and payment of ineligible claims to governmental medical reimbursement systems such as Medicare or Medicaid for the off-label use.

120. Relator McDermott also knew based upon his experience in the pharmaceutical industry that off-label promotion of *Rituxan* would result in the submission and payment of ineligible claims to governmental medical reimbursement systems such as Medicare or Medicaid for the off-label use, which is a reason Relator McDermott persistently raised the issue with Genentech. McDermott's conduct was therefore both lawful and protected in furtherance of a False Claims Act action.

121. Genentech fired Relator McDermott in retaliation for his having raised, either explicitly or implicitly the issue of the submission and payment of ineligible claims to governmental medical reimbursement systems such as Medicare or Medicaid for the off-label use of *Rituxan* to treat RA.

122. Genentech's discharge of Relator McDermott violated 31 U.S.C. § 3730 (h).

COUNT FOUR

29 M.R.S.A. § 831

Whistleblowers' Protection Act

123. Plaintiff McDermott realleges and reincorporates all preceding paragraphs of the Complaint as the initial paragraph of this Count IV.

124. Plaintiff McDermott reasonably believed Genentech's promotion of Rituxan for off-label treatment of RA was unlawful, and he complained about it to his superiors at Genentech, including Rice and Babler.

125. Genentech terminated Plaintiff McDermott in retaliation for McDermott's complaints about Genentech's illegal promotion of Rituxan for off-label treatment of RA in violation of the WPA.

WHEREFORE, Relator Paul P. McDermott, prays for the entry of judgment against Defendant Genentech and in his favor all relief necessary to make Relator whole including, but not limited to, reinstatement with the same seniority status that Relator would have had but for the wrongful discharge, two times the amount of back pay, interest on the back pay, compensatory and punitive damages, compensation for all special damages sustained as a result of the wrongful discharge, litigation costs, reasonable attorneys' fees and such further relief as is appropriate under the circumstances.

DATED at Portland, Maine this 1st day of June, 2007.

UNITED STATES OF AMERICA
ex rel. PAUL P. McDERMOTT

By:

/s/ George A. Zelcs

George A. Zelcs
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Telephone: (312) 641-9750
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/s/ Joseph H. Groff III

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/s/ Stephen M. Tillery

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/s/ Myron M. Cherry

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Jacie C. Zolna
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/s/ Jeffrey Neil Young

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Facsimile: (207) 725-1090
E-mail: jyoung@me-law.com

CERTIFICATE OF SERVICE

I, Jeffrey Neil Young, hereby certify that on June 1, 2007, I electronically filed Plaintiff's Corrected Second Amended Complaint with the Clerk of the Court using the CM/ECF system which will send notification of such filing(s) to the following: counsel to Defendant Genentech, Inc., John W. Kecker, David J. Silbert, Jan Neilsen Little, and Ryan M. Kent, Kecker & Van Nest LLP, 710 Sansome Street, San Francisco, CA 94111-1704; John H. Rich, III and Jennifer H. Pincus, Perkins, Thompson, Hinckley, & Keddy, One Canal Plaza, P.O. Box 426 DTS, Portland, ME 04112; and Paul E. Kalb and Stephen C. Payne, Sidley Austin LLP, 1501 K Street, NW, Washington, DC 20005; counsel to Defendant Biogen-Idec, Inc., William J. Kayatta, Jr. and Mark E. Porada, Pierce, Atwood LLP, One Monument Square, Portland, ME 04101-1110; Anton Valukas, Chris Gair, and Stephanie A. Scharf, Jennifer & Block, One IBM Plaza, Chicago, IL 60611; and counsel to Interested Party U.S.A., Evan J. Roth, U.S. District Attorney's Office, District of Maine, 100 Middle Street Plaza, Portland, ME 04101.

/s/ Jeffrey Neil Young
Jeffrey Neil Young
McTeague, Higbee, Case, Cohen
Whitney & Toker, P.A.
Four Union Park
P.O. Box 5000
Topsham, ME 04086
(207) 725-5581
jyoung@me-law.com

M.H.R.C CHARGE OF DISCRIMINATION <small>This form is affected by the Privacy Act of 1974; See Privacy Act Statement before completing this form.</small>	AGENCY <input type="checkbox"/> FEPA	CHARGE NUMBER E05-0496
	<input type="checkbox"/> EEOC	

MAINE HUMAN RIGHTS COMMISSION

NAME (Indicate Mr., Ms., Mrs) Mr. Paul McDermott	HOME TELEPHONE (Include Area Code) (207) 838-4914	
STREET ADDRESS 69 Hardy Road	CITY, STATE AND ZIP CODE Falmouth, ME 04105	DATE OF BIRTH

NAMED IS THE EMPLOYER, LABOR ORGANIZATION, EMPLOYMENT AGENCY APPRENTICESHIP COMMITTEE, STATE OR LOCAL GOVERNMENT AGENCY WHO DISCRIMINATED AGAINST ME (If more than one, list below).

NAME Genentech Inc.	NUMBER OF EMPLOYEES, MEMBERS 7,000 +/-	TELEPHONE (Include Area Code) (650) 225-1000
STREET ADDRESS 1 DNA Way, San Francisco, CA 94080	CITY, STATE AND ZIP CODE	COUNTY

NAME	TELEPHONE NUMBER	
STREET ADDRESS	CITY, STATE AND ZIP CODE	COUNTY

CAUSE OF DISCRIMINATION BASED ON (Check appropriate box(es)) <input type="checkbox"/> RACE <input type="checkbox"/> COLOR <input type="checkbox"/> SEX <input type="checkbox"/> RELIGION <input type="checkbox"/> NATIONAL ORIGIN <input type="checkbox"/> RETALIATION <input type="checkbox"/> AGE <input type="checkbox"/> DISABILITY <input checked="" type="checkbox"/> WHISTLEBLOWER <input type="checkbox"/> OTHER (Specify)	DATE DISCRIMINATION TOOK PLACE EARLIEST(ADEA/EPA) LATEST(ALL) 4/29/2005
--	---

THE PARTICULARS ARE (If additional space is needed, attach extra sheet(s)):

1. I was hired by Genentech as a sales person with the job title "Professional Education Liaison Rituxan RA" commencing in April, 2004. "RA" is an abbreviation for rheumatoid arthritis. My business card included the full title.
 2. At all times relevant herein, my office was based in Falmouth, Maine.
 3. My job responsibilities as a Professional Education Liaison Rituxan RA included meeting with rheumatologists to attempt to persuade them to prescribe Rituxan for off-label use to treat rheumatoid arthritis.
 4. The United States Food & Drug Administration ("USFDA") has approved Rituxan solely for the treatment of non-Hodgkin's Lymphoma, a cancer of the immune system.
 5. The USFDA has not approved the use of Rituxan for any purpose other than for the treatment of non-Hodgkin's Lymphoma.
 6. Pursuant to 21 U.S.C. §331(d), it is illegal for a drug manufacturer to promote or market use of a prescription drug, including Rituxan for off-label purposes, including for the treatment of rheumatoid arthritis.
 7. Approximately six months after I was hired, my job title was changed to delete the reference to "Rituxan RA." My business card was changed to reflect this deletion. However, no substantive change was made in my job responsibilities. This change in title was done, upon information and belief, at the behest of Genentech's legal department.
- (continued on Page 2)

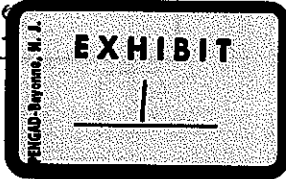
I also want the charge filed with the EEOC. I will advise the agencies if I change my address or telephone number and I will cooperate fully with them in the processing of my charge in accordance with their procedures.

NOTARY - (When necessary for State and Local Requirements)
Charles H. [Signature]
 I swear or affirm that I have read the above charge and that it is true to the best of my knowledge, information and belief.

I declare under penalty of perjury that the foregoing is true and correct.

Paul P. [Signature]
 Date 10-28-05 Charging Party (Signature)

SIGNATURE OF COMPLAINANT
Paul P. [Signature]
 SUBSCRIBED AND SWORN TO BEFORE ME THIS DATE (Day, month, and year) 28-Oct-2005



Paul McDermott v. Genentech Inc.

Charge of Discrimination

Page Two

8. In or about August 18, 2004, I attended a dinner at Morton's Restaurant in Boston, Massachusetts, the purpose of which was to promote the off-label use of Rituxan for treatment of rheumatoid arthritis under the guise of an educational event produced by an independent continuing medical education organization. In fact, upon information and belief, all of the material for the meeting was prepared by Genentech, and Biogen Idec Inc., which co-developed Rituxan, and their sales and marketing staffs.

9. In November 2004, I attended a meeting at Genentech's world headquarters in San Francisco, California, at which members of Genentech's legal department cautioned against putting anything in writing with regard to promotional work promoting Rituxan for off-label use.

10. On February 1, 2005, at a meeting of the Genentech national sales force in Orlando, Florida, I complained to Genentech Associate Director Robert Rice that Genentech sales representatives, including myself, were being required illegally to promote Rituxan for off-label treatment of rheumatoid arthritis during visits to offices of rheumatologists.

11. Although Robert Rice had a responsibility to advise Genentech management of the illegal sales or marketing activity about which I complained, Mr. Rice did not indicate that he would take any steps to do so.

12. The following day, on February 2, 2005, at a social event as part of the national meeting, I complained to Genentech Vice-President Martin Babler that Genentech sales representatives, including myself, were being required illegally to promote the use of Rituxan for off-label treatment of rheumatoid arthritis during visits to offices of rheumatologists. Mr. Babler responded that he would be "taking care" of the situation and warned me not to send any communication to him about the illegal promotional activities for Rituxan by facsimile, email, or voicemail.

13. On February 24, 2005, I met with Mr. Rice in Chicago, Illinois and again expressed concern about the illegal off-label promotional activities which I had spoken with him about three weeks earlier. Mr. Rice advised me that I should find a different position within Genentech within 60 days.

14. On March 4, 2005, eight days after I had repeated my concerns to Mr. Rice, during the course of a phone conversation with Genentech Senior Director Fred Logan and Genentech Senior Manager of Human Resources David Hooper, Genentech offered me a separation agreement including payment of \$20,900. I declined and replied that I was looking for a position with Genentech's Managed Care Group.

15. On April 29, 2005, I received by email a letter from Mr. Rice falsely claiming that I had resigned effective immediately. Three hours later my health insurance was discontinued.

16. Upon receipt of the email from Mr. Rice, I responded by email that his assertion that I had resigned was false. I never received any response from Mr. Rice anyone else from Genentech.

17. I believe that I performed my job at all times in a satisfactory fashion.

18. Genentech terminated my employment on April 29, 2005 in retaliation for my complaints about the illegal sales and promotion of Rituxan for off-label use to treat rheumatoid arthritis in violation, *inter alia*, of Maine's Whistleblower Protection Act.

MAINE HUMAN RIGHTS COMMISSION

Patricia E. Ryan
Executive Director

51 State House Station
Augusta ME 04333-0051

Tel. (207) 624-6050
FAX (207) 624-6063
TTY 1-888-577-6690

John P. Gause
Commission Counsel

www.maine.gov/mhrc

April 19, 2007

Paul P. McDermott
69 Hardy Road
Falmouth, ME 04105

RE: STATEMENT OF FINDING –
E05-0496, McDermott v. GENENTECH, INC.

Dear Mr. McDermott:

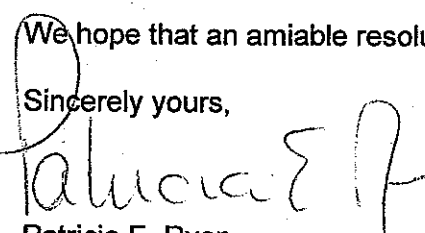
The Commission has conducted an investigation of the above complaint of discrimination and has determined that there are reasonable grounds to believe that unlawful discrimination has occurred. The decision was based on information received during the course of investigation of the complaint including the Investigator's Report, any written submissions, and any oral presentations made.

Pursuant to §4612(3) of the Maine Human Rights Act, the Commission will endeavor to resolve the reasonable grounds determination. A proposed Conciliation Agreement will be forthcoming from the Commission's Compliance Officer. If no settlement is reached, the Maine Human Rights Act authorizes the filing of a civil action in Superior Court.

It is important to note that all information relating to the conciliation process is confidential without the written consent of all parties. The Maine Human Rights Act provides that you may pursue this matter on your own. (See the attached section of the Maine Human Rights Act and Procedural Regulations).

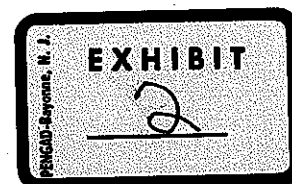
We hope that an amiable resolution can be achieved.

Sincerely yours,


Patricia E. Ryan
Executive Director

Enc.

cc: Jeffrey N. Young, Esq.



STATEMENT OF FINDING
REASONABLE GROUNDS DECISIONS

§4621. CIVIL ACTION

Within the time limited above, a person who has been subject to unlawful discrimination may file a civil action in the Superior Court against the person or persons who committed the unlawful discrimination.

2.09 PROCEDURE AFTER FAILURE OF CONCILIATION

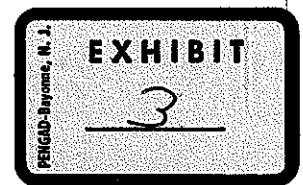
- C. When the Commission's legal counsel is unable to file expeditiously such a civil action, the Commission shall so notify the complainant of his/her right to file a civil action pursuant to 5 M.R.S.A. Chapter 337, subchapter VI, §4621, and make available a referral list of attorneys who have indicated an interest in undertaking such litigation. Upon his or her retainer by such a complainant, the Commission shall furnish the cooperating attorney, upon request, with access to the investigatory case file and will provide such technical assistance as possible under the existing circumstances. Referral under this sub-section does not terminate the Commission's jurisdiction of the proceeding.

MAINE HUMAN RIGHTS COMMISSION

**51 STATE HOUSE STATION
AUGUSTA, ME 04333-0051
PHONE: (207) 624-6050
FAX: (207) 624-6063**

FAX TRANSMITTAL

DATE: 4/25/2007
TO: Jeff Young, Esq.
FAX #: 725-1090
FROM: John Gause
OF PAGES INCL. COVER: 2
SUBJECT: E05 - 0496, McDermott v. Genentech, Inc





51 STATE HOUSE STATION
AUGUSTA, ME 04333-0051
www.maine.gov/mhrc

Executive Director
PATRICIA E. RYAN

Commission Counsel
JOHN P. GAUSE

April 25, 2007

Jeffrey Neil Young, Esq.
McTeague Higbee et al
PO Box 5000
Topsham ME 04086-5000

John Rich III, Esq.
Perkins Thompson
PO Box 426
Portland ME 04412-0426

RE: E05-0496: *McDermott v. Genentech*

Dear Mr. Young and Mr. Rich:

Please be advised that the Commission considers conciliation efforts in the above entitled matter to have failed. The case has been referred to attorney Young for appropriate action.

I am sorry that we were unable to resolve these matters to the satisfaction of all parties.

Sincerely yours,

Francis Davis, p.s.r.

Francis Davis
Compliance Officer

cc: Paul McDermott
John P. Gause, Esq.