

SEP 1 2004

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

v.

RODNEY E. DAUSCH
AND THOMAS O. OESTERLING,

Defendants.

1:04CV1772
C.A. No.

JUDGE MATIA

MAG. JUDGE PERELMAN

COMPLAINT

Plaintiff United States Securities and Exchange Commission ("Commission")
alleges as follows:

1. In August 2000, Defendants, Thomas O. Oesterling ("Oesterling"), formerly Gliatech Inc.'s ("Gliatech") Chief Executive Officer ("CEO"), President and Chairman of the Board of Directors, and Rodney Dausch ("Dausch"), formerly Gliatech's Chief Financial Officer ("CFO"), (collectively, "Defendants") failed to disclose material information in Gliatech's Form 10-Q for the period ended June 30, 2000 filed with the Commission. Specifically, Oesterling and Dausch failed to disclose known data integrity

problems with clinical studies relating to Gliatech's primary product, Adcon-L Anti-Adhesion Barrier Gel ("Adcon-L"). These data integrity problems played a significant role in the collapse of merger discussions between Gliatech and Guilford Pharmaceuticals, Inc., and in the resulting decline in the price of Gliatech's stock.

2. Dausch and Oesterling, directly and indirectly, have engaged and, unless enjoined, will continue to engage in acts, practices, and courses of business that violate Section 10(b) of the Securities and Exchange Act of 1934 ("Exchange Act") [15 U.S.C. §§ 78j(b)] and Rule 10b-5 [17 C.F.R. §§ 240.10b-5] thereunder, and, have aided and abetted, and unless enjoined, will continue to aid and abet acts, practices and courses of business that constitute violations of Section 13(a) of the Exchange Act [15 U.S.C. §§ 78m(a)] and Rules 12b-20 and 13a-13 [17 C.F.R. §§ 240.12b-20, 240.13a-13] thereunder.

3. The Commission brings this action to enjoin such acts, practices, and courses of business pursuant to Sections 20(e), 21(d), and 21(e) of the Exchange Act. [15 U.S.C. §§ 78t(a), 78u(d), and 78u(e)].

JURISDICTION AND VENUE

4. The Court has jurisdiction over this action pursuant to Sections 21(e) and 27 of the Exchange Act [15 U.S.C. §§ 78u(e), 78aa] and 28 U.S.C. § 1331. Venue is proper in this Court pursuant to Section 27 of the Exchange Act [15 U.S.C. § 78aa].

5. The acts, practices and courses of business constituting the violations alleged herein have occurred within the jurisdiction of the United States District Court for the Northern District of Ohio, Eastern Division and elsewhere.

6. Defendants, directly and indirectly, made use of the means and instrumentalities of interstate commerce and of the mails in connection with the acts, practices, and courses of business alleged herein.

7. Defendants will, unless enjoined, continue to engage in the acts, practices and courses of business set forth in this complaint, and acts, practices and courses of business of similar purport and object.

DEFENDANTS

8. On information and belief, Dausch, age 59, is a resident of Westchester, Pennsylvania. Dausch is licensed as a Certified Public Accountant. During the relevant time period, Dausch was Gliatech's Vice President of Finance and CFO. Dausch was employed at Gliatech from 1995 until August 2000.

9. Oesterling, age 66, is a resident of Chagrin Falls, Ohio. During the relevant time period, Oesterling was Gliatech's Chairman, President and CEO. Oesterling was employed at Gliatech from 1989 until the fall of 2000. Oesterling is now retired.

GLIATECH

10. At all relevant times, Gliatech was a Delaware corporation. Gliatech's main offices were located in Beachwood, Ohio. Gliatech was primarily a research and development company of products used to improve surgical outcomes and to treat neurological disorders. At all relevant times, Gliatech's common stock was traded on the National Association of Securities Dealers' Automated Quotation System.

11. Pursuant to Section 13(a) of the Exchange Act, and the rules and regulations thereunder, Gliatech filed periodic and other informational reports, including Forms 10-K and Forms 10-Q, with the Commission.

ADCON-L

12. Adcon-L Adhesion Barrier Gel ("Adcon-L") is a gel-like substance, which is applied to the patient's incision site during back surgery. The purpose of Adcon-L is to reduce scarring following back surgery. In December 1996, Gliatech submitted its application to distribute Adcon-L in the United States to the FDA. After the FDA's approval in May 1998, Adcon-L became Gliatech's only product to be marketed in the United States and its major source of revenue. However, as an express condition of its approval, the FDA required Gliatech to submit a completed study of clinical trials of Adcon-L ("U.S. Adcon-L Study") to the FDA.

Integrity Problems With the U.S. Adcon-L Study

13. In March 1999, Gliatech submitted the U.S. Adcon-L Study. At the time it submitted the study, Gliatech did not disclose that it had substituted data from another study into the U.S. Adcon-L Study.

14. In the summer of 2000, the FDA conducted an investigation of the U.S. Adcon-L Study. During that investigation, the FDA raised serious concerns about the integrity of the U.S. Adcon-L Study. The FDA's concerns arose from Gliatech's failure to disclose the data substitution and that Good Clinical Practices ("GCP") had not been followed in the connection with the U.S. Adcon-L Study.

Oesterling and Dausch's Knowledge of Adcon-L's Integrity Problems

15. During the course of the FDA's investigation in the summer of 2000, Oesterling and Dausch learned of the serious nature of Adcon-L's integrity problems. On or around June 30, 2000, a Gliatech consultant told Oesterling that the FDA had determined that Good Clinical Practices had not been followed in the connection with the U.S. Adcon-L Study. The consultant also explained to Oesterling that these GCP violations compromised the data in the study.

16. On July 10, 2000, Gliatech's Director of Clinical Research alerted Dausch that the FDA had just accused one of Gliatech's employees, a project assistant on the U.S. Adcon-L Study ("project assistant"), of falsifying study data. Later that day, Dausch told Oesterling that the FDA had concerns about how the U.S. Adcon-L Study was conducted and told him about the accusations against the project assistant.

17. During the following two weeks, Oesterling spoke to the project assistant on various occasions about the events that occurred with the data substitution and GCP violations. In these conversations, Oesterling learned of irregularities such as recording the data in pencil and erasures. He also learned that the project manager of the U.S. Adcon-L Study had directed the statisticians to substitute data for the clinical data in the Adcon-L Study.

18. Dausch also knew about Adcon-L's data integrity problems. As co-chair of Gliatech's committee that was established to oversee the FDA's investigation of the U.S. Adcon-L Study ("oversight committee"), Dausch developed an understanding of the issues being raised by the FDA. The oversight committee monitored the FDA's investigation and in some instances they analyzed data that the FDA was examining. For

example, one committee member prepared written analyses of the effect of scar score changes and erasures. Dausch was copied on both of these documents.

19. Dausch's July 13, 2000 notes that he took at an oversight committee meeting indicate that he knew about Adcon-L's problems. His nine pages of handwritten notes show that as of July 13, 2000, he knew critical evidence concerning Gliatech's GCP violations. Dausch's notes also show that he knew about the data substitution. In fact, his notes show that he knew that Gliatech might be forced to scrap the U.S. Adcon-L Study data and "Do a whole new read."

20. On or around July 26, 2000, Dausch received a timeline depicting critical events relating to the problems with the U.S. Adcon-L Study.

21. In August 2000, Gliatech and Guilford were in the final stages of the merger negotiations. On August 11, 2000, during discussions with the Guilford's CEO, Dausch and another Gliatech employee first informed the CEO of the merger company of the integrity problems related to the U.S. Adcon-L Study.

Dausch and Osterling's Failure To Disclose Integrity Problems In Form 10-Q

22. On August 14, 2000, Gliatech issued its Form 10-Q for the period ended June 30, 2000 ("Form 10-Q"). The Form 10-Q did not disclose the integrity problems with the U.S. Adcon-L Study.

23. Dausch signed the Form 10-Q and both Osterling and Dausch participated in its preparation.

COUNT I

Violations of Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 [17 C.F.R. § 240.10b-5] thereunder

24. Paragraphs 1 through 23 above are realleged and incorporated by reference.

25. Defendants, in connection with the purchase and sale of Gliatech's securities, directly and indirectly, by the use of the means and instrumentalities of interstate commerce, of the mails, or of the facilities of a national securities exchange: employed devices, schemes and artifices to defraud; made untrue statements of material fact and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and engaged in acts, practices and courses of business which operated or would operate as a fraud and deceit upon purchasers and sellers and prospective purchasers and sellers of such securities.

26. Defendants knew or were reckless in not knowing of the facts and circumstances described in paragraphs 1 through 23 above.

27. By reason of the activities described in paragraphs 1 through 23 above, Defendants violated Section 10(b) of the Exchange Act [15 U.S.C. § 78j(b)] and Rule 10b-5 thereunder [17 C.F.R. § 240.10b-5].

COUNT II

Aiding and Abetting Violations of Section 13(a) of the Exchange Act [15 U.S.C. § 78t(a)] and Rules 12b-20, 13a-1, and 13a-13 [17 C.F.R. §§ 240.12b-20, 240.13a-1, and 240.13a-13] thereunder

28. Paragraphs 1 through 23 above are realleged and incorporated by reference.

29. As set forth more fully above in paragraphs 1 through 23 above, Gliatech violated Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20 and 13a-13 [17 C.F.R. §§ 240.12b-20, 240.13a-13] promulgated thereunder.

30. By their conduct described in paragraphs 1 through 23 above, Defendants knowingly and substantially assisted Gliatech's violations of Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20, and 13a-13 [17 C.F.R. §§ 240.12b-20, 240.13a-1, and 240.13a-13] promulgated thereunder, and thereby aided and abetted Gliatech in such violations.

RELIEF REQUESTED

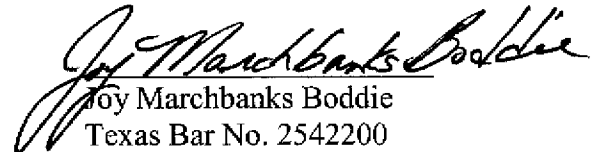
WHEREFORE, the Commission requests that this Court enter a judgment:

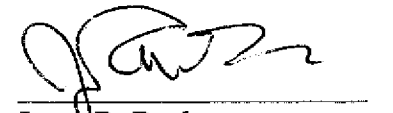
- A. finding that Defendants committed the violations alleged above;
- B. permanently enjoining Defendants from violating Sections 10(b) and Rules 10b-5 thereunder;
- C. permanently enjoining Defendants from aiding and abetting violations of Section 13(a) of the Exchange Act and Rules 12b-20, and 13a-13 thereunder;
- D. barring Oesterling from serving as an officer or director of any issuer required to file reports with the Commission under Sections 12(b), 12(g), or 15(d) of the Exchange Act [15 U.S.C. §§ 78l(b), 78l(g), and 78o(d)], pursuant to Section 21(d)(2) of the Exchange Act [15 U.S.C. § 78u(d)(2)];

- E. ordering Defendants to each pay an appropriate civil monetary penalty pursuant to Section 21(d)(3) of the Exchange Act [15 U.S.C. § 78u(d)(3)];
- F. retaining jurisdiction over this action to implement and carry out the terms of all orders and decrees that may be entered; and
- G. granting such other and additional relief as this Court deems just and proper.

Dated: August 31, 2004

Respectfully submitted,


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Civil Cover Sheet

The JS-44 Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Please refer to the instructions on page 2.

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1. (a) PLAINTIFFS

SECURITIES AND EXCHANGE COMMISSION

DEFENDANTS

RODNEY M. DAUSCH
THOMAS O. OESTERLING(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF _____
(EXCEPT IN U.S. PLAINTIFF CASES)COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT GEAUGA

(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND

(c) ATTORNEY'S NAME (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)

JOY M. BODDIE, JARETT B. DECKER
SECURITIES AND EXCHANGE COMMISSION, 175 W.
JACKSON BOULEVARD, SUITE 900
CHICAGO, IL 60604-2008 (312) 353-7300

ATTORNEYS (IF KNOWN)

JUDGE MATIA

II. BASIS OF JURISDICTION (PLACE A check IN ONE BOX ONLY)

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question (U.S. Gov't Not a Party)
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (FOR DIVERSITY CASES ONLY)

(PLACE A CHECK IN ONE BOX FOR PLAINTIFF AND IN ONE BOX FOR DEFENDANT)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of this State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business in this State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business in another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. ORIGIN

(PLACE A CHECK IN ONE BOX ONLY)

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from another district (specify) _____
- ☐ 6 Multidistrict Litigation
- ☐ 7 Appeal to District Judge from Magistrate Judgment

V. NATURE OF SUIT

Please click on the appropriate nature of suit

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Overpayment Recovery & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted Student Loans (Excluding Veterans) 153 Recovery of Overpayment of Vof's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Prod. Liability	PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel, Slander 330 Federal Employer's Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle 355 Motor Vehicle Product Liability 360 Other Pers. Injury	610 Agriculture 620 Other Food & Drug 625 Drug Related Seizure of Property 21 USC § 881 630 Liquor Laws 640 Railroad & Truck 650 Airline Regulations 660 Occupational Safety/Health 690 Other	422 Appeal 28 USC § 156 423 Withdrawal 28 USC § 157 PROPERTY RIGHTS 820 Copyrights 830 Patent 840 Trademark SOCIAL SECURITY 861 HIA (1395f) 862 Black Lung (823) 863 DIWC/DIWW (405(g)) 864 SSD Title XVI 865 RSI (405(g)) FEDERAL TAX SUITS 870 Taxes (U.S. Plaintiff or Def.) 871 IRS-Third Party 28 USC § 7609	400 State Reapportionment 410 Antitrust 430 Banks & Banking 450 Commercial/ICC Refs., etc. 460 Deportation 470 Racketeer Influenced and Corrupt Organizations (Civil RICO) 810 Selective Service 850 Securities/Commodities/Exchange 875 Customer Challenge 12 USC § 3410 891 Agricultural Acts 892 Economic Stabilization Act 893 Environmental Matters 894 Energy Allocation Act 895 Freedom of Information Act 900 Appeal of Fee Determination Under Equal Access to Justice Act 950 Constitutionality of State Statute 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS		
210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectmt 240 Torts to Land 245 Tort Product Liability 280 All Other Real Prop.	441 Voting 442 Employment 443 Housing/Accommodations 444 Welfare 440 Other Civil Rights	510 Motions to Vacate Sentence HABEAS CORPUS: 530 General 535 Death Penalty 540 Mandamus & Other 550 Civil Rights 555 Prison Conditions		

VI. CAUSE OF ACTION (Cite the U.S. civil statute under which you are filing and write brief statement of cause. Do not cite jurisdictional statute unless this is a diversity action) Securities Fraud [15 U.S.C. 78j(b) and reporting violations, 78t(a)]

VII. REQUESTED IN COMPLAINT:

☐ Check if this is a Fed. R. Civ. P. 23 Class Action

DEMAND: \$

CHECK YES ONLY IF DEMANDED IN COMPLAINT:
JURY DEMAND: ☐ YES ☐ NO

VIII. RELATED CASE(S)

IF ANY (SEE INSTRUCTIONS)

JUDGE

POLSTER

DOCKET NUMBER

1:04CV1613

8/31/04

Date

FOR CLERK'S OFFICE USE ONLY

RECEIPT NO.

AMOUNT \$

JUDGE

MAGISTRATE JUDGE

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO**

I. Civil Categories: (Please check one category only).

1. ☒ General Civil
2. ☐ Administrative Review/Social Security
3. ☐ Habeas Corpus Death Penalty

*If under Title 28, §2255, name the SENTENCING JUDGE: _____

CASE NUMBER: _____

II.

RELATED OR REFILED CASES. See LR 3.1 which provides in pertinent part: "If an action is filed or removed to this Court and assigned to a District Judge after which it is discontinued, dismissed or remanded to a State court, and subsequently refiled, it shall be assigned to the same Judge who received the initial case assignment without regard for the place of holding court in which the case was refiled. Counsel or a party without counsel shall be responsible for bringing such cases to the attention of the Court by responding to the questions included on the Civil Cover Sheet."

This action is ☒ **RELATED** to another **PENDING** civil case. This action is ☐ **REFILED** pursuant to LR 3.1.

If applicable, please indicate on page 1 in section VIII, the name of the Judge and case number.

III.

In accordance with Local Civil Rule 3.8, actions involving counties in the Eastern Division shall be filed at any of the divisional offices therein. Actions involving counties in the Western Division shall be filed at the Toledo office. For the purpose of determining the proper division, and for statistical reasons, the following information is requested.

ANSWER ONE PARAGRAPH ONLY. ANSWER PARAGRAPHS 1 THRU 3 IN ORDER. UPON FINDING WHICH PARAGRAPH APPLIES TO YOUR CASE, ANSWER IT AND STOP.

(1) **Resident defendant.** If the defendant resides in a county within this district, please set forth the name of such county

COUNTY: Geauga

Corporation For the purpose of answering the above, a corporation is deemed to be a resident of that county in which it has its principal place of business in that district.

(2) **Non-Resident defendant.** If no defendant is a resident of a county in this district, please set forth the county wherein the cause of action arose or the event complained of occurred.

COUNTY:

(3) **Other Cases.** If no defendant is a resident of this district, or if the defendant is a corporation not having a principle place of business within the district, and the cause of action arose or the event complained of occurred outside this district, please set forth the county of the plaintiff's residence.

COUNTY:

IV.

The Counties in the Northern District of Ohio are divided into divisions as shown below. After the county is determined in Section III, please check the appropriate division.

EASTERN DIVISION

- ☐ AKRON
☒ CLEVELAND
☐ YOUNGSTOWN

(Counties: Carroll, Holmes, Portage, Stark, Summit, Tuscarawas and Wayne)
(Counties: Ashland, Ashtabula, Crawford, Cuyahoga, Geauga, Lake,
Lorain, Medina and Richland)
(Counties: Columbiana, Mahoning and Trumbull)

WESTERN DIVISION

- ☐ TOLEDO

(Counties: Allen, Auglaize, Defiance, Erie, Fulton, Hancock, Hardin, Henry,
Huron, Lucas, Marion, Mercer, Ottawa, Paulding, Putnam, Sandusky, Seneca
VanWert, Williams, Wood and Wyandot)