

MAGISTRATE JUDGE DENLOW

JUDGE MANNING

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JUDGE MANNING

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CLERK U.S. DISTRICT COURT

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

2878 090

THOMAS SOUZA, On Behalf of Plaintiff and
All Others Similarly Situated,

Plaintiff,

vs.

NORTHFIELD LABORATORIES INC., AND
STEVEN A. GOULD,

Defendants.

Civil Action No.

JURY TRIAL DEMANDED

**CLASS ACTION COMPLAINT FOR
VIOLATIONS OF FEDERAL SECURITIES LAWS**

Plaintiff, individually and on behalf of all other persons similarly situated, by plaintiff's undersigned attorneys, for plaintiff's complaint against defendants, alleges the following based upon personal knowledge as to plaintiff and plaintiff's own acts, and upon information and belief as to all other matters, based on, *inter alia*, the investigation conducted by and through plaintiff's attorneys, which included, amongst other things, a review of the defendants' press releases, Securities and Exchange Commission ("SEC") filings by Northfield Laboratories, Inc. ("Northfield" or the "Company") and media reports about the Company. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE CASE

1. This is a securities class action on behalf of all persons and entities who purchased or otherwise acquired Northfield securities between February 20, 2004 and February 21, 2006, inclusive (the "Class Period"), seeking to pursue remedies for violations of the federal securities laws against the Company and certain of its officers.

JURISDICTION AND VENUE

2. The claims asserted arise under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act") (15 U.S.C. §§ 78j(b) and t(a)) and Rule 10b-5 (17 C.F.R. § 240.10b-5) thereunder, and §§ 11, 12(a)(2) and 15 of the Securities Act of 1933 (the "Securities Act") (15 U.S.C. §§ 77k, l(a)(2) and o). Jurisdiction is conferred by § 27 of the Exchange Act (15 U.S.C. § 78aa), § 22(a) of the Securities Act (15 U.S.C. § 77v(a)) and 28 U.S.C. § 1331.

3. Venue is proper in this District pursuant to § 27 of the Exchange Act, and § 22 of the Securities Act, as Northfield and/or the Individual Defendants conduct business in this district and the wrongful conduct giving rise to the violations of law complained of herein, including the preparation and dissemination to the investing public of false and misleading information, took place in this District.

4. In connection with the acts and conduct alleged herein, defendants, directly and indirectly, used the means and instrumentalities of interstate commerce, including the United States mails and the facilities of the national securities exchanges.

PARTIES

5. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased shares of Northfield stock at artificially inflated prices during the Class Period as described in the attached certification and was damaged thereby.

6. Defendant Northfield, a development stage company, engages in the research, development, testing, manufacture, marketing, and distribution of hemoglobin-based blood substitute products. It primarily develops PolyHeme, an oxygen-carrying blood substitute for the treatment of urgent life-threatening blood loss in trauma and resultant surgical settings. The Company's PolyHeme blood substitute is currently the subject of a Phase III clinical trial. The Company's corporate offices are located at 1560 Sherman Avenue, Suite 1000, Evanston, IL 60201-4800.

7. Defendant Steven A. Gould ("Gould") was at all relevant times hereto Chairman, Chief Executive Officer ("CEO") of Northfield. Defendant Gould, by virtue of his high-level position with the Company and committee memberships, and his knowledge and experience as a physician and co-founder of the Company, directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company and its business, operations, growth, financial statements and financial condition, including all concealed adverse information and reports of studies and data comprising the Company's clinical development program of the development of PolyHeme, as alleged herein. As Chairman and CEO, Gould prepared, reviewed and signed the Company's Registration Statements, in connection with the Company's public offerings of \$92 million worth of common stock in February 2004 and February 2005, as well as in connection with the Company's financing

activities totaling \$24.8 million in May and August of 2004. Defendant Gould was involved in drafting, producing, reviewing and/or disseminating the materially false and misleading press releases, statements and information alleged herein, knew or recklessly disregarded that materially false and misleading statements were being issued regarding the Company, and approved or ratified these statements, in violation of the federal securities laws.

DEFENDANTS' FRAUDULENT SCHEME AND COURSE OF CONDUCT

8. Defendants are liable for: (a) making false statements, *or* (b) failing to disclose adverse facts known to him about Northfield. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Northfield publicly traded securities was a success, as it: (a) deceived the investing public regarding Northfield's prospects and business; (b) facilitated sales of \$92 million worth of the Company's stock at artificially inflated prices; (c) facilitated financing activities totaling over \$24.8 million (d) artificially inflated the price of Northfield's publicly traded securities; and (e) caused plaintiff and other members of the Class to purchase Northfield's publicly traded securities at inflated prices.

OVERVIEW OF THE FRAUD

9. Northfield's sole business has been and is the development of PolyHeme, a blood substitute. Blood substitutes may reduce the risk of viral infections, while eliminating blood typing and matching prior to administration. Despite these potential advantages, the development of blood substitutes has proven expensive and difficult, with no blood substitutes having received marketing clearance from regulators. Studies involving HemAssist, another promising experimental blood substitute, were halted when it became clear that the use of the substitute was associated with a highly significant and alarming increase death rate in trauma patients.

10. Nevertheless, the pressing need for blood substitutes for use in combat and other high risk situations has continued to drive research efforts. In October 2002, a paper by defendant Gould and his colleagues was published in the Journal of The American College Of

Surgeons.¹ The paper referred to PolyHeme as “a universally compatible, immediately available, disease-free, oxygen-carrying resuscitative fluid being developed as a red cell substitute for use in urgent blood loss.” In its discussion of a study of 171 patients receiving rapid infusion of PolyHeme under a protocol designed to simulate the unavailability of red cells and the progressive fall in RBC [Hb] in bleeding patients, defendant Gould and his cohorts concluded:

PolyHeme *increases survival* at life-threatening RBC [Hb] by maintaining total [Hb] in the absence of red cell transfusion. PolyHeme *should be useful in the early treatment of urgent blood loss and resolve the dilemma of unavailability of red cells.*

11. While Defendant Gould and the Company published its *highly promising results for increased survival rates* under their protocol simulating the treatment of rapid blood loss with PolyHeme, defendants have never published the results of their earlier Phase III studies, detailing the alarming adverse events and *substantially increased mortality rates* found in that study.

12. Finally, on February 22, 2006, The Wall Street Journal revealed that 10 of 81 patients in these earlier PolyHeme studies had heart attacks, as compared with zero of 71 who received regular blood transfusions. While such a stark difference in serious adverse events would often be fatal for a drug or medical device under study, *these highly alarming and adverse results remained unpublished and unknown to the investment community.* On the news of February 22, 2006, the price of the Company’s stock tumbled, losing \$0.59 or 4.8%, from its closing price of \$12.23 on February 21, 2006, to close at \$11.64 on February 22, 2006, on heavy volume of over 4.1 million shares, nearly ten times normal.

13. During the Class Period, defendants concealed the fact that:

(a) 10 of 81 patients in an earlier PolyHeme study in surgery patients had heart attacks, compared with zero of 71 who got blood.

¹ Gould S.A. et al., The life-sustaining capacity of human polymerized hemoglobin when red cells might be unavailable; J. Am. Coll. Surg. 2002 Oct.; 195(4):445-52.

(b) the Company did not know why the heart attacks had occurred in the earlier trials;

(c) that entire communities were now subject to the undisclosed risks resulting from the Company's concealment and lack of knowledge regarding the outcome of the earlier trials;

(d) the earlier adverse clinical results had been withheld from prospective patients for the Company's latest clinical trials; and

(e) the Company had exploited "a breakdown in dialogue within HHS," one that served to conceal the full risks, benefits and nature of the Company's latest PolyHeme studies.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS

MADE DURING THE CLASS PERIOD

14. On February 19, 2004, defendants issued a press release entitled, "Northfield Laboratories Announces Investors Exercise Over-Allotment Option." The press release stated in part:

EVANSTON, Ill., Feb. 19 /PRNewswire-FirstCall/ -- Northfield Laboratories Inc. announced today that investors in its recent registered direct offering have exercised their option to purchase an additional 237,008 shares of common stock, for gross proceeds to Northfield totaling \$1,374,646. Including this option exercise, gross proceeds of the recent offering total \$16.4 million to date. Investors in the offering have the right to purchase up to an additional 409,483 shares of Northfield common stock before April 28, 2004. The offering was made from a shelf registration statement that became effective July 3, 2003.

SG Cowen Securities Corporation acted as placement agent for this transaction.

About Northfield Laboratories

Northfield Laboratories Inc. is the leader in developing an oxygen-carrying blood substitute, PolyHeme(R), for the treatment of urgent, large volume blood loss in trauma and resultant surgical settings. PolyHeme(R) is a solution of chemically modified human hemoglobin. In clinical trials to date, PolyHeme(R) has been administered in rapid, massive infusions to restore lost blood volume

and hemoglobin levels. PolyHeme(R) requires no cross matching. It is therefore compatible with all blood types. It has a shelf life of over 12 months.

15. On April 14, 2004, October 12, 2004, January 10, 2005, April 11, 2005, August 15, 2005 and January 9, 2006, defendants issued SEC Forms 10-Q. Each document contained a substantially identical text and discussion on the ongoing nature of the PolyHeme clinical trial and the lack of any recommendations from the Data Monitoring Committee for the modification of any aspect of the trial *based on available safety data*, under the heading, "ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS." As taken from the filing of January 9, 2006, defendants stated in pertinent part:

We are currently enrolling patients in a pivotal Phase III trial in which our PolyHeme(R) hemoglobin-based oxygen-carrying resuscitative fluid is being used for the first time in the U.S. to treat severely injured patients in hemorrhagic shock before they reach the hospital. Under this protocol, treatment with PolyHeme begins at the scene of the injury or in the ambulance and continues during transport and the initial 12-hour post-injury period in the hospital. Since blood is not presently carried in ambulances, the use of PolyHeme in this setting has the potential to improve survival and address a critical, unmet medical need.

As of December 31, 2005, 28 clinical sites in the United States were enrolling patients in our pivotal Phase III trial and four other sites had received final Institutional Review Board, or IRB, approval and were preparing to begin patient enrollment. Each of the sites participating in the trial is designated as a Level I trauma center, indicating its capacity to treat the most severely injured trauma patients. We anticipate a total of 30 or more clinical sites across the United States will eventually participate in the trial. The trial has an expected enrollment of 720 patients.

As part of our trial protocol, an Independent Data Monitoring Committee, or IDMC, is responsible for periodically evaluating the safety data from the trial and making recommendations relating to the continuation or modification of the trial protocol to minimize any identified risks to patients. The trial protocol includes four planned evaluations by the IDMC that occur after 60, 120, 250 and 500 patients have been enrolled and monitored for a 30 day follow up period. All four reviews have occurred and at the recommendation of the IDMC the trial continues without modification. The IDMC continues to receive and assess all cumulative safety data on the patients enrolled for the reviews, focusing on mortality and serious adverse events. We receive a recommendation from the IDMC after each review, but we will not have access to the trial data reviewed by the IDMC until the trial is completed and the database has been cleaned and locked by our contract research organization.

As of December 31, 2005, approximately 580 patients had been enrolled in the study. Our current goal is to complete the patient enrollment phase early in calendar year 2006. Our ability to achieve this goal will depend, in part, on the number of clinical sites participating in our trial and the ability of these sites to enroll patients at the projected rates.

The progress of our pivotal Phase III trial and the timing and outcome of the Food and Drug Administration, or FDA, review process are subject to significant risks and uncertainties, many of which are outside of our control.

We urge you to review the "Risk Factors" section in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission for a discussion of certain of these risks and uncertainties.

Since Northfield's incorporation in 1985, we have devoted substantially all of our efforts and resources to the research, development and clinical testing of our potential product, PolyHeme. We have incurred operating losses during each year of our operations since inception and expect to incur substantial additional operating losses for the next several years. From Northfield's inception through November 30, 2005, we have incurred operating losses totaling \$157,411,000.

We will be required to complete our pivotal Phase III trial and obtain FDA regulatory approval before PolyHeme can be sold commercially. The FDA regulatory process is subject to significant risks and uncertainties, and we therefore cannot at this time reasonably estimate the timing of any future revenues from the commercial sale of PolyHeme. The costs incurred by Northfield to date and during each period presented below in connection with our development of PolyHeme are described in the Statements of Operations in our financial statements.

Our success will depend on several factors, including our ability to obtain FDA regulatory approval of PolyHeme and our manufacturing facilities, obtain sufficient quantities of human red blood cells to manufacture PolyHeme in commercial quantities, manufacture and distribute PolyHeme in a cost-effective manner, enforce our patent positions and raise sufficient capital to fund these activities. We have experienced significant delays in the development and clinical testing of PolyHeme. We cannot ensure that we will be able to achieve these goals or that we will be able to realize product revenues or profitability on a sustained basis or at all.

16. Defendants' statements as indicated and referenced in ¶¶14-15 above, were false and misleading. Each and every one of the indicated and referenced statements served to actively conceal and falsely represent the highly adverse nature of the safety data determined from all of the PolyHeme clinical trials to date. Defendants were aware or in conscious and reckless disregard of the fact that data from their earlier "ANH study" had shown that as many 10 patients had heart attacks during their treatment with PolyHeme, resulting in at least 2 deaths, while not one of the patients who were administered blood experienced were similarly impacted.

17. At all times during the Class Period, defendants were aware or in conscious and reckless disregard that the investment community, clinicians involved with the ongoing PolyHeme trials and patients who were being treated with the blood substitute were wholly uninformed of the risks associated with its use, *including the dramatically increased rates of heart attacks and deaths as compared with patients who were given blood transfusions.*

THE TRUTH IS REVEALED

18. Finally, on February 22, 2006, the Wall Street Journal provided investors with shocking details of the truth regarding the Company's concealment of significant and alarming adverse events and deaths in the Company's previous PolyHeme study, as well as the undisclosed risks facing prospective patients in studies currently underway. The news article entitled, "Red Flags - Amid Alarm Bells, A Blood Substitute Keeps Pumping - Ten in Trial Have Heart Attacks, But Data Aren't Published; FDA Allows a New Study Doctors' Pleas Are Ignored," stated in part:

Several years ago a clinical trial of a blood substitute called PolyHeme finished with worrisome results. Ten of 81 patients who received the fake blood suffered a heart attack within seven days, and two of those died. None of the 71 patients in the trial who received real blood were found to have had a heart attack.

PolyHeme's maker, Northfield Laboratories Inc., quietly shut down the trial and didn't publicly disclose the results, which are described in internal documents viewed by The Wall Street Journal. It decided the heart attacks might have been due to doctor inexperience in using PolyHeme, not a problem with the product itself.

Now Northfield is in the middle of a new trial. A Food and Drug Administration official, Jay Epstein, calls the earlier data "alarming" but not sufficient to stop Northfield from trying out its product on hundreds of trauma patients.

The FDA is allowing Northfield to test its blood substitute without the consent of the trauma patients, who often are unconscious. In lieu of patient consent, the 31 medical centers testing the product are required to carry out community-awareness campaigns about the trials. Several hospitals have told community meetings that previous trials showed PolyHeme to be safe, failing to mention the 10 heart attacks in their printed materials.

Some veteran doctors are concerned about the push by Northfield, of Evanston, Ill., to test its product without publicly disclosing earlier results. Ronald M. Fairman, chief of vascular surgery at the Hospital of the University of Pennsylvania, says he repeatedly urged the company to publish the data but got nowhere. "Even now, it remains frustrating the multicenter results were not disclosed," he says.

Northfield's chief executive, Steven A. Gould, argues the heart attacks could well have been caused by doctors pumping too much total fluid -- PolyHeme plus real blood -- into patients. He says PolyHeme could help many people, such as those in an ambulance who don't have access to human blood. "Our experience suggests the risk-benefit balance is in the patient's favor," Dr. Gould says.

In a statement, Northfield denies it "resisted publication" but says: "We did not allocate resources to publication. In retrospect, reporting the full study results earlier would have been better."

Northfield says any American who doesn't wish to participate in the current PolyHeme trial should ask the company for a blue plastic wristband that would alert paramedics. Those who fail to get a wristband and find themselves in a hospital trauma unit "can withdraw from the study, without prejudice, at any time," the company says.

Northfield has raised \$194 million in stock offerings since going public on the Nasdaq Stock Market in 1994. Its market value stands at \$334 million on hopes that PolyHeme, its sole product, could be the first blood substitute approved by the FDA. Results of the new study are expected this year.

Scientists have been hunting for a safe, workable blood substitute for more than half a century. Unlike donated human blood, artificial blood may reduce the risk of hepatitis or HIV infection. It eliminates the need to match blood types of donor and recipient, and has a far longer shelf life without refrigeration.

One use for artificial blood is in the military. Blood needs to be refrigerated and usually can't be carried into combat. It goes bad in about 42 days, whereas PolyHeme lasts a year or more. Soldiers who would otherwise bleed to death on the battlefield might be saved if a medic could quickly infuse them with an oxygen-carrying blood substitute.

But companies seeking this lifesaver have often met with disappointment. Baxter International Inc. halted a U.S. study of its blood substitute HemAssist in 1998, because 24 of 52 trauma patients, or 46%, given HemAssist died compared with only eight of 46, or 17%, who received standard therapy. Study doctors said the product may have dangerously raised blood pressure. Shortly before HemAssist failed, Baxter spent \$190 million to buy another company with a blood substitute. It ultimately abandoned that product, too, after throwing a total of \$500 million into its blood-substitute ventures.

Today there are several companies remaining in the blood-substitute race, but Northfield is the only one known to be in final-stage clinical trials.

Northfield was founded in 1985. Among its founders was former Navy surgeon Gerald S. Moss, later dean of the University of Illinois at Chicago

College of Medicine. He had worked on a blood substitute beginning in 1969 under a contract with the Army and Navy. Later he worked with Dr. Gould, a surgeon, and the two were among those who started the company.

The making of PolyHeme begins with outdated donor blood. A protein called hemoglobin in red blood cells delivers oxygen throughout the body. Northfield bursts open red cells in giant metal vats, freeing the hemoglobin molecules inside.

Hemoglobin molecules are known to be dangerous if they aren't held within red blood cells. The molecules tend to seep into the walls of blood vessels and cause inflammation. Most relevant to heart attacks, they can constrict blood vessels and cause clotting. Northfield chemically links one hemoglobin molecule to another in a process called polymerization. Dr. Gould says this removes hemoglobin's toxicity.

John R. Hess, a University of Maryland research doctor, is skeptical. He once headed the Army's blood-substitute program but shut it down in 1996 after concluding that all the blood substitutes he evaluated were toxic. With hemoglobin, Dr. Hess says, "the lining of the blood-vessel wall becomes inflamed....There's no reason the modification should change this."

Northfield has voiced optimism for years. In May 1997, a company news release said, "PolyHeme is in the home stretch with market introduction planned for sometime during 1999." The company's then-chief executive, Richard DeWoskin, said, "We have advanced to the point that the question of science is now being replaced with the question of size and scope of the commercial market for our product."

At the time, Northfield was starting what was to be its pivotal trial. Patients were randomly assigned to a group receiving PolyHeme or a control group receiving real blood. This type of study is the gold standard in medicine. The patients in the trial were undergoing surgery to repair aneurysms, or ballooned sections, in their aortas. They gave their consent before participating.

After the Baxter product was implicated in deaths in March 1998, the FDA ordered Northfield's study enrollment target expanded to 600 patients from the original 240. Northfield remained upbeat. An August 1999 news release spoke of PolyHeme's "excellent safety profile." A news release in April 2000 said the study was "producing very important results" but was taking a long time to enroll enough patients. Then in the second half of 2001, Northfield abruptly shut down the study, explaining in a Securities and Exchange Commission filing that it was taking too long to complete.

In August 2001, Northfield tried a long-odds maneuver: It asked the FDA to approve PolyHeme based on earlier research on hospital trauma patients. In that research, PolyHeme wasn't compared with a control group receiving standard therapy. Instead, Northfield compared the results with other hospitals' historical experience with patients who needed blood but didn't get any. These patients were Jehovah's Witnesses who declined blood for religious reasons. In November 2001, the FDA refused to consider the application, citing concern about the validity of the comparison, according to a Northfield SEC filing.

Critical Question

The sudden halt to the big randomized PolyHeme trial left unanswered a critical question: What were the results? Doctors who had taken part were curious. In an arrangement that doctors often reject today, Northfield restricted access to the full data and individual doctors knew only what happened to their own patients.

At the University of Pennsylvania, Dr. Fairman says he and a colleague, Albert Cheung, repeatedly called Northfield's Dr. Gould. "We said, 'Let's sit down and write up the data,' " Dr. Fairman recalls. "He wouldn't do it." Dr. Cheung proposed a meeting in Philadelphia of doctors at the 21 hospitals that had taken part in the study. He says Dr. Gould agreed to the meeting, then canceled it at the last minute.

T.J. Gan, a Duke University anesthesiologist involved in the study, says he called Northfield three years ago to ask if results had been published. He says Dr. Gould told him, "Someone's working on it." Dr. Gan says, "Regardless of whatever the problem, you publish it and outline the results." In its statement, Northfield says company officials don't recall the specifics of any discussion with Dr. Cheung about a meeting or the conversation with Dr. Gan.

Dr. Gould says he did inform the FDA of the aneurysm trial's results. The company now says it plans to make public a medical abstract of the study in April.

Besides the heart attacks and deaths in those taking PolyHeme, the trial suggested the product was linked with other serious adverse events such as heart rhythm aberrations and pneumonia. These events occurred in 54% of the PolyHeme patients versus 28% in the control group, according to Northfield's internal documents. The higher rate of heart attacks and serious events was considered statistically significant, meaning there is minimal likelihood they happened by chance. Overall, eight PolyHeme patients died versus four on conventional therapy, a difference that wasn't found to be statistically significant.

Such a stark difference in serious adverse events would often be fatal for a drug or medical device under study. Still, Northfield persevered.

Dr. Gould says the company doesn't believe PolyHeme caused the heart attacks. Before surgery, patients had their own blood drawn for possible use during the operation. Dr. Gould says several hospitals gave patients both PolyHeme and real blood. Together, he says, the amount of fluid was too much. "It can't be determined," he says, whether the heart attacks were due to the "capability and experience" of doctors "or to the product."

William D. Hoffman, chief of the cardiac-surgery intensive-care unit at Massachusetts General Hospital in Boston, says blood substitutes made with hemoglobin as a starting point, a class that includes PolyHeme, are associated with heart attacks and strokes. "It is self-serving and potentially misleading to associate harmful effects with something other than the test drug," says Dr. Hoffman, who used to work for another artificial-blood company but left after a dispute with executives there.

The FDA's Dr. Epstein, who is director of the agency's blood-products office, sides with Dr. Gould, calling Northfield's theory a plausible one. "Of course it's alarming there were excess deaths in the treatment group," he says.

"We are highly mindful of the adverse events." But, he goes on, "the adverse-event profile in the aneurysm trial, while significant, was not a show-stopper." The FDA's review suggested that "volume overload" rather than "any intrinsic toxicity of the product" was responsible for the cardiac events, he says.

As a result, Northfield was able to embark on a big new trial -- this time in trauma patients such as victims of shootings or car accidents. It started signing up trauma centers in December 2003 and as of early this year about 600 people had taken part. Half get PolyHeme and the other half get saline solution plus real blood. The study measures the death rate at 30 days. Northfield's hope is that PolyHeme will be found equivalent to -- or at least not provably worse than -- the standard therapy. As of late last year, an independent data monitoring board hadn't found any statistical differences between the two groups large enough to warrant halting the study.

Dr. Gould says Northfield typically pays hospitals around \$10,000 a patient to participate. Northfield agreed to pay \$336,000 to the University of Texas Health Science Center at Houston and \$132,468 to the University of Kentucky Medical Center, hospital records show. The hospitals say the money merely covers costs in collecting the data. "This is not a profit-making endeavor -- it is a scientific one," says University of Kentucky surgeon Andrew C. Bernard. Others participating include the Mayo Clinic, Duke University and Lehigh Valley Hospital in Allentown, Pa.

In the trauma study, patients are in hemorrhagic shock, meaning they are bleeding so profusely that their blood pressure plummets. The typical patient can't offer the informed consent that normally is required for clinical trials. A 1996 FDA rule says it is acceptable to give trauma patients experimental treatments without their knowledge. Without the rule, the agency says, trials would be impossible and society wouldn't benefit from advances in trauma care.

Playing Down Risks

In place of individual consent, the FDA has required Northfield and the hospitals participating in the trauma trial to hold public meetings at churches, city halls and the like in their communities. Materials used at the meetings and filed to the FDA often played down the risks of PolyHeme.

The Lehigh Valley Hospital materials for local meetings said, "Past studies have shown that PolyHeme...has not caused organ damage." Materials from the Brooke Army Medical Center near San Antonio for meetings last July were even more categorical: "In clinical trials to date, PolyHeme has demonstrated no clinically relevant adverse effects. Up to now, PolyHeme has not caused any clinically bad problems."

"Aneurysm-surgery patients are vastly different from trauma patients," said Col. John Holcomb, a trauma doctor at Brooke. "I know that there are no safety issues." A doctor at Lehigh didn't return a phone call seeking comment.

Northfield did tell trauma doctors about the heart attacks in the earlier study but did so confidentially and with an explanation that it didn't believe PolyHeme was responsible, according to company documents and interviews with doctors. The University of Kentucky's Dr. Bernard says there is a limit on what

the public can be told about the earlier trial results because "everything in the study is confidential."

Early last year, Keith Berman, a Pasadena, Calif., medical-products consultant who has studied blood substitutes, urged the FDA to make the earlier trial's results public. Last year, the agency required Northfield to mention on its Web site "serious cardiovascular adverse experiences" with PolyHeme. Five of the 31 hospitals in the trauma study followed suit, but well after many trauma patients had been treated.

Because Northfield needs only about 120 more people to complete its study, any individual's chance of being enrolled is low. However, those who are still worried can get the blue plastic wristband from the company to signal that they refuse to take part.

While Northfield says PolyHeme could be useful in rural ambulances, battlefields and other settings where real blood is out of reach for hours, it hasn't conducted a large-scale test focusing solely on that notion. It says assembling patients for such a trial would be too difficult and time-consuming. "We all recognize that doing the [trauma] trial in an urban setting was not ideal, but this was the only way to get the trial done," says a Northfield spokeswoman.

19. Finally, investors learned the shocking truth about the Company's concealment adverse events occurring in its earlier clinical trials from the investment community, as well as clinicians and patients participating in the Company's latest clinical studies. On the news of February 21, 2006, the price of the Company's stock tumbled, losing \$0.59 or 4.8%, from its closing price of \$12.23 on February 21, 2006, to close at \$11.64 on February 22, 2006, on heavy volume of over 4.1 million shares, nearly ten times normal.

20. The almost 4.8% decline in Northfield's stock price on February 22, 2006, at the end of the Class Period, was a direct result of the nature and extent of defendants' suddenly being revealed to investors and the market. The shocking disclosure and magnitude of Northfield's stock price decline negates any inference that the loss suffered by plaintiff and other Class members was caused by changed market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the defendants' conduct.

21. During the same period in which Northfield's stock price fell almost 4.8% on February 22, 2006, as a result of defendants' fraud being revealed, the Standard & Poor's 500 securities index was flat. The economic loss, i.e., damages, suffered by plaintiff and other

members of the Class was a direct result of defendants' fraudulent scheme to artificially inflate Northfield's stock price and the subsequent significant decline in the value of Northfield's stock when defendants' prior misrepresentations and other fraudulent conduct was revealed.

22. During the Class Period, defendants concealed the fact that:

(a) 10 of 81 patients in an earlier PolyHeme study in surgery patients had heart attacks, compared with zero of 71 who got blood.

(b) the Company did not know why the heart attacks had occurred in the earlier trials;

(c) that entire communities were now subject to the undisclosed risks resulting from the Company's concealment and lack of knowledge regarding the outcome of the earlier trials;

(d) the earlier adverse clinical results had been withheld from prospective patients for the Company's latest clinical trials; and

(e) the Company had exploited "a breakdown in dialogue within HHS," one that served to conceal the full risks, benefits and nature of the Company's latest PolyHeme studies.

APPLICABILITY OF PRESUMPTION OF RELIANCE

FRAUD-ON-THE-MARKET DOCTRINE

23. At all relevant times, the market for Northfield securities was an efficient market for the following reasons, among others:

(a) Northfield's stock met the requirements for listing, and was listed and actively traded on the Nasdaq Exchange, a highly efficient and automated market;

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

(c) Northfield regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases

on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services.

24. As a result of the foregoing, the market for Northfield's securities promptly digested current information regarding Northfield from all publicly available sources and reflected such information in Northfield's stock price. Under these circumstances, all persons who purchased or acquired Northfield's securities during the Class Period suffered similar injury through their purchase of the aforementioned securities at artificially inflated prices and a presumption of reliance applies.

NO SAFE HARBOR

25. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Northfield who knew that those statements were false when made.

CLASS ACTION ALLEGATIONS

26. Plaintiffs bring this action as a class action under Federal Rule of Civil Procedure 23, on behalf of all persons who purchased or acquired the securities of Northfield between February 20, 2004, and February 21, 2006, (the "Class Period"). Excluded from the Class are

defendants, any entity in which a defendant has or had a controlling interest and members of defendants' families.

27. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. During the Class Period, Northfield had more than 26 million shares of stock outstanding, owned by thousands of persons. There were also \$92 million worth of Northfield common stock sold pursuant to the Company's registration statements and prospectus in February 2004 and registration statements and prospectus in February 2005, as well as all prior registration statements/prospectus of the same. Record owners and other class members may be identified from records maintained by Northfield and/or its transfer agents and may be notified of the pendency of the action by mail, using a form customarily used in securities class actions.

28. There is a well-defined community of interest in the questions of law and fact involved in this case. There are no conflicts between plaintiffs and the Class, and plaintiff's claims are typical of those of other Class members. The questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include the following:

(a) Whether §§10(b) and 20(a) of the Exchange Act were violated by Northfield and the Individual Defendants;

(b) Whether Defendants misrepresented material facts;

(c) Whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether Defendants knew or should have known that their statements were false and misleading;

(e) Whether the prices of Northfield securities were artificially inflated during the Class Period; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

29. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all class members is impracticable. Furthermore, the damages suffered by individual Class members may be relatively small, and the expense and burden of litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action. Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel competent and experienced in class and securities litigation.

COUNT I

For Violation of §10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

30. Plaintiff incorporates ¶¶1-29 by reference.

31. During the Class Period, all of the defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were materially false and misleading in that they contained material misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

32. All of the defendants violated §10(b) of the Exchange Act and Rule 10b-5 in that they:

- (a) Employed devices, schemes, and artifices to defraud;
- (b) Made untrue statements of material facts or omitted to state material facts necessary in order to make statements made, in light of the circumstances under which they were made, not misleading; or

(c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiffs and others similarly situated in connection with their purchases or acquisitions of Northfield securities during the Class Period.

33. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Northfield securities during the Class Period. Plaintiff and the Class would not have purchased, acquired or exchanged Northfield securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

34. As a direct and proximate result of defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases and acquisitions of Northfield securities during the Class Period.

COUNT II

For Violation of §20(a) of the Exchange Act Against Defendant Gould

35. Plaintiff incorporates ¶¶1-34 by reference.

36. Defendant Gould prepared, or was responsible for preparing, the Company's press releases and SEC filings. By reason of his positions as an officer of Northfield he had the power and authority to cause Northfield to engage in the wrongful conduct complained of herein. Northfield controlled Defendant Gould and all of the Company's employees. By reason of such wrongful conduct, Defendant Gould and Northfield are liable pursuant to §20(a) of the Exchange Act.

PRAYER FOR RELIEF

37. WHEREFORE, plaintiff on behalf of himself and the Class, pray for judgment as follows:

A. Declaring this action to be a class action properly maintained pursuant to Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding plaintiff and other members of the Class compensatory damages;

C. Awarding plaintiff and members of the Class pre-judgment and post-judgment interest, as well as reasonable attorneys' fees, expert witness fees, and other costs and disbursements; and

D. Awarding plaintiff and other members of the Class such other relief as this Court may deem just and proper under the circumstances.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: April 17, 2006



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Counsel for Plaintiff

**PLAINTIFF CERTIFICATION
PURSUANT TO FEDERAL SECURITIES LAWS**

Thomas H. Souza, ("Plaintiff"), declares, as to the claims asserted under the federal securities laws, that:

1. Plaintiff has reviewed the Complaint and retains Scott & Scott, LLC and such co-counsel it deems appropriate to associate with to pursue such action on a contingent fee basis.
2. Plaintiff did not purchase the security that is the subject of this action at the direction of Plaintiff's counsel, or in order to participate in any private action.
3. Plaintiff is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.
4. Plaintiff's transaction(s) in the **Northfield Laboratories, Inc. (NFLD)** security that is the subject of this action during the Class Period is/are as follows:

<u>No of Shares</u>	<u>Buy/Sell</u>	<u>Date</u>	<u>Price Per Share</u>
15	B	10/25/05	12.13
15	S	3/21/06	9.30

5. During the three years prior to the date of this Certification, Plaintiff has never served, nor sought to serve, as a class representative in a federal securities fraud case.
6. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the Court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 11th day of April, 2006, at Falmouth, MA (city, state).

Your Printed Name: Thomas H. Souza

Signature: 

