

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

DONALD PATRIZZO, Individually and On Behalf of All Others Similarly Situated,)	
)	CIVIL ACTION NO.
Plaintiff,)	
)	
vs.)	CLASS ACTION COMPLAINT
)	
NORTHFIELD LABORATORIES INC. AND STEVEN A. GOULD)	
)	<u>JURY TRIAL DEMANDED</u>
Defendants.)	

Plaintiff, Donald Patrizzo, (“Plaintiff”), alleges the following based upon the investigation of Plaintiff’s counsel, which included, among other things, a review of the defendants’ public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Northfield Laboratories, Inc. (“Northfield” or the “Company”) securities analysts’ reports and advisories about the Company, and information readily obtainable on the Internet.

NATURE OF THE ACTION AND OVERVIEW

1. This is a federal class action on behalf of purchasers of the publicly traded securities of Northfield between February 20, 2004 and February 21, 2006 (the “Class Period”), seeking to pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Northfield is a development stage company that was founded in 1985. Since its inception, Northfield devoted all of its efforts and resources to the development and clinical testing of its sole product, PolyHeme, blood substitute.

3. Products, like PolyHeme, are in demand. In fact, scientists have been searching for a safe, workable blood substitute for more than 50 years. The pursuit was motivated by the fact that artificial blood helps reduce the risk of hepatitis or HIV infection, eliminates the need to match blood types of donor and recipient, and has a far longer shelf life without refrigeration. .

4. In the late 1990s, Northfield conducted a Phase III clinical trial of PolyHeme known as the Acute Normovolemic Hemodilution clinical trial (the “ANH clinical trial”). The ANH trial had 600 patients that were randomly assigned to a group receiving PolyHeme and a control group receiving real blood.

5. During the ANH clinical trial, Northfield described PolyHeme Group as having an “excellent safety profile” and also stated that this study was “producing very important results.” Then in the second half of 2001, Northfield abruptly shut down the study, explaining in a SEC filing, that it was taking too long to complete. To date, Northfield has not published the full results of the study.

6. On February 22, 2006, a story in *The Wall Street Journal* revealed why Northfield never revealed the results of the study. According to the article entitled “Amid Alarm Bells, A blood Substitute Keeps Pumping,” 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.

7. The lack of disclosure allowed Northfield to continue touting PolyHeme's safety. In fact, Northfield was able to begin its current phase III trial. At this time, Northfield is testing its blood substitute without the consent on trauma patients, who often are unconscious. In lieu of patient consent, the 31 medical centers testing the product were 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.

8. The markets reaction to the disclosure was swift. On February 22, 2006, shares of Northfield fell to \$11.64 per share, down from \$12.23 per share. By February 24, 2006, shares of Northfield declined to \$10.54 per share.

9. On March 10, 2006, *The Wall Street Journal* revealed that the federal Office for Human Research Protections has expressed "urgent ethical concerns" to the Food and Drug Administration about the conduct of Northfield's study. In reaction to this development, shares of Northfield fell \$1.15 per share, or 10.31 percent, to close, on March 10, 2006, at \$10.00 per share

10. On March 16, 2006, Northfield announced that it had received an informal request to voluntarily provide certain information to the staff of the SEC's Midwest Regional Office relating to the clinical development of its PolyHeme product for elective surgery. On this news, Northfield's stock declined another \$0.33 per share to close at \$9.65 per share.

11. On March 20, 2006, *The Wall Street Journal* revealed that three medical-ethics professors, in an open letter to research boards at hospitals where a blood substitute is being studied without patients' consent, said the research "fails to meet ethical and regulatory standards." In

reaction to this latest development, Northfield's stock shed another \$0.37 per share, to close on March 20, 2006, at \$9.57 per share.

JURISDICTION AND VENUE

12. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. §240.10b-5).

13. This Court has jurisdiction over the subject matter of this action pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. § 1331.

14. Venue is proper in this Judicial District pursuant to §27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b). Many of the acts and transactions alleged herein occurred in substantial part in this Judicial District. Additionally, the Company maintained an executive office in this Judicial District during the Class Period.

15. In connection with the acts, conduct and other wrongs alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

16. Plaintiff, Donald Patrizzo, as set forth in the accompanying certification, incorporated by reference herein, purchased Northfield securities at artificially inflated prices during the Class Period and has been damaged thereby.

17. Defendant Northfield is a Delaware corporation with its principal executive offices located at 1560 Sherman Avenue, Suite 1000, Evanston, Illinois 60201.

18. Defendant Steven A. Gould (“Gould”) is a founding member of Northfield’s scientific team and had served as the Chairman and Chief Executive Officer of Northfield since July 2002. From July 1993 to July 2002, defendant Gould served as President and a director of Northfield. Prior to that time, defendant Gould served as a Consultant and Principal Investigator for Northfield’s clinical trials.

19. Defendant Gould is referred to hereinafter as the Individual Defendant. The Individual Defendant, because of his position with the Company, possessed the power and authority to control the contents of Northfield’s quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. The defendant was provided with copies of the Company’s reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of his positions and access to material non-public information available to them, the defendant knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations which were being made were then materially false and misleading. The Individual Defendant is liable for the false statements pleaded herein, as those statements were each “group-published” information, the result of the collective actions of the Individual Defendant.

SUBSTANTIVE ALLEGATIONS

Background

20. 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 PolyHeme is in Phase III clinical trial.

**Materially False And Misleading
Statements Issued During The Class Period**

21. On August 16, 2004, Northfield filed its annual report with the SEC on Form 10-K. The Company's Form 10-K was signed by Defendant Gould and included the following discussion of the Company's only product PolyHeme:

Northfield Laboratories Inc. is a leader in the development of a safe and effective alternative to transfused blood for use in the treatment of acute blood loss. Our PolyHeme blood substitute product is a solution of chemically modified hemoglobin derived from human blood. PolyHeme simultaneously restores lost blood volume and hemoglobin levels and is designed for rapid, massive infusion. PolyHeme requires no cross-matching, and is therefore immediately available and compatible with all blood types. PolyHeme has an extended shelf life compared to blood. We believe PolyHeme is the only blood substitute in development that has been well tolerated when infused in patients in clinical trials in sufficient quantities for the treatment of urgent, large volume blood loss in trauma and surgical settings, with a particular focus on situations where donated blood is not immediately available.

As part of our trial protocol, an independent data monitoring committee, or IDMC, consisting of independent medical and biostatistical experts 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 protocol includes four planned evaluations by the IDMC that occur after predefined numbers of patients have been enrolled and monitored for a 30-day follow up period. The IDMC will focus its initial review on mortality and serious adverse events and will review all safety data as the trial continues. We will 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.

In July 2004, the IDMC recommended that our Pivotal Phase III Prehospital Trial continue without modification based on the committee's initial review of blinded data on mortality and serious adverse events from the first predefined evaluation of the patients enrolled in the trial.

We have previously conducted Phase II and Phase III clinical trials of PolyHeme at multiple locations in the United States in trauma and emergency surgical applications, in elective surgical procedures, and in situations of compassionate use in life-threatening situations. The observations in these trials have indicated the potential clinical utility of PolyHeme in the treatment of urgent blood loss and life-threatening hemoglobin levels. In a trial of hospitalized trauma patients, an analysis of the data revealed that PolyHeme significantly improved survival compared to historical control patients who did not receive blood. Our trials have involved high dosage and rapid infusion of PolyHeme in situations that are life-threatening and where massive blood loss routinely occurs. We believe that this application addresses the largest world-wide clinical need for this type of product and represents the greatest potential market opportunity. We believe we are the only company in our field with an oxygen-carrying blood substitute that has been rapidly infused at doses as high as 20 units (1,000 grams) or twice the blood volume of the average adult.

22. On August 15, 2005, Northfield filed its annual report with the SEC on Form 10-K.

The Company's Form 10-K was signed by Defendant Gould and included the following description of the Company's sole product PolyHeme:

We are pursuing a unique regulatory strategy in order to seek Food and Drug Administration, or FDA, approval of PolyHeme. We are conducting the first-ever pivotal Phase III trial in the United States in which a hemoglobin-based oxygen carrier is being used to treat severely injured and bleeding patients, beginning at the scene of injury and continuing during transport to the hospital and the early period of hospitalization. Our current trial is based on our experience in prior clinical trials documenting the potential life-sustaining capability of PolyHeme when given in rapid, massive infusions to critically injured patients in the hospital. Some of these patients

received up to 20 units of PolyHeme, equivalent to twice their normal blood volume. Because of the life-sustaining potential of PolyHeme, our trial is being conducted under a federal regulation, 21 CFR 50.24, that permits certain types of emergency research using an exception from the requirement for prospective informed consent by individual patients.

We have also taken advantage of Special Protocol Assessment, or SPA, one of the features of the Food and Drug Modernization Act of 1997. Our SPA reflects an agreement with FDA on our trial design, the trial endpoints and the broad concepts for clinical indications those endpoints would support in an application for product approval by FDA. The assessment of efficacy in our trial will be based on the data on patient survival at 30 days. A key feature of our SPA is the agreement on dual primary endpoints of superiority and non-inferiority between the treatment and control groups. Either of these endpoints may be used to provide evidence of efficacy.

As part of our trial protocol, an Independent Data Monitoring Committee, or IDMC, consisting of independent medical and biostatistical experts is responsible for periodically evaluating the safety data from the trial and making recommendations relating to continuation or modification of the trial protocol to minimize any identified risks to patients. The IDMC has completed the first three of four planned reviews of data from the initial 60, 120 and 250 patients enrolled in the trial and has recommended on each occasion that the trial continue without modification. This is the first time that a trial of a hemoglobin-based oxygen carrier has passed this patient evaluation milestone in a high risk trauma population. The final interim analysis is scheduled to occur after 500 patients have been enrolled, and we anticipate being able to announce that milestone before the end of calendar 2005.

Our scientific research team has been responsible for the original concept, the early development and evaluation and clinical testing of PolyHeme, and has authored over 100 publications in the scientific literature relating to hemoglobin-based oxygen carrier research and development. Members of our scientific research team have been involved in development of national transfusion policy through their participation in the activities of the National Heart Lung Blood

Institute, the National Blood Resource Education Panel, the Department of Defense, the American Association of Blood Banks, the American Blood Commission, the American College of Surgeons and the American Red Cross.

OUR PIVOTAL PHASE III TRIAL

As of August 1, 2005, 21 clinical sites in the United States were enrolling patients in our pivotal Phase III trial and six other sites had received final Institutional Review Board, or IRB, approval and were preparing to begin patient enrollment. Multiple additional sites were engaged in the required public disclosure and community consultation process. 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 that a total of 25 or more clinical sites across the United States will eventually participate in the trial. The trial has an expected enrollment of 720 patients.

TRIAL DESIGN AND CLINICAL ENDPOINTS

We have reached agreement with FDA on Special Protocol Assessment, or SPA, for our pivotal Phase III trial. SPA is designed to facilitate the review and approval of drug and biological products by allowing for FDA evaluation of the trial sponsor's proposed design and size of clinical trials intended to form the primary basis for an efficacy claim in a Biologics License Application, or BLA, submitted to FDA. If agreement is reached between FDA and the trial sponsor, SPA will document the terms and conditions under which the clinical trial will be conducted. Our SPA reflects an agreement with FDA on our trial design, the trial endpoints and the broad concepts for clinical indications those endpoints would support in an application for product approval by FDA.

Our pivotal Phase III trial is being conducted under a federal regulation that permits research to be conducted in certain emergent, life-threatening situations using an exception from the requirement for prospective informed consent by individual patients. Participation by each clinical trial site is overseen by an IRB. Under the applicable

federal regulation, an IRB may give approval for patient enrollment in trials in emergency situations without requiring individual informed consent provided specific criteria are met.

Patients must be in a life-threatening situation for which available treatments are unproven or unsatisfactory and scientific evidence must be needed to assess the safety and effectiveness of alternative treatments. The experimental therapy being evaluated must also provide patients potential for direct clinical benefit. In addition, medical intervention must be required before informed consent can be obtained and it must be impracticable to conduct the trial using only consenting patients. Where informed consent is feasible, the sponsor's consent procedures and forms must be reviewed and approved by the IRB, and attempts to obtain informed consent must be documented by the sponsor. Before enrollment can begin, the regulation requires public disclosure of information about the trial, including the potential risks and benefits, and the formation of an independent monitoring committee to oversee the trial. Consultation must also occur with representatives of the community where the study will be conducted and from which the study population will be drawn. Each of the clinical sites currently participating in our trial has completed the required public disclosure and community consultation procedures and received IRB approval to enroll patients in accordance with the trial protocol.

Under our trial protocol, patients enrolled in the trial are randomly assigned to either a treatment group or a control group. The treatment group receives PolyHeme at the scene of the injury or in the ambulance during transport and continues to receive PolyHeme, if necessary, during the initial 12 hour post-injury period in the hospital. Patients in the treatment group may receive a maximum of six units of PolyHeme. The control group receives saline solution in the field and donated blood, if necessary, in the hospital.

Evaluation of the efficacy data generated in our pivotal Phase III trial will focus on patient survival at 30 days after the date of injury. The mortality rate observed for patients in the treatment group in our trial will be compared statistically with the mortality rate for patients in the control group. A key feature of our SPA is the agreement on dual primary end points of superiority and non-inferiority between the treatment and control groups. The trial design is unusual in that either

of the primary endpoints of superiority or non-inferiority may be used to provide evidence of efficacy.

Our trial is being conducted primarily in urban settings because urban Level I trauma centers have the patient volume, resources and sophistication to conduct a clinical trial of this complexity. In urban areas, however, transit times in the ambulance may be brief, and the control group will reach the hospital, where patients will have access to blood, in relatively short periods of time. The observed outcome in our trial may therefore not demonstrate the expected magnitude of survival benefit that might occur if the trial were being conducted in the rural setting, where more extended transport times are typical and where the availability of blood may be limited. It is therefore possible that the observed survival rate in the treatment group may trend towards the survival rate observed in patients in the control group who have rapid access to blood. This outcome would represent non-inferiority, which would satisfy one of the dual primary endpoints for efficacy in our trial protocol.

23. On January 9, 2006, Northfield filed its quarterly report with the SEC on Form 10-Q. The Company's Form 10-Q was signed by defendant Gould and reaffirmed the Company's previous statements with respect to its PolyHeme product and the ongoing Phase III trial. This Form 10-Q is identical to other Form 10-Q signed by defendant Gould and filed by the Company with the SEC on April 14, 2004, October 12, 2004, January 10, 2005, April 11, 2005, and October 11, 2005.

24. The statements contained in ¶¶ 21-23 were materially false and misleading when made because defendants failed to disclose or indicate the following: (1) that PolyHeme, the Company's sole product, posed serious risks to users of the product; (2) specifically, the Company failed to disclose that at trial Polyheme was linked to heart attacks, heart rhythm aberrations, pneumonia and death; (3) that these problems were statistically significant, meaning that there was minimal likelihood that they occurred by chance; and (4) that defendants concealed these facts in

order to preserve PolyHeme's ability to continue testing so that the product could be approved by the FDA enabling Northfield to capture and control the lucrative blood substitute market.

The Truth Begins to Emerge

25. On February 22, 2006, *The Wall Street Journal* published an article entitled "Amid Alarm Bells, A Blood Substitute Keeps Pumping." The article, in relevant part, read:

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.

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.

26. On this news, shares of Northfield fell \$0.59 per share, or 4.82 percent, to close on February 22, 2006, at 11.64 per share. By the weeks end, shares of Northfield had fallen to \$10.54 per share.

POST CLASS PERIOD STATEMENTS

27. On March 10, 2006, *The Wall Street Journal* published another article entitled "Blood-Substitute Study Is Criticized by U.S. Agency." The article, in relevant part, read:

A little-known federal agency charged with protecting patients in medical research has expressed ethical concerns about a study of a Northfield Laboratories Inc. blood substitute being given to hundreds of trauma patients without their consent.

Criticism of the 720-patient trial has been mounting from doctors and medical-ethics officials as a key senator is investigating the Northfield trial. Two hospitals participating in the study have suspended enrolling patients in it since a Wall Street Journal story about the study was published Feb. 22.

The federal Office for Human Research Protections has expressed "urgent ethical concerns" to the Food and Drug Administration about the conduct of the trauma study, says Sen. Charles Grassley, the Iowa Republican who is chairman of the Senate Finance Committee. Sen. Grassley declined to elaborate, but committee investigators are planning to meet with OHRP officials today to be briefed on the agency's concerns.

Sen. Grassley is investigating whether patients in the new study are aware of the previous study's deaths and heart attacks, and whether it's appropriate to conduct the new study without patients' consent.

William Hoffman, chief of cardiac-surgery intensive care at Massachusetts General Hospital and former medical director of Biopure Corp., a blood-substitute company in Cambridge, Mass., says the FDA "should have monitored what went on in the communities in terms of informing people" about deaths and heart attacks.

The new Northfield study is also drawing questions about whether it's ethical to withhold donor blood from study patients when the benefits of PolyHeme are as yet uncertain. In the current issue of the journal *Ethics & Human Research*, Nancy M.P. King, a social-medicine professor at the University of North Carolina School of Medicine, writes that denying half of the patients blood in the hospital doesn't meet a key FDA criterion for allowing a non-consent trial, which is that standard therapy be "unproven or unsatisfactory."

28. In reaction to this development, shares of Northfield fell \$1.15 per share, or 10.31 percent, to close, on March 10, 2006, at \$10.00 per share.

29. On March 16, 2006, Northfield announced that it had received an informal request to voluntarily provide certain information to the staff of the SEC's Midwest Regional Office relating to the clinical development of its PolyHeme product for elective surgery. On this news, Northfield's stock declined another \$0.33 per share to close at \$.9.65 per share.

30. On March 20, 2006, *The Wall Street Journal* published an article entitled 'Use of Substitution For Blood Draws Ethics Challenge.' The article, in relevant part, read:

Three medical-ethics professors, in an open letter to research boards at hospitals where a blood substitute is being studied without patients' consent, said the research "fails to meet ethical and regulatory standards."

The medical ethicists called on the hospitals to at least sharply alter the details of the study of the Northfield Laboratories Inc. blood substitute.

They wrote that any litigation over the blood-substitute study "would likely do damage to Northfield, to the hospitals and universities that are running what we believe to be an ethically flawed study" and to "the credibility of" the Food and Drug Administration, which approved the research.

This new challenge to the study, which is under way at 31 hospitals around the U.S., emerges as the Securities and Exchange Commission begins an investigation into Northfield and its research into the blood substitute. Northfield said late last week that it plans to comply with the SEC's request for documents about clinical research into the blood substitute, called PolyHeme.

The open letter to the hospitals' "institutional review boards" supervising clinical research, and to those considering participating in the study, is slated to be published in a coming issue of *The American Journal of Bioethics*. Its authors are Robert M. Nelson, a physician specializing in critical care and anesthesia at the University of Pennsylvania School of Medicine; Nancy M.P. King, social-medicine professor at the University of North Carolina School of Medicine, and Ken Kipnis, a medical-ethics professor at the University of Hawaii.

Their focus is on the study, in 720 badly hemorrhaging trauma patients in 18 states, of the Northfield blood substitute. Half the patients are to receive PolyHeme both in the ambulance and the hospital, while the other half get standard therapy -- saline solution in the ambulance followed by donor blood in the hospital. It is the hospital portion of the study that has drawn the greatest fire. This is because blood, the standard of care for badly hemorrhaging trauma victims, can be withheld from half the patients -- without their consent -- under terms of the study.

The FDA didn't respond to requests for comment on the "open letter." Northfield said it "believes the scientific and ethical basis for continuing treatment with PolyHeme in the hospital is the potential to improve the outcome associated with the use of donated blood in the early hospital period in critically injured patients." Northfield also notes that efforts are made to obtain consent from patients and their

families, although this may not occur in many instances. It and the FDA have said a blood substitute holds great promise, especially in trauma care and in the military. The authors said it isn't proper to withhold blood from patients who haven't consented to being part of the study and that, "at a minimum," the ambulance portion of the study should be separated from the in-hospital part.

Separately, the SEC is investigating Northfield and the way it has conducted and reported clinical studies of its blood substitute.

31. In reaction to this latest development, Northfield's stock shed another \$0.37 per share, to close on March 20, 2006, at \$9.57 per share.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

32. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased the securities of Northfield during the Class Period and who were damaged thereby. Excluded from the Class are defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

33. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Northfield's securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Northfield or its transfer agent and may be notified of the

pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

34. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

35. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

36. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the federal securities laws were violated by defendants' acts as alleged herein;

b. whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Northfield; and

c. to what extent the members of the Class have sustained damages and the proper measure of damages.

37. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of

individual 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.

UNDISCLOSED ADVERSE FACTS

38. The market for Northfield's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and misleading statements and failures to disclose, Northfield's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Northfield securities relying upon the integrity of the market price of Northfield's securities and market information relating to Northfield, and have been damaged thereby.

39. During the Class Period, defendants materially misled the investing public, thereby inflating the price of Northfield's securities, by publicly issuing false and misleading statements and omitting to disclose material facts necessary to make defendants' statements, as set forth herein, not false and misleading. Said statements and omissions were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about the Company, its business and operations, as alleged herein.

40. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, defendants made or caused to be made a series of materially false or misleading statements about Northfield's business, prospects and operations. These material misstatements and omissions had the cause and effect of creating in the market an unrealistically positive assessment of

Northfield and its business, prospects and operations, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein.

LOSS CAUSATION

41. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

42. During the Class Period, Plaintiff and the Class purchased securities of Northfield at artificially inflated prices and were damaged thereby. The price of Northfield common stock declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER

43. As alleged herein, defendants acted with scienter in that defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, defendants, by virtue of their receipt of information reflecting the true facts regarding Northfield, their control over, and/or receipt and/or

modification of Northfield's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Northfield, participated in the fraudulent scheme alleged herein.

44. During the Class Period, and with the Company's stock trading at artificially inflated prices, Northfield raised \$15 million in a January 26, 2004 offering and another \$77 million in a January 19 2005 offering. Additionally, Northfield raised \$23.4 million in financing in May 2004 and \$1.4 million in funding in August 2004.

**Applicability Of Presumption Of Reliance:
Fraud-On-The-Market Doctrine**

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

46. (a) Northfield stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

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

(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; and

(d) Northfield was followed by several securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of

their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

48. As a result of the foregoing, the market for Northfield securities promptly digested current information regarding Northfield from all publicly-available sources and reflected such information in Northfield stock price. Under these circumstances, all purchasers of Northfield securities during the Class Period suffered similar injury through their purchase of Northfield securities at artificially inflated prices and a presumption of reliance applies.

NO SAFE HARBOR

49. 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.

FIRST CLAIM **Violation Of Section 10(b) Of** **The Exchange Act And Rule 10b-5** **Promulgated Thereunder Against All Defendants**

50. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

51. During the Class Period, defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Northfield securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

52. Defendants (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Northfield securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

53. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the business, operations and future prospects of Northfield as specified herein.

54. These defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of

conduct as alleged herein in an effort to assure investors of Northfield value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statements made about Northfield and its business operations and future prospects in the light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Northfield securities during the Class Period.

55. Each of the Individual Defendant's primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendant were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of his responsibilities and activities as a senior officer and/or director of the Company was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of and had access to other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

56. The defendants had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to

ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Northfield's operating condition and future business prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by defendants' overstatements and misstatements of the Company's business, operations and earnings throughout the Class Period, defendants, if they did not have actual knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

57. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Northfield securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of Northfield's publicly-traded securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by defendants, or upon the integrity of the market in which the securities trades, and/or on the absence of material adverse information that was known to or recklessly disregarded by defendants but not disclosed in public statements by defendants during the Class Period, Plaintiff and the other members of the Class acquired Northfield securities during the Class Period at artificially high prices and were damaged thereby.

58. At the time of said misrepresentations and omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Northfield

was experiencing, which were not disclosed by defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Northfield securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

59. By virtue of the foregoing, defendants have violated Section 10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

60. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM
Violation Of Section 20(a) Of
The Exchange Act Against the Individual Defendant

61. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

62. The Individual Defendant acted as controlling persons of Northfield within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendant had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendant were provided with or had

unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

63. In particular, each of these defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

64. As set forth above, Northfield and the Individual Defendant each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendant are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action, designating Plaintiff as Lead Plaintiff and certifying Plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

(b) Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated:

Respectfully submitted,

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