



1530 '97 AUG -6 A9:58

August 5, 1997

Docket Number 95S-0158
Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr. rm. 1-23
Rockville, MD 20857

RE: Investigational New Drug Application #6859

Dear Sir/Madam:

In accordance with 21 CFR §312.54 we are enclosing a copy of the information that has been publicly disclosed by the Institutional Review Board (IRB) at Parkland Memorial Hospital, Dallas, TX, concerning research involving an exception to informed consent. This includes an advertisement that appeared on April 13, 1997, in three local newspapers, *The Dallas Morning News*, *The Dallas Weekly* (Attachment 1), and *El Sol de Texas* (Attachment 2); an advertisement that appeared on June 22, 1997, in the same three local newspapers (Attachment 3); a press release from April 16, 1997 (Attachment 4); and a press release posted on the Internet, on Parkland Memorial Hospital's Home Page (http://www.swmed.edu/home_pages/parkland/pr/drugtest.html) (Attachment 5). In accordance with 21 CFR §312.54, this information is also being submitted to the IND file.

Based on information received from the clinical site, the investigator and IRB achieved community consultation by printing advertisements describing the clinical trial and the product in local newspapers (Attachment 1, 2, 3) and including a telephone number and/or an address to allow individuals to provide comments and ask for more information about the product.

If there are any questions concerning this information, please contact me at (847)270-5313.

Sincerely,



Maulik Nanavaty, Ph.D.
Director Regulatory Affairs
Blood Substitutes Program

95S-0158

SUP6

12.

CONTENTS OF APPLICATION

This application contains the following items: (Check all that apply)

1. Form FDA 1571 [21 CFR 312.23(a)(1)]
2. Table of Contents [21 CFR 312.23(a)(2)]
3. Introductory statement [21 CFR 312.23(a)(3)]
4. General Investigational plan [21 CFR 312.23(a)(3)]
5. Investigator's brochure [21 CFR 312.23(a)(5)]
6. Protocol(s) [21 CFR 312.23(a)(6)]
- a. Study protocol(s) [21 CFR 312.23(a)(6)]
- b. Investigator data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572
- c. Facilities data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572
- d. Institutional Review Board data [21 CFR 312.23(a)(6)(iii)(b)] or completed Form(s) FDA 1572
7. Chemistry, manufacturing, and control data [21 CFR 312.23(a)(7)]
- Environmental assessment or claim for exclusion [21 CFR 312.23(a)(7)(iv)(e)]
8. Pharmacology and toxicology data [21 CFR 312.23(a)(8)]
9. Previous human experience [21 CFR 312.23(a)(9)]
10. Additional information [21 CFR 312.23(a)(10)]

13. IS ANY PART OF THE CLINICAL STUDY TO BE CONDUCTED BY A CONTRACT RESEARCH ORGANIZATION? YES NO
- IF YES, WILL ANY SPONSOR OBLIGATIONS BE TRANSFERRED TO THE CONTRACT RESEARCH ORGANIZATION? YES NO
- IF YES, ATTACH A STATEMENT CONTAINING THE NAME AND ADDRESS OF THE CONTRACT RESEARCH ORGANIZATION, IDENTIFICATION OF THE CLINICAL STUDY, AND A LISTING OF THE OBLIGATIONS TRANSFERRED. See IND 6859:000

14. NAME AND TITLE OF THE PERSON RESPONSIBLE FOR MONITORING THE CONDUCT AND PROGRESS OF THE CLINICAL INVESTIGATIONS

Robert J. Przybelski, M.D.
Medical Director

15. NAME(S) AND TITLE(S) OF THE PERSON(S) RESPONSIBLE FOR REVIEW AND EVALUATION OF INFORMATION RELEVANT TO THE SAFETY OF THE DRUG

Robert J. Przybelski, M.D.
Medical Director

I agree not to begin clinical investigations until 30 days after FDA's receipt of the IND unless I receive earlier notification by FDA that the studies may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold. I agree that an Institutional Review Board (IRB) that complies with the requirements set forth in 21 CFR Part 56 will be responsible for initial and continuing review and approval of each of the studies in the proposed clinical investigation. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.

<p>16. NAME OF SPONSOR OR SPONSOR'S AUTHORIZED REPRESENTATIVE</p> <p>Robert J. Przybelski, M.D. Medical Director</p>	<p>17. SIGNATURE OF SPONSOR OR SPONSOR'S AUTHORIZED REPRESENTATIVE</p> 	
<p>18. ADDRESS (Number, Street, City, State and Zip Code)</p> <p>120 & Wilson Road Round Lake, IL 60073</p>	<p>19. TELEPHONE NUMBER (Include Area Code)</p> <p>(847)270-5309</p>	<p>20. DATE</p> <p>July 31 '97</p>

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

Public reporting burden for this collection of information is estimated to average 100 hours per response, including the time for reviewing instructions, reviewing existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

DHHS Reports Clearance Officer
Paperwork Reduction Project 0910-0014
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Please DO NOT RETURN this application to this address.



Parkland Trauma Center to Test New Drug

Blood product may save lives

Parkland Memorial Hospital is among 35 major trauma centers that are evaluating a new treatment for critically injured patients with severe blood loss. The treatment involves administering an experimental blood product to such patients, who face a major risk of dying despite the best medical care. Baxter Healthcare, Inc., has developed the product, Diaspirin Cross-linked Hemoglobin (DCLHb™), which is being tested during the emergency treatment of trauma patients in shock. The trial, which is authorized by the U.S. Food and Drug Administration, requires public notice because it will occur under emergency conditions that may require an exception from informed consent. This notice attempts to address questions about the trial.

Q. Why is this trial being performed?

A. Seriously injured patients frequently arrive at the hospital in shock with significant blood loss. Despite the best care medicine has to offer, as many as 40 percent of the most critically injured patients will die from their injuries. Studies suggest that DCLHb™ may improve the chance of survival following severe blood loss. The product has the greatest chance of improving survival and reducing complications when it is given immediately after the beginning of catastrophic shock and bleeding.

Q. What is DCLHb™?

A. DCLHb™ is a purified hemoglobin (the part of blood that carries oxygen) preparation made from human blood that has become outdated on blood bank shelves and is no longer usable for transfusions. It is filtered and heated to reduce the risk of blood-borne infections including AIDS. DCLHb™ may restore blood pressure, increase blood flow to vital organs and carry oxygen to cells and tissues. Because blood typing is not required and the product can be stored in the Emergency Department, DCLHb™ can be given immediately after a patient's arrival, saving critical moments in stabilizing a trauma patient.

Q. Does DCLHb™ replace the need for blood transfusion?

A. DCLHb™ is administered in addition to transfusions that may be needed to treat the injured patient. (Since the product is made from human blood, it would not be suitable in treating patients whose religious beliefs forbid blood transfusions.) Patients will still get all standard therapies in this study, including blood, fluids and surgery. Although DCLHb™ may reduce the number of blood transfusions required to treat the injured, volunteer blood donations are still vital.

Q. What is an exception from informed consent and why is it necessary?

A. Because trauma patients are often so severely injured, they may not be able to give their consent to participate in the drug trial. Still, they are in critical need of immediate treatment. The U.S. Food and Drug Administration has granted an exception from informed consent in such cases. They have carefully evaluated DCLHb™ and determined that the potential benefits greatly outweigh the risks of participating in the trial. As a result, patients may be enrolled in this study and receive DCLHb™ when informed consent is not possible.

We will make every attempt to obtain consent from patients, their legal representatives, or family before DCLHb™ is given, and all patients and their family members will be completely informed of their participation as soon as possible. At all times, the patient or their representatives may decline further participation in the study. There are no known risks to patients who decide not to continue in the study.

Q. What are the risks and side effects of DCLHb™?

A. DCLHb™ has been extensively studied in randomized trials involving more than 700 patients over a four-year period to evaluate its effects. Of the approximately 350 who received the drug, a few temporary side effects were noted. These included changes in some lab test results, a temporary and harmless yellowing of the skin (unrelated to liver damage), temporary reddening of the urine due to the red color of DCLHb™, nausea, and back, abdominal and muscle pain. Blood pressure may be elevated following administration; however, this may be beneficial to patients in shock, whose blood pressure is dangerously low. Independent experts will monitor patient safety throughout the trial. Parkland is participating in this drug trial because the benefits to severely injured trauma patients may greatly exceed known side effects of the treatment.

Q. Who will be eligible to participate?

A. Approximately 30 patients with low blood pressure and in shock from blood loss following traumatic injury will be enrolled at Parkland over the next 18 months. Approximately half of these patients will receive the blood product along with other treatment. This product will be given only to patients who have such major blood loss that standard therapy may not be enough to save their lives. A total of 850 patients will be enrolled nationwide at 35 trauma centers. This trial is being performed under the guidelines and approval of the Institutional Review Board of The University of Texas Southwestern Medical Center at Dallas and the U.S. Food and Drug Administration. No additional charges will be incurred by patients as a result of participation.

We at Parkland are excited about the potential that products such as DCLHb™ may have to not only save lives, but also to extend the useful life of a very scarce resource — human blood supplies. This product is an example of how research can expand the safety net, and it is another example of why blood donations are critical to help save lives.



Parkland Health & Hospital System
5201 Harry Hines Boulevard Dallas, Texas 75235

Attachment 2

Centro de Trauma de Parkland Hará Pruebas para una Droga Nueva

Un producto de la sangre que podría salvar las vidas

Parkland Memorial Hospital está entre los 35 centros de trauma principales que están evaluando un tratamiento nuevo para pacientes heridos críticamente con una pérdida de sangre severa. El tratamiento incluye el aplicar un producto experimental de sangre a esos pacientes que enfrentan un riesgo mayor de morir a pesar del mejor cuidado médico. Baxter Healthcare, Inc., a desarrollador del producto, Diapsirin Cross-linked Hemoglobin (DCLHb™) con el cual se están haciendo pruebas durante el tratamiento de emergencia en los pacientes de trauma que están en estado de choque. El experimento, el cual está autorizado por U.S. Food and Drug Administration (Administración de Drogas y Alimentos de E.U.), requiere de noticia pública porque ocurrirá bajo condiciones de emergencia que pueden necesitar una excepción de la información de autorización. Esta noticia intenta dirigirse a las preguntas que pueden tener sobre el experimento.

P. ¿Porqué se está haciendo el experimento?

R. Con frecuencia llegan al hospital pacientes heridos muy seriamente y en estado de choque con una pérdida de sangre muy significativa. A pesar del mejor cuidado que ofrece la medicina, la mayoría de un 40% de los pacientes heridos más críticamente morirán de sus heridas. Los estudios sugieren que la DCLHb™ puede mejorar la probabilidad de sobrevivir después de una pérdida de sangre severa. El producto tiene la gran posibilidad de mejorar la sobrevivencia y reducir las complicaciones cuando se aplica inmediatamente después de empezar el catastrófico estado de choque y sangramiento.

P. ¿Qué es la DCLHb™?

R. La DCLHb™ es hemoglobina purificada (es la parte de la sangre que lleva el oxígeno) es una preparación que se hace de sangre humana con fecha expirada que se encuentra en los esantes del banco de sangre y ya no puede usarse para las transfusiones. Se filtra y se calienta para reducir el riesgo de infecciones que puede causar la sangre, incluyendo el SIDA. La DCLHb™ restablece la presión de la sangre, aumenta la corriente de la sangre a los órganos vitales y lleva el oxígeno a las células y a los tejidos. Porque no requiere de un tipo de sangre y el producto puede guardarse en el Departamento de Emergencia, la DCLHb™ puede aplicarse inmediatamente después de llegar el paciente, salvando así momentos críticos para estabilizar a un paciente de trauma.

P. ¿Puede reemplazar la DCLHb™ la necesidad de una transfusión de sangre?

R. La DCLHb™ se aplica además de las transfusiones que podrían necesitarse para tratar al paciente herido. (Porque el producto está hecho de sangre humana, no será apropiado para tratar a los pacientes a quienes sus creencias religiosas les prohíben las transfusiones de sangre). Los pacientes todavía podrán recibir todas las terapias normales en este estudio, que incluye sangre, líquidos y cirugía. Aunque la DCLHb™ podría reducir el número de transfusiones de sangre que se necesitan para tratar una herida, las donaciones voluntarias de sangre todavía siguen siendo muy importantes.

P. ¿Qué es una excepción de la información autorizada y porqué es necesaria?

R. Debido a que con frecuencia los pacientes de trauma están heridos muy severamente, y no pueden dar su autorización para participar en el experimento de la droga. Aún existe la necesidad crítica para un tratamiento inmediato. La Administración de Drogas y Alimentos de E.U. (U.S. Food and Drug Administration) a permitido que se haga una excepción de la información autorizada para estos casos. Ellos han evaluado cuidadosamente la DCLHb™ y han determinado que la posibilidad de los beneficios es más grande y pesa más que los riesgos de participar en el experimento. Cómo resultado los pacientes podrán registrarse en este estudio y recibir la DCLHb™ cuando no sea posible

obtener la información autorizada.

Haremos todo lo posible para obtener la forma de autorización de los pacientes, de sus representantes legales o de su familia antes de que les apliquen la DCLHb™, y todos los pacientes y sus familias serán informados completamente de su participación tan pronto que sea posible. En todo momento, el paciente o su representante puede asegurarse a una participación fuera en el estudio. No se sabe de riesgos para los pacientes que decidan no continuar con el estudio.

P. ¿Cuáles son los riesgos y efectos secundarios de la DCLHb™?

R. La DCLHb™ a sido estudiada extensamente en experimentos casuales que incluyen a más de 700 pacientes sobre un período de cuatro años para evaluar sus efectos. Aproximadamente de 350 pacientes que recibieron la droga, se observaron unos cuantos efectos secundarios temporales. Estos incluyeron cambios en algunos resultados de laboratorio, un color amarillo temporal en la piel que no hace daño (no tiene relación con daño al hígado), enrojecimiento temporal en la orina debido al color rojo de la DCLHb™, náusea, dolor abdominal, muscular y en la espalda. La presión de la sangre podría elevarse después de que se aplica; sin embargo, esto podría ser de beneficio para los pacientes en estado de choque, que tienen la presión de la sangre peligrosamente baja. Expertos independientes vigilarán la seguridad del paciente a través de todo el experimento. Parkland está participando en este experimento de la droga porque los beneficios para los pacientes de trauma que están heridos muy severamente podrían exceder bastante los efectos secundarios del tratamiento.

P. ¿Quién será elegible para participar?

R. Aproximadamente 30 pacientes que tengan presión baja de la sangre y que estén en estado de choque debido a la pérdida de sangre después de una herida traumática serán registrados en Parkland en los próximos 18 meses. Aproximadamente la mitad de estos pacientes recibirán el producto de la sangre junto con otro tratamiento. Este producto solamente se les aplicará a los pacientes que tengan una pérdida de sangre mayor y la terapia normal no podría ser suficiente para salvar sus vidas. Un total de 850 pacientes serán registrados en toda la nación en 35 centros de trauma. Este experimento se está haciendo bajo las reglas y aprobación del Institutional Review Board of The University of Texas Southwestern Medical Center at Dallas y la U.S. Food and Drug Administration (Junta Directiva de Revisión Institucional de University of Texas Southwestern Medical Center en Dallas y la Administración de Drogas y Alimentos de E.U.). No habrá cargos adicionales para los pacientes cómo resultado de su participación.

Nosotros en Parkland estamos muy contentos sobre la posibilidad de que el producto DCLHb™ podría no solamente salvar vidas, pero también extender la vida útil de un recurso que asusta mucho - productos de sangre humana. Este producto es un ejemplo de cómo la investigación puede extender su red de seguridad, y es otro ejemplo de porque las donaciones de sangre son críticas para ayudar a salvar las vidas.



Parkland Health & Hospital System
5201 Harry Hines Boulevard Dallas, Texas 75235

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Blood product may save lives

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We at Parkland are excited about the potential that products such as DCLHb™ may have to not only save lives, but also to extend the useful life of a very scarce resource — human blood supplies. This product is an example of how research can expand the safety net, and it is another example of why blood donations are critical to help save lives.

To provide comments and for more information about this product, please call 214-648-5430.



Parkland Health & Hospital System
5201 Harry Hines Boulevard Dallas, Texas 75235

P . A . R . K . L . A . N . D
 NEWS TIPS NEWS TIPS NEWS TIPS

April 16, 1997
 For Immediate Release

Contact: Susan K. Wilson
 Work: (214) 590-8054
 Pager: (214) 786-0527

New drug tested on critically injured trauma patients

DALLAS — Parkland Health & Hospital System's Trauma Department is one of approximately 35 sites testing a new drug that may help save the lives of some of the most critically injured trauma patients.

Approximately 40 percent of all such patients die as a result of shock due to blood loss, despite the best medical care available.

The new drug is a blood product made from expired human red blood cells suspended in a solution. It is being tested on the most severely injured patients at major trauma centers across the country to prevent the harmful effects of severe blood loss in trauma patients. The blood product is manufactured by Baxter Healthcare Corporation's Blood Substitutes Division.

About 850 patients who are at risk of dying from their injuries will be part of the nationwide trial. Because of the critical nature of their injuries, few if any of these patients will be capable of giving informed consent before the drug is administered.

Half of these patients will receive the drug; the other half will receive a saline solution. These patients also will be given all other standard therapies and procedures normally used to treat shock patients, including blood, fluids and surgery.

The drug is a purified hemoglobin solution, called Diaspirin Cross-Linked Hemoglobin (DCLHb™), which has been authorized for clinical testing by the Food and Drug Administration after four years of human clinical trials involving more than 700 patients, including 139 shock and trauma patients.

DCLHb™ will be administered only to the most severely injured trauma patients to help stabilize shock and improve patient outcome, according to Dr. David Provost, chief clinical investigator for the drug at Parkland and assistant professor of surgery at The University of Texas Southwestern Medical Center.

The solution is made from outdated or expired human red blood cells — blood supplies that would otherwise be removed from blood banks and destroyed. Instead, in a new process developed by Baxter, the blood is treated to remove the hemoglobin, the oxygen-carrying component of the blood, from the blood cells. Then it is pasteurized. It does not need to be cross-matched and can easily be stored in emergency departments for immediate use in the most critical trauma cases. (Since the product is made from human blood, it would not be suitable in treating patients whose religious beliefs forbid blood transfusions.)

The new treatment can shave from five to 45 minutes from the time it takes to obtain blood for transfusion. For example, matching the victim's blood type with blood bank supplies can take as long as 45 minutes.

"When patients have serious traumatic blood loss, the cells are deprived of the oxygen carried by the hemoglobin and begin to die," Provost said. "Their blood pressure drops, their organs begin to die, and finally, the patient dies."

The only way to intervene in this process is to immediately replace the blood that carries the oxygen-rich hemoglobin to the cells.

DCLHb™ can be given to a patient of any blood type without delay, since it contains only the hemoglobin from the blood cell, not the antigens found on the surface of

—more—

Parkland Health & Hospital System

Department of Media/Public Relations • 5201 Harry Hines Blvd. • Dallas TX 75235 • 214 590 8054
 This news release is available on our World Wide Web home page at <http://www.swmed.edu/home>

New drug — add one

the cell. The hemoglobin carries oxygen, and may improve oxygen delivery to the organs that need it most, help reverse the destructive effects of shock, and save lives.

Because of the critical nature of this type of emergency, the FDA has granted an exception from informed consent normally required in a new drug study. As soon as possible, however, the patient or the family will be informed of the study and can decide if they wish to continue participating.

Parkland was chosen as a test site because of its reputation as a major trauma center and its status as the primary teaching hospital for UT Southwestern.

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Parkland Health & Hospital System

Department of Media/Public Relations • 5201 Harry Hines Blvd. • Dallas TX 75235 • 214 590 8054

This news release is available on our World Wide Web home page at http://www.swmed.edu/home_pages/parkland

**Parkland Memorial Hospital****News Tips****News Tips****News Tips****New Drug Test**

April 8, 1997
For Immediate Release

Contact: Susan K. Wilson
Work: (214) 590-8054

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DCLHbTM can be given to a patient of any blood type without delay, since it contains only the hemoglobin from the blood cell, not the antigens found on the surface of the cell. The hemoglobin carries oxygen, and may improve oxygen delivery to the organs that need it most, help reverse the destructive effects of shock, and save lives.

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Authorized by:

Dept. of Corporate Communications - Parkland Health & Hospital System - 5201 Harry Hines Blvd. - Dallas TX 75235 - 214
590 8054

Send comments, questions or suggestions via E-Mail: WebMaster@parknet.pmh.org
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08/19/97

1295-8520-0

1781210

00368/00500

ANAWATV

847 270-5313

WATER HEALTHCARE/W G SCI CTR

R 120 & WILSON RD
ROUND LAKE

IL 60073

296-711-1576

SOCKET NUMBER 955-0158
SOCKETS MGMT. BRANCH (HFH 035)
DD & DRUG ADMINISTRATION

2420 PARKTOWN DRIVE
CHVILLE

MD

20857



272

Rev. Date 6/96
PART #147856

GRFE 507