U.S. SENATE COMMITTEE ON
Finance
SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN
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For Immediate Release
Thursday, Feb. 23, 2006

Grassley Questions FDA's Sanction of Blood Substitute Study Without Patient Consent

WASHINGTON – Sen. Chuck Grassley, chairman of the Committee on Finance, today questioned why the Food and Drug Administration would allow a company to test a blood substitute on trauma patients in 18 states without meaningful patient consent, with allegations of public safety risks from the product, as reported in yesterday's Wall Street Journal.

"If you're in a car accident, of course you want emergency doctors to save your life," Grassley said. "But no reasonable person would expect to be treated as an experimental subject without consent. The idea that the FDA would put the burden on the public to opt out of this mass experiment is outrageous. Why should Americans have to wear a bracelet at all times to protect themselves from a government-sanctioned medical experiment if they happen to get into a car accident? I understand the value of a viable blood substitute, but I'm really disturbed by what I'm hearing about the FDA's role here and I want to find out what's going on."

The text of Grassley's letter to the FDA follows.

February 23, 2006

Via Electronic Transmission

Dr. Andrew C. von Eschenbach
Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. von Eschenbach:

The yellow "LIVESTRONG" wristband, promoted by the Lance Armstrong Foundation, is truly a marketing phenomenon and a remarkably effective symbol on behalf of a noble cause – the battle with cancer. It was no surprise to learn that you wear one. I write today, however, because I am concerned about a far less popular and not widely worn wristband. If unsuspecting Americans were aware of the import of this light-blue wristband, it might well be a marketing phenomenon, too. It is outrageous that, for all intents and purposes, the FDA allowed a clinical trial to proceed, which makes every citizen in the United States a potential "guinea pig," without providing a practical,

informative warning to the public.

As a United States Senator representing the State of Iowa and as Chairman of the Committee on Finance (Committee), which has jurisdiction over the Medicare and Medicaid programs, I am responsible for oversight of matters that affect my constituents and the beneficiaries of these federal health care programs. Accordingly, I have been persistent in my efforts to examine the performance of the Food and Drug Administration (FDA) in recent years. Yesterday, the *Wall Street Journal* (WSJ) ran an article entitled, "Amid Alarm Bells, A Blood Substitute Keeps Pumping," that was indeed alarming.

According to the article, the FDA is allowing a manufacturer, Northfield Laboratories, Inc., to test its product, a blood substitute called PolyHeme, in a clinical trial (the PolyHeme Study) without the consent of trauma patients, who often may be unconscious and/or otherwise incapable of providing informed consent. The PolyHeme Study is being conducted pursuant to an infrequently used FDA regulation, which allows for waiver of the informed consent typically required in clinical trials, if some sort of community outreach program is implemented, among other requirements. It is the community outreach that brings the light-blue wristbands into the mix.

For example, if you live in, next to, or travel through a state participating in the PolyHeme Study – California, Colorado, Delaware, Georgia, Illinois, Indiana, Kansas, Kentucky, Michigan, Minnesota, New York, North Carolina, Ohio, Pennsylvania, Tennessee, Texas, Utah, and Virginia – and you suffer a traumatic injury and receive emergency medical treatment at a participating trauma center in that state, you may, without your consent, become a human research subject for an experimental blood product (if other contingencies are also met). That is, unless you happen to be wearing a light-blue wristband imprinted with the following: "I decline the Northfield PolyHeme Study" (see attached). I suspect many people, if they knew this, might reasonably ask, "where do I get my wristband?"

It also comes as no surprise that this question is not a readily answerable one. Certainly, it's not apparent from any information on the FDA's website. Nonetheless, an unknown number of community meetings were reportedly held in the participating states. At these meetings, anyone who knew of and took time to attend a meeting could opt out of the PolyHeme Study by requesting – and wearing continuously for an undetermined period of time – one of these light-blue wristbands. However, I am skeptical that any participating medical centers managed to conduct effective, practical outreach to the community and to provide a meaningful, informative warning to the public about the PolyHeme Study. Researchers in at least one state (Oregon) suspended participation in the PolyHeme Study when it was unable to obtain local approval because the community meetings were sparsely attended. According to a news report published in the *Journal of Clinical Investigation* in July 2004, Loyola University Health System in Chicago engaged in an extensive effort to reach potential participants in specific communities. However, the turnout at meetings was "surprisingly low, averaging...between 0–5 people of those who responded." The author of this news report raised an important question: "Is this in absentia approval for the trial an inherent flaw in the initial regulation whereby people, thinking they personally are unlikely to end up in the trial, don't bother with the outreach and are therefore not truly informed?"

Despite the recent media attention associated with the PolyHeme Study, more remains unknown than known about it today. Accordingly, as Chairman of the Committee, I request that the FDA address this issue by providing the public with meaningful information related to what it should already have known about the PolyHeme Study. In addition, at the earliest opportunity, but no later than March

8, 2006, please provide my Committee with a detailed briefing regarding the PolyHeme Study. Over the next few days, my Committee staff will contact your staff with more specific requests for information, but at the minimum your staff should be prepared to address the following issues related to the PolyHeme Study:

1. What oversight, if any, has FDA conducted related to the PolyHeme Study?

2. What consultation with representatives of the community was conducted?

3. What public disclosure to communities was conducted prior to initiation of the PolyHeme Study?

4. Were known adverse events, including but not limited to those reported in the WSJ, disclosed with the risks and expected benefits information?

5. Has Northfield Laboratories, Inc., met all regulatory reporting requirements related to its PolyHeme product, including but not limited to timely reporting of all adverse events?

Finally, I request a detailed list and summary of all clinical trials, between January 1, 1996, and the date of this request, conducted pursuant to the FDA regulation governing exception from informed consent requirements for emergency research.

Thank you in advance for having your staff contact my Committee staff by March 1, 2006, to coordinate this briefing.

Sincerely,

Charles E. Grassley
United States Senator

Attachment