

Blood clotting SW
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LRM ID: RJP188

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
Washington, D.C. 20503-0001

Friday, February 6, 1998

LEGISLATIVE REFERRAL MEMORANDUM

URGENT

TO: Legislative Liaison Officer - See Distribution below
FROM: Janet R. Forsgren (for) Assistant Director for Legislative Reference
OMB CONTACT: Robert J. Pellicci
PHONE: (202)395-4871 FAX: (202)395-6148
SUBJECT: JUSTICE Report on HR1023 Ricky Ray Hemophilia Relief Fund Act of 1997

DEADLINE: Monday, February 9, 1998

In accordance with OMB Circular A-19, OMB requests the views of your agency on the above subject before advising on its relationship to the program of the President. Please advise us if this item will affect direct spending or receipts for purposes of the "Pay-As-You-Go" provisions of Title XIII of the Omnibus Budget Reconciliation Act of 1990.

COMMENTS: The House Judiciary Subcommittee on Immigration and Claims is scheduled to markup HR 1023 on Wednesday, February 11th. **YOUR PROMPT ATTENTION IS REQUESTED.**
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SUBJECT: JUSTICE Report on HR1023 Ricky Ray Hemophilia Relief Fund

**RESPONSE TO
LEGISLATIVE REFERRAL
MEMORANDUM**

If your response to this request for views is short (e.g., concur/no comment), we prefer that you respond by e-mail or by faxing us this response sheet. If the response is short and you prefer to call, please call the branch-wide line shown below (NOT the analyst's line) to leave a message with a legislative assistant.

You may also respond by:

(1) calling the analyst/attorney's direct line (you will be connected to voice mail if the analyst does not answer); or

(2) sending us a memo or letter

Please include the LRM number shown above, and the subject shown below.

TO: Robert J. Pellicci Phone: 395-4871 Fax: 395-6148
Office of Management and Budget
Branch-Wide Line (to reach legislative assistant): 395-7362

FROM: _____ (Date)
 _____ (Name)
 _____ (Agency)
 _____ (Telephone)

The following is the response of our agency to your request for views on the above-captioned subject:

Concur

 No Objection

No Comment

See proposed edits on pages

Other: _____

FAX RETURN of _____ pages, attached to this response sheet



U.S. Department of Justice
Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

DRAFT

The Honorable Lamar Smith
Chairman, Subcommittee on
Immigration and Claims
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515-6216

Dear Mr. Chairman:

This provides the views of the Department of Justice on H.R. 1023, the "Ricky Ray Hemophilia Relief Fund Act of 1997." This bill would create a fund to pay \$100,000 to each person (or heir) who has suffered any form of blood-clotting disorder, who contracted HIV after treatment with blood-clotting agents between July 1, 1982, and December 31, 1987.

General Comments

1. Policy. Manufacturers of anti-hemophilic factor concentrates utilize blood to create blood-clotting factors. During the period encompassed by the bill (1982 through 1987), anti-hemophilic fraction concentrates were used by hemophiliacs to prevent and control bleeding. Also, during the 1980's, the scientific community became aware of AIDS and HIV and sources of transmission, including blood, and means for reducing the risk of transmission.

The government agencies' response to the public health issues the occurrence of AIDS raised has been the subject of intense review, including the 1995 Institute of Medicine Report. The Department of Health and Human Services (HHS) has embraced the goals reflected in the report's recommendations. We understand that HHS has established a task force to assess all of the recommendations in light of current practices.

We are concerned about the precedent this bill would set. We do not believe that the federal government's regulatory responsibilities should expose it to liability as an insurer for the failures of private entities which the government regulates.

2. Litigation. The extent to which the federal government had, or did not have, the power to cause blood banks, the blood

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industry and fractionators to adopt protective measures (including screening of high risk groups and surrogate testing) is a major aspect of the issues being debated. Moreover, litigation pending in the Northern District of Illinois raises these issues as well as additional related issues. MDL 986, In re Factor VIII or IX Concentrate Blood Products Liability Litigation. (This is the same litigation referenced in Title II of the bill.)

As part of a partial settlement of the litigation, blood product industry companies agreed to pay \$12,188,100 to the United States to settle and obtain releases of claims for reimbursement for federally-funded health care provided to persons with hemophilia who became infected with HIV and who received blood products during 1978 to 1985. Individuals and their representatives who "opt-in" to the settlement are entitled to receive \$100,000 and will be released from governmental health care reimbursement claims.

The four corporations and their affiliates that have agreed to settle on these terms are Alpha Therapeutic Corporation, Armour Pharmaceutical Company, Baxter Healthcare Corporation and Bayer Corporation. Each company is obligated to pay a specific percentage of the total amount to be paid. The federal government's health care has been provided under CHAMPUS, health benefit plans offered by the Department of Defense and the Department of Veterans Affairs, Medicare, Medicaid (a federally-subsidized, state-operated program), the Indian Health Service and the Federal Employees Health Benefits Program. In May, 1997, the District Court approved this settlement. However, "opt-out" plaintiffs continue to litigate the issues.

Statutory and Technical Issues

1. Section 101(a) authorizes the appropriation of \$750 million. If the full sum authorized is not appropriated, or is inadequate to pay all claims, there needs to be a provision for payment of claims on the basis of available appropriations on a first come/first paid basis or some other statutory formula.

It is unlikely that reasonable persons would view the \$100,000 per person payable under H.R. 1023 to be full compensation. Moreover, the infected individual will not at all be assisted by a payment to the individual's estate. Thus, the bill requires a payment that cannot be viewed as compensatory; the bill itself refers to the payments as "humanitarian." Section 103(e). The policy basis for selection of the figure of \$100,000 is not self-evident. Obviously, the decision to authorize the appropriation of \$750 million (Section 101(e)) raises very substantial fiscal issues as well.

2. Section 103(e) provides that payment under the legislation would "be in full satisfaction" of all the claims against the

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