

June 1, 2005 - Slaughter, Colleagues Call for Investigation

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Into FDA Decision on Emergency Contraception

55 Members are Concerned the FDA Made a Political Decision Influenced by Religious Extremists

Washington, DC. This past week, 55 Members of Congress, led by Rep. Louise Slaughter, Ranking Member for the House Rules Committee, sent a letter to Dara Corrigan, Acting Principal Deputy Inspector General at the U.S. Department of Health and Human Services requesting an investigation into the FDA.

"We cannot allow the FDA to be hijacked by the extremist political agenda of the radical right. The FDA has a responsibility to adhere to the principles of science and health, not politics and religion," said Congresswoman Slaughter.

The letter calls upon the Inspector General to conduct an investigation into whether an atypical "minority opinion" unduly influenced FDA's decision in May 2004 to reject Barr Laboratories' application to sell emergency contraception (EC) over-the-counter.

A recent exposé in the May issue of *The Nation* reported that in 2004, when the Food and Drug Administration (FDA) was considering allowing over-the-counter sales of EC, it requested a "minority opinion" by dissenting panelist and evangelical conservative Dr. W. David Hager. Allegedly, this "minority opinion" was solicited to justify a political decision to prevent the over-the-counter sales of EC.

This request came shortly after the FDA's Advisory Panel voted overwhelmingly in favor (23-4) of allowing over-the-counter sales of Barr Laboratories' Plan B emergency contraceptive. The Advisory Panel concluded, emergency contraception meets standard criteria for over-the-counter use.

Emergency contraception is often the only contraceptive option for the 300,000 women who are sexually assaulted each year. Scientific data suggest that increased timely access to emergency contraception could significantly reduce our nation's staggering rates of unintended pregnancies and decrease the number of abortions performed in our nation by hundreds of thousands.

"Should this investigation confirm that science and safety have taken a back seat to politics, then the FDA must be held accountable," stated Rep. Slaughter.

A PDF copy of the signed letter is available upon request.

Letter text follows:

Ms. Dara Corrigan

Acting Principal Deputy Inspector General

Office of Inspector General

U.S. Department of Health and Human Services

Room 5250, The Cohen Building

330 Independence Avenue, S.W.

Washington, DC 20201

Dear Ms. Corrigan:

We are very concerned about recent reports that in 2004, the Food and Drug Administration (FDA) requested a "minority opinion" by dissenting panelist and evangelical conservative Dr. W. David Hager, during its consideration of Barr Laboratories' application to allow over-the-counter sales of emergency contraception (EC). According to reports, this "minority opinion" was requested by the FDA to outline a rationale for why over-the-counter sales of EC should be rejected, and came shortly after the FDA's Advisory Panel voted overwhelmingly in favor (23-4) of over-the-counter sales of Barr Laboratories' Plan B emergency contraceptive. We, therefore, request an investigation into whether this atypical "minority opinion" unduly influenced FDA's decision in May 2004 to reject Barr Laboratories' application.

We are deeply disturbed by reports that FDA disregarded the recommendation of its expert Advisory Panel and instead may have used the opinion of just one of the dissenting panelists to justify a politically motivated decision to deny women access to EC. As the FDA's Advisory Panel concluded, emergency contraception meets standard criteria for over-the-counter use: low-toxicity, no potential for overdose or addiction, no teratogenicity (is not harmful to an existing pregnancy), no need for medical screening, self-identification of the need, uniform dosage and no important drug interactions.

To make such an important decision based on politics instead of science has serious implications for the health of women across the country. The Alan Guttmacher Institute estimates that increased use of EC accounted for up to 43 percent of the total decline in abortion rates between 1994 and 2000. In addition, EC is often the only contraceptive option for the 300,000 women who are raped each year. Unfortunately, many women do not know about EC and many face insurmountable barriers in accessing this important product. A recent study in the Annals of Emergency Medicine found that less than 17 percent of hospitals dispense emergency contraception at the woman's request, without restrictions. Yet, scientific data suggest that increased timely access to EC could significantly reduce our nation's still staggering rates of unintended pregnancy and decrease the number of abortions performed in our nation by hundreds of thousands.

The recent reports about Dr. Hager raise serious concerns that science and safety have taken the back seat to politics in the FDA's decision not to permit over-the-counter sales of EC. The scientific facts irrefutably show that EC is a safe, effective way for women to prevent unintended pregnancy. We, therefore, urge you conduct a thorough investigation into reports that the FDA requested a "minority opinion," and determine if sound scientific methodologies were employed when this decision was made to overrule the FDA's advisory panel.

Thank you for your attention to this important matter. We look forward to your response.

Sincerely,

Letter Signatories

Louise M. Slaughter

Neil Abercrombie

Gary L. Ackerman

Tom Allen

Tammy Baldwin

Shelley Berkley

Howard L. Berman

Sherrod Brown

Lois Capps

Michael E. Capuano

Joseph Crowley

Elijah Cummings

Danny K. Davis

Susan Davis

Diana L. DeGette

Rosa DeLauro

Norm Dicks

Eliot Engel

Lane Evans

Sam Farr

Bob Filner

Raúl M. Grijalva

Jane Harman

Maurice Hinchey

Rush Holt

Jay Inslee

Steve Israel

Patrick J. Kennedy

Dennis Kucinich

Tom Lantos

Rick Larsen

Sheila Jackson Lee

John Lewis

Carolyn Maloney

Doris O. Matsui

Jim McDermott

James P. McGovern

Gregory W. Meeks

George Miller

Gwen Moore

Jim Moran

John Olver

Linda Sánchez

Bernard Sanders

Janice D. Schakowsky

Debbie Wasserman Schultz

Christopher Shays

Hilda L. Solis

Pete Stark

Edolphus Towns

Diane E. Watson

Henry Waxman

Robert I. Wexler

Lynn Woolsey