

July 24, 2000

Jane Henney, M.D., Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Dr. Henney:

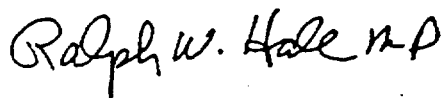
The undersigned organizations, representing 340,000 physicians, are very concerned about restrictions we understand the Food and Drug Administration (FDA) has proposed for distribution and administration of the drug mifepristone.

We understand that the FDA has proposed at least five restrictions on access to the drug. These requirements are not based upon scientific facts, do not follow current medical practice, and impose inappropriate conditions on the practice of medicine.

We would like the opportunity to meet with you and your staff to discuss this important issue. It's imperative that the FDA fully understands the effect that these proposals would have on the quality of health care. It's equally imperative that the FDA's work be based solely on evidence from the drug's clinical trials, and be entirely free from any political influence.

Thank you for your interest in this important issue. We look forward to meeting with you and your staff at your earliest opportunity to discuss our concerns in greater detail.

Sincerely,



Ralph Hale, MD —  
Executive Vice President  
The American College of Obstetricians and  
Gynecologists



E. Ratcliffe Anderson, Jr., MD  
Executive Vice President  
American Medical Association

APPEARS THIS WAY  
ON ORIGINAL

06-4974

ROUTING HISTORY  
DATE: AUG 02, 2000

FDA Control Number: 00 4973                      Tracer #:              OS #:  
Date of Correspondence: 07/24/00              Date Into FDA: 08/02/00  
To: JANE E HENNEY HF-1

From: RALPH W HALE, THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

Synopsis: ENCLOSES THE AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS'  
ANALYSIS OF POSSIBLE FDA RESTRICTIONS ON MIFEPRISTONE

Lead Office: HFD-1                                      Home Office: HF-40

Contact/Phone#: \_\_\_\_\_

Date Due Out of FDA: 08/16/00                      Closed Date: OPEN

Copies: GENERAL DISTRIBUTION  
HF-1 JANE E HENNEY  
HF-40 \_\_\_\_\_  
HF-10 \_\_\_\_\_  
HF-40 \_\_\_\_\_

Coordination:

Signature Required:

| Assigned By | Assigned To | Referred Act | Status            |
|-------------|-------------|--------------|-------------------|
| HF-40       | _____ HFD-1 | 08/02/00 DR  | Referred 08/02/00 |

Remarks: PLEASE SEND COPY OF RESPONSE TO \_\_\_\_\_, HF-40. SEE ALSO  
TRAC #00-4974

APPEARS THIS WAY  
ON ORIGINAL