March 4, 2003

Commissioner Mark McClellan
Dan Troy, General Counsel
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. McClellan and Mr. Troy:

On August 20, 2002, Concerned Women for America, the American Association of Pro-Life Obstetricians and Gynecologists, and the Christian Medical Association filed a Citizen Petition requesting the FDA to withdraw its approval of mifepristone. (A copy of the Petition is enclosed.) On February 20, 2003, the six-month deadline for a response from the FDA passed.[1]

We would like to know when FDA believes it will issue its response to the Petition, and we also would like your assurance that the individuals responsible for the violations detailed in it are not preparing the agency's response.

In a potentially related matter, on February 20, 2003, the *Houston Chronicle* reported that a young teenager aborted her second-trimester baby in a school restroom after taking a pill she allegedly received from her boyfriend's sister.[2] The article, which is enclosed, raises troubling questions. Was the drug mifepristone?[3] If so, how and from whom was the drug obtained? We note that FDA's Mifeprex website was updated to include a warning about the illegal distribution of the drug ("Do Not Buy Mifeprex over the Internet") indicating that a black market for abortifacients may be developing in the United States.

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[1] We believe that 180 days, the period which FDA claims to be the maximum response time needed for answering such petitions, *see* 21 C.F.R. § 10.30(e)(2), provided the agency with ample time to address the numerous issues raised in our petition.

[2] Lucas Wall, *Teen Who Took Pill Aborts Fetus In School Restroom*, Houston Chronicle, Feb. 20, 2003.

[3] We also note that the second drug used in the Mifeprex Regimen (misoprostol (Cytotec)) could also have been used to induce the Texas abortion. Its non-authorized distribution to a minor would probably involve similar violations of federal and state law and would also warrant FDA investigation.

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Because of the potential that dangerous violations of the FDA's restrictions on mifepristone were involved, we believe that the FDA should investigate this matter and perhaps refer the case to the appropriate authorities for a criminal review. If the drug used was mifepristone, what will the FDA do to ensure that the offending health care providers do not violate the FDA's restrictions on mifepristone again? More generally, what is the FDA doing to ensure that mifepristone is being administered only in accordance with the FDA's restrictions? The Citizen Petition, at pp. 71-75, describes the ways in which numerous abortion providers are openly deviating from FDA's approved regimen for this Subpart H, restricted distribution drug. To date, we are not aware that any actions have been taken to enforce FDA's restrictions as the agency pledged to do (*see* Citizen Petition at p. 71, fn. 310).

We look forward to your response. In the meantime, feel free to contact us if you have any further questions.

Sincerely,

Sandy Rios

Sandy Rios
President

Cc: Claude Allen, Deputy Secretary, Department of Health and Human Services
Jay Lefkowitz, Domestic Policy Advisor