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2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5074
FACSIMILE (202) 225-3974
MINORITY (202) 225-5051
TTY (202) 225-6852

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March 25, 2003

The Honorable Tommy G. Thompson
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Secretary:

I am writing regarding a recent *Wall Street Journal* article that indicates that there are numerous prescription drugs on the market that have never been approved by FDA.¹

According to the article, the hormone replacement therapy Estratest has been on the market since 1964 without receiving FDA approval. FDA explicitly rejected an application for application for approval of the drug in 1979, and has failed to act on an application that was resubmitted in 1981. The article also indicates that Solvay, the manufacturer of this drug (which had \$178 million in sales last year), has repeatedly either stated or implied that the drug had received FDA approval. And it also appears that many health officials, and even doctors that prescribe the drug, are unaware that the drug has never been approved.

This is an alarming situation, made even more so by the fact that, according to the article, “there are plenty of other drugs that have never been approved by the FDA,” including drugs with safety concerns, that are currently on the market.² Doctors and prescription drug consumers rely on FDA to approve drugs, and they assume that if a drug is on the market it has been shown, consistent with federal law, to be safe and effective. There is no excuse for any widely used and marketed drug to be unapproved for use.

¹*Unapproved Drugs Linger on the Market*, Wall Street Journal (Mar. 20, 2003).

²*Id.*

It is particularly alarming that Estratest, a hormone replacement therapy drug, is one of the drugs that is being marketed without the FDA approval that would indicate that it is safe and effective. As you know, a large study by the NIH released last year indicated that the risks of hormone replacement therapy for women outweigh the benefits of this treatment.³ Just last week, a new study found that the use of hormone replacement therapy drugs offered women no meaningful improvement in their quality of life.⁴ Given these findings, it is astonishing that FDA has continued to let this drug remain on the market for over four decades without explicit indications that it is safe and effective.

In order to help me understand the scope of this problem and the potential risks to consumers, I am requesting that you provide me with the following information:

- (1) A list of all prescription drugs that are currently on the market that have never been approved by FDA, including information on the date these drugs were first marketed and the current status of FDA review of these drugs.
- (2) A description of FDA policy regarding requirements that approval be obtained for drugs that are currently marketed without FDA approval.
- (3) A description of FDA policies that are in effect (a) regarding adverse event reporting for drugs that are marketed without FDA approval (b) ensuring that doctors and health officials are aware of whether a drug that is on the market has not been approved by FDA, and (c) ensuring that drug manufacturers do not mislead consumers or health professionals about the status of unapproved products.
- (4) A list of drugs that were marketed prior to receiving FDA approval and that have subsequently received FDA approval in recent years.
- (5) A list of drugs that were marketed prior to receiving FDA approval and that have subsequently been taken off the market by FDA in recent years, and the reason for these actions.

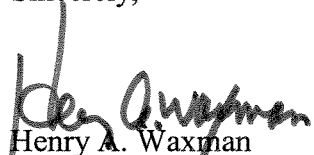
³Deborah Grady et al., *Cardiovascular Disease Outcomes during 6.8 Years of Hormone Therapy: Heart and Estrogen/Progestin Replacement Study Follow-Up (HERS II)*, Journal of the American Medical Association, 49–57 (July 3, 2002); Stephen Hulley et al., *Noncardiovascular Disease Outcomes during 6.8 Years of Hormone Therapy: Heart and Estrogen/Progestin Replacement Study Follow-Up (HERS II)*, Journal of the American Medical Association, 58–64 (July 3, 2002).

⁴Jennifer Hays et al., *Effects of Estrogen plus Progestin on Health-Related Quality of Life*, New England Journal of Medicine (May 8, 2003) (forthcoming).

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Thank you for your prompt response to this request. If there are any questions, please feel free to contact Brian Cohen of my staff at (202) 225-5051. We would appreciate a reply by April 8, 2003.

Sincerely,

A handwritten signature in black ink, appearing to read "Henry A. Waxman". The signature is written in a cursive style with a large initial "H".

Henry A. Waxman
Ranking Minority Member