110TH CONGRESS
2D SESSION

S. CON. RES. 88

Expressing the sense of Congress that the Food and Drug Administration's (FDA) new policy restricting women's access to medications containing estriol does not serve the public interest.

IN THE SENATE OF THE UNITED STATES

JUNE 10, 2008

Mr. CORNYN (for himself and Mr. BUNNING) submitted the following concurrent resolution; which was referred to the Committee on Health, Education, Labor, and Pensions

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CONCURRENT RESOLUTION

Expressing the sense of Congress that the Food and Drug Administration's (FDA) new policy restricting women's access to medications containing estriol does not serve the public interest.

Whereas menopause is often a challenging transition for millions of women that requires specialized medications and medical treatments;

Whereas physicians prescribe a variety of pharmaceutical treatment options to treat women experiencing the symptoms of menopause;

Whereas individual women respond differently to different treatment options;

Whereas women's physicians determine on a case-by-case basis which treatment option is optimal for each woman;

Whereas many physicians prescribe compounded estrogen and other bioidentical hormone treatments for patients for a variety of reasons;

Whereas many physicians prescribe compounded estrogen treatments that contain estriol to treat menopausal and perimenopausal women;

Whereas estriol is one of three estrogens produced by the human body;

Whereas estriol has been prescribed and used for decades in the United States;

Whereas Congress has long recognized active pharmaceutical ingredients meeting standards set by the United States Pharmacopeia as permissible options for physician prescribing and pharmacy compounding;

Whereas the Food and Drug Administration (FDA) has announced that it will no longer permit compounding pharmacists to prepare medications containing estriol pursuant to a doctor's prescription;

Whereas insurers are now denying women reimbursement for compounded medications containing estriol as a result of the FDA's announcement; and

Whereas the FDA has acknowledged that it is unaware of any adverse events associated with use of compounded medications containing estriol: Now, therefore, be it

Resolved by the Senate (the House of Representatives concurring), That it is the sense of the Congress that—

(1) physicians are in the best position to determine which medications are most appropriate for their patients;

(2) the Food and Drug Administration (FDA) should respect the physician-patient relationship; and

(3) the FDA should reverse its policy that aims to eliminate patients' access to compounded medications containing estriol that their physicians prescribe for them, unless the FDA holds a public comment period on the issue and can document evidence of adverse events and other safety issues to justify such policy.

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