110th CONGRESS
2d Session
H. CON. RES. 342

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 HOUSE OF REPRESENTATIVES

May 6, 2008

Mr. ROSS (for himself, Mrs. EMERSON, Ms. BALDWIN, Mr. BURGESS, Mr. FARR, Mr. CARTER, and Ms. GIFFORDS) submitted the following concurrent resolution; which was referred to the Committee on Energy and Commerce

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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 House of Representatives (the Senate 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.

Final House Status Report for H.CON.RES.342:

Title: 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.

Sponsor: Rep Ross, Mike [AR-4] (introduced 5/6/2008) Cosponsors (58)

Latest Major Action: 5/7/2008 Referred to House subcommittee. Status: Referred to the Subcommittee on Health.

COSPONSORS(58), ALPHABETICAL

Rep Allen, Thomas H. [ME-1] - 6/11/2008
Rep Bachus, Spencer [AL-6] - 6/23/2008
Rep Baldwin, Tammy [WI-2] - 5/6/2008
Rep Berry, Marion [AR-1] - 6/4/2008
Rep Biggert, Judy [IL-13] - 7/31/2008
Rep Bishop, Rob [UT-1] - 6/4/2008
Rep Bonner, Jo [AL-1] - 7/10/2008
Rep Boozman, John [AR-3] - 6/4/2008
Rep Boren, Dan [OK-2] - 6/20/2008
Rep Boyda, Nancy E. [KS-2] - 6/24/2008

Rep Brown-Waite, Ginny [FL-5] 6/3/2008

Rep Burgess, Michael C. [TX-26] - 5/6/2008

Rep Burton, Dan [IN-5] - 6/11/2008

Rep Capps, Lois [CA-23] - 7/22/2008

Rep Carter, John R. [TX-31] - 5/6/2008

Rep Chandler, Ben [KY-6] - 6/4/2008

Rep Cooper, Jim [TN-5] - 6/11/2008

Rep Courtney, Joe [CT-2] - 11/19/2008

Rep Doyle, Michael F. [PA-14] - 6/5/2008

Rep Emerson, Jo Ann [MO-8] - 5/6/2008

Rep Eshoo, Anna G. [CA-14] - 6/19/2008

Rep Farr, Sam [CA-17] - 5/6/2008

Rep Frank, Barney [MA-4] - 7/10/2008

Rep Franks, Trent [AZ-2] - 6/25/2008

Rep Giffords, Gabrielle [AZ-8] - 5/6/2008

Rep Gohmert, Louie [TX-1] - 6/24/2008

Rep Gonzalez, Charles. [TX20] 6/23/2008

Rep Goode, Virgil H., Jr. [VA-5] - 6/19/2008

Rep Granger, Kay [TX-12] - 6/3/2008

Rep Grijalva, Raul M. [AZ-7] - 6/4/2008

Rep Hall, Ralph M. [TX-4] - 6/3/2008

Rep Hinchey, Maurice D. [NY-22] - 7/22/2008

Rep Johnson, Timothy V. [IL15]9/25/2008

Rep Kuhl, John Jr. [NY29] 6/4/2008

Rep LaHood, Ray [IL-18] - 6/23/2008

Rep Lofgren, Zoe [CA-16] - 6/11/2008

Rep Marchant, Kenny [TX-24] - 9/11/2008

Rep McCaul, Michael T. [TX-10] - 6/5/2008

Rep Michaud, Michael H. [ME-2] - 6/5/2008

Rep Miller, Jeff [FL-1] - 6/19/2008

Rep Mitchell, Harry E. [AZ-5] - 6/19/2008

Rep Murphy, Tim [PA-18] - 6/11/2008

Rep Musgrave, Marilyn [CO4] - 6/19/2008

Rep Pastor, Ed [AZ-4] - 6/11/2008

Rep Paul, Ron [TX-14] - 5/22/2008

Rep Poe, Ted [TX-2] - 7/31/2008

Rep Sanchez, Linda T. [CA39] 7/10/2008

Rep Shays, Christopher [CT-4] - 6/4/2008

Rep Smith, Lamar [TX-21] - 7/31/2008

Rep Snyder, Vic [AR-2] - 6/5/2008

Rep Stearns, Cliff [FL-6] - 6/4/2008

Rep Thornberry, Mac [TX-13] - 6/3/2008

Rep Tiberi, Patrick J. [OH-12] - 7/10/2008

Rep Wamp, Zach [TN-3] - 5/22/2008

Rep Weller, Jerry [IL-11] - 6/5/2008

Rep Wexler, Robert [FL-19] - 6/4/2008

Rep Wittman, Robert [VA-1] - 7/10/2008

Rep Wolf, Frank R. [VA-10] - 7/22/2008

Congress of the United States
Washington, DC 20515

June 2, 2008

Help Maintain Women's Access to Needed Medication

Dear Colleague,

We are asking you to join us in cosponsoring H.Con.Res.342, a sense of the Congress resolution opposing the FDA's recent decision to ban estriol unless a doctor files an investigational new drug application (IND). Estriol is used in compounded hormone preparations by hundreds of thousands of women to treat the symptoms of menopause. Compounded medications, which are regulated at the state level, are customized medications only available by a doctor's prescription.

This action was taken by the FDA on January 9th, and was requested by a Citizen Petition filed by a pharmaceutical company with competing products. At the press conference announcing its decision, the FDA could not cite a single adverse event or specific safety concern with estriol.

Physicians have prescribed compounded estrogens with estriol for decades. Estriol is the weakest of the three estrogens produced by the female body, and is produced in abundance during pregnancy. It is a component of over 80 percent of all compounded estrogen medications, so eliminating its availability would unnecessarily disrupt the lives of countless women.

The FDA's only justification for its action is that estriol is not a component of an FDA-approved drug. However, it has a United States Pharmacopoeia (USP) monograph, which has always been the standard for determining whether an ingredient can be used in compounded medications. Congress is on record endorsing the USP standard, state boards of pharmacy allow it, and we know of no other precedent for FDA banning an ingredient with a USP monograph absent documented health and safety issues.

Estriol also has promise in the treatment of women with Multiple Sclerosis. Women with MS who become pregnant often go into remission, and this has been correlated to the production of estriol. Advanced clinical trials conducted by UCLA and funded in part by the NIH are now underway to treat women with MS who are not pregnant with estriol. The initial results are promising, and it may in fact be an approved drug in the near future.

The FDA action also interferes with the doctor/patient relationship. Doctors are in the best position to determine the best medications for their patients, and absent real safety issues FDA should not impose themselves into this relationship. If the FDA is successful in banning estriol, every woman who now uses it will have to return to her doctor to find a new combination that may not be as appropriate for her medical needs. This is at best an unnecessary and unjustifiable expense and inconvenience, and at worst it could seriously disrupt or deny the medical treatment deemed appropriate by a woman's doctor.

Requiring doctors to file an IND as the FDA has proposed is not a workable solution. The IND process is not meant for this situation and would tie up both doctors and FDA personnel with unnecessary paperwork. Potentially thousands of applications would have to be submitted.

Some insurance companies have also stopped reimbursing for compounded estrogens that contain estriol based on FDA's announcement. This represents a denial of care to women who otherwise cannot afford a medication deemed necessary by their physician.

Please support the women in your district and join us in cosponsoring H.Con.Res.342. To cosponsor or for more information, please contact Kate Callanan (Ross) at 5-3772 or Jeffrey Connor (Emerson) at 5-4404.

Mike Ross
Member of Congress

Jo Ann Emerson
Member of 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

Final Senate Status Report for S.CON.RES.88:

Title: A 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.

Sponsor: Sen Cornyn, John [TX] (introduced 6/10/2008) Cosponsors (2)

Latest Major Action: 6/10/2008 Referred to Senate committee. Status: Referred to the Committee on Health, Education, Labor, and Pensions.

COSPONSORS(2), ALPHABETICAL

Sen Bunning, Jim [KY] - 6/10/2008 Sen Inhofe, James M. [OK] - 6/17/2008