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Possible Amendments to the FY 2005 Agriculture Appropriations, Part II

The following are amendments that were made in order pursuant to unanimous consent agreement.

Under an open rule, new amendments may be offered without notice.

Rep. Hefley #8. The amendment reduces Agriculture Appropriations bill by 1% (\$167.7 million).

Rep. Tiahrt #12. According to the sponsor, the amendment would restrict all travel funds of USDA employees who work in Washington, DC, until the Agriculture Secretary implements a voluntary program for beef slaughtering establishments to test for Bovine Spongiform Encephalopathy (Mad Cow Disease). **(This amendment should be subject to a point of order.)**

Reps. Chabot/Royce #7. The amendment would eliminate the Market Access Program (MAP), a subsidy designed to help corporations expand markets oversees. According to the sponsor's description, MAP gives away tens of millions of taxpayer dollars to industry associations to market their products overseas annually.

Rep. Kaptur. The amendment provides \$6 million for the Farmers Market Promotion Program. This program was authorized by the 2002 <u>but has never been funded</u>. As a result of the intended offset already being used, the sponsor will have to redraft the amendment on the floor.

Rep. Baca. The amendment increases funding \$3.5 million for the Office of Civil Rights by \$250,000 and minority programs, including \$1 million for tribal extension grants, \$750,000 for 2501 Outreach to Minority Farmers, and \$1.5 million for Hispanic Serving Institutions. The amendment reduces \$3.5 million from rural development.

Rep. Baird may offer an amendment regarding livestock compensation. **Text is not available.**

Reps. Maloney/Waxman. The amendment inserts at the end of the bill the following:

SEC. 759. None of the funds made available in this Act may be used to restrict to prescription use a contraceptive **that is determined to be safe and effective for use**

without the supervision of a practitioner licensed by law to administer prescription drugs under section 503(b) of the Federal Food, Drug, and Cosmetic Act (emphasis added).

The Maloney Amendment appears to have no effect on current law and merely restates current FDA law and policy regarding prescription drugs and over-the-counter drugs. Oral contraceptives as a class of drugs are only available by prescription. In the US, currently there are no oral contraceptives approved to be sold over-the-counter. Among other things, in order to qualify for over the counter status a drug must:

- 1) be proven safe and effective for use without a doctor's supervision and
- 2) must have an easily understood label.

On May 7, 2004, the FDA rejected an over-the-counter application for the morning-after pill because "...we have concluded that you have <u>not provided</u> adequate data <u>to support a conclusion that Plan B can be used safely by young adolescent women for emergency contraception without the professional supervision of a practitioner licensed by law to administer the drug" (emphasis added). In other words, the petitioners for OTC status could not prove #1 above, that the drug was safe and effective without a doctor's supervision, and the FDA rejected their petition.</u>

Source: FDA Non-Approvable Letter, http://www.fda.gov/cder/drug/infopage/planB/planB_NALetter.pdf

The Maloney amendment says no funds may be used to keep a contraception drug as prescription-only <u>if</u> it has been determined to be safe and effective without a doctor's supervision. There is <u>not</u> an oral contraceptive that has been determined to be safe and effective without a doctor's supervision.

Therefore, the Maloney amendment would not change the current status of any contraceptive drug. If, in the future and during FY05, a contraceptive drug was found to be safe and effective without a doctor's supervision, then the Maloney amendment would prevent FDA personnel from restricting such a drug to prescription only. But since no drug has been deemed to fit this status, the Maloney amendment only prohibits a hypothetical situation and thus has no current effect on the FDA.

Note: The sponsor is claiming this amendment deals with the morning-after pill (what she likely will call "emergency contraception"). The FDA recently rejected an application to switch the morning-after pill to over-the-counter status because it could not be proven safe and effective for teen use without a doctor's supervision. The FDA followed the law on the decision and the law is in accordance with the Maloney amendment. This drug was specifically rejected as over-the-counter because it was deemed unsafe, or could not be proven safe.

Rep. Obey may offer an amendment regarding information technology systems. **Text is not available.**

Rep. Obey may offer an amendment regarding OMB Circular A-76. Circular A-76 governs the federal government's outsourcing policies. For more information, please see the following CRS report: http://www.congress.gov/erp/rs/html/RS21489.html **Text is not available.**

Rep. Tancredo. The amendment prohibits the use of funds under the heading "Food and Nutrition Service – Food Stamp Program" in violation of Section 213a of the Immigration and Nationality Act which requires that, "...the appropriate entity of the federal government, a state, or any political subdivision of a state shall request reimbursement by the sponsor [of an alien] in an amount which is equal to the costs of such benefit [provided to the alien]." According to the sponsor, immigrant sponsors make a legally binding guarantee that the immigrant they are sponsoring will not become a 'public charge' (dependent on welfare programs). The federal government is authorized to seek reimbursements of these sponsors, and if necessary, sue to recover the costs. This amendment would encourage the Department to do so.

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