

Subcommittee Approves ADUFA, AGDUFA and Student Health Care Legislation

Washington, D.C. — The Subcommittee on Health today approved three bipartisan bills: H.R. 2851, "Michelle's Law," H.R. 6432, the "Animal Drug User Fee Amendments of 2008," and H.R. 6433, the "Animal Generic Drug User Fee Act of 2008." All three bills were forwarded to the full Committee by voice vote.

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"I thank my colleagues for working in a bipartisan manner to move these bills forward and urge all Members of this Committee to support them," said Rep. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce. "These bills provide common-sense protection for sick students and ensure that FDA is able to safely and efficiently review animal drugs."

H.R. 2851, "Michelle's Law," sponsored by Rep. Paul Hodes (D-NH), allows full-time students over the age of 18 who become severely ill to maintain their parents' health insurance if they take a certified medical leave of absence from school. This bill would require group health plans and insurance plans in the individual market to continue coverage for sick students for up to one year.

"By passing bipartisan bills to reauthorize ADUFA and to establish a new animal generic drug user fee, we are ensuring that innovative,

affordable and safe pharmaceutical products are approved to treat our nation's pets and food producing animals in a timely fashion," said Rep. Frank Pallone, Jr. (D-NJ), Chairman of the Subcommittee on Health. "The Subcommittee also supported Michelle's Law so that college students no longer have to choose between getting a college education and addressing a serious illness or disease."

"Michelle's Law is inspired by Michelle Morse, a full time college student who died tragically from cancer while undergoing the stress of a full load of classes and chemotherapy treatments," Rep. Paul Hodes (D-NH) said. "We can and should do better for our students and families. I am pleased that the Energy and Commerce Committee is moving this bipartisan legislation that creates better health care solutions for families across the country."

Both H.R. 6432, the "Animal Drug User Fee Amendments of 2008" (ADUFA), and H.R. 6433, the "Animal Generic Drug User Fee Act of 2008" (AGDUFA), provide the Food and Drug Administration (FDA) with the necessary structure and resources necessary for the timely and thorough review of applications for brand-name and generic animal drugs. The user fees established for these programs supplement existing appropriations to FDA.

ADUFA was originally enacted in 2003 and expires on October 1, 2008. The program authorizes FDA to collect fees from the animal health industry to be used for the review and approval of animal health products. The fees supplement the Agency's annual Congressionally-approved appropriations and help to expedite the review of animal drug applications. AGDUFA, which would be a new user fee program, has been proposed by the Administration to support the review of generic animal drug applications.

Additional information on the legislation is available on the Committee's web site.

Prepared by the Committee on Energy and Commerce

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