



## **NEWS RELEASE**

### **Committee on Energy and Commerce Rep. John D. Dingell, Chairman**

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### **Committee Approves ADUFA, AGDUFA and Student Health Care Legislation**

*Washington, D.C.* – The Committee on Energy and Commerce today completed a markup of three bipartisan bills. H.R. 2851, “Michelle’s Law,” was approved with forty Members voting “aye” and two voting “present.” H.R. 6432, the “Animal Drug User Fee Amendments of 2008,” and H.R. 6433, the “Animal Generic Drug User Fee Act of 2008,” both passed by voice vote. The bills will now be sent to the full House of Representatives for consideration.

“These important public health bills provide common-sense protection for sick students and ensure that FDA is able to safely and efficiently review animal drugs,” said Rep. John D. Dingell (D-MI), Chairman of the Committee on Energy and Commerce. “I applaud my colleagues on both sides of the aisle for working cooperatively on these bills, consistent with the finest traditions of this Committee.”

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. An amendment making technical changes was offered by Rep. Frank Pallone, Jr. (D-NJ), Chairman of the Subcommittee on Health, and accepted by voice vote. An additional amendment offered by Reps. Michael Burgess (R-TX) was ruled non-germane by the Chairman.

“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 Committee 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. I look forward to all three of these bills heading to the House floor.”

“No college student should be forced to undergo a full course load while being treated for serious illness,” Rep. Hodes said. “Today, we took another step forward in passing

this legislation to honor Michelle's memory and to ensure no American student ever has to suffer her fate."

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. Pallone offered an amendment to H.R. 6432 that makes a series of technical and conforming changes and takes a significant step toward addressing public health concerns regarding the use of antimicrobial drugs in food-producing animals by adding an antimicrobial ingredient reporting requirement. This amendment, which had been negotiated among majority and minority Members and the FDA, was agreed to by voice vote. Additionally, an amendment offered by Rep. Steve Buyer (R-IN) to give FDA the authority to destroy counterfeit or adulterated animal drugs at ports of entry was also agreed to by voice vote.

AGDUFA, which would be a new user fee program, has been proposed by the Administration to support the review of generic animal drug applications. Pallone offered an amendment making technical changes to the bill that was approved by voice vote.

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