

April 18, 2012

The Honorable Chris Van Hollen United States House of Representatives 1707 Longworth House Office Building Washington, DC 20515

Dear Representative Van Hollen:

AARP is pleased to endorse your legislation, the Patient Safety and Drug Labeling Improvement Act, to address the issue of whether generic drug manufacturers have a duty to include new warnings about potentially serious side effects on their labels as they become known. Your bill would accomplish this by giving generic drug makers the same ability to update their labeling as currently exists for manufacturers of brand name drugs.

AARP believes generic drugs are one of the safest and most effective ways for consumers to lower their prescription drug costs, and we encourage our members to use generic drugs whenever possible. However, AARP is concerned that, unlike brand name drug manufacturers, generic drug manufacturers cannot be held liable for inadequate drug warning labels due to their inability to directly update their labels under current law.

As noted in an AARP Foundation amicus brief submitted in *Pliva v. Mensing*, AARP believes that holding generic drug makers to a lower standard will effectively punish consumers for choosing generic drugs and send the message that generics are less trustworthy than name brand drugs — directly counter to the intent of the Hatch-Waxman Act. We are encouraged by your bill and hope it will serve to not only ensure patients have adequate legal protections, but also prompt improvements to the FDA process for updating warning labels when new information about potentially harmful side effects comes to light.

We thank you for your leadership in this area, and we look forward to working with you and your colleagues on both sides of the aisle to advance the Patient Safety and Drug Labeling Improvement Act. If you have any further questions, please feel free to call me or have your staff contact KJ Hertz of our Government Affairs staff at 202-434-3770.

Sincerely,

Joyce A. Rogers Senior Vice President Government Affairs