Consumers Union
Nonprofit Publisher of Consumer Reports

March 19, 2007

The Honorable Henry Waxman
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Waxman:

Consumers Union, the independent, non-profit publisher of *Consumer Reports*, congratulates you on the introduction of the "Enhancing Drug Safety and Innovation Act of 2007." The enactment of your bill will save countless lives in the years to come by giving the FDA stronger legal authority to ensure the safety of drugs and devices that have been approved and are in the marketplace.

Consumers Union has endorsed S. 484, a bill by Senators Kennedy, Enzi and others, as a good first step in giving consumers peace of mind about the safety of drugs in their medicine cabinets. Your bill builds on the structure of that legislation, but also includes many important strengthening features that we very strongly support.

Because most drugs are tested on so few people for such a short period of time before FDA approval, it is impossible to know all of their possible side effects, both good and bad, before they are marketed. Therefore we deeply appreciate your bill's provisions that will

--let consumers know through a symbol on the packaging that a drug is new to the marketplace;

--provide for a system of safety reviews, including one at the point a drug has been on the market 7 years (which is about the average time it takes to detect most side effects);

--expand S. 484's possible moratorium on mass marketing (direct-to-consumer) advertising from two years to three years;

--increase the public's knowledge of possible safety issues by making public any industry-FDA debates about various safety concerns and how to address them. These provisions will help address the FDA morale and culture problems identified by the Institute of Medicine and others, because they will bring more transparency to the drug safety process and ensure a very public record of the science involved.

Consumers Union
Headquarters Office
101 Truman Avenue
Yonkers, New York 10703-1057
(914) 378-2029
(914) 378-2992 (fax)

Washington Office
1101 17th Street, NW #500
Washington, DC 20036
(202) 462-6262
(202) 265-9548 (fax)

West Coast Office
1535 Mission Street
San Francisco, CA 94103-2512
(415) 461-6747
(415) 431-0906 (fax)

South West Office
506 West 14th Street, Suite A
Austin, TX 78701
(512) 477-4431
(512) 477-8934 (fax)

As you so well know, recent high profile drug safety cases, such as Vioxx, Paxil, and others, have shown that the FDA does not have effective legal authority to require quick, decisive action when safety concerns have been raised. All too often the agency has to negotiate for label changes and watch helplessly as promised safety studies go undone. Your bill makes it crystal clear that the FDA can enforce labeling changes, safety studies, and take other actions to protect the public—and that it can impose significant Civil Monetary Penalties for failures to comply with needed safety actions.

In the past, drug companies have basically shown consumers the clinical trials they wanted to make public, while hiding the ones that show that the drug may be no better than a placebo or have a serious side effect. Title III of your bill builds on the clinical trials registration and result proposals in S. 484, but includes more trials, ensures that they are reported in a timely manner, and closes other abusive loopholes.

We look forward to working with you to enact this important legislation, and we have some other proposals for improving the quality of the FDA's safety work without slowing the approval of life-saving new drugs and devices that we hope may be considered during the legislative process. For example, we believe more could be done to

--strengthen the Office of Surveillance and Epidemiology without creating bureaucratic delay;

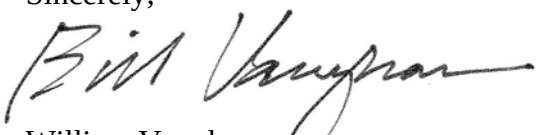
--do more to promote a climate of scientific openness within the FDA;

--recruit non-conflicted Advisory Committee members, and

--expand the language in your bill on Medicare databases to set a specific goal for the active, aggressive use of data to determine short- and long-term safety and effectiveness.

Congratulations again on a bill that will truly save lives, help avoid many of the types of drug safety crises we have experienced in the past, and bring greater consumer peace of mind about the safety of medicines.

Sincerely,



William Vaughan
Senior Policy Analyst (Health)
Washington Office