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The Honorable Edward M. Kennedy
Chairman
United States Senate
Committee on Health, Education, Labor and Pensions
Washington, D.C. 20510

RE: OPPOSITION TO S. 838 IN ITS CURRENT FORM

Dear Mr. Chairman:

Consumers Union opposes S. 838, which your committee is scheduled to mark up on August 1. It will not make the current requirements for pediatric exclusivity safe, targeted or effective. In addition, it will lead to higher prescription drug prices, which impose a financial burden on our country's consumers – especially the uninsured, the underinsured, and Medicare beneficiaries.

Current law, which expires at the end of the year, grants a six-month patent extension to a manufacturer as an incentive to test a drug on children. We understand that the law generally has been effective in generating pediatric drug studies to provide needed data that informs clinical practice and adds new information to drug product labeling specific to pediatric prescribing. However, we do not believe that granting additional patent extensions is in the best interest of consumers as a whole. One consequence of pediatric exclusivity is that it has delayed the introduction of more affordable generic alternatives for some very important and widely used drugs – which has proven to be very lucrative for brand name companies, and detrimental to consumers who are struggling to pay higher prices for prescription drugs.

The Food and Drug Administration (FDA) estimates that because of these delays consumers will have to pay an additional \$14 billion in higher drug costs. In the case of drugs with particularly high sales levels, exclusivity is worth considerably more than the cost of doing a study on children. For example, the *Wall Street Journal* estimates that the additional six months of exclusivity granted to Schering-Plough for testing Claritin in children will be worth \$975 million in additional revenue. This is more than 130 times the General Accounting Office's estimate of the \$7.5 million it costs to do a clinical trial. This can translate into windfall profits for an industry that is already the most profitable in the nation.

Furthermore, the law has not been successful in encouraging the testing and pediatric labeling of some therapeutically important drugs widely used in children pediatric populations. Moreover, in some cases, important labeling changes have been unnecessarily delayed, even though the necessary clinical trials have been done and exclusivity has been granted. Such delays in testing and providing physicians with critical information puts children at risk of adverse effects from the use of inappropriate drugs, or improper drug dosages.

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We believe that if this provision is reauthorized, it should, at minimum, include the following improvements:

1. **Assure that all drugs that are likely to be used in children will be tested for pediatric use.**

The brand name drug industry has begun to test many more drugs on children as a result of pediatric exclusivity. However, many drugs that need to be studied and labeled for use on children remain unreviewed. The bill does take one important step in the right direction by making funds available for the testing of older, off-patent drugs that are not eligible for exclusivity, and requiring that the information obtained through this testing be reflected in labeling changes. This effort is needed because, according to the FDA, the drugs most likely to be used by children are now off-patent.

We believe that additional measures must be taken to ensure that pediatric testing is conducted. The law should require drug companies to test all drugs that are likely to be used on children as a condition of drug approval. The FDA has estimated the annual cost of conducting those studies if they had been required between 1993 and 1997 at \$80 million. This is a modest cost in exchange for lucrative monopolies granting the rights to market a prescription drug. Congress should enact legislation requiring testing of all new drugs likely to be used in children to affirm the FDA's authority.

2. **Require that drug companies make relevant labeling changes in a timely manner.** The bill creates a set of deadlines by which drug companies must complete labeling changes -- after the company receives exclusivity. However, this approach maintains the basic flaw in current law, by granting exclusivity before companies have made appropriate labeling changes. We believe that the grant of exclusivity should be conditioned upon all necessary labeling changes being made prior to a grant of exclusivity. By granting exclusivity only after companies have made labeling changes, the FDA would retain a powerful incentive to assure that changes are made.

3. **Effectively target patent exclusivity, limiting excessively long periods.** Congress should modify the six month blanket exclusivity to ensure that drug companies are not receiving an excessive financial benefit in comparison to the costs incurred in conducting these studies.

4. **Require a report evaluating the impact of the legislation.** Require a report on the effectiveness of this legislation in making important drugs available to children, and the impact of patent extensions on the prices paid by the elderly and the uninsured.

Thank you for your attention to this important issue. Consumers Union believes that these changes could transform this legislation into a bill that provides a boost to pediatric testing without over-compensating the pharmaceutical industry.

Sincerely,

Janell Mayo Duncan

Janell Mayo Duncan
Legislative Counsel