STATEMENT OF
THE COMPETITIVE ENTERPRISE INSTITUTE AND CONSUMER ALERT
ON THE SENATE PROPOSAL TO CODIFY
THE FOOD AND DRUG ADMINISTRATION'S PEDIATRIC RULE

The Senate is currently considering a bill (S. 2394) that would codify what is known as the Food and Drug Administration's "Pediatric Rule". Under this bill, FDA would be given the authority to require pediatric testing, by pharmaceutical companies, of adult-labeled drugs that have significant therapeutic potential for children. Proponents argue that it is necessary because many drugs prescribed for children have not been formally tested on them. Children often react differently than adults to medications, and therefore adult tests of such drugs are an inadequate basis for their "off-label" use for children.

More information about drugs is certainly a worthy goal. However, proposals to mandate such information tend to ignore the inevitable trade-off between drug testing and drug availability. Expanded testing requirements will almost certainly result in a longer, more expensive drug development and approval process. This process is already too long and costly as it is. According to a recent CEI poll of oncologists, for example, over 60 percent of these specialists believe that FDA is too slow in approving new therapies. http://cei.org/gencon/003,02985.cfm Pharmaceutical companies must already weigh a huge array of factors in deciding whether to proceed with a new candidate drug. If the possibility of mandatory off-label pediatric testing is added to that list, then it becomes even more likely that certain candidate drugs will be dropped from consideration. The result will be fewer available drugs for adults and children alike.

FDA's ultimate sanction against a company that declines to undertake mandatory pediatric testing is to disapprove it or remove it from the market. But as one pediatrician has noted, "there are many drugs that are tremendously useful for children even though they are not labeled for pediatric use. The possibility that the FDA might remove these drugs from the market is unimaginable."

Proponents of the bill point to incidents of adverse drug reactions by children. Clinical testing, however, simply cannot discover every possible drug reaction. There is only one guarantee of zero surprise drug side effects, and that is zero drug approval. Moreover, some of the incidents cited by proponents simply do not withstand scrutiny. For example, both the *New York Times* and *USA Today*, in their editorials on this issue (April 7 and 8, respectively), described a 1999 incident in which seven infants in Tennessee required surgery for stomach obstructions after being given erythromycin to

prevent a whooping cough outbreak. The editorials claimed that pediatric testing of erythromycin would have prevented this.

The details of this episode, however, demonstrate exactly the opposite. Approximately 200 newborns, all below the age of one month, received erythromycin; of them, seven developed what is known as pyloric stenosis and successfully underwent surgery as a result. Despite the fact that erythromycin is an exceptionally familiar drug to pediatricians, this was a previously unknown side effect to which only infants below the age of one month were susceptible. *A controlled study in which infants this young were given this drug purely for research purposes, on a scale large enough to find this side effect, would be totally unethical.* Moreover, even after the Tennessee experience, the drug of choice for treating whooping cough in infants is *still erythromycin*.

Finally, proposals for mandatory pediatric testing are already spurring calls for mandated off-label testing for other special populations, ranging from pregnant and lactating women to geriatric patients. Calls for such mandates will be extremely difficult to resist once the pediatric precedent is set. The same will be true of proposals to mandate testing drugs not just for off-label populations, but for off-label indications as well.

At heart, off-label use is an issue of how medicine is practiced. Physicians may well vary in how much information they require before undertaking such use; that is a matter best left to individual doctors. Once off-label testing mandates are imposed, this issue is taken out of the hands of individual physicians, because no doctor at all will have access to drugs that do not meet these standards. Congress should carefully consider whether it wishes to venture down this path.

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Both CEI and Consumer Alert have long been involved in the issue of FDA reform, and are currently engaged, together with the Association of American Physicians and Surgeons, in litigation challenging the validity of FDA's Pediatric Rule. Nothing in this statement should be construed as attempting to aid or hinder the passage of any bill before Congress.