

Today Rep. Henry A. Waxman, Sen. Edward M. Kennedy, and Rep. Tom Allen introduced the Non-Prescription Drug Modernization Act which would permit FDA to act quickly to protect consumers from unsafe or ineffective over-the-counter drugs.

An FDA advisory panel recently recommended that over-the-counter (OTC) cough and cold medications for children under the age of six should be banned after it found that those products lacked evidence of efficacy, and, in rare cases, could cause serious harm. Yet, under current law, to follow its committee's recommendations, FDA must go through a rulemaking process that could take years to complete. In the interim, these drugs, which may cause serious harm, could continue to be marketed. The Non-Prescription Drug Modernization Act would give FDA the authority to act quickly to revoke authorization to market such drugs without a lengthy rulemaking. The Act would also transfer oversight of OTC drug advertising from the FTC to the FDA, which already regulates the advertising for prescription drugs, and would require FDA to review the current OTC regulatory regime to assess whether it is outdated.

Documents and Links

- [Press Release](#)
- [Bill Text](#)
- [Bill Fact Sheet](#)