

## **FOR IMMEDIATE RELEASE**

### **U.S. Healthcare Stakeholders Uncertain about Benefits of Risk Evaluation Program, According to Tufts Center for the Study of Drug Development**

BOSTON – Jan. 12, 2011 – Drug developers, healthcare providers, insurance companies, and others involved in the delivery of healthcare in the United States are uncertain about the benefits of a risk evaluation program introduced three years ago by the Food and Drug Administration (FDA), according to the Tufts Center for the Study of Drug Development.

Key findings of Tufts CSDD's assessment of the Risk Evaluation & Mitigation Strategy (REMS) program, the first systematic look at the initiative since the FDA introduced it in 2008, were reported in the January/February *Tufts CSDD Impact Report*, released today.

"A majority of the organizations told us they felt the REMS program needs a major overhaul, and said that a REMS is a poor substitute for other improvements needed system-wide in drug education, communication, use monitoring, patient access, and delivery of care," said Christopher-Paul Milne, associate director at Tufts CSDD, who conducted the assessment.

Drug developers must create a REMS as part of a new product approval application, and sometimes for a previously approved product, when the FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks.

According to Milne, "Most respondents said it is virtually impossible to measure the benefits of a REMS, compared to its burdens on patient access and cost of health care delivery, for a newly approved drug, and that even for an already-approved drug, it would likely require two years or more to effectively conduct such an assessment."

Among other findings developed by the survey were the following:

- \* Three-quarters of respondents thought that the REMS program needs a major overhaul.
- \* Sixty-eight percent said that REMS are a poor substitute for other improvements needed system-wide in drug education, communication, monitoring of use, patient access and delivery of care.
- \* Eighty-six percent felt that under current guidelines, risk and benefit information was not well balanced in REMS communications.
- \* Only 22% of respondents thought the REMS program has been an improvement over the existing risk management system.

Milne noted that the REMS program will likely impact a growing number of healthcare stakeholders as the number of products with REMS expands in coming years.

#### **About the Tufts Center for the Study of Drug Development**

The Tufts Center for the Study of Drug Development (<http://csdd.tufts.edu>) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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