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Lack of Clinically Useful Diagnostics Hinder Growth in Personalized Medicines, According to Tufts Center for the Study of Drug Development

BOSTON – July 19, 2011 – Lack of evidence that links diagnostic tests to health outcomes has led payers in the United States to be skeptical about the clinical usefulness of those tests and is hindering the growth of personalized medicines, according to a newly completed analysis by the Tufts Center for the Study of Drug Development.

While the number of personalized medicines and companion diagnostics in use in the U.S. has gradually increased—from a handful in 2001 to several dozen in 2011—surveys conducted by Tufts CSDD show that lack of evidence concerning the clinical usefulness of many current companion diagnostics is a major factor limiting the potential of personalized medicine.

“Scientifically, the process of biomarker discovery and validation in general, and parallel development of drugs and companion diagnostics in particular, has been slow. Additionally, regulatory and reimbursement issues have limited uptake in clinical practice, particularly with respect to companion diagnostics, but also for drugs lacking effective diagnostics,” said Joshua Cohen, Ph.D., senior research fellow at Tufts CSDD and author of the study.

Without clinically useful diagnostics, development of personalized medicine is likely to continue at a relatively slow pace, he noted.

Companion diagnostics are tests linked to a therapeutic drug that stratify populations into responders and non-responders and indicate the likelihood of adverse events in particular patients.

The study, reported in the July/August Tufts CSDD Impact Report, released today, also found that:

* Lack of clinical usefulness of many companion diagnostics has led payers to deny or restrict reimbursement of tests.

* A minority of U.S. payers require documentation that a diagnostic test has been conducted prior to prescribing personalized drugs – even when the diagnostic is included on the label.

* Pharmacogenomic experts foresee moderate growth over the next five years in post hoc development of companion diagnostics to personalize already approved drugs, co-development of companion diagnostics, and personalized drugs.

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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