MANHATTAN INSTITUTE FOR POLICY RESEARCH

Press Release
June 28, 2011

Contact: Bridget C. Carroll
(646) 839-3313
bcarroll@manhattan-institute.org

No Magic Pill:
CER "Averages" Would Leave Millions without the Drugs That Work for Them

New York, NY: Comparative effectiveness research (CER) has been heralded as a way to reduce health-care costs by determining which treatments provide the most benefit for the largest number of patients.In their new report, *Blue Pill or Red Pill: The Limits of Comparative Effectiveness Research*,researchers Tomas Philipson and Eric Sun of the Manhattan Institute's Project FDA find that CER may fail to provide successful strategies for lowering health care costs if reimbursement policies for programs like Medicare and Medicaid restrict access to therapies that aren't deemed "winners" in CER trials.

In declaring drug "winners" and "losers," CER trials provide ammunition for government agencies to restrict access for more expensive prescription drugs, regardless of whether they work for individual patients. Philipson and Sun warn that "losing" drugs can remain important and effective options for many patients.

President Obama said in a press conference in 2009, "if there's a blue pill and a red pill, and the blue pill is half the price of the red pill and works just as well, why not pay half price for the thing that's going to make you well?" But when cutting the red pill would deny coverage to thousands of individuals who would benefit from its use, it's hard to determine a real "winner."

Why Poorly Designed CER Studies are a Problem

The 2009 federal stimulus bill and the 2010 Affordable Care Act provided hundreds of millions of taxpayer dollars for CER. Eventually, the results of CER studies may be used to dictate health-care reimbursement policies.

- **CER relies on "averages"** derived from the greatest number of people who are responsive to one treatment over other treatments. **The result:** the average provides a distinct "winner" and "loser" in drug trials and could leave subgroups and individual patients withoutaccess to the treatments they need.
- **Cost pressures may lead policymakers to promote cheaper generic medicines** through "one size fits all" guidelines. This can lead to worse health and higher costs for many patients who don't respond to drugs considered "winners" based on average results from CER clinical trials. **The result:** Drug coverage under Medicare and Medicaid may be subject to CER outcomes. In one 2005 study on antipsychotic drugs in the Medicaid program, 75 percent of people who did not respond to the "winning" drug responded to the "losing" drug. This trial demonstrates the negative effects that coverage denial can have on individuals outside the "average."
- **Difference and dependence** are not taken into consideration in many present CER studies. **The result:** CER studies may not control for differences of age, race, and sex which are important

factors that can affect how any individual will react to a drug or therapy. What may on average be a "winning" therapy, may simply not work for a large number of patients.

- **The goal of CER is cutting healthcare costs,** howeverPhilipson and Sun found that applying restrictive reimbursement to the Medicaid program for antipsychotics would reduce patient health by more than 13,000 quality-adjusted life years (QALYS). **The result:** 75 percent of patients who didn't respond to generics would be in worse health because, under a restrictive policy, they wouldn't have any other therapeutic options. When each QALY is valued at $100,000, a standard practice in the peer-reviewed economic literature, restricting drug access would increase health-care costs by $1.3 billion, outweighing the Medicaid savings.

Philipson and Sun's Solutions

- **CER should take an individualized approach to medicine,** taking into account information about how individuals respond differently to the same medicines, and how failure with one therapy can predict success with another.
- **The discussion around CER must shift from "winners" and "losers" to effective treatment options.**Instead of seeking cost savings through an "average," CER should implement new clinical trial designs, including "crossover design" strategies in which patients are switched from one treatment to another within a study and "adaptive assignments," in which patients are switched between treatments based on their responses. This strategy can help physicians develop more personalized–and successful–treatment programs rather than complying with "one size fits all" coverage decisions.
- **CER should deal with diseases, medications, and patient populations on a case-by-case basis,** rather than rely on the centralized, population-average approach presently conducted.

Tomas J. Philipsonis chairman of the Manhattan Institute's Project FDA, a managing director at Precision Health Economics, the Daniel Levin Chair in Public Policy at the Irving B. Harris Graduate School of Public Policy Studies, and a member of the Department of Economics at the University of Chicago.**Eric Sun** is a resident in the department of anesthesiology at Stanford University and a visiting fellow at the Bing Center for Health Economics at the RAND Corporation.

The Manhattan Institute's**Project FDA** is a committee of physician-scientists, economists, medical ethicists, and policy experts that conducts research and holds forums on ways to streamline and accelerate medical innovation.

The report is available at http://www.manhattan-institute.org/html/fda_04.htm. If you would like to schedule an interview with Tomas Philipson or Eric Sun,pleasecontactBridget C. Carroll at 646-839-3313 or bcarroll@manhattan-institute.org.

The Manhattan Institute, a 501(c)(3), is a think tank whose mission is to develop and disseminate new ideas that foster greater economic choice and individual responsibility.

www.manhattan-institute.org