

**Prescription Project conference, “Righting the Script”**

Opening Remarks

Robert Restuccia, Executive Director, The Prescription Project

My name is Rob Restuccia, I am the Executive Director of the Prescription Project and Community Catalyst.

Welcome to *Righting the Script*, the first Prescription Project conference. With a new Administration and Congress, national health reform on the agenda, and growing concerns about the safety and cost of pharmaceuticals, the timing could not be better to bring us together around a new reform agenda.

The Prescription Project was created by the Pew Charitable Trusts and is led by Community Catalyst, a Boston-based consumer organization that works with and supports organizations in over 40 states to forge a movement for quality, affordable health care.

Three years ago, we started planning for this Project against a backdrop of spiraling prescription drug costs and concerns about the safety and efficacy of the pharmaceuticals. A constant stream of articles and court cases challenged the actions of drug companies and regulators.

Vioxx had been shown to have caused tens of thousands of unnecessary deaths, and an editor of the *New England Journal of Medicine* said he'd been – quote – “hoodwinked” by Merck, the maker of the drug.

A multi-state lawsuit against Warner Lambert for the off-label marketing of Neurontin resulted in a settlement of over \$400 million and new awareness of the problems of off-label marketing.

Glaxo Smith Kline was sued for suppressing evidence of harm in children from the anti-depressant Paxil.

In the context of this myriad of problems, the Project was launched in 2007 to develop and advocate policy solutions. The Project works to change the practices of academic medical centers, and to change state and federal policies. We made great strides in all these areas since our inception.

We have seen a sea change among Academic Medical Centers. A 2006 article in the Journal of the American Medical Association by Troy Brennan and David Rothman, the Associate Director of the Project and of Institute of Medicine as a Profession, set new standards for conflict of interest policies at Academic Medical Centers. This article served as the basis of the Project's recommendations. Our staff worked closely with a number of leading Academic Medical Centers. Two of the leaders are in the audience today, Dr. Barbara Barnes from the University of Pittsburgh and John Randolph, from the UMass Memorial Medical Center. In June of this year, we were heartened to see that the Association of American Medical Colleges – the trade association for U.S. medical schools and teaching hospitals -- made recommendations very similar to our own.

The Project also has a bottom up strategy for Academic Medicals Centers. Medical students concerned about the influence of pharmaceutical companies on the quality of their education are pushing for change. We collaborated with American Medical Student Association to create a web-based Scorecard that ranks 151 medical schools across the country on their conflict of interest policies. The Scorecard has shown a dramatic change in such policies over the past year. Over 44% of schools have revisited their policies and now nearly 20% receive top grades.

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While institutional change is important, public policy change is critical to addressing our concerns about pharmaceuticals. The Project understood that the reform often starts in states, often called the laboratories of democracy. Since the launch of the Project:

- 5 states have passed or improved gift bans or laws requiring pharmaceutical companies to disclose their relationship to physicians;
- 3 states have defended prescription data privacy laws and recently won a favorable decision in the 1<sup>st</sup> Circuit Court of Appeals
- 7 states have established prescriber education programs— academic detailing —through statute or agency action.

You will hear much more about our state work tomorrow.

Over the past year the Project has increasingly focused on federal reform efforts. The Project reached out to consumer organizations, private payers, physician organizations and others and developed a broad-based coalition to promote the Physician Payments Sunshine Act, introduced by Senators Kohl and Grassley in the Senate and Representatives DeFazio and Stark in the House. Senator Baucus has included this kind of disclosure in his recent health reform white paper, so it is now squarely on the Congressional agenda. Additionally, the Project has worked closely with legislative staff on developing a federal academic detailing program based on the work of Jerry Avorn and Frank May at Harvard Medical School.

The key agency for pharmaceutical reform is the FDA, and the Project has worked to make it more responsive to the public interest. We petitioned FDA regarding Internet medical device advertisements, industry dissemination of off-label information, and adverse impact of direct-to-consumer advertising. We supported a successful petition that challenged the marketing of cough and cold meds for children under 6.

When we began planning this conference months ago, we never anticipated the unprecedented times we are in today. Though these are indeed challenging times, challenges bring opportunity. New leadership means we have an even better chance for real change on pharmaceutical policies, a reformed FDA, comparative effectiveness legislation and new initiatives to limit inappropriate marketing.

This conference today brings together leading voices on many of these issues with folks that are out in the trenches working for policy change.

I want to thank the Pew Trusts for their support, which made this day and all of our work possible, and particularly Hope Cooper, our program officer, who has been made invaluable contributions to the project.

I want to thank the partners and panelists, and workshop leaders, and all the Community Catalyst who helped bring this together.

It's my privilege really to introduce one of my heroes. I have been working on issues of health access for many years, and Chairman Waxman has been a hero to all of us in the health access area. The Medicaid program, in particular, is a very different program because of his extraordinary work. In some ways, I think people who have benefited from the program haven't fully appreciated his role.

Chairman Henry Waxman represents California's 30th Congressional District and is the incoming Chairman of the House Committee on Energy and Commerce. In 2007, he became Chairman of the Committee on Oversight and Government Reform. He conducted investigations into a wide range of topics from the high cost of prescription drugs to waste, fraud, and abuse in government contracting.

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Chairman Waxman is a leader on health and environmental issues, has fought for universal health insurance, comprehensive Medicare and Medicaid coverage, tobacco regulation, AIDS research and treatment, air and water quality standards, pesticide regulations, nursing home quality standards, women's health research and reproductive rights, and affordable prescription drugs.

Please join me in welcoming Chairman Henry Waxman.

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