

NDHI Congressional Briefing: The State and Future of Physician-Industry Collaborations: Spreading Some Sunshine on the Outlook for Innovative Patient Care

Executive Summary June 13, 2012

The National Dialogue for Healthcare Innovation (NDHI) held a Congressional briefing in Washington, D.C on June 13, 2012. The discussion focused on how to ensure principled physician-industry collaboration that serves the public interest and furthers the discovery of new cures, treatments and medical technologies. The briefing is part of NDHI's ongoing efforts to raise awareness, educate key stakeholders and inform decision makers of the importance of principled physician-industry collaboration.

More than 130 attended the hour-long briefing, including over 60 Congressional staff with representation from both parties and chambers, as well as several committees with healthcare jurisdiction. Attendees heard from a panel of experts representing industry, professional societies, patient advocacy groups and academic medical centers, as well as a clinical trial patient.

Mary R. Grealy, President of Healthcare Leadership Council (HLC), opened the discussion with an introduction of HLC and provided context about the impact of Sunshine provisions, followed by examples of innovation resulting from physician-industry collaboration and why it's important, background on the media scrutiny and discussion around the issue, and the formation of NDHI and its progress to date.

Panel Discussion

Each panelist provided remarks and perspectives that underscore the patient and economic benefits resulting from principled collaboration and shared examples that demonstrated the value of innovation. The panel was moderated by Mary R. Grealy.

- Richard K. Murray, M.D., Vice President and Head, Global Center for Scientific Affairs,
 Office of the Chief Medical Officer, Merck & Co., Inc. discussed the FDA approval of
 lovastatin, the first statin to revolutionize the treatment of hypercholesterolemia. His presentation
 illustrated how the FDA, academia and industry were able to work together to produce a
 breakthrough drug for the prevention of heart disease that might otherwise have not been
 developed. The availability of lovastatin meant physicians were able, for the first time, to obtain
 large reductions in serum cholesterol in patients. Learn more about statins and its innovation and
 patient benefits by reading the case study.
- William Silverman, DO, Family Practice Physician & former Trustee, American
 Osteopathic Association (AOA) underscored the importance of sharing ideas without fear of
 retribution. The ability to share ideas among physicians and researchers has led to the
 discovery of treatments for patients, such as arthritis, diabetes and smoking cessation.
 Additionally, knowledge sharing at medical conferences and educational forums is vital to
 helping physicians and students learn more about new pharmaceutical therapies and surgical
 techniques that ultimately improve patient care.

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- Phyllis E. Greenberger, MSW, President & CEO, Society for Women's Health Research (SWHR) – provided non-profit perspective on the impact of conflict of interest rules to funding advanced research and the challenges of raising funds to support women and minorities in clinical trials. SWHR is dedicated to improving women's health through advocacy, education and research and hosts education forums with doctors and researchers. While SWHR received most of its funding and financial contributions from pharmaceutical and medical device companies, conflict of interest rules have prevented industry from supporting non-profits, causing some patient groups to reduce staff and cut budgets to programs.
- David Charles, M.D., Chief Medical Officer, Vanderbilt Neuroscience Institute highlighted
 the importance of physician-industry collaboration for the development of the next generation of
 healthcare innovation and investments in educational programs that train physicians on safe
 and effective use of devices. Dr. Charles also discussed his involvement in collaborative efforts
 around clinical research for Deep Brain Stimulation (DBS), which would not have been possible
 without principled collaboration with a medical device company. Learn more about DBS by
 reading the case study.
- William Schmalfeldt, Clinical Trial Patient shared his perspective as a patient with Parkinson's disease and his progress as a result of involvement in clinical trials for DBS.

A&Q

Some of the questions raised during the Q&A session were:

- Do we have adequate safeguards in place for physician-industry collaboration?
- Accredited CME is now required to report by the health care law, was this an oversight for CME in the Sunshine Act?
- What are some developments in gender based research and what is on the horizon?
- What about the layering of new laws and regulation what are some barriers to collaboration?

Conclusion

While the Patient Protection and Affordable Care Act included "sunshine" provisions to ensure transparency and public disclosure, the dialogue on what's best for patients continues. Panelists underscored that disclosure and transparency are necessary but the need for principled physician-industry collaboration is vital to ensure continued innovation.

Please visit www.ndhi.org for more information about NDHI and to access materials from the Congressional briefing, including panelist bios and presentations, innovation fact sheet and <u>case studies</u> that have resulted from principled physician-industry collaboration.

