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Realizing the Promise of Cancer-Preventing Drugs and Vaccines

Hill Briefing
Monday, July 20, 2009
3:00 – 4:30 pm
Senate Dirksen Building
Room G11

ISSUE SUMMARY

Opportunities

As a Nation, we are missing 3 important opportunities:

1. **To reduce the burden of cancer.** While we have successfully discovered ways to prevent cancer with some drugs, we are not able to pursue development of other preventive agents due to barriers that inhibit science or fail to stimulate adequate investment in chemoprevention research.
2. **To further accelerate the national priority of disease prevention.** While recognizing and embracing the importance of healthy living and early detection to reduce the risk of cancer, the value of research on drug interventions are often overlooked in the context of prevention.
3. **To maintain and advance our position as a global leader in science in this emerging field.** The environment in other nations is simply more supportive of chemoprevention research than it is in this country.

Barriers

Several major barriers deter the research community and businesses from investing time, attention, and funding in chemoprevention research:

1. The process for conducting clinical trials and seeking drug approval using new scientific techniques – namely biomarkers - is largely uncharted.
2. Patent and intellectual property law for preventive drugs and vaccines that require longer clinical trials are too limiting.
3. Reimbursement for preventive agents is highly uncertain.

Solutions

1. Cancer-preventing drug and vaccine research should be prioritized and well funded; the drug approval process should be updated to support the science and accelerate discovery.
2. Patent and intellectual property protection and tax incentives should be implemented for preventive drugs and vaccines to make the business model feasible and stimulate significant investment.
3. Reimbursement for cancer-preventing agents should be provided to assure patient access.

AGENDA

Welcome
Senator Dianne Feinstein, vice-Chair, C-Change
Tom Kean, MPH, Executive Director, C-Change

Introduction
Victor G. Vogel, MD, MHS American Cancer Society
Moderator

Patient Perspective
Marty Smith, co-survivor

Overview of Challenges & Opportunities
Ronald B. Herberman, MD, University of Pittsburgh Cancer Institute

SUPPORTING THE SCIENCE

Biomarker and Clinical Trial Development through National Collaborations
Samir N. Khleif, MD, National Cancer Institute / Food and Drug Administration

Cancer chemoprevention Clinical Trial Design and an Uncharted Regulatory Pathway
Frank Meyskens, MD, Chao Family Comprehensive Cancer Center University of California – Irvine

STIMULATING THE BUSINESS MODEL

Limitations in patent and intellectual property law
Catherine P. Bennett, MA, JD, Cancer Survivor, Prevent Cancer Foundation Board

Uncertainty of reimbursement
Bruce Pyenson, FSA, MAAA, Milliman, Inc

Discussion / Q&A