PROGRAM

Legislative Issues of Interest to Universities, Non-Profits and the Pharmaceutical Industry

February 27, 2003

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11:30 a.m.	Meeting Begins
11:40 a.m.	Participants are seated
11:45 a.m.	Opening Remarks: Sheldon Steinbach
11:55 a.m.	Self-introduction of participants and their organizations
12:00 noon	Bruce Kuhlik, General Counsel, PhRMA "Current State of Play: Hatch-Waxman Act"
12:20 p.m.	Lunch Served
12:30 p.m.	Andy Cohn, Director of Public Policy, WARF Pat Harsche, President, AUTM "Technology Transfer—University Priorities"
12:45 p.m.	Sean Darragh, Vice President, PhRMA "Patents and the International Situation"
1:00 p.m.	Richard Turman, AAU "Animal Terrorism and Legal Rights for Animals" from the university perspective
1:15 p.m.	Valerie Volpe, PhRMA "The Bayh-Dole Act: Is it Under Political Attack and What Should be Done" from a PhRMA perspective
1:30 p.m.	"The Research and Experimental Exception in the Patent Law" from a university/medical school perspective
1:45 p.m.	Closing Remarks: Sheldon Steinbach "Where Do We Go From Here?": Regional conferences, Hill briefings, media, Cross-fertilization
2:00 p.m.	Adjournment

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LIST OF ATTENDEES
FEBRUARY 27, 2003 MEETING

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MEMORANDUM

TO: Meeting Participants

FROM: Chris Wilson
Michael J. Remington

DATE: September 30, 2002

RE: Luncheon Meeting Concerning the Bayh-Dole Act

Public policy and governmental relations representatives of various university and medical research associations and one university foundation as well as representatives of the Pharmaceutical Research and Manufacturers Association (PhRMA) met on September 26, 2002 at 11:30 a.m. at the Jefferson Hotel in Washington, D.C. The purpose of the meeting was twofold: (1) for the attendees to get to know each other better; and (2) to discuss the current legislative proposals affecting the pharmaceutical industry and the university community and their negative impact on the Bayh-Dole Act, and in doing so to share the policy goals and prerogatives of the participants' organizations in an attempt to find common ground.

Present at the luncheon meeting were the following:

- Sheldon Steinbach, Esq., Vice President and General Counsel, American Council on Education (ACE)
- Richard Harpel, Director, Federal Relations-Higher Education, National Association of State Universities and Land-Grant Colleges (NASULGC)
- Kate Phillips, President, Council on Governmental Relations (COGR)
- Robert Hardy, Associate Director, Council on Governmental Relations (COGR)
- Richard J. Turman, Director of Federal Relations, Association of American Universities (AAU)
- Michael J. Remington, Esq., Drinker Biddle & Reath LLP
- Christopher E. Wilson, Government Affairs Specialist, Drinker Biddle & Reath LLP
- Stephen Heinig, Senior Staff Associate, Division for Biomedical and Health Sciences Research, Association of American Medical Colleges (AAMC)
- Andy Cohn, Director of Public and Governmental Relations, Wisconsin Alumni Research Foundation (WARF)
- Norman J. Latker, Esq., Browdy & Niemark
- John T. Kelly, M.D., Ph.D., Senior Vice President, Scientific & Regulatory Affairs, PhRMA
- Valerie Volpe, Senior Director-Alliance Development, PhRMA
- Rachel Kerestes, Director of Policy, PhRMA
- Missy Jenkins, Senior Director, Federal Affairs, PhRMA

- Sara Radcliffe, Director, Science and Regulatory Affairs, PhRMA
- Gregory J. Glover, M.D., Esq., Ropes & Gray

OPENING REMARKS

Valerie Volpe welcomed all participants and provided a brief overview of her job duties and the priorities of PhRMA in forging working relationships with parties that share common interests. She additionally stated that PhRMA perceives the legislation proposed by Sens. McCain and Schumer (S. 812) and recently passed by the Senate, and House companion legislation (H.R. 5311), as a "threat" and that she hoped it could be discussed over the course of the meeting.

Dr. John Kelly echoed Valerie's remarks and additionally noted that collaboration between universities and the pharmaceutical industry is "critical" as "future progress is not ensured." Both Valerie and John made the fundamental point that pharmaceutical companies and universities engage in their respective activities to benefit the public (*e.g.*, the patient).

Lastly, Mike Remington welcomed all and made special note of Norm Latker's presence at the meeting by commenting on Norm's vast institutional memory regarding the creation of the Bayh-Dole Act. Mike also noted that a meeting agenda had been prepared to ensure a balanced and open exchange of the various perspectives.

OPENING PRESENTATION

As a foundation for discussion among the participants, Dr. Gregory Glover gave a Power Point presentation entitled: "Importance of Patents to the Discovery & Development of New Treatments & Cures." Greg's presentation consisted of a general overview of the pertinence of patent law to the research and development of pharmaceutical products by universities and the pharmaceutical industry. Additionally, he provided a specific discussion regarding the impact that the Bayh-Dole Act and the Hatch-Waxman Act have had on the development of health care products. Lastly, Greg outlined PhRMA's key concerns with regards to S. 812 and H.R. 5311, stating that the proposed legislation seeks to alter the spirit of the Bayh-Dole Act.

As a follow-up to Greg's discussion of S. 812 and H.R. 5311, Richard Harpel asked him whether or not the proposed legislation had any redeeming value or if the legislation should be "killed" outright. Greg, Missy Jenkins, Valerie Volpe and Rachel Kerestes all agreed the proposed legislation should be "killed" and that the two bills were solutions in search of a problem.

Upon completion of Greg's presentation, John suggested that it would be beneficial if Greg's Power Point presentation was converted to document form and distributed to all participants. All attendees agreed.