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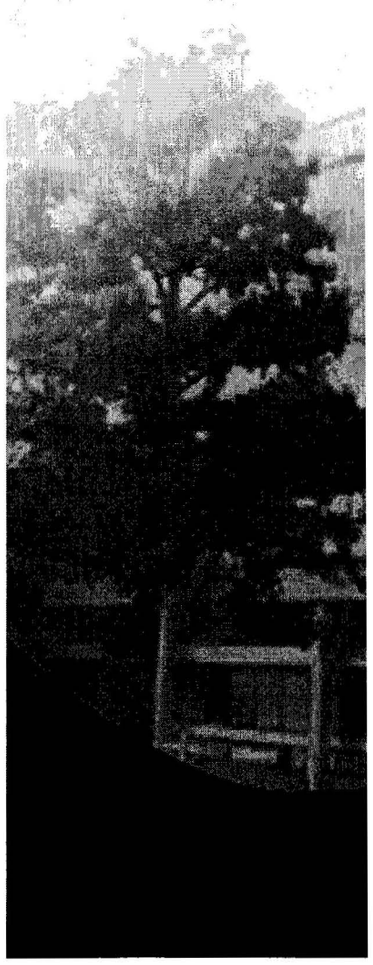

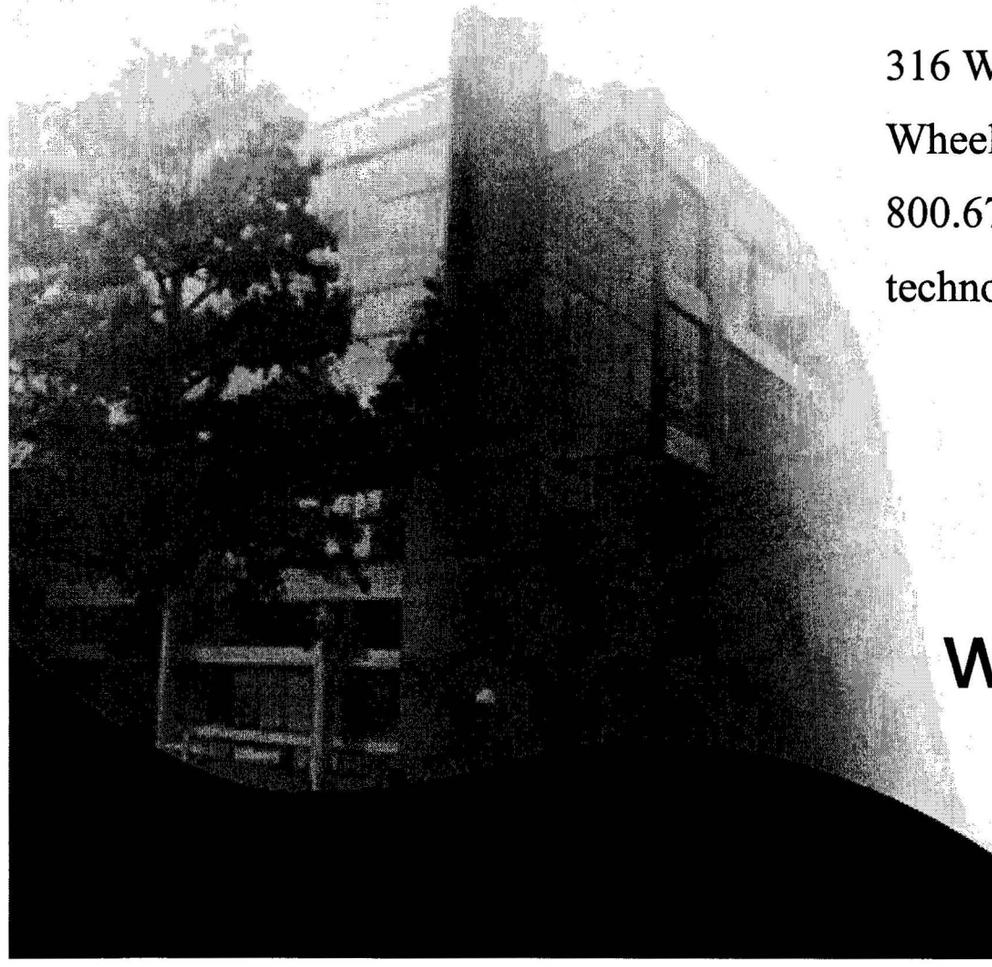

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# Razing the Tollbooths

**A call for restricting patents on basic biomedical research** By GARY STIX

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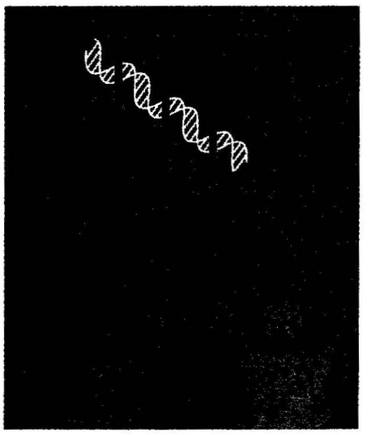

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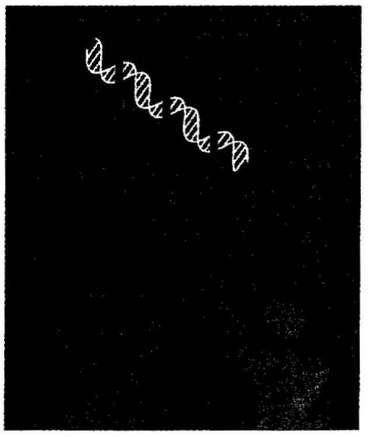

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# I, Clone

**The Three Laws of Cloning will protect clones and advance science** By MICHAEL SHERMER

**In his 1950 science-fiction novel** *I, Robot,* Isaac Asimov presented the Three Laws of Robotics: "1. A robot may not injure a human being, or, through inaction, allow a human being to come to harm. 2. A robot must obey the orders given it by human beings except where such orders would conflict with the First Law. 3. A robot must protect its own existence as long as such protection does not conflict with the First or Second Law."

The irrational fears people express today about cloning parallel those surrounding robotics half a century ago. So I would like to propose Three Laws of Cloning that also clarify three misunderstandings: 1. A human clone is a human being no less unique in his or her personhood than an identical twin. 2. A human clone has all the rights and privileges that accompany this legal and moral status. 3. A human clone is to be accorded the dignity and respect due any member of our species.

**Clone all you like—you'll never produce another you.**

Although such simplifications risk erasing the rich nuances found in ethical debates over pioneering research, they do aid in attenuating risible fears often associated with such advances. It appears that the Raelians have not succeeded in Xeroxing themselves, but it is clear that someone, somewhere, sometime soon is going to generate a human clone. And once one team has succeeded, it will be Katy bar the door for others to bring on the clones.

If cloning produces genetic monstrosities that render it impractical as another form of fertility enhancement, then it will not be necessary to ban it, because no one will use it. If cloning does work, however, there is no reason to forbid it, because the three common reasons given for implementing restrictions are myths. I call them the Identical Personhood Myth, the Playing God Myth, and the Human Rights and Dignity Myth.

The Identical Personhood Myth is well represented by activist Jeremy Rifkin: "It's a horrendous crime to make a Xerox of someone. You're putting a human into a genetic straitjacket." *Baloney.* He and fellow cloning critics have the argument bass ackward. As environmental determinists, they should be arguing: "Clone all you like—you'll never produce another you, because environment matters as much as heredity." The best scientific evidence to date indicates that roughly half the variance among us is accounted for by genetics and the rest by environment. It is impossible to duplicate the near-infinite number of permutations that come into play during the development of each individual, so cloning is no threat to unique personhood.

The Playing God Myth has numerous promoters, among the latest being Stanley M. Hauerwas, a professor of theological ethics at Duke University: "The very attempt to clone a human being is evil. The assumption that we must do what we can do is fueled by the Promethean desire to be our own creators." In support of this myth, he is not alone. A 1997 *Time*/CNN poll revealed that 74 percent of 1,005 Americans answered "yes" to the question "Is it against God's will to clone human beings?" *Balderdash.* Cloning may seem to be "playing God" only because it is unfamiliar. Consider earlier examples of once "God-like" fertility technologies that are now cheerfully embraced because we have become accustomed to them, such as in vitro fertilization and embryo transfer.

The Human Rights and Dignity Myth is embodied in the Roman Catholic Church's official statement against cloning, based on the belief that it denies "the dignity of human procreation and of the conjugal union," as well as in a Sunni Muslim cleric's demand that "science must be regulated by firm laws to preserve humanity and its dignity." *Bunkum.* Clones will be no more alike than twins raised in separate environments, and no one is suggesting that twins do not have rights or dignity or that they should be banned.

Instead of restricting or preventing the technology, I propose that we adopt the Three Laws of Cloning, the principles of which are already incorporated in the laws and language of the U.S. Constitution, and allow science to run its course. The soul of science is found in courageous thought and creative experiment, not in restrictive fear and prohibitions. For science to progress, it must be given the opportunity to succeed or fail. Let's run the cloning experiment and see what happens. SA

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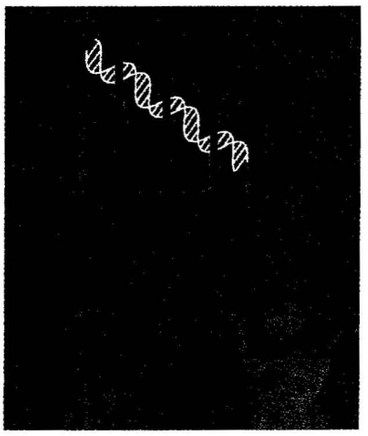

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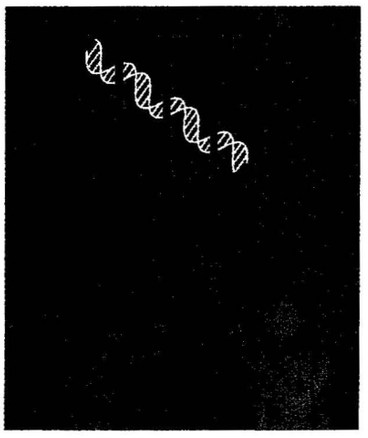

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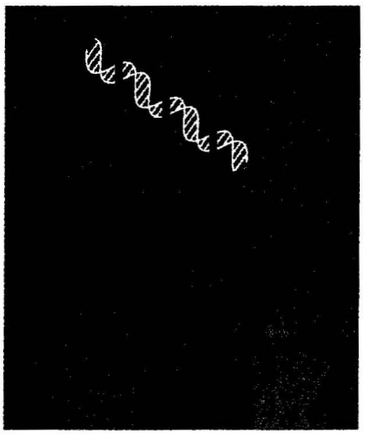

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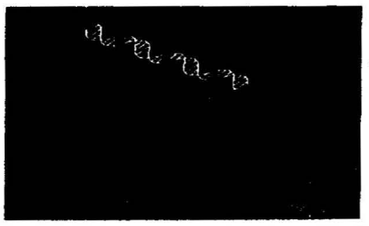

Rai and Eisenberg cite the case of a patent obtained by teams at Harvard University, the Massachusetts Institute of Technology and the Whitehead Institute for Biomedical Research in Cambridge, Mass. It covers methods of treating disease by regulating cell-signaling activity involving nuclear factor kappa B (NF-κB), which controls genes for processes ranging from cell proliferation to inflammation in various maladies. Those institutions and Ariad Pharmaceuticals (also in Cambridge), the exclusive licensee of the patent, are now suing Eli Lilly, claiming that two of its drugs—one for osteoporosis, one for sepsis—infringe the patent. Ariad has contacted more than 50 other companies that are researching or commercializing drugs that work through this pathway, asking them for licensing fees and royalties. The broad-based patent does not protect specific drugs. Instead it has become a tollbooth for commercial drug research and development on the NF-κB pathway. "In this case, as in many others, upstream [precommercial] patents issued to academic institutions serve as a tax on innovation, diluting rather than fortifying incentives for product development," the authors wrote in the winter-spring issue of *Law and Contemporary Problems*. (Their other article on the Bayh-Dole Act appeared in the January-February issue of *American Scientist*.)

Rai and Eisenberg suggest that the law should be altered to make it easier for the government—in particular, the National Institutes of Health—to specify that such upstream research remain public and not be subject to patents. They also recommend facilitating the government's ability to mandate the nonexclusive licensing of a patent at reasonable rates. Both actions are permitted under the current law but have almost never been exercised; the law makes it cumbersome to do so.

Fiddling with Bayh-Dole does bear risks. For instance, an executive-branch agency such as the NIH could be subject to political pressure in barring patents: an administration opposed to using embryos in scientific investigations might order an agency to withhold patents on such research. But university technology-transfer offices, Rai and Eisenberg contend, cannot be entrusted to make decisions about when to forgo patenting, given that a big part of their mission is to bring in licensing revenues. So more leverage is needed to ensure that basic biomedical research remains open to ■

JENNIFER KANE



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**From:** "Wilson, Christopher E." <Christopher.Wilson@dbr.com>
**To:** "'cohn@warf.org'" <cohn@warf.org>, "'richard_turman@aau.edu'" <richard_turman@aau.edu>, "'njl@browdyneimark.com'" <njl@browdyneimark.com>
**Date:** Thu, Apr 10, 2003 12:27 PM
**Subject:** PhRMA/University Meeting Notes

Gentlemen:

Please find attached a finalized version of the meeting notes from our informal working lunch on February 27, 2003.

I look forward to seeing you all at our next gathering.

Regards,

Chris

Christopher E. Wilson
Government Affairs Specialist
Drinker Biddle & Reath LLP
1500 K Street, N.W.
Suite 1100
Washington, D.C. 20005-1209
(202) 354-1324



**CC:** "Remington, Michael J." <Michael.Remington@dbr.com>

MEMORANDUM

TO: Meeting Participants
FROM: Chris Wilson
Michael J. Remington
DATE: April 4, 2003
RE: Luncheon Meeting Concerning Legislative Issues of Interest to Universities, Non-Profits and the Pharmaceutical Industry

Public policy and governmental relations representatives of various university, technology transfer and medical research associations and one university foundation as well as representatives of the Pharmaceutical Research and Manufacturers Association (PhRMA) met on February 27, 2003 at 11:30 a.m. at Savino's Cafe in Washington, D.C. The purpose of the meeting was twofold: (1) for the attendees to get to reacquainted since September's meeting; and (2) to discuss the current public policy proposals and legal movements affecting the pharmaceutical industry and the university community both domestically and internationally and their negative impact on the Bayh-Dole Act. In doing so, participants hoped to share the policy goals and prerogatives of their respective 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)
- 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
- Patricia Harsche, Vice President, Planning and Business Development, Fox Chase Cancer Center; President, Association of University Technology Managers (AUTM)
- Valerie Volpe, Senior Director-Alliance Development, PhRMA
- Bruce Kuhlik, Senior Vice President & General Counsel, PhRMA
- Sean Darragh, Deputy Vice President, International Policy, PhRMA
- Erika King, Assistant General Counsel, PhRMA

**OPENING REMARKS**

Shelley Steinbach welcomed all participants and noted that there is an "interesting" array of issues to be discussed among meeting participants. Specifically, Shelley mentioned the growing animal rights movement as a problem that both the university and the pharmaceutical communities must face. He also referred to the notebooks that we provided to meeting participants. Stating that "no one gets anything done in D.C. alone," Steinbach emphasized the need for all participants to remain in contact after the meeting when issues arise. Following Shelley's opening remarks, he invited participants to give brief self-introductions.

**OPENING PRESENTATIONS**

*Bruce Kuhlik: "Current State of Play: Hatch-Waxman Act*

Bruce Kuhlik began the discussion with a brief overview of what transpired last year in Congress with



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regard to patent law. Specifically, Bruce mentioned S. 812, which passed the Senate, as a bill PhRMA opposed vehemently and noted that it was "bad policy" all around. He said PhRMA was pleased that the bill never became law.

Bruce went on to recall PhRMA's astonishment when the President on October 21, 2002 announced from the Rose Garden a proposed new rule-making at the FDA concerning patent law. Kuhlik stated that the new rule does two things: 1) it restricts the types of patents listed in the Orange Book; and 2) it provides just one 30-month stay during a patent litigation proceeding. According to Bruce, PhRMA companies looked at the proposed rule and decided they could live with it, provided some "tweaking" occurred. Additionally, Bruce acknowledged that whatever faults the rule may have, they were not as severe as those present in S. 812.

Bruce stated that the final rule will be issued by late March or early April 2003 and that pertinent congressional hearings can be expected to follow soon thereafter. He was asked to provide copies of the comments submitted by PhRMA to the FDA during the rulemaking process to the meeting participants. [After the meeting, he did so electronically. Mike Remington forwarded these materials to all participants for insertion in their notebooks.]

Robert Hardy noted that COGR's review of the proposed rules revealed that the "takings" aspect of previous patent law reform proposals was not present and that COGR was pleased that was so. Bruce added that the new rule should put universities "in good stead" as regular patent enforcement tools will remain in place.

Andy Cohn inquired as to what "technical" concerns PhRMA had with the proposed rules. Bruce noted that an unintended consequence of the rules would allow generic drug companies to "play games" with patent certifications. PhRMA offered guidance in its comments that would quash that possibility.

[After the meeting, Bruce also provided a memo summarizing public comments on the FDA's NPRM, a summary of FDA's proposed regulations, and a chart on the "Generic Industry Flip-Flop."]

*Andy Cohn and Pat Harsche: "Technology Transfer—University Priorities"*

Pat Harsche and Andy Cohn discussed the priorities of universities. Harsche opened by providing a brief history of AUTM, noting that its 30th anniversary is near. Consisting of 3200 members from 34 countries, AUTM has a "diverse" membership, though its diversity makes it difficult for AUTM to take a unified position on any given issue. Pat made special note of AUTM's website, www.autm.net, as a valuable resource of information on technology transfer issues. She also stated that AUTM has just revised its technology transfer manual and that it should be available soon through the website.

Richard Turman noted that he relies on Pat and AUTM a great deal, especially as a communications tool. In that vein, Mike Remington inquired whether AUTM could communicate at the state level (because public policy issues arise there too). Pat Harsche said that AUTM has the ability to communicate with its members state-by-state and it plans to create a committee in each state.

Andy Cohn stated that he was a member of AUTM's new public policy committee. He added that he is "more than a little disturbed" by the number of attacks on Bayh-Dole. Andy made it clear to all present that Bayh-Dole "must be preserved" as the legislation "revolutionized" technology transfer. Secondly, Andy stated that he has concerns about the *Bristol-Myers* case that created a gaping exception for pharmaceutical companies that seek FDA approvals to conduct research on university-held patents. Andy also raised the Federal Circuit decision issued in 2002 in *Madey v. Duke University* in which the court denied the experimental use exception in the patent law to all academic scientific research, even when that research is manifestly noncommercial. Lastly, Andy made all meeting participants aware that WARF (with support from ACE and NASULGC) is working on a collaborative research bill to be introduced, hopefully, this session of Congress.

Shelley Steinbach asked if there is any opposition to the collaborative research bill. Both Andy and Mike Remington stated that there is some opposition, particularly from some patent lawyers and the American



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Intellectual Property Law Association. Richard Harpel noted that there is a great deal more recognition on Capitol Hill that intellectual property is a "big deal" to universities, but that could be a double-edged sword as Members can both support your efforts and also threaten to thwart your prerogatives.

*Sean Darragh: "Patents and the International Situation"*

Sean Darragh prefaced his presentation by acknowledging that patent rights in the global arena are not hanging by a hair; rather they are hanging by a "split end." Sean provided the participants with an overview of the evolution of the debate on patents as it has occurred globally. Sean noted that the debate traces itself back to the emergence of the HIV/AIDS epidemic in Africa. This epidemic brought a great deal of attention on the fact that poor, underdeveloped countries simply could not afford to purchase the medicines necessary to abate the spread of the disease. Immediately, the public perception was forged that pharmaceutical companies were greedy, uncaring and unwilling to help. However, according to Sean, the public perception is wrong as 95% of all drugs being used in Africa are not covered under patent law. Admittedly, according to Sean, PhRMA did not handle the public affairs situation well.

Sean explained that there is global movement, led by China and India, to eviscerate the entire patent system. Despite concessions made by the U.S. in the DOHA Round of trade talks providing for a moratorium on patent prosecutions with regard to certain medicines in poor countries, there is a cry for patents to be lifted on all medical devices too, not just medicines. PhRMA worked with the Biotechnology Industry Association (BIO) to ensure that further expansion of a moratorium did not take place.

Sean stated that PhRMA is happy with the initial moratorium agreement as well as with the President's policy announcement made in the course of his State of the Union address asking for $15 billion to fight AIDS in Africa.

Concerns were raised by several meeting participants that a moratorium would lead to the flooding of the market with cheap generic drugs. Sean responded that no flooding would take place as there is not enough money to be made in the developing world to necessitate heavy investment there.

Other participants were curious as to how the U.S. enforces patent agreements and punishes violators overseas. Both Sean Darragh and Mike Remington pointed out that a country with an ineffective and inadequate patent law could be hit with trade sanctions in the form of tariffs on products that the offending country exports to the U.S. The USTR also keeps a "special 301" list for countries with records of inadequate intellectual property laws.

In terms of the academic community's viewpoint on international patent law, Shelley Steinbach noted that the community is just getting its feet wet in the WTO. He said that it is vitally important, as much of the university community's research is marketed overseas, that the community create a presence in the international arena.

*Richard Turman: "Animal Terrorism and Legal Rights for Animals"*

Richard Turman opened his presentation by offering to host the next luncheon meeting, perhaps at AAU's office in Washington, D.C.

Richard stated that there is a visible need for universities to engage with PhRMA on animal rights issues, especially as the level of attention to the issues rises in the media and as the level of violence inflicted upon researchers increases. Valerie Volpe concurred with Richard and offered to create an opportunity for him or someone else from the academic community to brief the pertinent PhRMA personnel on the issues. Richard welcomed the suggestion.

Richard elaborated further on the "large and growing" movement to provide legal rights to animals. Specifically, he said that there is a move towards the creation of case law and that some consider animal rights to be the next generation of civil rights. Richard mentioned a proposal being formulated by the New York City Bar



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Association and the ABA that would extend some guardianship rights to animals. If the resolution passes the City Council, it is possible, according to Turman, that the ABA would seek Congressional approval as well.

Shelley noted that the animal rights issue will "keep us [meeting participants] together for a long time." Pat Harsche agreed with Shelley and added that an entire generation of students are currently being educated under the premise that scientific research on animals is wrong. Thus, according to Pat, future researchers and younger ones today are less inclined to support the academic community in its fight to maintain the right to perform research on animals. Richard stated that Hill staffers, who are predominantly young, also are more inclined to support animal rights advocates.

*Valerie Volpe: "The Bayh-Dole Act: Is It Under Political Attack and What Should Be Done?"*

Valerie wrapped up the organized presentation period by acknowledging that those in support of current patent law are fighting a tough public relations war, especially when lives are at stake. To counter public sentiment on the side of those in favor of removing patent protections to assist the sick and dying, Valerie suggested that educational conferences are needed on a regional basis as well as in Washington, D.C. The premise of the conferences would be to highlight the important discoveries that have been made, and lives saved, by virtue of the patent protections inherent in the Bayh-Dole Act. Valerie finds it "unacceptable" that those who malign the Bayh-Dole Act have suffered no consequences for their actions. For her, it is time to start being proactive and not just reactive. In this regard, Valerie suggested the need for Hill briefings to educate a select number of members and staff. These briefings could be done individually or collectively.

**INFORMAL DISCUSSION**

Norm Latker offered his opinion with regard to the ongoing debate on the Bayh-Dole Act. Primarily, Norm stated that he finds it disheartening not to hear discussion about the principles underlying the Bayh-Dole Act. The guiding principle present during the creation of the Act was that production must come before distribution and that incentives must be in place for interested parties to partake in the research and development of medicines, according to Norm. Norm believes that the general public and some decision-makers do not understand the principles behind the Bayh-Dole Act and that educating those in the dark is vitally necessary.

Richard Turman agreed with Norm and noted that when he was on the Hill a couple of years ago with regard to a bill offered by Sen. Wyden he found himself having to educate many staffers on the basics of the Bayh-Dole Act. Additionally, he said that unless there is a threat of action on the Hill with regard to Bayh-Dole, few staffers are interested in learning the background and underlying principles of the Act. Richard suggested that the 23rd birthday of the Act could serve as a valuable "hook" for supporters of the Bayh-Dole Act to engage and educate individuals on the benefits of the Act.

Rich Harpel echoed Richard Turman's frustration when interacting with Hill staffers on issues concerning the Bayh-Dole Act. Rich believes staffers are not grounded in the basic principles of the Act and, at times, he has found that some staffers incorrectly assume that research and development performed by virtue of the Act's protections is federally funded and, therefore, it belongs to the public.

Mike Remington stated that he "sort of panics" when he learns of hearings on the Hill with respect to the Bayh-Dole Act as he knows that there is a lot of misinformation floating around in the congressional offices. Because of this, Mike agreed with Valerie's recommendation for a proactive approach, stating that a good offense on the Hill acts as a good defense too. In that vein, Remington noted that a regional education conference in Wisconsin is expected to be set up in the near future. Funding assistance for the conference could come from an organization headed by former Patent Commissioner, Bruce Lehman. He could provide seed money to spearhead the effort. All participants acknowledged that a regional conference is needed and that additional ones should take place. Rich Harpel added that the assistance of state Centers of Excellence should be sought when coordinating a conference as the support of state governments would be helpful.

Andy Cohn suggested setting up a subcommittee that would be in charge of organizing the conferences.



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Pat Harsche suggested that it would be appropriate to hold a program during AUTM's 30th anniversary program in San Antonio, TX in the Spring of 2004 It was agreed by all meeting participants that a program should take place in conjunction with AUTM's San Antonio meeting. That conference could be a "grand finale" for the Bayh-Dole Act's 20th birthday (measured from the 1984 amendments). Richard Turman added that he would like at least one conference to take place in Washington, D.C. There seemed to be a consensus on that point too.

In closing, Shelley Steinbach thanked all for attending and stated that the meeting was productive. It was agreed by all present that further meetings should take place, but in the meantime additional discussion on the topics raised during this meeting should continue on an informal basis between individuals and organizations within the group.

**SUMMARY OF CONSENSUS ITEMS**

- Bruce Kuhlik would distribute to participate copies of PhRMA's comments submitted to the FDA during its rulemaking process on applications for FDA approval to market a new drug: Patent Listing Requirements. [This has already been done.]

- As regards, FDA and Hatch-Waxman reform, PhRMA will monitor regulatory and legislative developments and keep the group informed.

- Sean Darragh's prepared remarks would be distributed electronically to all participants pursuant to request.

- PhRMA will keep the group informed of international developments; individual group members and the organizations they represent may weigh-in (with letters to USTR Ambassador Robert Zoellick) as they deem appropriate.

- Educating elected officials, Hill staffers and the general public by way of conferences and public relations tools is imperative. At least one regional conference should take place in 2003 in Madison, Wisconsin, and perhaps another in Tennessee, California, or in Washington, D.C. Also during 2003, Hill briefings should be explored. Additionally, the parties should consider a 23rd birthday party celebration on December 12 for the Bayh-Dole Act, as enacted on December 12, 1980.

- Mike Remington and Andy Cohn are authorized to meet with Bruce Lehman about the Wisconsin regional conference.

- A "briefing" should take place between PhRMA and the university community with regards to terrorism and animal rights issues.

- Further informal meetings to discuss legislative and regulatory proposals that impact the pharmaceutical industry and universities should continue.



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## TELEFAX CONTROL SHEET

**SENT TO:** Jennifer Washburn

**DATE SENT:** 4/24/03

**SUBJECT:** Tech. Trans.

**No. of pages (including this cover sheet):**

**FROM:** Norm Latker

**Remarks:** Jennifer

Enclosed is an outstanding and comprehensive history by Ed MacCordy who was one of the areas most innovative and respected members.

NJL



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| To | : | 17188323568 |
| Document pages | : | 029 |
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| End time | : | Apr-22 12:46pm |
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| Status | : | OK |

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DATE SENT: 4/22/03

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FROM: Naom Latker

Remarks: Jennifer
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See III (c)(d) of IPA regarding process of licensing. As you will NOTE the type of licensing was left to the IPA holder.



IPA holder


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DATE SENT: 4/22/03

SUBJECT: IPA, etc.

No. of pages (including this cover sheet):

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Remarks: Jennifer

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December 4, 2002

Gregory J. Glover, M.D., Esq.
Ropes & Gray
One Franklin Square
1301 K Street, NW, Suite 800 East
Washington, DC 20005-7008

Dear Gregory:

I very much enjoyed your presentation at the September 26, Industry-University meeting. In the 70's we needed to educate the Congress along the same lines to gain support of Bayh-Dole. I'm enclosing one of my old presentations that just resurfaced that parallels your thoughts but from DHEW's perspective at that time.

I think that one of industry's problems these days is the fact that there appears to be no focus in the executive that understands the reality of drug development. I had thought that this would be a basic responsibility of the President's science advisor but it seems that it must be taught to every new administration. It might be well to consider establishing an industry-university team to brief each new science advisor. The university element would help to defuse the ever present populist opposition to patents. I had hoped that the September 26, group might head in that direction.

Sincerely,

Norman J. Latker

c.c.: Shelly Steinbach
Kate Phillips
Mike Remington
John Kelly

Norman J. Latker

c.c.: Shelly Steinbach
Kate Phillips
Mike Remington
John Kelly

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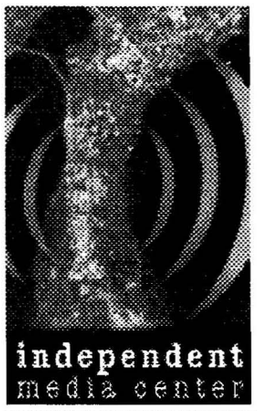



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## UW-Madison Doles Out Dubious Degrees

by Charlie Van Hise *8:00am Thu May 16 '02* (Modified on 9:34pm Wed Aug 21 '02)

phone: 262-9036

UW-Madison's 2002 graduation ceremony includes two rather dubious honorary degree awards to apologists for university privatization and corporate globalization.

While many students, friends, and relatives should be justifiably proud of the diplomas they will be lining up to receive this coming graduation weekend, there are a few more dubious degrees being doled out by UW-Madison, as well.

Many may recall that last year's ceremony was marred by the keynote speech of Charlene Barshefsky, former U.S. Trade Representative under Pres. Clinton and chief apologist for such undemocratic free trade regimes as the World Trade Organization (WTO). Even as she gave another tired university-sanctioned plea for everyone to just jump on the corporate globalization bandwagon, UW graduates were facing a harsh economic future with unprecedented downsizing, slashed benefit packages and blatant union busting statewide. Thanks to NAFTA alone, Wisconsin has lost over 19,000 jobs since 1994 as companies shut down and relocated elsewhere in this race to the bottom.

This year UW-Madison has once again found it fit to honor not one – but two - technocratic architects of university privatization and corporate globalization. Among those receiving special honorary degrees on Fri. May 17th at 5:30 pm in the Kohl Center are Norman J. Latker and David S. Ruder.

Mr. Latker is probably most infamous for his role in crafting the Bayh-Dohl Act. Passed in 1980, this federal legislation allows universities to patent and then sell-off the results of public research to private interests. UW-Madison now ranks among the top ten in terms of royalty income, exceeding $20+ million per year. UW has also become rather fond of boasting about its numerous spin-off corporations – such as Middleton-based Gala

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Designs where genetically engineered dairy cows are being forced to crank out pharmaceutical products in their milk. A recent survey of U.S. industrial patents found that over 73% were largely derived from work done at taxpayer expense at institutions like UW-Madison. Corporations get their own federal tax breaks – to the tune of $2+ billion per year - for giving kick-backs in the form of research "donations" to the same universities from which they later leverage lucrative results. One sure hopes Mr.Latker has gotten his fair share of the cream off the top of all this public largesse over the years.

As for Mr. Ruder, he's working diligently to tweak the legal standards in favor of U.S. corporations in the era of cutthroat global competition. He was chair of the Security and Exchange Commission under Reagan/Bush from 1987-1989 when the SEC ran interference on behalf of U.S. corporations facing domestic pressure for propping up the South African apartheid regime and other heinous dictatorships. Ruder has since moved on to become a law prof. at Northwestern and president of the Corporate Counsel Center. In case any budding profiteers want to capture pearls of wisdom straight from his lips, they should ante up $850 each to attend the 40th Annual Corporate Counsel Institute. The two day session includes several workshops addressing such vexing corporate issues as: "Mergers and Acquisitions," "Intellectual Property," and "What to do when the Press Calls." When not greasing the skids for private interests in the global capital markets, Mr. Ruder is greasing palms for the UW Law School, having raised $6.6 million for the newly remodeled "aircraft hanger" on Bascom Hall.

Mr. Latker and Mr. Ruder definitely deserve some sort of recognition for enabling such amazingly irresponsible mercenary behavior - maybe a delicious pie in the face?

add your own comments

**Can Van Hise bake pies as well as facts?**

by Richard Latker *9:34pm Wed Aug 21 '02*
address: Lot 1, DD228, Fei Ngo Shan, Hong Kong pristine@asia.com

Dear Indymedia:

I've only now come across your May 16, 2002 article "UW-Madison Doles Out Dubious Degrees." I know it's rather late for a reply. Still, the writer did have it wrong, and I'd appreciate the chance to set the record straight.

Thanks & regards,
Richard Latker

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**Iraq Journal**
A collection of regular print, audio, and video reports from Iraq

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Helping the public recognize

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Thanks & regards,
Richard Latker

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I share Charlie Van Hise's suspicion of the 1980 Bayh-Dole Act, of which my father, Norman Latker, was a key architect (UW-Madison Doles Out Dubious Degrees, May 16, 2002). It was a fundamental rightward shift in intellectual property policy that, while perhaps bringing new drugs to market more quickly, has ultimately served to bolster corporate control over academia and erode research independence at state universities. The issue has prompted spirited disagreements between my father and I for many years.

Accusing my father of "amazingly irresponsible mercenary behavior" is quite ridiculous, however. And assuming that he has "gotten his fair share of the cream off the top", would be just plain wrong. What he did get was *fired*. His boss at the time--Secretary of Health, Education and Welfare (HEW) Joseph Califano—was a bitter opponent of the bill. Mr. Califano wasted no time in terminating my father's employment once it became clear that the latter was the intellectual force behind the legislation. While he became something of a Republican cause celebre, it was quite some time before my father was once again gainfully employed. Our family lived on government severance pay and, when that ran out, my mother's modest salary as government biological scientist.

Just before the bill came to a vote in 1980, Califano himself was fired by President Jimmy Carter, and my father reinstated for a time. But he was never employed or compensated by the giant agro-chem and pharmaceutical corporations that so vastly benefited from his efforts. While my father has received a handsome collection of awards and certificates over the years for his efforts on Bayh-Dole, he has never shared in the corporate spoils. No kickbacks, no stock options and no briefcases full of cash.

What had motivated my father, then a civil-servant patent attorney in HEW, to assist Senators Birch Bayh (D) and Robert Dole (R ) in redrafting the country's patent legislation was not a desire to empower Monsanto or Genentech. It was a libertarian-inspired frustration that medical advances developed in universities were not finding their way to market, due to federal government lethargy in disseminating the intellectual property it controlled. HEW was sitting on a mound of unutilised advances in drugs and medical technology that it "owned" by virtue of the fact that federal funds had supported a portion of the initial research. Senator Bayh, one of the country's more liberal legislators at the time, had personal reasons to move the bill through congress: his wife was dying of cancer. He stated publicly that the sluggish pharmaceutical development pipeline had reduced treatment options for her.



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Both Senator Bayh and my father believed that they were empowering universities—not corporations—by giving them commercial control over the innovations they developed. An obvious majority of research scholars at the time supported the bill, too. Few envisioned how corporations would use the new legislation to leverage control over academic research in public institutions. Nor did they really appreciate the deleterious effect the bill would have on American agriculture.

My father, who voted for Nader in 2000, nowadays spends his time picking hopeless fights with nasty suburban property developers. He might even enjoy the pie in the face you prescribe for him, if it tasted good and was delivered in a spirit of democratic debate. He takes attacks on his political legacy in good cheer. But to demonize him as a greed-driven "mercenary" when you are not acquainted with the facts is mean-spirited, and undermines the credibility of your argument.

Richard Latker
(former state secretary of the Wisconsin Labor-Farm Party, a convenor of the UW-Greens in 1987, and occassional all-night production editor at the Madison Insurgent)

ps: an aside --- (One of the few politicians at the time who did understand the ramifications of the Bayh-Dole legislation was Wisconsin congressional representative Robert Kastenmeier, who alienated core academic supporters at UW-Madison with his opposition to the bill. His arguments were spot on. Unfortunately, rather than speak out against the very corporate influence he had predicted would emerge, Kastenmeier began pandering to university corporate donors in the mid-1980s at the expense of his Dane family farm/Madison Left constituency. His muddled stance contributed to his defeat in 1990.)

pss: note spelling of Robert Dole (not "Dohl").



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SENATOR BOB DOLE
901 15TH STREET, N.W.
SUITE 410
WASHINGTON, D.C. 20005

September 24, 2002

Valerie Volpe
Senior Director
Public Policy Advocacy
Pharmaceutical Research & Manufacturers of America
1100 Fifteenth Street, N.W.
Washington, D.C. 20005

Dear Valerie:

It is my understanding that on September 26, 2002, representatives of the university community will be meeting with representatives of the pharmaceutical industry to discuss current policy changes that have negative implications for the Bayh-Dole Act. Due to an out-of-town commitment, I cannot personally attend the meeting. I, however, wanted to bless it in spirit, and hope you will convey to the group my thoughts on this matter.

The Bayh-Dole Act is one of my proudest accomplishments, not only because of its success for the federal government, universities, non-profits and the private sector, but also for the true beneficiaries – members of the public who benefit from scientific advances, especially in the health care arena. In my opinion, the Act's statutory policy and objectives have been met in spades. The Act has created a favorable environment for collaborative research; stimulated a profession of technology transfer; promoted commercialization, free competition and the availability of inventions. The net-results are quantifiable in the form of life-saving advances, new products and even new industries. Patients, and their families, benefit.

Unfortunately, the Act is under increasing attack. It, therefore, is especially important for the university community (which receives millions of dollars in federal funding) to create channels of communications and alliances with the private sector (which works cooperatively with universities to commercialize the fruits of research.)

The Act, enacted on December 12, 1980, and later amended on November 8, 1984, has never had an appropriate birthday party. I hope you will consider an event or a series of events to commemorate the Act's success. Hopefully, I can also meet with your group in the near future.

In the meantime, please accept my very best regards.

Sincerely,

BOB DOLE

cc: The Honorable Birch Bayh

In the meantime, please accept my very best regards.

Sincerely,

BOB DOLE

cc: The Honorable Birch Bayh

# PROGRAM

## Current Legislative Proposals and their Negative Impact on Bayh-Dole

**September 26, 2002**

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| | | |
|---|---|---|
| 11:30 a.m. | Meeting Begins | |
| 11:45 a.m. | Participants are seated | |
| | Opening Remarks: | Valerie Volpe<br>Dr. John Kelly<br>Michael Remington |
| 11:50 a.m. | Self-introduction of participants and their organizations | |
| 12:00 noon | Gregory Glover, MD, JD.<br>"Protection of Collaborative Research – A PhRMA Perspective" | |
| 12:20 p.m. | Questions and Discussion | |
| 12:40 p.m. | University representatives<br>"Protection of Collaborative Research – A University Perspective" | |
| 1:00 p.m. | Howard Cohen, Esq.<br>"Political Assessment and Examination of Current Political Situation on Private Sector Investments, Research and Development" | |
| 1:10 p.m. | "Political Assessment"<br>from the university perspective | |
| 1:20 p.m. | "The Bayh-Dole Act: Preservation, Protection and Commemoration"<br>from the university perspective | |
| 1:40 p.m. | "The Bayh-Dole Act: Preservation, Protection and Commemoration"<br>from PhRMA's perspective | |
| 1:50 p.m. | Closing Remarks: | Valerie Volpe<br>Are There Issues on Which We Should Coordinate?<br>"Where Do We Go From Here?" |
| 2:00 p.m. | Adjournment | |


| | | |
|---|---|---|
| 1:50 p.m. | Closing Remarks: | Valerie Volpe<br>Are There Issues on Which We Should Coordinate?<br>"Where Do We Go From Here?" |
| 2:00 p.m. | Adjournment | |

**From:** "Valerie Volpe" <wolpe@phrma.org>
**To:** <sheinig@aamc.org>, <richard_turman@aau.edu>, <sheldon_steinbach@ace.nche.edu>, <njl@browdyneimark.com>, <kphillips@cogr.edu>, <rhardy@cogr.edu>, <Michael.Remington@dbr.com>, <rharpel@nasulgc.org>, "John Kelly" <JKELLY@phrma.org>, "Missy Jenkins" <MJENKINS@phrma.org>, "Rachel Kerestes" <RKERESTES@phrma.org>, "Sara Radcliffe" <SRADCLIF@phrma.org>, <gglover@ropesgray.com>, <cohn@warf.ws>
**Date:** Thu, Oct 3, 2002 12:12 PM
**Subject:** Sept.26 Meeting Follow-Up

On behalf of John Kelly and myself, once again I thank you for taking the time from your demanding schedules to participate in the September 26th meeting. As agreed, Greg Glover's slide presentation is attached. Also attached are the meeting notes. Please feel free to make comments or changes regarding the notes and I will resend a new version to reflect those changes. In addition, in order to follow up on the suggestions made at the meeting, I would appreciate feedback on the following:

1) Frequency of subsequent meetings - quarterly, etc?
2) A December event to celebrate the successes of Bayh-Dole. Should we decide to move forward on this, please indicate whether or not you would like to be part of a "committee" of sorts to plan the event.
3) Dissemination of information on priority issues for the university/academic community.

All of us at PhRMA look forward to working with you to protect the work we all do to bring treatments to patients. Thank you again.

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



- 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

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## 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.



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## INFORMAL DISCUSSION

With Greg Glover's presentation stimulating questions regarding the Bayh-Dole Act and proposed legislative changes, the rest of the luncheon was devoted to an exchange of viewpoints among all participants regarding areas of mutual and exclusive interest. Participants also engaged in self introductions and described their respective organizations.

John Kelly opened the discussion by acknowledging that in today's political climate the issue of prescription drug "cost" weighs heavily on the minds of PhRMA and its member companies. Though university representatives recognized the importance of cost discussions to the political debate, they stated in general terms that "cost" issues were not their primary concern. However, to the extent that universities engage in less collaborative research, that is of concern to them.

Shelley Steinbach noted the importance of personal relationships in Washington, D.C., and sounded a refrain that meetings of this sort are extremely valuable. Shelley also recognized that joint meetings stimulated mutual understanding with the possibility of achieving joint positions.

As the discussion continued, Richard Turman made the point that the issue of "tech transfer" is important to his organization as it involves both research and government relations aspects. However, Richard cautioned that universities are "reluctant to get political."

Valerie Volpe urged universities to consider cost issues by noting that pharmaceutical companies will be reluctant to invest in research of drugs tailored for "boutique" diseases when there is a good chance that the companies will not recoup their investments.

Rich Harpel stated that the Bayh-Dole Act means different things to universities, but most importantly the Act provides an "environment of cooperation" between universities and pharmaceutical companies. It is for this reason that universities have an interest in preserving Bayh-Dole, according to Rich. Rich further stated that he has found that current Hill staff don't know much about the legislative intent of Bayh-Dole and that a lot of his time is spent "tutoring" Hill staff to some extent.

Kate Phillips also recognized the benefits of Bayh-Dole, but stated that the Council on Government Relations, is agency-focused, not Hill-focused. Nonetheless, she noted that she perceives "hostility" toward Bayh-Dole in many directions and that this hostility is troublesome. She made special mention of a "challenge" coming from Sen. Ron Wyden. Robert Hardy echoed Kate's statement and further added that it is essential from COGR's perspective to "preserve the central integrity of Bayh-Dole."

Andy Cohn mentioned three areas of concern for WARF that he hoped others will find common interest in: 1) collaborative research patent reform (a bill will soon be introduced in the U.S. House of Representatives); 2) sovereign immunity reform (which should not unnecessarily destroy state university patent rights); and 3) growing legal concerns regarding patent infringement issues and a broad research exception.



common interest in: 1) collaborative research patent reform (a bill will soon be introduced in the U.S. House of Representatives); 2) sovereign immunity reform (which should not unnecessarily destroy state university patent rights); and 3) growing legal concerns regarding patent infringement issues and a broad research exception.

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Rich Harpel noted that he and representatives from the NASULGC had "conversations" with Sen. Patrick Leahy and his staff regarding S. 2031, the sovereign immunity legislation. Rich found the dividing lines to be between the university community and the entertainment community. Further, he stated that he found the issue to be a conflict between state government and the federal government, thus it is a constitutional issue. According to Rich, the bill is on hold indefinitely, and that is good.

Upon hearing the concerns raised by participants, John Kelly acknowledged that there is "no lack of attacks" going on with regards to patent law and pharmaceutical research. He stated that "periodic" ongoing discussions could be helpful as it is in everyone's interest to weigh in with their concerns for all to hear. Attendees agreed.

In light of John's statement, Richard Turman stated two areas of common interest between universities and PhRMA, notably the doubling of funding for NIH and the use of animals for research.

Robert Hardy followed up by noting that he sees an "erosion" in NIH's commitment to Bayh-Dole and that NIH managers view Bayh-Dole as "more of an option" than before.

Mike Remington said that reorganization of the U.S. Patent and Trademark Office, especially with regards to fees, should also be a mutual concern for both universities and PhRMA. According to Mike, good government should be a shared goal. Attendees seemingly agreed.

Richard Turman stated that the university community is very concerned with "bias and patient safety issues." Further, he noted that presidents and chancellors are "keenly" aware and interested in human subject issues, another issue of mutual concern between universities and PhRMA companies.

Stephen Heinig said his primary interest is keeping information in the public domain. John Kelly agreed that that is an important concern, especially with regards to clinical trials. He then referenced a pamphlet handed out at the luncheon entitled " Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results."

Andy Cohn voiced a plea for mutual cooperation in the stem cell research debate. Valerie Volpe said that PhRMA has "no position" in the debate. However, she mentioned that PhRMA is supporting and funding individual member organizations that are active in the issue.

Aware of everyone's areas of interest, John Kelly acknowledged his amazement at how much commonality there was. He suggested that all parties should come together and celebrate the upcoming birthday of the Bayh-Dole Act amendments on December 12. All parties agreed that would be a beneficial thing.

Further, Mike Remington offered a suggestion that there should be an additional grass-roots approach to the celebration whereby individual companies and universities work together at



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the state and congressional district level in acknowledging the importance of the Bayh-Dole Act. That suggestion also received favorable acceptance.

In closing, it was agreed by all that patent law is necessary for the development of collaborative research between universities and pharmaceutical companies, to the betterment of the public. All attendees agreed that further meetings should occur, and that parties could approach each other directly on pressing issues of concern.



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## SUMMARY OF CONSENSUS ITEMS

- Dr. Glover's Power Point presentation would be distributed electronically to all participants.
- Informal meetings to discuss legislative proposals that impact on the pharmaceutical industry and universities are productive and should occur periodically.
- The "success" of the Bayh-Dole Act is critical to the future of collaborative research and the ability of universities and pharmaceutical companies to engage in inventive activities and to bring new products and processes to the market. However, because the Bayh-Dole is under criticism, its success should not be taken for granted.
- The parties should consider a 22nd birthday celebration on December 12 for the Bayh-Dole Act, as enacted on December 12, 1980.
- The parties should consider a grass-roots approach to Bayh-Dole programs to occur at a handful of universities where successful collaborative research and technology transfer have occurred.
- Patent law is necessary not only for inventive activities on university campuses and in pharmaceutical companies but also for collaborative activities between and amongst these entities. As a general proposition, legislative efforts to decrease patent protections should be seriously scrutinized by the respective parties which, based on their own priorities, should express opposition.



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# Protection of Collaborative Research – A PhRMA Perspective:

# The Importance of Patents to the Discovery and Development of New Treatments and Cures

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# Overview

- Development of New Treatments and Cures
- Important Role of Patents
- The Relevance of the Hatch-Waxman Act to Patent Protection for New Treatments and Cures
- S.812/HR 5311: Recent Proposed Legislative Changes to the Hatch-Waxman Act
- Effects of Proposed Legislative Changes for Research Institutions

# Development of New Treatments and Cures

- Development of new treatments and cures depends upon the work of both academic research institutions and commercial entities.
- Both have critical roles to play.
- Each depends upon the other.

# Role of Research Institutions

- Research institutions play an essential role, particularly with regard to basic research.
- Universities, private foundations and charities fund and perform research that identifies potential new treatments and cures.
- This work is an essential prerequisite to the developmental work of commercial entities.

# Role of Commercial Entities

- Commercial entities continue the development process by
  - performing the R&D necessary to evaluate the viability of drugs for human use,
  - conducting the Phase I-III trials necessary to assess safety and efficacy, and
  - helping to support the work of research institutions, through grants, licensing agreements and other arrangements.