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May 28, 1997

The Honorable «Name»
 «Capitol Address»
 «City», «State» «Zip»
 Facsimile: («Capitol Fax Area _____»)

Post-it® Fax Note	7871	Date	5/28	Fa pages	2
To	Susan Gregg	From	Lisa Hudson		
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Phone #		Phone #			
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Dear «Salutations»:

On behalf of the California Healthcare Institute (CHI), whose 150 members include our state's leading academic research organizations, as well as commercial biopharmaceutical and medical device firms, I would like to draw your attention to an issue of critical importance for biomedical research and development. It involves the efforts of a small Seattle biotech company called CellPro, using a little-known provision of federal law, to thwart the U.S. patent system. If CellPro's scheme succeeds, it will undermine the present system of technology transfer from California universities and research institutes to commercial business.

The facts are these. In the 1970s and 1980s, scientists at Johns Hopkins University made certain discoveries in the area of stem cell production for cancer patients. Johns Hopkins patented this technology then, in accordance with National Institutes of Health guidelines, licensed the inventions to Becton Dickinson and Baxter Healthcare for production and marketing. Subsequently CellPro developed a similar technology. In March 1997, after lengthy litigation, a federal jury unanimously decided that CellPro "knowingly and willfully" infringed on Johns Hopkins' patents.

Undeterred by the court's decision, CellPro proceeded to petition the Secretary of Health and Human Services to exercise so-called "march-in rights" under the Bayh-Dole Act. In effect, this provision allows the government to bypass the standard patent and license process if (a) an invention is based on government-funded research and (b) the Secretary of HHS determines that a special license should be granted for compelling public health reasons. CellPro contends that unless it receives a special license, cancer patients will be denied access to stem cell technology.

This claim is false. Based on its license from Johns Hopkins, Baxter Healthcare has developed an effective stem cell selection system for cancer patients. This system is widely used in Europe, and is currently under review by the FDA for approval in the U.S. In fact, despite the finding of patent infringement, Johns Hopkins, Becton Dickinson and Baxter Healthcare have asked the court to continue to allow CellPro to sell its product until the FDA approves an

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Representative «Name»

CellPro

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alternative. In addition, CellPro would be allowed to complete FDA-approved clinical trials, and would not be required to make royalty payments in connection with products it provides free of charge or at cost.

CellPro should not be permitted to achieve by administrative action what it could not achieve in negotiation with the rightful patent holders or in federal court. If CellPro is able to use the Bayh-Dole Act as a crowbar to pry open our patent system, all nonprofit medical research institutions will suffer the consequences. Because unless they can secure solid rights to their intellectual property, the licenses they grant will be practically worthless. Absent the economic incentives to invent commercially viable products, and without the royalty income such products produce, our research institutions will simply do less. And all of us will suffer.

Rep. John Porter (R-IL) has summarized the case against CellPro's petition in a "Dear Colleague" letter on May 21, 1997. I strongly urge you to support California's great biomedical research enterprise, join Rep. Porter's efforts and contact Secretary Shalala to advise her to reject this petition.

Please contact me if you would like more detailed information.

Sincerely,



David Gollaber, Ph.D.

President

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