

ASKING FOR MONEY BACK—CHILLING COMMERCIALIZATION OR  
RECOUPING PUBLIC TRUST  
IN THE CONTEXT OF STEM CELL RESEARCH?

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As publicly funded institutions have increasingly embraced the goal of commercializing scientific research, concerns about private appropriation have become familiar refrain. One commonly suggested remedy is to create some kind of “recoupment” provision whereby the State, on behalf of the public, receives a certain percentage of profits realized. The Bayh-Dole Act originally included a recoupment provision but it was deleted by a legislative committee. Countries around the globe attempting to emulate Bayh-Dole have, whether by design or default, reinforced the underlying logic against recoupment, which is essentially as follows: obligations to provide direct financial returns undermine the commercialization process and therefore threaten what the public cares about most, i.e. the production of new goods. Despite regular controversies over alleged windfalls to industry, this logic has continued to prevail—until now. The California Institute of Regenerative Medicine (CIRM) has recently issued two intellectual property policies applicable to non-profit and for-profit grant recipients respectively, each of which contains mechanisms to recoup a portion of the public’s tax dollar investment. Why? This Article aims to explore that question by: one, further explaining the curious history in which the wisdom against recoupment came to prevail; two, probing the details of CIRM’s intellectual property policies and examining the arguments for and against the recoupment formulae they establish; and three, revealing the limits of

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what is actually known about whether such mechanisms exert a chilling effect on the commercialization process, and whether or not a direct financial return is what the public values most. In the end, the value of recoupment may be best conceived of in democratic terms: as one means of attempting to balance a host of conflicting views, and preserving public trust as the many promises of biotechnology become increasingly integral to nation-building strategies and our lives.

## I. INTRODUCTION

Since the early twentieth century when academic scientists in the U.S. began to patent inventions made possible with public funds, concerns about private actors appropriating the lion's share of any financial benefits that accrue from those inventions have been raised.<sup>1</sup> Why, critics charged, should taxpaying members of the general public have to pay twice for the same invention or be subject to higher monopoly pricing when the invention reaches the market?<sup>2</sup> In more recent years, as publicly funded institutions increasingly embraced the goal of commercializing scientific research through formalized "technology transfer" to industry, concerns about private appropriation, high pricing, and double payment have become familiar refrain. Occasionally, when perceived abuses attract sufficient public attention—when for example, Taxol<sup>®</sup>, a "blockbuster" drug substantially developed with public tax dollars, delivers annual returns greater than \$500 million to Bristol Myers Squibb Inc.<sup>3</sup>—two kinds of remedies are commonly suggested. The first is to develop some form of control on pricing, making the product affordable to a wider segment of the population while reducing private profit. The second remedy is to

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<sup>1</sup> A.J. Glover, an influential individual in the Wisconsin dairy industry, for example, commented as follows in response to the decision made by Harry Steenbock during the 1920s to patent a process for irradiating foods:

Why should the public devote money to discovering new truths only to permit them to be patented and their use determined by some corporations? It seems to me that information discovered by the use of public money belongs to the public and it is difficult for me to understand how such discoveries can be patented and some private corporation determine how they shall be used.

Rima D. Apple, *Patenting University Research: Harry Steenbock and the Wisconsin Alumni Research Foundation*, 80 *ISIS* 375, 378 (1989).

<sup>2</sup> This argument has been made or noted by several commentators. *See, e.g.*, Peter Arno & Michael Davis, *Paying Twice for the Same Drugs*, *Wash. Post*, Mar. 27, 2002, at A21; Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 *Va. L. Rev.* 1663, 1666-67 (1996).

<sup>3</sup> According to one source, the U.S. National Institutes of Health (NIH) invested \$484 million to fund research that ultimately allowed Bristol Myers Squibb to market Taxol. *See* Aaron S. Kesselheim & Jerry Avorn, *Biotechnology Products and University-Based Science*, 293 *JAMA* 2861, 2863 (2005).

create some kind of “recoupment” or “payback” provision whereby the State, on the public’s behalf, receives a certain percentage of profits realized, in other words, a direct financial return on investment.<sup>4</sup> Contrary to what some critics of the status quo allege, as initially drafted, the Bayh-Dole Act explicitly contemplated recoupment, not pricing control.<sup>5</sup> Curiously, with U.S. global competitiveness seemingly on the line, the recoupment provision was deleted before Bayh-Dole passed into law.<sup>6</sup> Whereas pricing control has subsequently gained temporary traction at the federal government level, post-Bayh-Dole reforms have not included any sort of recoupment mechanism.

Meanwhile, Bayh-Dole has become the paradigm to which several other countries aspire.<sup>7</sup> The thrust of these reforms outside the U.S. has been to vest intellectual property ownership in research institutions rather than individual inventors or research funding bodies on the strength of the view that it “provides greater legal certainty, lowers transaction costs, and fosters more formal and efficient channels for technology transfer.”<sup>8</sup> But in the process of trying to emulate Bayh-Dole (whether by design or default) each of these countries has reinforced the view that a mechanism to recoup public investment is neither needed nor desirable, in effect institutionalizing the underlying logic against recoupment. That logic is essentially as follows: what the public cares about most is the production of new consumable goods, not a direct financial return. Providing for direct financial return would create a disincentive for private parties to partner with publicly funded research institutions, undermining the commercialization

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<sup>4</sup> Throughout this Article these two terms will be used interchangeably. The two primary policy documents analyzed below, however, employ the term “revenue sharing” to capture both sharing of revenues between research institutions and individual scientists as well as between those two collectively and the State of California. The former type of revenue sharing is, as explained below, required under current federal legislation whereas the latter type is not unless it is an explicit part of a licensing agreement between the funding organization and the recipient of those funds. For greater clarity, the term “revenue sharing” used below will refer solely to sharing between research institutions and individual scientists, not recoupment.

<sup>5</sup> See S. 414, 96th Cong. § 204 (1980) (enacted); H.R. 6933, 96th Cong. § 390(b) (1980) (enacted). See also John H. Raubitschek & Norman J. Latker, *Reasonable Pricing—A New Twist For March-In Rights Under the Bayh-Dole Act*, 22 Santa Clara Computer & High Tech. L.J. 149, 163 (2005).

<sup>6</sup> The legislation was originally titled the *University and Small Business Patent Procedures Act*. See Pub. L. No. 96-517, 94 Stat. 3015, 3019-27 (1980) (codified as amended at 35 U.S.C. §§ 200-212 (2006)).

<sup>7</sup> See generally David C. Mowery & Bhaven Sampat, *The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?*, 30 J. Tech. Transfer 115 (2005); Ken Howard, *Global Biotech Expansion Taking Cues from Bayh-Dole*, 22 Nature Biotech. 919 (2004); Thomas J. Siepmann, *The Global Exportation of the U.S. Bayh-Dole Act*, 30 U. Dayton L. Rev. 209 (2004).

<sup>8</sup> See Organisation for Economic Co-operation and Development, *Patents and Innovations: Trends and Policy Challenges* 20 (2004), <http://www.oecd.org/dataoecd/48/12/24508541.pdf>.

process and therefore threatening what the public cares about most, *i.e.* the production of new goods.

Despite regular controversies over alleged windfalls to industry, this logic has continued to prevail until recently. The California Institute of Regenerative Medicine (CIRM), a funding agency established by popular vote in 2004 to advance stem cell research in California, has developed two intellectual property policies and, contrary to conventional wisdom, each contains one or more mechanisms to recoup a portion of the public's tax dollar investment. The policy applicable to non-profit grant recipients became an official State regulation in July 2007,<sup>9</sup> and the policy applicable to for-profit grant recipients was approved by the Office of Administrative Law in March of 2008.<sup>10</sup> Two California Senators have introduced a bill to similar effect during the past year,<sup>11</sup> and several other States in the midst of implementing stem cell research programs of their own seem poised to institute recoupment mechanisms as well.<sup>12</sup>

The question then, is why have we witnessed this sudden departure from the norm against seeking direct financial returns from publicly funded research? This Article aims to explore that question by: one, further explaining the curious history in which the wisdom against recoupment came to prevail; two, probing the details of CIRM's intellectual property policies and examining the arguments for and against the recoupment formulae they establish; and three, revealing the limits of what is actually known about (a) whether such mechanisms exert a chilling effect on the commercialization process, and (b) whether a direct financial return really is what the public values most.

It is important to stress at the outset that the primary focus here is upon recoupment and its potential impact on the commercialization process. However, as foreshadowed above, the historical context surrounding this notion of recoupment and the arguments for and against it are inevitably intertwined with parallel efforts to institute

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<sup>9</sup> See California Institute of Regenerative Medicine, Adopted CIRM Regulations: Chapter 3 – Intellectual Property Requirements for Non-Profit Organizations (2007), <http://www.cirm.ca.gov/reg/default.asp> [hereinafter CIRM, Non-Profit Regulations], Cal. Code Regs. tit. 17, § 100300-10 (2006).

<sup>10</sup> See California Institute of Regenerative Medicine, Adopted CIRM Regulations: Chapter 4 – Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations (2007), <http://www.cirm.ca.gov/reg/default.asp> [hereinafter CIRM, For-Profit Regulations], Cal. Code Regs. tit. 17, § 100400-10 (2006). Both sets of regulations are subject to amendment in accordance with California law; in fact, proposed amendments to each set of regulations are currently open for public comment. See California Institute for Regenerative Medicine, Adopted CIRM Regulations, <http://www.cirm.ca.gov/reg/default.asp>.

<sup>11</sup> Cal. S. 771, 2007-2008 Leg., Reg. Sess. (2007).

<sup>12</sup> A summary of other State-based stem cell research programs as well as a list of private foundations that employ payback requirements is provided in the intellectual property policy initially proposed by CIRM. See California Institute of Regenerative Medicine, Policy for For-Profit Organizations 19-20, 45 (2006), <http://www.cirm.ca.gov/faq/pdf/ForProfitOrg.pdf> [hereinafter CIRM, Initially Proposed For-Profit Policy].

some level of pricing control with respect to healthcare products developed with public tax dollars. Those efforts, which at least after the passage of Bayh-Dole have generally received far greater attention than the recoupment issue, are thus incorporated throughout the analysis below.

## II. DEVELOPMENT OF THE STATUS QUO

### A. Recoupment Lost Under Bayh-Dole

By late 1980, after a number of precursors, two patent reform bills were winding their way through the Senate and House of Representatives. Both originally contained a recoupment mechanism of some kind. The relevant provisions in Senate Bill 414 read:

§204. Return of Government investment.

(a) If after the first United States application is filed on a subject invention, a nonprofit organization, a small business firm, or an assignee of a subject invention of such an organization or firm to whom such invention was assigned for licensing purposes, receives \$70,000 in gross income for any one calendar year from the licensing of a subject invention or several related subject inventions, the United States shall be entitled to 15 per centum of all income in excess of \$70,000 for that year other than any such excess income received under nonexclusive licenses (except where the nonexclusive licensee previously held an exclusive or partially exclusive license).

(b) (1) Subject to the provisions of paragraph (2), if after the first United States patent application is filed on a subject invention, a nonprofit organization, a small business firm, or an assignee of a subject invention of such an organization or firm, receives gross income of \$1,000,000 for any one calendar year on sales of its products embodying or manufactured by a process employing one or more subject inventions, the United States shall be entitled to a share, the amount of which to be negotiated but not to exceed 5 per centum, of all gross income in excess of \$1,000,000 for that year accruing from such sales.

“ (2) In no event shall the United States be entitled to an amount greater than that portion of the Federal funding under the funding agreement or agreements under which the subject invention or inventions was or were made expended on activities related to the making of the invention or inventions less any amounts received by the United States under subsection (a) of this section. In any case in which more than one subject invention is involved, no expenditure funded by the United States shall be counted more than once in determining the maximum amount to which the United States is entitled.

(c) The Director of the Office of Federal Procurement Policy is authorized and directed to revise the dollar amounts in subsections (a) and (b) of this section at least every three years in light of changes to the Consumer Price Index or other indices which the Director considers reasonable to use.

(d) The entitlement of the United States under subsections (a) and (b) shall cease after (i) the United States Patent and Trademark Office issues a final rejection of the patent application covering the subject invention, (ii) the patent covering the subject invention expires, or (iii) the completion of litigation (including appeals) in which such a patent is finally found to be invalid. (emphasis added)<sup>13</sup>

Section 204 thus contained two separate recoupment provisions: the first (§ 204(a)) was a 15% share of *gross* licensing revenues once they surpassed a \$70,000 per year threshold; the second (§ 204(b)) was a share, not to exceed 5%, of sales from products generating greater than \$1,000,000 in *gross* income. Referred to unitarily as the “payback provision”, section 204 figured prominently in debates over the bill. Senators who supported S. 414 cited section 204 repeatedly in order to deflect those who argued that the proposed legislation amounted to a giveaway of taxpayer property.<sup>14</sup> For example, in a statement printed in the Congressional Record, Senator Edward Kennedy (D-Mass.) wrote:

Some are concerned that allowing private entities to obtain patent rights to inventions made with public funds would result in “giveaways” or unwarranted private gain. One of the key features of S. 414 is the “payback” provision, which requires the small business or university contractor to return to the Government the amount of the original funding. This payback provision, together with others which allow the Government to monitor and improve the efforts being taken to secure commercialization of the inventions, will help insure that the broadest public interest is being served.<sup>15</sup>

Elsewhere, Senator Robert Dole (R-Kan.) argued that the provision was integral to the bill’s purpose:

S. 414 aims at replacing the almost adversarial relationship that now exists between business and Government, with a true and genuine partnership in which everyone can benefit: the American public, businesses, and last but

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<sup>13</sup> S. 414, 96th Cong. § 204 (1980) (enacted).

<sup>14</sup> See, e.g., 126 Cong. Rec. 2, 1797, 1799, 1992, 1996, 2006 (1980); 126 Cong. Rec. 7, 8739, 8741, 8743 (1980).

<sup>15</sup> 126 Cong. Rec. 2, 1799 (1980).

not least the Government will reap tax profits from increased productivity, increased employment, at no cost thanks to the special provision in the bill, section 204 that guarantees the Government return of its investment in research funds.<sup>16</sup>

Meanwhile, the recoupment provision contained in House Bill 6933 was playing a similar role despite being less well defined. Rather than setting specific thresholds when repayment obligations would come into play, section 390(b) mandated the Office of Federal Procurement Policy to craft regulations providing for “payment to the Government for Federal funding of research and development activities through the sharing of royalties and/or revenues with the contractor. Such regulations shall provide, to the extent appropriate, a standard contractual clause to be included in all Federal research and development contracts.”<sup>17</sup>

A broad exemption immediately followed 390(b) allowing funding agencies to waive “all or part of the payment” in any one of several circumstances.<sup>18</sup> While the bill went through Committee hearings, one representative pointed out that this exemption had

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<sup>16</sup> 126 Cong. Rec. 2, 1992 (1980).

<sup>17</sup> H.R. 6933, 96th Cong. § 390(b) (1980) (enacted).

<sup>18</sup> Section 390(c) enumerated these circumstances as follows:

Such regulations may allow the agency to waive all or part of the payment...at the time of contracting or at the request of the contractor where the agency determines that –

- (1) the probable administrative costs are likely to be greater than the expected amount of payment; or
- (2) the Federal Government’s contribution to the technology as licensed or utilized is insubstantial compared with the private investment made or to be made in technology; or
- (3) the contractor is a small business, educational institution, or nonprofit organization; or
- (4) the total Government funding of the technology with the contractor is less than \$1,000,000; or
- (5) the payment would place the contractor at a competitive disadvantage or would stifle commercial utilization of the technology; or
- (6) it is otherwise in the best interests of the Government and the general public.

the potential to render the recoupment provision meaningless.<sup>19</sup> However, other representatives were seemingly unaware of the recoupment mechanism's deficiencies. The provision thus served to diffuse the "giveaway" concern. Consider the following exchange between Millicent Fenwick (R-N.J.) and Thomas Railsback (R-Ill.):

Mrs. FENWICK. I thank my colleague for yielding. I, too, support this measure. I think it is long overdue. The figures the gentleman has given us are most convincing.

However, I do notice that the public has spent some \$50 billion in research. I would like to be assured if my understanding of the bill is correct. Is there now in this legislation a provision which will mean that the Secretary will be empowered to require return of a part of any profits to the Treasury so that if the invention produces a large profit for the company to which the patent has been allocated, some money will return to the Treasury;

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<sup>19</sup> The Committee on the Judiciary reviewed and approved the House Bill in August 1980. However, one member of the Committee, Jack Brooks (D-Tex.), dissented, commenting in part as follows:

While there are provisions in the bill for recovery of government-funded research and development costs in certain instances, the exceptions for reimbursement have a tendency to render the provisions meaningless. Section 390(c)(2) permits exemptions from reimbursement where the Federal government's contribution to the technology as licensed or utilized is insubstantial compared with private investment made or to be made. The private investment "to be made" is highly speculative at best. Any good accountant should be able to show that the government's investment is minimal compared to what the marketer "expects" to spend.

Section 390(c)(4) permits waiver or reimbursement where the government funding of the technology with the contractor is less than \$1 million, a clearly arbitrary exclusion.

Section 390(c)(5) permits foregoing payment when it would place the contractor at a competitive disadvantage or would stifle commercial utilization of the technology. How repayment of research and development costs would place a contractor at a competitive disadvantage is not quite clear where an exclusive license precludes competition.

Subsection 6 permits exemption from payment when "it is otherwise in the best interest of the government and the general public." It is hard to imagine a taxpayer who, having funded the cost and borne the risk of the research and development of a product, would conclude that it is in his best interest not to be reimbursed from the proceeds accruing to the contractor.

H.R. Rep. No. 96-1307, pt. 1, at 6490 (1980).

Mr. RAILSBACK. Yes. That is the provision for recoupment and it is in the bill. I think that particular provision is a good idea and something I think we should support.

Mrs. FENWICK. That is a part of the legislation?

Mr. RAILSBACK. Yes, that is correct.<sup>20</sup>

Another proponent of the bill, Robert Kastenmeier (D-Wis.), later buttressed the point:

It could be argued that the development of new goods and manufacturing processes will repay the Government for its R. & D. investment simply through new tax revenues. While this is true, this bill goes even further by providing for payments to the Government through the sharing of royalties or revenues. This recoupment provision will compensate the Government for its investment and prevent the contractor from achieving “windfall profits” at the expense of the taxpayers while still encouraging commercialization of the inventions.<sup>21</sup>

In the end, both S. 414 and H.R. 6933 passed by significant majorities. Curiously though, despite the emphasis placed upon the recoupment provision in each chamber of Congress, when the House and Senate met in conference to reconcile their respective patent reform bills *neither* provision was retained, and without any recorded protest.<sup>22</sup> Washburn suggests that this was the combined result of the political climate at the time—the U.S. was widely believed to be falling behind its global competitors and the legislation was seen as instrumental to reversing that trend—and the shrewd work of one key bureaucrat, Norman Latker. During a 2003 interview, Washburn quotes Latker as saying that: “We all hated [the recoupment provision], but we felt this was a way of buying off the opposition . . . It was a political ploy.”<sup>23</sup> When contacted for further explanation Latker commented as follows:

A system for identifying what was to be returned to the government was determined to be too complex to administer. I believe the legislative history for [Bayh-Dole] indicates something to the effect that the administrative costs would probably exceed what could be recouped. Further, it was my view that it was clearly unfair to make any attempt to recoup all of the Federal expenditure on both grants that produced commercialized inventions and those that did not from the few winners.

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<sup>20</sup> 126 Cong. Rec. 22, 29897 (1980).

<sup>21</sup> 126 Cong. Rec. 22, 29899 (1980).

<sup>22</sup> See generally Jennifer Washburn, *University, Inc.: The Corporate Corruption of American Higher Education* (2004) (determining that this amendment received no comment whatsoever in either the House of Representatives or the Senate).

<sup>23</sup> *Id.* at 68.

Finally, those supporting the passage of [Bayh-Dole] believed that the public's reward was the delivery of life supporting inventions for their use which was one of the purposes for the initial investment not being met before [Bayh-Dole].<sup>24</sup>

Time, of course, was also a factor as the end of the Congressional session fast approached, Senator Birch Bayh (D-Ind.)—the other principal sponsor of S. 414—had failed to be re-elected, and versions of the legislation had already died twice in Committee. Thus, whether due to the economic downturn, reasons of political expediency, or genuine worries about administrative costs,<sup>25</sup> the recoupment provision did not survive. Other checks against undue private appropriation also failed to be incorporated or were subsequently removed. Most notably, President Ronald Reagan unilaterally decided in 1983 to extend Bayh-Dole to larger corporations as opposed to only small businesses, universities and nonprofit organizations.<sup>26</sup> As amendments and other pieces of legislation were added to this general framework throughout the 1980s and 1990s,<sup>27</sup> the idea of utilizing a recoupment provision did not resurface despite a number of controversies and efforts to reduce the pricing of healthcare products developed in significant part with public funds.

#### B. Senator Wyden's Failed Campaign

In 2000 Senator Ronald Wyden (D-Or.) injected new life into the recoupment idea. In addition to raising concerns about pricing, he proposed that the public should receive at least a modest financial return from blockbuster drugs (defined as those which generate greater than \$500 million in annual revenues) that emerged from federal government grants. The National Institutes of Health (NIH) set out to study the issue.<sup>28</sup>

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<sup>24</sup> E-mail from Norman Latker to author (Mar. 29, 2007, 14:33 PST) (on file with author).

<sup>25</sup> In 2004, Bayh commenting to the NIH, stated: "In fact, this payback provision of Section 204 was later dropped from the bill altogether because the agencies said that the administrative costs of tracking university royalties would far outweigh any monetary benefits from the one-in-a-million breakthrough invention." Statement of Senator Birch Bayh to the National Institutes of Health (May 25, 2004), *available at* <http://www.ott.nih.gov/policy/meeting/Senator-Birch-Bayh.pdf> (perhaps this was what Latker was describing above, but no official record of this information was found).

<sup>26</sup> *See generally* Eisenberg, *supra* note 2, at 1694-95 (detailing these and other legislative changes).

<sup>27</sup> *Id.* at 1715-17.

<sup>28</sup> Interestingly, their report summarizes what happened to the recoupment provision differently than above, suggesting that the absence of a recoupment provision played a much more decisive role:

In terms of process, the NIH conducted a “comprehensive cross-analysis of all 47 FDA-approved drugs meeting the \$500 million/year threshold,” “reviewed studies that have examined the impact of federally supported biomedical research and the return on investment that such research generates,” and “contacted a number of sources,” including the Council of Government Relations, the Association of University Technology Managers (AUTM), the Biotechnology Industry Organization (BIO), the Pharmaceutical Research and Manufacturers Association (PHARMA), other companies and federal agencies with active technology transfer programs.<sup>29</sup>

At each turn, the likelihood of introducing some form of recoupment mechanism seemed to reduce. NIH faced a general tracking problem to begin with, noting that it “encountered difficulty in being able to cross-reference NIH grants and contracts that gave rise to inventions with any patents or licenses covering the final product, as well as an inability to identify other federal and/or non-federal sources of funds that contribute to an inventive technology.”<sup>30</sup> The reason being, “implementing regulations of the Bayh-Dole Act do not require that investigators provide such information to the funding agency, and it is generally not provided. As a result, tracking down the ‘pedigree’ of these drugs had to be done manually and on a case-by-case basis.”<sup>31</sup> In the end, then, of the 47 drugs belonging to the \$500 million/year group, only four—Taxol<sup>®</sup>, Epogen<sup>®</sup>,

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The Bayh-Dole Act was passed after Conferees made two changes in the language, in response to concerns that the process for determining repayment was threatening to cause an impasse in deliberations. First, several attempts to develop a mechanism for collecting repayment funds failed because there was no agreement on whether the funds would be returned to the agencies or to general revenue, or how the collection and auditing functions would be conducted. There were also fears that the costs of the infrastructure required to administer such a program would exceed the amounts collected.

To obtain passage of the legislation, members of Congress agreed that recoupment provisions would be dropped. However, due to concerns of some members of Congress that large companies would benefit from public dollars without a return to the taxpayer, large companies were removed from eligibility in the final bill. With these changes, the bill was passed and the Act today remains applicable to universities, nonprofit organizations and small businesses. In 1983, by Presidential Memorandum, President Ronald Reagan extended the implementation to large companies. And, in 1987, implementation of the Act was extended to these companies as part of an Executive Order issued by President Reagan.

NIH, A Plan to Ensure Taxpayers’ Interests are Protected § C-5 (July 2001), <http://www.nih.gov/news/070101wyden.htm> [hereinafter NIH, Taxpayers’ Interests].

<sup>29</sup> *Id.* § A.

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* § D-1.

Procrit<sup>®</sup>, and Neupogen<sup>®</sup>—were found conclusively to have been developed in part with NIH funding.<sup>32</sup>

Secondly, the NIH cited three recent studies all suggesting that the rate of *indirect* return to taxpayers from federally funded research was, in the absence of any form of direct recoupment, already phenomenal. The National Science Foundation estimated that the government's rate of return on "investment for basic research can be as high as 40 percent when all the numbers are totaled, including taxes generated from product development."<sup>33</sup> The U.S. Congressional Joint Economic Committee stated that "although the rate of return on publicly funded research is difficult to quantify, the benefit of increased life expectancy in the U.S. as a result of advances in health care creates annual net gains of about \$2.4 trillion", thus "if only 10 percent of these increases in value (\$240 billion) are the result of NIH-funded medical research, it indicates a payoff of about 15 times the taxpayers' annual NIH investment of \$16 billion."<sup>34</sup> A study commissioned by the Mary Woodward Lasker Charitable Trust found that:

[T]he total economic value to Americans of reductions in mortality from cardiovascular disease averaged \$1.5 trillion annually in the 1970-1990 period. So if just one-third of the gain came from medical research, the return on the investment averaged \$500 billion a year. That's on the order of 20 times as large as average annual spending on medical research—by any benchmark an astonishing return for the investment.<sup>35</sup>

Although speculative, each of these statements supported the view that the indirect returns from funding scientific research far exceed what might be directly recovered from licensing and/or product sales revenues.<sup>36</sup>

Finally, the idea of recoupment was strongly opposed by several of the groups that were consulted, chief among them AUTM, BIO, and PHARMA:

NIH explored the notion of possible royalty redirection for "blockbuster" drugs under licenses arising from the Bayh-Dole Act. This suggestion was met with strong resistance from the academic community

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<sup>32</sup> *Id.* § D.

<sup>33</sup> *Id.* § C-7.

<sup>34</sup> Joint Economic Committee, U.S. Senate, *The Benefits of Medical Research and the Role of the NIH* 17 (2000), quoted in NIH, Taxpayers' Interests, *supra* note 28, § C-7.

<sup>35</sup> Lasker/Funding First, Mary Woodward Lasker Charitable Trust, *Exceptional Returns: The Economic Value of America's Investment in Medical Research* 8 (2000), <http://www.laskerfoundation.org/advocacy/pdf/exceptional.pdf>.

<sup>36</sup> See Kerry Grens, *An Economic Gamble: What Does Society Get for the Billions it Spends on Science?*, *The Scientist*, July 2007, at 28, available at <http://www.the-scientist.com/article/home/53302/> (reviewing these and other estimates of the indirect returns from funding scientific research).

because it was perceived as a tax that would, at best, have no net effect on the price of a therapeutic drug and, at worst, increase its cost. Further, it was argued that such redirection of royalties would undermine the research enterprise, drain funds for academic development, and discourage faculty members from embarking in the technology transfer process. Moreover, there is concern that any movement to extract a direct financial return for the investment would dampen, if not destroy, industry's willingness to establish agreements with academic institutions, as was the case when NIH imposed the reasonable pricing clause in its CRADAs.<sup>37</sup>

Not surprisingly, then, the “plan to ensure taxpayers’ interests are protected” ultimately formulated by the NIH in July 2001 fell far short of establishing any sort of recoupment mechanism.<sup>38</sup> Instead, the NIH advocated that existing policies should be modified “to ensure that grantees and contractors report to the agency the name, trademark or other appropriate identifiers of a therapeutic drug that embodies technology funded by the NIH once it is FDA-approved and reaches the market;” that a publicly accessible “web-based database” be developed to house this information; and, that a group should be established to continue a “thoughtful dialogue on the appropriate returns to the public.”<sup>39</sup> It is unclear whether any further progress has been made. Bristol Myers Squibb, the producer of Taxol<sup>®</sup> (towards which NIH contributed \$484 million), did agree to repay royalties at 0.5 percent of its worldwide sales. However, by 2002, despite \$9 billion in worldwide profits for Bristol Myers Squibb, NIH had received only \$35 million, \$10 million short of even the small sum agreed upon.<sup>40</sup>

### C. Calls for Recoupment Continue

Senator Wyden is not alone in his campaign. Others continue to be concerned with the private appropriation of what were historically understood as public goods, *i.e.* scientific discoveries and inventions. This is particularly true in the case of inventions relating to the human genome, which, if characterized as the “common heritage of humankind,” many assert ought to be outside the realm patentable subject matter altogether. Other proposals have been less extreme, but do build-in some notion of recoupment. The Human Genome Organization’s Ethics Committee, for instance, recommended that “profit-making entities [engaged in genetics research] dedicate a percentage (*e.g.* 1% – 3%) of their annual net profit to healthcare infrastructure and/or to

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<sup>37</sup> NIH, Taxpayers’ Interests, *supra* note 28, § D-1.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* § E.

<sup>40</sup> Aaron S. Kesselheim & Jerry Avorn, *Biotechnology Products and University-Based Science—Reply*, 293 JAMA 2863 (2005), available at <http://jama.ama-assn.org/cgi/reprint/293/23/2863>.

humanitarian efforts.”<sup>41</sup> Kesselheim and Avorn have argued that a set payback obligation should be instituted across the board, to any recipient of public funds for research.<sup>42</sup> Another pair, Herder and Dyck Brian, have argued that certain initiatives into which a sizeable number of publicly funded resources (intellectual property, facilities, researchers) have been consolidated, should be subject to some kind of recoupment.<sup>43</sup> To date, none of these calls for recoupment have been heeded. However, as explained in detail next, a public referendum held in November 2004 in the State of California produced a different result.

### III. CIRM’S INTELLECTUAL PROPERTY REGULATIONS

In response to restrictions placed by President Bush upon research with stem cells derived from human embryos in August 2001,<sup>44</sup> a group of Californian citizens coalesced in support of a State-funded stem cell research initiative, which translated into Proposition 71 for the purposes of the November 2004 general election. Motivated by the possibility that stem cell research might cure his diabetic son, Robert Klein, a graduate of Stanford Law School and successful real estate developer, was Proposition 71’s principal author, chair of the “Yes on 71” campaign, and its largest donor.<sup>45</sup> Amid repeated promises that stem cell research *would* (as opposed to *may*) cure a host of illnesses, supporters of Proposition 71 also claimed that the initiative—then expected to be financed by tax-exempt bonds—would pay for itself or even generate a surplus for the State. On national television, Klein asserted that “California [would] gain jobs, new tax revenues and intellectual property revenues to pay back the taxpayers.”<sup>46</sup> A study commissioned by the “Yes on 71” campaign predicted that California would earn from

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<sup>41</sup> Human Genome Organisation (HUGO) Ethics Committee, Statement on Benefit Sharing (Apr. 9, 2000), available at [http://www.hugo-international.org/Statement\\_on\\_Benefit\\_Sharing.htm](http://www.hugo-international.org/Statement_on_Benefit_Sharing.htm). *But see* Lorraine Sheremeta & Bartha Maria Knoppers, *Beyond the Rhetoric: Populations Genetics and Benefit-Sharing*, 11 Health L.J. 89, 112-13 (2003) (describing how the chair of the HUGO Ethics Committee recently retreated from this particular recommendation).

<sup>42</sup> Aaron S. Kesselheim & Jerry Avorn, *University-Based Science and Biotechnology Products: Defining the Boundaries of Intellectual Property*, 293 JAMA 850, 854 (2005), available at <http://jama.ama-assn.org/cgi/reprint/293/7/850>.

<sup>43</sup> *See* Matthew Herder & Jennifer Dyck Brian, *Canada’s Stem Cell Corporation: Aggregate Concerns and the Question of Public Trust*, 77 J. Bus. Ethics 73 (2008).

<sup>44</sup> President George W. Bush, Address to the Nation on Stem Cell Research (Aug. 9, 2001) (transcript available at <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>) ; *see also* National Institutes of Health, Federal Policy, <http://stemcells.nih.gov/policy/>.

<sup>45</sup> *See* Center for Genetics and Society, The California Stem Cell Program at One Year: A Progress Report 8 (2006), <http://genetics.live.radicaldesigns.org/downloads/200601report.pdf>.

<sup>46</sup> *Id.* at 9.

\$537 million to \$1.1 billion in royalties from research funded by Proposition 71.<sup>47</sup> These promises and strategic references to direct financial returns for taxpayers are reminiscent of the debates over Bayh-Dole. Like the federal legislation 24 years earlier, Proposition 71 passed by a wide majority (59 to 41 percent), enshrining a right to conduct stem cell research within the Californian Constitution, and earmarking \$3 billion dollars for research to be dolled out by the California Institute for Regenerative Medicine (CIRM) over a ten-year period.<sup>48</sup> CIRM is governed by a 29-member Independent Citizens' Oversight Committee (ICOC), of which Klein is now the chair.<sup>49</sup>

However, unlike Bayh-Dole, an obligation to payback the State managed to survive the legislative process. Rather than codifying the details of this obligation (as § 204 of S. 414 did, for example, in setting a threshold for when payback would apply), subsection 125290.30(h) of the California Stem Cell Research and Cures Act (the Cures Act) simply reads:

The ICOC shall establish standards that require that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State of California to benefit from the patents, royalties, and licenses that result from basic research, therapy development, and clinical trials with the need to assure that essential medical research is not unreasonably hindered by the intellectual property agreements.<sup>50</sup>

Choosing not to set the finer details may have been wise given that any future amendments to the legislation require a 70% majority. On the other hand, it vests an untested body, the ICOC, with a great deal of discretion to develop policies in an area (intellectual property) that States have very little experience with relative to the federal government.<sup>51</sup>

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<sup>47</sup> Laurence Baker & Bruce Deal, Analysis Group, Inc., Economic Impact Analysis: Proposition 71, California Stem Cell Research and Cures Initiative 9 (2004), [http://www.ag-inc.com/AnalysisGroup/uploadedFiles/News\\_and\\_Events/News/Proposition\\_71\\_report.pdf](http://www.ag-inc.com/AnalysisGroup/uploadedFiles/News_and_Events/News/Proposition_71_report.pdf).

<sup>48</sup> See Center for Genetics and Society, *supra* note 45, at 5.

<sup>49</sup> CIRM, Independent Citizens Oversight Committee of the CIRM, <http://www.cirm.ca.gov/faq/pdf/Members.pdf> (last visited Apr. 14, 2008).

<sup>50</sup> Cal. Const. art. XXXV, §§ 1-7; Cal. Health & Safety Code §§ 125290.10-.70 (West 2006). In this sense, the provision is similar to the recoupment provision contained in H.R. 6933, 96th Cong. (1980), minus the exemptions.

<sup>51</sup> See generally Sean M. O'Connor, *Intellectual Property Rights and Stem Cell Research: Who Owns the Medical Breakthroughs?*, 39 New Eng. L. Rev. 665 (2004) (discussing why this should perhaps be of considerable concern).

In any event, CIRM has set to its task of developing such policies and in February and December of 2006, after consultation with some stakeholders,<sup>52</sup> the ICOC approved of intellectual property policies applicable to non-profit and for-profit organizations, respectively. CIRM has the power to enact these policies as official State regulations once they have gone through a period of public comment. Although both were originally held up by litigation challenging the constitutionality of the Cures Act,<sup>53</sup> the policies governing non-profit award recipients became binding regulations as of July 14, 2007 whereas the policies governing for-profit entities were enacted as regulations in March 2008. The particulars of each set of regulations are presented below followed by a summary of the bill introduced in the California legislature. While the primary focus remains upon the mechanisms for recoupment that they contain, these regulations also include a host of provisions that could prove equally, if not more, relevant to the process of commercializing stem cell-based inventions into clinical applications. However, those other provisions—save for those pertaining to pricing, which, as explained above, dovetail to some extent with recoupment—are beyond the scope of this analysis unless they explain how the mechanics of recoupment will work in practice.

#### D. Recoupment from Non-Profits

Similar to what is required under Bayh-Dole, CIRM requires that grantee organizations “share a fraction of any net revenues with the inventor(s) in accordance with their established policies.”<sup>54</sup> However, unlike the federal legislation, the regulations also seek to obtain a financial return on the public’s research investment through the recovery of 25% of the grantee organization’s revenue share from licenses for CIRM-funded patented inventions.<sup>55</sup> There are a number of important caveats to this rule. First, net revenues from a license or licenses of a CIRM-funded patented invention must exceed \$500,000 in the aggregate before the obligation to repay 25% is triggered. Second, *net* revenues do not include the inventor’s share and “the direct costs incurred in the generation and protection of the patents from which the revenues are received.”<sup>56</sup> Third, in the (likely) event that multiple sources of funding are used to support the research leading to net revenues in excess of the \$500,000 threshold, “the return to the

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<sup>52</sup> Precisely who CIRM has chosen to consult with has been the source of some controversy: *see* Center for Genetics and Society, *supra* note 45, at 8.

<sup>53</sup> This lawsuit was initially dismissed by the Superior Court of California, later rejected on appeal, and most recently denied permission for re-hearing. *See People’s Advocate, et al. v. Indep. Citizens’ Oversight Comm., et al.*, No. HG05 206766, 2006 WL 1417983 (Cal. May 12, 2006); Press Release, CIRM, California Stem Cell Case Advances (Mar. 20, 2007), *available at* <http://www.cirm.ca.gov/press/pdf/2007/03-20-07.pdf>.

<sup>54</sup> CIRM, Non-Profit Regulations, *supra* note 9, § 100308(a).

<sup>55</sup> *Id.* § 100308(b).

<sup>56</sup> *Id.* § 100308(a).

State of California of any resultant revenues shall be proportionate to the support provided by CIRM for the discovery of the invention.”<sup>57</sup> Finally, the CIRM-mandated 25% fee will go to the General Fund of the State of California *unless* such action violates any federal law.<sup>58</sup>

That the 25% payback accommodates for the fact that the costs incurred by grant recipients in patenting and licensing stem cell inventions may vary significantly from one case to the next demonstrates sensitivity to the realities of technology transfer faced by academic institutions. It also contrasts with the licensing revenue payback provision contained in the Senate precursor bill to the Bayh-Dole Act, § 204(a) of S. 414, which failed to take those costs into account, requiring a 15% return from *gross* licensing revenues once the threshold was met.<sup>59</sup> The provisions to do with pricing in the non-profit regulations—which are few compared to the for-profit regulations—also appear to be sensitive to the non-profits’ position within the commercialization process. Because such institutions are primarily engaged in basic research, and license technologies to industry for product development, the regulations only attempt to constrain grant recipients that enter into exclusive licensing agreements—the type of agreement where the opportunity to charge higher prices is greatest for want of market competitors. Specifically, § 100306(d) provides:

Grantee organizations shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies and diagnostics only to persons with plans to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, such licensees will agree to provide to patients whose therapies and diagnostics will be purchased in California by public funds the therapies and diagnostics at prices negotiated pursuant to the California Discount Prescription Drug Program . . . to eligible Californians under that program.<sup>60</sup>

Contrary to the CRADA agreements utilized by NIH circa the early 1990s, the regulations do not attempt to impose any sort of “reasonable pricing” requirement to *all* therapies and diagnostics developed with CIRM funds. This pricing provision for non-profits is far more limited in scope. Also, while CIRM does retain the authority to refer any alleged breach of these terms and conditions to the Attorney General of California or exercise its march-in rights to compel new licenses,<sup>61</sup> this policy places the onus *prima*

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<sup>57</sup> *Id.* § 100308(c).

<sup>58</sup> *Id.* § 100308(b).

<sup>59</sup> S. 414, 96th Cong. § 204(a) (1980) (enacted).

<sup>60</sup> CIRM, Non-Profit Regulations, *supra* note 9, § 100306(d).

<sup>61</sup> *Id.* § 100310(a)(2).

*facie* upon the grant recipient to ensure that access plans are adhered to by exclusive licensees.<sup>62</sup>

#### E. Recoupment from For-Profits

The recoupment requirements applicable to for-profit entities are more complex. In essence, the regulations envision three general scenarios. The first scenario pertains to net licensing revenues generated from CIRM-funded patented inventions. Where net licensing revenue streams are in excess of \$500,000, less the direct costs in securing and protecting the patents from which revenues are received, the for-profit awardee must allocate 25% of those revenues to the State's General Fund.<sup>63</sup> The situation where multiple sources of funding are involved in the creation of the patented invention(s) leading to the revenues is again anticipated. The "return to the State of California on Net Licensing Revenue...shall be proportionate to the support provided by the CIRM."<sup>64</sup>

"Net Commercial Revenue," that is, revenue from a "self-commercialized product resulting from CIRM-funded Research (regardless of whether a CIRM-funded patented invention is involved)" is the second scenario captured by the regulations.<sup>65</sup> Here, for-profit grantees are required to return royalties capped at three times the total awarded money after revenues exceed the \$500,000 threshold.<sup>66</sup>

The third kind of scenario captured by the regulations relates to blockbuster-type revenues. Essentially, two forms of payback are contemplated. First, if Net Commercial Revenue surpasses \$250 and \$500 million per year blockbuster-type milestones, then the for-profit entity is required to "pay to the State of California a one-time blockbuster payment of three times the total amount of the Grant."<sup>67</sup> Second, in the event that CIRM has contributed more than \$5 million (in the aggregate) in funding and the Net

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<sup>62</sup> *Id.* § 100306(e)-(h). However, given the limited budgets of most technology transfer offices there is perhaps reason to be skeptical of their ability to perform this type of policing.

<sup>63</sup> CIRM, For-Profit Regulations, *supra* note 10, § 100408(a)(1). Originally, this figure was set at 17% on the view that for-profits are not required and generally do not share a portion of revenues with employee researchers. *See* CIRM, Initially Proposed For-Profit Policy, *supra* note 12, at 34.

<sup>64</sup> CIRM, For-Profit Regulations, *supra* note 10, § 100408(a)(2).

<sup>65</sup> *Id.* § 100408(b).

<sup>66</sup> *Id.* § 100408(b)(1).

<sup>67</sup> *Id.* § 100408(b)(2). As presently worded, these milestones are tied to revenues from self-commercialized CIRM-funded patented inventions. Interestingly, however, proposed amendments to the regulations would make those milestone payments applicable provided that the self-commercialized product was the result of CIRM funding regardless of whether any patented inventions were secured. *See* California Institute for Regenerative Medicine, Proposed Regulation § 100408(b)(2), <http://www.cirm.ca.gov/reg/pdf/reg100408.pdf>.

Commercial Revenue associated with a CIRM-funded Patent Invention is in excess of \$500 million in any year, the for-profit organization must pay the State “one percent of Net Commercial Revenue in excess \$500 million for the life of the patent.”<sup>68</sup>

Each of these three sets of provisions is an effort to recoup a direct financial return for the State under different circumstances. In all three scenarios, a CIRM-funded patented invention is involved, but the provisions may be broadened to encompass commercially successful projects regardless of whether a patented invention is tied to CIRM funds. The first two scenarios also attempt to protect the State’s recoupment interest regardless of the size and capacity of the awardee. Smaller for-profit awardees are less likely than larger established firms to have the resources to carry a stem cell-based therapy through the end of clinical trials.<sup>69</sup> If CIRM makes an award to a smaller company, it may enter into one or more licensing relationships with larger companies to develop products. If CIRM makes an award to a larger firm, it may succeed in developing a stem-cell application entirely on its own. The first and second scenarios thus aim to ensure that the State will recoup a share of revenues in either event.

The third form of recoupment—one-time blockbuster payments and a 1% royalty on select stem cell products—blends together and fine tunes what Senator Wyden sought to accomplish with the sales payback provision embodied by S.414, § 204(b).<sup>70</sup> Rather than leaving the payback amount open to negotiation, CIRM opted to fix it in the regulations. Presumably because industry appears most reticent to share profits from the sales of even blockbuster products,<sup>71</sup> CIRM must also have invested \$5 million and a CIRM-funded patented invention must be involved before the 1% royalty comes into play.<sup>72</sup>

The provisions pertaining to product pricing are more comprehensive than those included in the non-profit regulations, undoubtedly because for-profits are far more apt to sell products to healthcare providers or consumers directly. However, they are also relatively circumscribed. The for-profit regulations require award recipients and/or their exclusive licensees to have a plan to provide uninsured California patients access to resultant drug therapies.<sup>73</sup> But in contrast to the non-profit regulations, no such plan is needed with respect to the provision of therapies that are not drug-based or diagnostics by for-profits, creating an incentive for awardees to develop such therapies and

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<sup>68</sup> CIRM, For-Profit Regulations, *supra* note 10, § 100408(b)(3).

<sup>69</sup> See CIRM, Initially Proposed For-Profit Policy, *supra* note 12, at 21–26 (describing this process).

<sup>70</sup> S. 414, 96th Cong. § 204(b) (1980) (enacted).

<sup>71</sup> This can be inferred from the NIH’s failed efforts to recoup 0.5 % of Bristol Myers Squibb’s sales of Taxol, as described by Kesselheim & Avorn, *supra* note 40, at 2863.

<sup>72</sup> CIRM, For-Profit Regulations, *supra* note 10, § 100408(c)(2).

<sup>73</sup> *Id.* § 100407(a).

diagnostics.<sup>74</sup> The access plan is to be provided to CIRM, but CIRM is not obliged to make the plan available for review by the public. The substantive requirements of such access plans are also not transparent. Rather, at present, the regulations simply require that “the access plan . . . be consistent with industry standards [extant] at the time of commercialization.”<sup>75</sup> Drug-based therapies resulting from CIRM funds have to be provided at a prices negotiated pursuant to the California Discount Prescription Drug Program.<sup>76</sup>

In sum, CIRM’s two intellectual property regulations, and the recoupment and pricing provisions they contain, are highly nuanced seemingly in an effort to balance a variety of interests and concerns. Nevertheless, these regulations, either in their present or previous form, have attracted some vocal opponents, including members of the State legislature.<sup>77</sup>

#### F. California Senate Bill 771

Believing that CIRM’s regulations “do not go nearly far enough”<sup>78</sup> to benefit taxpayers, California Senators Sheila Kuehl and George Runner introduced legislation to amend the Cures Act on February 23, 2007. As noted above, the Cures Act presently requires the ICOC to establish “standards that require all grants and loan awards be subject to intellectual property agreements.”<sup>79</sup> Senate Bill 771, following amendments made on April 17, 2007 (which are highlighted below), states that those standards shall:

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<sup>74</sup> This should perhaps be of significant concern since there is fairly strong evidence that access to diagnostics has proven complicated by the exclusive licensees. *See, e.g.* Jon F. Merz et al., *Industry Opposes Genomic Legislation*, 20 *Nature Biotech.* 657, 657 (2002); Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 *J. Molecular Diagnostics* 3, 3 (2003); Michelle R. Henry et al, *DNA Patenting and Licensing*, 297 *Science* 1279, 1279 (2002).

<sup>75</sup> CIRM, For-Profit Regulations, *supra* note 10, § 100407(a)(2). Significantly, proposed amendments to the regulations would change this, requiring that plan be subject to CIRM’s approval after a public hearing and opportunity for public comment. *See* CIRM, Proposed Regulation § 100407(a)(3), <http://www.cirm.ca.gov/reg/pdf/reg100407.pdf>.

<sup>76</sup> CIRM, For-Profit Regulations, *supra* note 10, § 100407(b).

<sup>77</sup> *See* Cheryl Miller, *Knives Come Out on Stem Cell Bill*, *The Recorder*, Mar. 30, 2007, available at <http://www.law.com/jsp/article.jsp?id=1175245434373>.

<sup>78</sup> Press Release, Senator Sheila Kuehl, Bipartisan Bill To Ensure State’s Return from Stem Cell Patenting and Licensing Introduced (Feb. 23, 2007), available at <http://dist23.casen.govoffice.com> (follow “News Room\Press Release” hyperlink; then follow “See all items . . .” hyperlink).

<sup>79</sup> Cal. Const. art. XXXV, §§ 1-7; Cal. Health & Safety Code §§ 125290.30(h) (West 2006).

(A) Require every recipient of a grant or loan award for research to provide to the state 25 percent of the net licensing revenues it receives associated with any institute-funded patented invention beyond a reasonable revenue threshold that the ICOC may establish. Net licensing revenue shall include all forms of financial consideration from licensing and shall be defined as gross licensing revenues, less patent expenses and reasonable payments to inventors.

(B) Require every recipient of a grant or loan award for research to grant exclusive licenses involving institute-funded patented inventions relevant to the development of therapies, drugs, and diagnostics only to organizations that have plans which the institute determines will provide substantial access to the resultant therapies, drugs, and diagnostics to uninsured Californians. In addition, the licensees shall agree to provide to patients whose therapies, drugs, and diagnostics will be purchased in California with public funds, ~~the therapies, drugs, and diagnostics~~ *any drugs* at the federal Medicaid price. *A licensee shall not be required to establish a new best price for any drugs that the licensee develops with institute funds in order to comply with this subparagraph. Each licensee shall agree to provide any therapies or diagnostics that are not drugs at the best price for which the licensee provides those therapies or diagnostics to any purchaser.*

(C) Require any recipient of a grant or loan award for research that commercializes any product that it develops using institute funds to agree, as a condition of accepting the funds, to make royalty payments to the state equal to 2 to 5 percent of the revenues over the life of the product, depending on the level of funds provided and contribution of institute-funded patented inventions to the development of the product.<sup>80</sup>

Senate Bill 771 is thus at once more blunt and vague than CIRM's policies. In terms of recoupment, what constitutes a "reasonable revenue threshold" is left to be determined. Instead of limiting royalties to three times CIRM's original award, one-time blockbuster payments, or a 1% royalty, Senate Bill 771 would require a 2-5% share of revenues over the life of any products developed with CIRM funds. Originally, the pricing provision required exclusive licensees to develop access plans and all products—diagnostics, drugs, and other therapies – were to be made available at the federal Medicaid price. However, after CIRM voted unanimously to oppose Bill 771<sup>81</sup> and industry representatives criticized the bill, this pricing provision was watered down: according to the revised wording, recipients of CIRM funding are only required to ensure

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<sup>80</sup> S.B. 771, 2007-2008 Senate (Cal. 2007).

<sup>81</sup> Press Release, CIRM, Stem Cell Board Calls State Legislation 'Premature' (Apr. 11, 2007), available at <http://www.cirm.ca.gov/press/pdf/2007/04-11-07.pdf>.

that licensees make therapies and diagnostics (which are not drugs) available at the “best price” provided by any purchaser.<sup>82</sup>

Following these amendments, the fate (and substance) of the bill took several swift turns. First the bill was relegated to a “suspension file” on May 21, 2007, suggesting an end to the bill’s journey through the legislative process. But after a hearing on May 31, the Senate voted unanimously (38-0) in favor of the bill on June 6, passing it to the Assembly for first reading. Then another twist: on June 28 the entire contents of the bill were supplanted by provisions designed to deal with a different issue altogether (testamentary instruments). Having nothing to do with CIRM funds, the bill subsequently went through three readings in the Assembly, returned to the Senate to do the same, and was chaptered as a California statute in October.<sup>83</sup> Senator Kuehl has reintroduced draft legislation to address recoupment and pricing concerns during 2008.<sup>84</sup> However, the likelihood of it actually being enacted would seem highly questionable in light of the above, perhaps even more so if CIRM manages to implement regulations of its own in the interim.

#### IV. ARGUMENTS (EVIDENCE) FOR AND AGAINST

As explained at the outset, the dominant rationale against recoupment is that it will exert a chilling effect on the process of commercializing scientific discoveries into marketable products. This chilling effect argument can be broken down into three kinds of claims, several of which will be familiar from the debates leading up to the enactment of Bayh-Dole and also in the context of Senator Wyden’s campaign; namely: recoupment creates disincentives to engage in research, generates inefficiencies in the commercialization process, and adds unnecessary uncertainties. Although these claims overlap, it is important to consider each (and the premises and limited evidence they rest upon) in depth against the particulars of CIRM’s regulations. The question of whether CIRM’s recoupment mechanisms, as a matter of pure economic forecasting, are likely to produce significant returns for the State is deferred until the final part of this Article.

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<sup>82</sup> This is presumably in response to the negative input received by the Senate Health Committee from industry representatives regarding the bill’s previous wording. See Kuehl & Runner, Senate Health Committee Analysis of S.B.771, S. Health Comm., 2007-2008 Senate (Cal. 2007), at 11 (2007), available at [http://info.sen.ca.gov/pub/07-08/bill/sen/sb\\_0751-0800/sb\\_771\\_cfa\\_20070410\\_114110\\_sen\\_comm.html](http://info.sen.ca.gov/pub/07-08/bill/sen/sb_0751-0800/sb_771_cfa_20070410_114110_sen_comm.html).

<sup>83</sup> For a history of Senate Bill 771, see California State Senate, Official California Legislative Information, [http://www.leginfo.ca.gov/pub/07-08/bill/sen/sb\\_0751-0800/sb\\_771\\_bill\\_20071010\\_history.html](http://www.leginfo.ca.gov/pub/07-08/bill/sen/sb_0751-0800/sb_771_bill_20071010_history.html) (last visited Apr. 14, 2008).

<sup>84</sup> S.B. 1565, 2007-2008 Senate (Cal. 2008).

### G. Inventing Disincentives

Recoupment, by definition, means that there will be less total monetary return for all those typically involved in successfully commercializing an invention or inventions. These include publicly funded scientists, research institutions, technology transfer offices, and private companies. The claim therefore, is that there is less incentive for each of these actors to engage in the commercialization process. In this section, the incentives for each of these actors are considered in turn.

Research institutions are required under Bayh-Dole to share some portion of revenues with the inventors and they are free to devote the remainder to “research and educational purposes” as they see fit. At least part of the reason why revenues generated from formalized technology transfer are so highly prized is because these revenues generally come with no other strings attached.<sup>85</sup> It is also true that many scientists today appear to be motivated not just by the prospect of kudos from their peers, but also by the economic gains which flow from a successful commercial venture.<sup>86</sup> However, it does not follow that public sector research programs would slow significantly because of the inclusion of a recoupment provision. Logically, simply being able to *do* the research must be the most important consideration to public sector scientists and institutions (because without it, neither kudos nor cash will be forthcoming). As scientific research projects (especially in the realm of biotechnology) have continued to scale up, increasingly massive amounts of money are needed to acquire all the necessary equipment, pay large numbers of research staff, and carry out the project over an extended period of time. Therefore, it is difficult to imagine a scenario in which public sector scientists or their parent institutions would decline a significant grant (and forego the kudos associated with it) because it contains a *potential* obligation to payback a *percentage* of revenues *if* their revenues exceed the costs incurred by the institution during the research and commercialization process and *if* those net revenues surpass the \$500,000 mark<sup>87</sup>—*a fortiori* in the context of stem cell research where traditional sources of funding in the U.S. (*i.e.* federal funding) are presently limited.

However, recoupment could certainly make the job of technology transfer officials at universities and other non-profit institutions more difficult. Technology

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<sup>85</sup> See *e.g.* Josephine Johnston, *Health Related Academic Technology Transfer: Rethinking Patenting and Licensing Practices*, 9 Int’l J. Biotech. 156 (2007).

<sup>86</sup> One study of 102 U.S. universities demonstrated that higher inventors’ royalty shares are associated with higher licensing income at the university, controlling for other factors, suggesting that monetary incentives from inventions have real effects in the university sector. See Saul Lach & Mark Schankerman, *Royalty Sharing and Technology Licensing in Universities*, 2 J. Eur. Econ. Ass’n 252 (2004).

<sup>87</sup> The vast majority of licensing agreements do not produce anywhere near this much revenue annually. In fiscal year 2004, the average licensing agreement at the University of California at San Francisco—one of the leading performers in commercializing biotechnologies—generated somewhere around \$60,000. See Office of the President, University of California Technology Transfer Program, Annual Report, Fiscal Year 2004 17 (2004), available at <http://www.ucop.edu/ott/ars/ann04/ar04.pdf>.

transfer is like the lottery. Invention disclosures seldom translate into significant returns; therefore, the few that do, the ‘winners’, have to compensate for all the others. Having to share a “large fraction of the revenues from licensed technologies” could thus be a bitter pill to swallow.<sup>88</sup> However, retaining ownership rights and general control over how to license CIRM-funded inventions (nonexclusively versus exclusively)<sup>89</sup> represents a higher priority for technology transfer offices. The Director of Stanford’s Office of Technology and Licensing, for instance, explained that she and directors at other California academic research institutions readily agreed to the 25% payback on net licensing revenues out of fear that CIRM would attempt to retain ownership over inventions.<sup>90</sup>

Recoupment does add another challenge to technology transfer officials’ efforts to license technologies to companies, for on the private sector side the incentives are different—cash is clearly the dominant motivation. Beyond mere intuition, some evidence has been cited in support of the claim that recoupment will chill private sector participation. This evidence emanates from the NIH’s efforts to impose a “reasonable pricing” requirement upon private companies entering into exclusive licensing agreements with NIH laboratories. Starting in 1989 all such “Cooperative Research and Development Agreements” (CRADAs) included a provision requiring that there be “a reasonable relationship between the pricing of a licensed product, the public investment in that product, and the health and safety needs of the public.”<sup>91</sup> As noted in Senator Wyden’s Report, “[s]hortly after the policy of ‘reasonable pricing’ was introduced, industry objected to it, considering it a form of price control.”<sup>92</sup> The Report goes on to conclude that the “consequences of NIH’s ‘reasonable pricing clause’ policy can be seen in the relatively flat growth rate of CRADAs that occurred between 1990 and 1994, and the subsequent rebound in CRADAs following revocation of the policy.”<sup>93</sup>

However, the actual numbers shown in an appendix cited by the Wyden Report are less convincing. The number of “standard” CRADAs increased steadily through 1989, the year the reasonable pricing policy was put in place, when over 40 standard CRADAs were executed. In the years that followed—both before and after the policy was dropped in 1995—the number of standard CRADAs fluctuated consistently from

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<sup>88</sup> Richard J. Gilbert, *California’s Stem Cell Initiative: Converting the Legal and Policy Challenges*, 21 Berkeley Tech. L.J. 1107, 1122 (2006).

<sup>89</sup> Each set of CIRM’s regulations express a preference for nonexclusive licensing but fall short of being prescriptive in this regard.

<sup>90</sup> Katharine Ku, Director, Office of Technology Licensing, Stanford University, Current Issues in Technology Licensing, Address at Stanford Law School (Apr. 10, 2007).

<sup>91</sup> NIH, Taxpayers’ Interests, *supra* note 28, § C-6.

<sup>92</sup> *Id.*

<sup>93</sup> *Id.*

roughly the low thirties to the high forties.<sup>94</sup> More data is now available. The NIH's Office of Technology Transfer website tabulates not only standard CRADAs (which continue to fluctuate, albeit at slightly lower levels), but also ones entered into in respect of "materials," increasing the total numbers considerably.<sup>95</sup> The number of executed CRADAs in the latter category is seemingly unavailable pre-1995, which perhaps explains why they were not cited in the Wyden Report to support the claim that CRADAs rose once the reasonable pricing policy was dropped.

It is also important to remember that this evidence has to do with reasonable pricing, not recoupment *per se*. A requirement that there exists a "reasonable relationship" between pricing and public investment presumably represents a much greater unknown (and therefore a much greater worry to private businesses) than a predefined payback requirement at least up to a point where the amount to be paid back is seen as prohibitive. However, whether or not this evidence supports the contention that recoupment will, in fact, exert a chilling effect upon private participation, stem cell research presents a somewhat unique case. Recall that California's Cures Act and the major influx of public tax dollars it carries, was considered necessary not simply because President Bush had limited the availability of federal funds, but also because private companies were increasingly hesitant to structure their business models around stem cell technologies that would take ten or more years to develop. Not unlike other promising areas of biotechnology, after an initial flurry of investor excitement, venture capital financing for stem cell research was in short supply because of the projected lag in product development.<sup>96</sup> In other words, private companies were already reticent to gamble on stem cell research as a field. A sizeable portion of the \$3 billion available to CIRM was presumably meant to help address that problem. Thus, for companies that have decided to take on the risks inherent in stem cell research, such a significant sum of money seems likely to outweigh any disincentives that payback obligations might pose in the minds of private players *provided* other sources of funding (free from such encumbrances) remain unavailable.<sup>97</sup>

This is more likely to hold true if CIRM's intellectual property regulations applicable to for-profit entities remain the governing law rather than Senate Bill 771 (or any subsequently introduced bill containing substantially similar provisions). For several reasons alluded to in the foregoing, the latter is less favorable to industry. First, whereas

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<sup>94</sup> *Id.* at app. 4, available at <http://www.nih.gov/news/wydenreportappendices2001.pdf>.

<sup>95</sup> See NIH, Office of Technology Transfer Activities [http://ott.od.nih.gov/about\\_nih/statistics.html](http://ott.od.nih.gov/about_nih/statistics.html) (last visited Apr. 20, 2007).

<sup>96</sup> See Lutz B. Giebel, *Stem Cells – A Hard Sell to Investors*, 23 *Nature Biotech.* 798 (2005); Gretchen Vogel, *Stem Cells Lose Market Luster*, 299 *Science* 1830 (2003). Cf. Vicki Brower, *Human ES Cells: Can You Build a Business Around Them?* 17 *Nature Biotech.* 139 (1999) (discussing the difficulties of forming a viable business plan due to lags in product development).

<sup>97</sup> True, federal policy could quickly change with a new administration in 2009. However, the NIH is not likely to award grants to the private sector comparable to those in the process of being made available by the CIRM, and as just stated, venture capital has not proven to be a stable source of financing for stem cell research.

CIRM's regulations stipulate a clear threshold when payback obligations come into play, Senate Bill 771 would potentially allow CIRM to set the threshold on a case-by-case basis, arguably creating considerable uncertainty.<sup>98</sup> Second, outside blockbuster situations, CIRM's policy caps the total payback from non-licensing revenues at three times the amount of the original award it made to the grantee; Senate Bill 771 sets no such limit. Third, the obligations around access and pricing are much broader under the Senate Bill than the regulations. Fourth, CIRM's regulations provide for one-time blockbuster payments and a 1% share of revenues if CIRM contributed more than \$5 million towards a product that generates over \$500 million in annual sales. However, Senate Bill 771 would require a 2-5% share of sales from all products developed with CIRM funds (whether they achieve blockbuster status or not).

The California biotech sector, as represented by the California Healthcare Institute (CHI), was outspoken in its opposition of the Senate Bill, arguing that the measure is "sure to discourage the private investment needed to bring state-funded science to market."<sup>99</sup> CHI has also given critical feedback to CIRM in response to its proposed for-profit regulations. It appears, however, that the provisions in the regulations pertaining to pricing and access constitute a greater worry to CHI's membership than those designed to recoup direct financial returns for the State.<sup>100</sup> In fact, opinion within the private sector about how much of a deterrent recoupment obligations are seems to be mixed. Whereas some company executives claim they will not apply for CIRM funding as a result of recoupment,<sup>101</sup> others have already done as

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<sup>98</sup> See discussion *infra* Part IV.C.

<sup>99</sup> Miller, *supra* note 77.

<sup>100</sup> In its written comments delivered to CIRM, CHI noted that over 80% of its members "indicated that they would be *much less likely* to consider licensing a technology, or investing in a start-up company based on a technology that carried [the proposed] pricing and access mandates." In contrast, no such evidence was cited in relation to the payback requirements in the proposed regulations. Rather, while recommending that a different definition of "net revenue" be employed and that payback requirements be limited to instances where "CIRM grant money is tied directly to a developed product," CHI "acknowledge[d] and appreciate[d] the inclusion of language allowing for a threshold and maximum amount of revenue to be returned to the State." Letter from David L. Gollaher, President and CEO, CHI, to Scott Tocher, Interim Counsel, CIRM (Oct. 5, 2007), *available at* [http://www.chi.org/uploadedFiles/CHI%20IPPFPO%20Comments\\_100507.pdf](http://www.chi.org/uploadedFiles/CHI%20IPPFPO%20Comments_100507.pdf).

<sup>101</sup> See Steve Johnson, *Stem Cell Firms Resisting Cash Lure*, S.J. Mercury News, Dec. 20, 2007.

much,<sup>102</sup> or expressed their willingness to do so when a call for applications suitable to their business model is made.<sup>103</sup>

#### H. Creating Inefficiencies

A second breed of argument against recoupment is that it potentially creates a variety of inefficiencies, which, on balance, will slow the commercialization process. The first such inefficiency is that recoupment triggers a responsibility to track how public funds are used and that tracking is likely to be labor-intensive and costly. To be sure, one of the key factors that stymied Senator Wyden's campaign was the fact that it proved incredibly difficult to track precisely what funds (public versus private) were used to develop which products. Of the 47 drugs falling into the blockbuster category, only four could be conclusively linked to NIH funding.<sup>104</sup> However, tracking is much less burdensome if the responsibility to do so is dealt with *ex ante*. Furthermore, in marked contrast to regulations enacted pursuant to Bayh-Dole, CIRM's regulations (for both non-profits and for-profits) do precisely that. They place the primary onus (and thus the bulk of the administrative costs) of tracking the relative contribution of its awards upon grant recipients while reserving the right to conduct an audit if necessary. The policies also require funding recipients to report to CIRM patent filings and licensing agreements within specified timeframes.<sup>105</sup> Private companies' need to protect proprietary interests presumably added to the difficulty of tracking, *ex post*, NIH funds in relation to the 47 drugs identified by Senator Wyden. To avoid being subject to an audit and potentially being forced to disclose proprietary interests, private companies are probably inclined to comply with CIRM's requirements, and therefore tracking should in principle come at little expense to the public purse.

Given that the onus is placed primarily upon the grantee under the CIRM scheme, the second inefficiency argument—that the costs upon the State of administering and enforcing payback provisions will outweigh the gains—largely falls away. However, it is of course possible, though unlikely, that the costs of enforcement could become sizeable in the event that a number of grantees begin to produce highly profitable stem cell based therapies, yet claim that the CIRM's funds did not aid in their development. Although surpassing \$500,000 in net licensing revenues is a significant milestone, it will not sustain the business in perpetuity. The grantee will probably want to apply for future

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<sup>102</sup> For instance, in response to a recent call for applications for "Disease Team Planning Awards"—a call ostensibly suited more towards academic researchers—CIRM received 66 letters of intent, 10 of which were from the private sector; Press Release, CIRM, CIRM Announces Extensive Interest in Disease Team Planning Awards (Dec. 28, 2007), *available at* <http://www.cirm.ca.gov/press/pdf/2007/12-28-07.pdf>.

<sup>103</sup> See Johnson, *supra* note 101.

<sup>104</sup> See NIH, Taxpayers' Interest, *supra* note 28, at § D.

<sup>105</sup> CIRM, Non-Profit Regulations, *supra* note 9, § 100302. CIRM, For-Profit Regulations, *supra* note 10, § 100402.

CIRM funding, and a claim that CIRM's funds were not involved in the development of the patented invention(s) responsible for generating those licensing revenues is likely to undermine its chances of obtaining CIRM funding again.

Alternatively, if a grantee develops a blockbuster stem cell product generating annual sales greater than \$250 or \$500 million, it may be happy to risk losing future CIRM funding to avoid making royalty payments. If the proposed amendments to the for-profit regulations are passed, however, blockbuster payments will come into play when the product resulted from any CIRM-funded project, whether or not a CIRM-funded patented invention contributed to such blockbuster revenues.<sup>106</sup> This might be a much harder distinction for the grantee to sustain. In addition, there is at least some incentive for the grantee to comply with the payback obligation; becoming the first or one of the few entities to produce a *bona fide* stem cell therapy and returning a small portion of its economic value to the State could translate into significant goodwill for the grantee.

The third and final inefficiency argument is that recoupment creates an unnecessary "middleman."<sup>107</sup> Instead of simply providing funds to kick-start technology transfer between public and private sector institutions, recoupment positions the State (through CIRM) to intervene at later stages in the commercialization process. More than simply passively receiving payback royalties, proponents of this argument suggest that as the funding body comes to expect returns it will want to have a greater say in the decisions that are made, but ultimately add little value to the commercialization process.<sup>108</sup> Anecdotally, however, some technology transfer officials report that certain funding bodies are already guilty of this in the absence of any recoupment mechanism. The degree to which funding bodies choose to intervene may therefore ultimately depend more on the philosophy and confidence of those in charge at CIRM in the existing commercialization process and the actors that make it work. CIRM's two sets of intellectual property regulations evince a clear intention to leverage the experience and expertise already extant in research institutions, particularly their technology transfer offices and established linkages with the private sector. Consistent with the current schema, grantees have authority to decide whether to patent inventions and how to license them to third parties. Although a preference for nonexclusive licenses is expressed, there is flexibility to enter into exclusive ones if "necessary to provide economic incentives required to enable commercial development and availability of the inventions,"<sup>109</sup> which is not contingent on a prior demonstration of the same to CIRM.<sup>110</sup>

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<sup>106</sup> See CIRM, Proposed Regulation § 100407(b)(2), <http://www.cirm.ca.gov/reg/pdf/reg100407.pdf>.

<sup>107</sup> Nicos A. Nicola, *Why Government and Charitable Research Funding Agencies Should Not Seek Commercial Control or Returns from the Research They Fund*, 30 *Clinical & Experimental Pharmacology & Physiology* 116, 116 (2002).

<sup>108</sup> *Id.*

<sup>109</sup> CIRM, Non-Profit Regulations, *supra* note 9, § 100306(b); CIRM, For-Profit Regulations, *supra* note 10, § 100406(b).

In relation to CIRM's regulations then, this last inefficiency argument seems highly speculative at best. It is just as plausible that recoupment could encourage CIRM to take a more hands-off approach if it begins to believe that their involvement may slow commercialization and thus the delivery of any financial returns.

### I. Causing Uncertainties

There are multiple sources of uncertainty surrounding CIRM. Both public and private institutions engaged in scientific research have grown familiar with the Bayh-Dole Act and developed a host of skills and expertise based upon it and the accompanying legislation. Therefore, the introduction of policies or legislation that departs from the Bayh-Dole Act carries uncertainty that could potentially damage the development of stem cell products. Some are particularly concerned that vesting such a tremendous amount of discretionary power in an untested body, CIRM, will prove unwise.<sup>111</sup> If uncertainty is truly the underlying worry, then the recoupment provisions can be seen as a means to bound CIRM's discretion. Compared to past and presently competing recoupment formulae contained in precursor versions of Bayh-Dole and Senate Bill 771, the parameters of CIRM's recoupment provisions are well defined.<sup>112</sup> True, in situations where multiple sources of funding are involved, CIRM's policies could be found invalid due to the supremacy of the federal legislation.<sup>113</sup> However, each policy provides for that eventuality, stating that recoupment will not occur if it would result in a violation of federal law. That the recoupment provisions should be deleted for uncertainty thus seems to fall in the category of a red herring.

## V. RECOUPING PUBLIC TRUST?

In the end, much of the foregoing reduces to speculation, as opposed to evidence-based argumentation about whether recoupment and/or pricing controls will hamper the commercialization of stem cell technologies, or introduce disincentives, inefficiencies or

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<sup>110</sup> In contrast, awardees must justify why they do not wish to comply with CIRM's materials sharing requirements. CIRM, Non-Profit Regulations, *supra* note 9, § 100304; CIRM, For-Profit Regulations, *supra* note 10, § 100404.

<sup>111</sup> See O'Connor, *supra* note 51, at 678 (arguing that because CIRM has considerable discretionary power, Californians cannot gauge the true economic impact of Proposition 71).

<sup>112</sup> It is worth reiterating that the California Healthcare Institute, in its feedback to CIRM about the For-Profit Regulations, claimed that it was the provisions surrounding pricing and access that promised to "create a great deal of uncertainty," Letter from David L. Gollaher, *supra* note 100, at 5, and thus "create a substantial disincentive to commercial interest in licensing CIRM-funded inventions from for-profit grantees", *id.* at 3, not the recoupment provisions.

<sup>113</sup> *Id.*

the like. None of this represents a novel chapter in history. Policy decisions about how best to realize the economic and social benefits of scientific research have been and will continue to be made in the absence of better evidence; to some extent that is simply the nature of the beast. However, it is also the product of individuals and groups pursuing some mixture of their own interests (at times through powerful lobbies) and what they genuinely believe to be in the best interests of others (including the general public). The primary “evidence” cited over and over again to show that federally funded inventions lay fallow in academic laboratories and thus justify the enactment of Bayh-Dole suffered from severe selection bias.<sup>114</sup> Yet, as indicated in the NIH Report to Senator Wyden, university and industry representatives alike (AUTM, BIO, and PHARMA) continue to express it as a truth-claim because it is consistent with their worldview. In reality, we do not know how instrumental Bayh-Dole was in terms of facilitating commercialization,<sup>115</sup> just as we are unable to say whether “the resulting level of private investment would be adequate to actualize the full potential of social well-being from technological advances” if the private sector were subject to obligations to provide direct financial returns.<sup>116</sup>

In this context of inescapable uncertainty, two more layers of informed speculation ought to be added. The first casts serious doubt on whether CIRM’s efforts to recoup will actually translate into significant monetary returns, while the second—which raises the specter of public distrust—serves to reveal recoupment’s potential non-economic returns.

Contrary to what the “Baker-Deal” study commissioned by the “Yes on 71” campaign predicted, others have noted that CIRM’s \$3 billion in funding is likely to produce only marginal direct financial returns. Gilbert demonstrates this using two approaches. The first modifies the Baker-Deal study to account for the “time cost” of

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<sup>114</sup> See Eisenberg, *supra* note 2, at 1702 (arguing that those inventions owned by the government which were not patented had already been examined and subsequently rejected by private entities).

<sup>115</sup> Opinions differ radically about this, and depend upon what is meant by the term “commercialization,” or more precisely, what counts as a metric thereof. According to one often cited source, patenting and licensing by academic institutions were already on the rise prior to the passage of Bayh-Dole, spearheaded by a handful of key institutions such as Stanford University, the Massachusetts Institute of Technology, and the University of Wisconsin. While an increase in patenting and licensing can now be observed across U.S. academic institutions, those early leaders still account for the majority of so-called commercialization activity. See generally, D.C. Mowery et al., *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act* (2004); D.C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 Res. Pol’y 99 (2001). Another notable commentator has opined that while the rise of academic patenting has almost certainly increased “commercialization deals” (i.e. agreements between universities and companies), whether that increase in deals can be equated to an increase in the translation of scientific discoveries into commercial products is contingent upon the “industry in question and the particular nature of the technology.” Mark. A. Lemley, *Are Universities Patent Trolls?* 11-12 (Stanford Public Law Working Paper, No. 980776, 2007), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=980776](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=980776).

<sup>116</sup> Baruch Brody, *Public Goods and Fair Prices*, 26 *Hastings Center Report* 5, 9 (1996).

revenues that occur far in the future, and projects that the State will earn between \$31 and \$62 million, a far cry from the \$537 million to \$1.1 billion estimate provided by Baker-Deal.<sup>117</sup> Gilbert's second approach relies on actual royalty income collected by U.S. universities, hospital and non-profit research institutes as surveyed by AUTM, and predicts that the State's return in "current dollars" will only amount to about 0.60% of total R&D expenditures.<sup>118</sup> Assuming that these figures are more reliable and that the arguments offered above downplaying the inefficiencies involved in enforcing recoupment are incorrect, then what possible justification remains for recoupment?

The problem lies in the fact that that information—that the \$3 billion was unlikely to produce a direct financial return for the State—was not what California residents were told by those behind the ballot measure. The development of stem cell "cures" was the promise most frequently made, although financial returns also figured prominently in the lead-up to the 2004 public referendum.<sup>119</sup> One could therefore also speculate that any attempts by CIRM to abrogate its statutory duty to implement and enforce recoupment measures,<sup>120</sup> could result in a backlash of public distrust and force political action. Great hype followed by unmet expectations is, unfortunately, a familiar cycle in the biotechnology realm. Still, stem cell research, particularly with \$3 billion of public tax dollars behind it, is particularly morally contentious.<sup>121</sup> Public statements made of late by

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<sup>117</sup> Gilbert, *supra* note 88, at 1139.

<sup>118</sup> *Id.* at 1140.

<sup>119</sup> Tamra Lysaght, Rachel A. Ankeny & Ian H. Kerridge, *The Scope of Public Discourse Surrounding Proposition 71: Looking Beyond the Moral Status of the Embryo*, 3 J. Bioethical Inquiry 109, 114 (2006).

<sup>120</sup> Such as pushing for an amendment to the Cures Act or by simply choosing not to enforce the recoupment provisions.

<sup>121</sup> For example, Caulfield has commented that:

The problem of unmet expectations seems particularly problematic in the context of socially controversial technologies such as human genetics and stem cell research. If the promise of tangible clinical benefits is used to counter an intuitive moral reservation about a given technology, we may be creating a circumstance where loss of public trust is inevitable. Rightly or not, many individuals have serious concerns about the development of certain technologies. Will the public feel betrayed if clinical benefits do not materialize? While one could argue that the promise of cures and immediate benefits has always accompanied biomedical research, the moral concerns associated with much of biotechnology may make unfulfilled promises more damaging to public trust than in less socially contentious areas.

Timothy Caulfield, *Popular Media, Biotechnology, and the 'Cycle of Hype'*, 5 Hous. J. Health L. & Pol'y. 213, 224–25 (2005) (footnotes omitted).

CIRM towards scaling back expectations would appear to acknowledge public distrust as a real risk.<sup>122</sup>

In any event, the specter of public distrust (and the negative repercussions it could visit upon stem cell science in California) helps to cast the importance of the recoupment provision in non-monetary terms, and therein lies what has been lost in the debates over the relative incentives and inefficiencies: the genesis of recoupment, as an idea, rests in its non-economic value. Proponents of precursor versions of the Bayh-Dole Act cited the payback provisions time and again during debates in the Senate and House of Representatives, primarily to diffuse concerns that the legislation amounted to a complete giveaway of taxpayer goods.<sup>123</sup> In other words, far beyond a political ploy, the primary value of recoupment may lie in its *symbolic* importance as a compromise between those who, on the one hand, are completely opposed to patenting inventions made with public funds and licensing them to industry for commercialization purposes, and those wholeheartedly in favor thereof. Its purpose, then, is ultimately *democratic*, as one means of attempting to balance conflicting views and values.

Although non-quantifiable, the symbolic/democratic value of recoupment should not be summarily dismissed. Concerns that Bayh-Dole facilitates private appropriation of public goods at taxpayer expense do not continue to resurface simply because critics fail to comprehend the complexities of technology transfer and commercialization. Rather, they continue to be raised because at least a minority of individuals and groups hold the view that the balance of incentives, benefits, costs, and burdens that result from the federal scheme is somehow not right or unfair. Being told that Bayh-Dole was never intended to address pricing concerns (even if true) while simultaneously being informed that recoupment is not feasible in practice—after it was repeatedly highlighted as a key feature of the legislation during Congressional debates—would therefore seem ill comfort to this constituency. From this perspective, the passage of Proposition 71 in California and CIRM's intellectual property regulations mark an important commitment to strive to do a little better. Of course, legitimate concerns about whether the pricing provisions extend far enough and whether recoupment obligations can be successfully enforced do exist, and should arguably receive much greater attention.<sup>124</sup> But at least the Cures Act

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<sup>122</sup> In November 2006, in total contrast to the promises made prior to the passage of Proposition 71, CIRM released a "Strategic Plan" in which it admitted that it would be highly unlikely that any stem cell-based therapies would be fully commercialized during its tenure. See Mary Engel, *Reality Check for Stem Cell Optimism*, L.A. Times, Dec. 3, 2006, at B1.

<sup>123</sup> See *supra* notes 15-16, 20-21 and accompanying text. Admittedly some did claim that recoupment would deliver great financial returns as well.

<sup>124</sup> There are significant reasons to doubt that any of CIRM's provisions will work in practice. To begin, the "plans" to enable the uninsured to access therapies simply have to be "consistent with industry standards", and industry does not have a history of making therapies, even ones developed primarily through public funding, cheaply available. For example, the National Cancer Institute provided \$44.6 million to develop the cancer drug Avastin, yet Genentech (a California-based company), set the price at \$100,000 a year. Second, the California Discount Prescription Drug Program is a brand new measure, which some suggest is apt to face legal challenge. Third, and most importantly, in California many therapies are not purchased with

and CIRM's policies, as a starting point, give credence to those who hold that the status quo is not sufficient, that while the development of new stem cell-based cures is valued, other elements of the scheme—accountability, fiscal responsibility, and the chance of improving human health on a population basis—should be valued even more.<sup>125</sup> If this is the case, then the overarching goal of producing cures no longer represents a trump card up the sleeve of recoupment's opponents.

In the end, if symbolic importance is to be the underlying justification for recoupment (and possibly pricing controls as well), then CIRM's intellectual property regulations could be drafted in a much simpler fashion. Rather than utilizing nuanced provisions that attempt to account for a variety of different scenarios, CIRM could stipulate that all recipients of funds shall repay a certain percentage of revenues (whether licensing revenues or product sales) resulting from any stem cell research activities, regardless of CIRM's actual contribution and/or additional sources of funding. Equally, CIRM could stipulate that every recipient must develop a plan to ensure access to any resulting medical interventions. The latter would seem particularly apt to trigger the ire of industry as evidenced by the response to Senate Bill 771. But perhaps it is time for all parties concerned to recognize that, much like stem cell research as a scientific field, recoupment is only a flash point for a host of conflicting assumptions, views, and values, the balance of which ought to be continuously reassessed under a liberal democracy. Surely this should be how we should proceed as science and technology, and biotechnology in particular, figure more and more prominently in nation-state-building strategies,<sup>126</sup> not to mention the strategies of States within nation-states. Regenerative

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public funds, and many Californians are not eligible for the discount program, thus these protections simply do not come into play in many cases. Thus, CIRM's pricing provisions arguably fall "far short of ensuring that all Californians will have affordable access to the therapies, drugs and cures that their tax dollars fund." See *Affordable Access to Stem Cell Cures Hits Hard Sledding*, California Stem Cell Report, Dec. 5, 2006, 16:15 PST, <http://californiastemcellreport.blogspot.com/2006/12/affordable-access-to-stem-cell-cures.html>. Also, various individuals and groups who hold these views are quoted or referred to in Miller, *supra* note 77. See also David E. Winickoff, *Governing Stem Cell Research in California and the USA: Towards a Social Infrastructure*, 24 *TRENDS in Biotech.* 390 (2006).

<sup>125</sup> Of course, it is possible to argue that population health is *not* significantly valued by California voters as evidenced by the fact that, while voting in favor of Proposition 71, they rejected Proposition 72, which would have extended the scope of health insurance in the State. In addition, an argument can be made that the Cures Act is likely to exacerbate existing inequalities insofar as the issue of "biological access" has been left unaddressed, *i.e.* taken steps to generate a sufficient number of stem cell lines so as to ensure that a reasonable, ethnically diverse percentage of the population will be able to avail of any resulting stem cell-based therapies involving transplantation. For a full discussion of this issue, see Hilary Bok et al., *Justice, Ethnicity, and Stem-Cell Banks*, 364 *Lancet* 118 (2004); Ruth R. Faden et al., *Public Stem Cell Banks: Considerations of Justice in Stem Cell Research and Therapy*, 33 *Hastings Center Rep.* 13 (2003).

<sup>126</sup> See generally S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (2005) (comparing the politics and policy of the life sciences in Britain, Germany,

medicine, after all, promises not only regeneration of the *human* body but also regeneration of the body *politic*.<sup>127</sup>

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the United States, and in the European Union as a whole; a major theme is how policies for the life sciences have been incorporated into “nation-building” projects).

<sup>127</sup> This phrase is borrowed from Charis Thompson, Address at the Stanford Center for Biomedical Ethics: Stem Cell Nations (Oct. 16, 2006).