

DESIGNING AN EFFECTIVE PROGRAM OF STATE-SPONSORED HUMAN EMBRYONIC STEM CELL RESEARCH

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I. INTRODUCTION

Research on human genetics and cell biology periodically has given rise to intense, polarized debates about whether such research should be permitted and, if so, whether it should be financed by government. From the eugenics movement early in the 20th Century,¹ through the debate in

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1. DANIEL J. KEVLES, IN THE NAME OF EUGENICS (1985).

the 1970s over recombinant DNA research,² to the attempts by Presidents William J. Clinton and George W. Bush to define the federal role in research on human embryonic stem cells (hESC), political leaders have found themselves torn between the enormous potential human benefits that might flow from increasing knowledge about human genetics and the intense beliefs of some that such research is immoral.

In the wake of federal restrictions on hESC research, California as well as some other states are considering or have established programs to support this research. This Article reviews the current state of federal and state policies, including the difficulties states have encountered in setting up their own programs, with special attention given to the problems encountered in setting up the California Institute for Regenerative Medicine (CIRM).

California's initiative to create CIRM, which sponsors hESC research within the state, was significantly delayed by a series of political and legal battles over the structure, procedures and policies of CIRM, including its policies regarding intellectual property rights emanating from its grants. CIRM's problems reflect the underlying political and economic environment that any state faces in creating a successful stem cell research program. To be efficiently implemented, all government-supported research projects that have commercial potential must overcome the danger of "pork barrel" effects and the political problem of accommodating confidential peer review. In addition, some problems associated with this program arise from its particular characteristics: its narrow scope, which is an example of "earmarking" government research expenditures; the bitter public controversy over the legitimacy of stem cell research; and unrealistic perceptions that political leaders and the public maintain about the short-run therapeutic advances and financial payoffs from this research. This Article explores these problems and discusses the extent to which the structure of CIRM is likely to lead to an effective response to them.

The federal government operates under two policies that restrict hESC research. First, the Dickey Amendment, which has been added as a rider to appropriations bills annually since 1995,³ bars the use of federal funds for any activity that destroys or endangers embryos or that creates embryos for research purposes. It also prevents the use of federal funds to extract stem cells from embryos, but does not prohibit research on stem cells that

2. See generally Roger G. Noll & Paul A. Thomas, *The Economic Implications of Regulation by Expertise: The Case of Recombinant DNA Research*, in RESEARCH WITH RECOMBINANT DNA (1977).

3. Pub. L. No. 104-99, § 128 (renewed each year in appropriations bills).

were extracted using funds from other sources. Second, President Bush directed federal agencies in 2001 to prohibit the use of federal funds to support hESC research except on stem cell lines that were developed before the directive was issued.⁴ Because of contamination and other problems with these lines, the federal policy is widely regarded as having severely inhibited the most promising hESC research projects.⁵ The President's policy directive not only has dubious legal status, but it also does not make clear exactly what is and is not banned. Consequently, organizations that receive federal research grants have been forced to develop their own interpretations of the directive with essentially no assistance from the federal government. The President's policy directive is controversial even among Republicans in Congress. In May 2005, the Castle-DeGette Bill, which would allow federal funds to be used on new stem cell lines, passed in the House of Representatives by a vote of 238-194.⁶ Introduced in the Senate as the Specter-Harkins Bill, it then passed in July 2006 but was vetoed by the President.⁷

Meanwhile, over thirty states have enacted, have failed to enact, or currently are considering legislation related to hESC research.⁸ Although California's program is the largest—designed to spend about \$300 million annually for ten years—five other states have established state-sponsored hESC research programs: Connecticut (\$10 million per year for ten years), Illinois (the governor allocated \$10 million for stem cell research from the

4. Press Release, President Discusses Stem Cell Research, The White House (Aug. 1, 2001), <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html>.

5. See *Exploring the Promise of Embryonic Stem Cell Research: Hearing Before the S. Special Comm. on Aging*, 109th Cong. (2005).

6. See U.S. Congressman Mike Castle, *Castle-DeGette Legislation H.R. 810 Passes the U.S. House! Final Vote: 238 to 194*, May 24, 2005, <http://www.house.gov/castle/Castle%20DeGette%20ESCR.html>.

7. See U.S. Senate Legislation & Records Home, Vote Summary, http://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=109&session=2&vote=00206 (last visited Aug. 25, 2006) (concerning Senate passage); Sheryl Gay Stolberg, *First Bush Veto Maintains Limits on Stem Cell Use*, N.Y. TIMES, July 20, 2006, available at <http://www.nytimes.com/2006/07/20/washington/20bush.html?ex=1155009600&en=035c3f389da0659e&ei=5070> (concerning the veto and unsuccessful override attempt).

8. The discussion of state legislation for and against stem cell research was compiled from the following websites: GRC State Stem Cell Research News and Alerts, What's New in State Stem Cell Legislation and Funding, http://grassrootsconnection.com/state_stem_cell_resources.htm (last visited Aug. 25, 2006); National Conference of State Legislatures, State Embryonic and Fetal Research Laws, <http://www.ncsl.org/programs/health/genetics/embfet.htm> (last visited Aug. 25, 2006); National Conference of State Legislatures, Genetics Legislation Database, <http://www.ncsl.org/programs/health/genetics/geneticsDB.cfm> (last visited Aug. 25, 2006).

state's portion of the settlement of the tobacco litigation, with a larger appropriation pending as of June 2006), Maryland (authorization passed but appropriation pending), New Jersey (\$8.5 million and \$14.5 million for the past two years, with further appropriation pending), and Ohio (research institution established in 2003 with \$19.5 million in one-time state funding). Several other states are considering programs, including proposals in New York and Pennsylvania to spend \$100 million annually. Smaller programs are being considered by state legislatures in Delaware, Florida, and Texas. Meanwhile, New York Mayor Michael Bloomberg donated \$100 million of his own money to support stem cell research at Johns Hopkins University.⁹

On the other side, Indiana, Louisiana, and South Dakota have passed legislation banning hESC research, and Kentucky, Mississippi, and Missouri are considering such legislation. Arizona, Missouri, Nebraska, and Virginia have laws banning the expenditure of state funds on hESC research, although Missouri faces a ballot initiative to overturn that legislation.

The purposes for enacting state-sponsored hESC research programs are diverse. Most obvious is a philosophical disagreement with the President. Another motive is the practical objective of seeking effective treatments for several important and heretofore incurable diseases. These programs also create an opportunity for a state to gain strategic advantage for its higher education and biotech industries, to obtain royalties from patents arising from the research, and to reduce state spending on medical care.

California's experience shows that setting up an effective research program is difficult. While spending money is easy, spending money without causing a political backlash is difficult. Several problems stand in the way of establishing an effective program, but this Article focuses on four that are especially important: (1) uncertainties about federal policy and politics; (2) difficulties of using government research programs to attract industry; (3) organizational challenges in creating a merit-based method of providing financing through government agencies; and (4) difficulties concerning the assignment of the intellectual property rights arising from state-sponsored research. These problems are not insurmountable, but state governments have little or no experience in dealing with them, and as a result they may be prone to make mistakes.

The remainder of this Article discusses the underlying economics and politics that shape states' responses to these issues, and then examines

9. See Sara Kugler, *New York Mayor Donates \$100 Million to Johns Hopkins*, WTOP (Feb 2, 2006), <http://www.wtopnews.com/?nid=25&sid=688013>.

how California has dealt with these issues. This Article has three main conclusions. First, to avoid inefficiencies arising from the politicization of grants, agencies that implement research programs must base their decisions on merits as determined by competitive peer review. The California program is well designed in this regard. Second, intense political polarization over the legitimacy of hESC research inevitably slows implementation and increases the costs of these programs, as exemplified by CIRM. Third, in designing an intellectual property regime for hESC research programs, some political leaders have vastly overestimated the potential revenue from licensing research results, and as a result have proposed licensing rules that may undermine the viability of the research program. California is no exception. State legislators have proposed rules for licensing patents from CIRM's projects that make grants from CIRM substantially less attractive to leading research institutions than grants from the federal government and private foundations. Because state-sponsored hESC research programs will account for a small fraction of all biomedical genetics research, states cannot realistically expect to receive substantially more favorable licensing arrangements than those available from other sources.

II. THE ECONOMICS AND POLITICS OF R&D PROGRAMS

California's hESC program will support basic research in genetics, but it also has a practical orientation that plausibly will lead to commercial development. This Part summarizes three key economic and political factors that are likely to affect adversely the performance of an hESC research and development ("R&D") program. The first factor is the salience and controversial nature of stem cell research among the general population, which creates a political environment in which the program and its implementing agency are constantly subjected to intense scrutiny and criticism irrespective of how the policy evolves. The second factor is that the policy instruments for increasing a society's overall investment in research inevitably have undesirable effects that can offset the benefits of the program. Third, the political process creates additional impediments to effectively managing R&D programs that have substantial and immediate commercial significance.

A. Salience and Polarization

Government research programs rarely achieve high political salience, and so rarely are created and sustained because they enjoy widespread grassroots support. As a result, neither the federal government nor any state has ever had a coherent technology policy. Instead, technology policy is a fragmented mish-mash of largely unrelated programs, nearly all of

which generate little interest outside of the communities that are directly involved with them.

The most important exception to the lack of salience of technology policy pertains to defense-related R&D during the Cold War. From the late 1940s to the late 1980s, fear of military confrontation with the Soviet Union created a durable base of political support for large expenditures on R&D that was related to national defense. In the late 1980s, as the Soviet Union collapsed, support for defense-related R&D waned. As a result, real federal R&D expenditures declined in every field of R&D except biological sciences, and the federal government's share in U.S. R&D subsequently fell roughly by half.¹⁰

Another area of relatively high political salience in the United States is health care. The high salience of health has sustained substantial federal expenditures on research in biomedical sciences. hESC research is a type of practically significant basic research in biological sciences that derives support from the widespread beliefs that science is useful in creating more effective treatments for illnesses and that the government bears some responsibility for the effectiveness of the health care system.

An important difference between hESC research and most other research in biological sciences is opposition among a significant minority of the population. Various public opinion polls, stating the issue in different ways, report significant numbers of respondents who favor hESC research between 55 and 60 percent, with a few as low as 50 percent or as high as 70 percent. The fraction of respondents who oppose hESC research hovers around 20 to 25 percent, and an additional 10 to 15 percent oppose government funding of this research.¹¹

The controversy about hESC research is intensely polarizing politics: a clear majority that supports stem cell research is pitted against a large minority that wants to stop this research. Intense polarization creates a circumstance in which battles are never won because losers do not accept defeat, as exemplified by the continuing political battles over abortion, school prayer, evolution versus creationism in school curricula, and flag burning decades after court decisions appeared to have resolved the core constitutional issues about them. The rise of programs to support hESC

10. See generally Linda R. Cohen & Roger G. Noll, *Research and Development after the Cold War*, in *COMMERCIALIZING HIGH TECHNOLOGY: EAST AND WEST* (Judith B. Sedatis ed., 1997); Roger G. Noll, *Federal R&D in the Antiterrorist Era*, in *INNOVATION POLICY AND THE ECONOMY* 3, (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2003).

11. For a summary of these polls, see Polling Report.com, *Origin of Human Life*, <http://www.pollingreport.com/science.htm> (last visited Aug. 25, 2006).

research in a few states, the reaction of its opponents to use numerous legal and political means to stop it, and the inability of most states and Congress thus far to speak definitively on the matter all illustrate the extent of political polarization and the paralysis that it creates.

B. The “Public Good” Rationale for Government R&D

The product of research is information, which is a public good in that once knowledge has been obtained by one person, the costs of discovering the information need not be repeated in order for a second person to gain access to it.¹² By contrast, ordinary economic goods are rivalrous. For example, if one person consumes a hamburger, a second person cannot consume it also. Unlike hamburgers, information is difficult to privatize. Even in the presence of strong intellectual property (IP) rights, creating and exploiting new knowledge enables others to draw inferences about the knowledge and how they might use it without violating its IP rights.

These features of new knowledge lead to socially inefficient under-investment in creating fundamental new information. As well, the same features can lead to socially inefficient over-investment in “copy-cat” R&D. This sort of research seeks to “invent around” the original discoverer’s intellectual property rights by creating the closest thing to a copy that differs sufficiently to avoid infringing those rights.¹³

The presence of these inefficiencies creates a policy dilemma for officials in that the policies that might ameliorate investment inefficiencies also create other costs that can offset these benefits. Both subsidies and IP rights increase an innovator’s net financial reward from R&D and thereby reduce under-investment in research. Subsidies reduce the expected financial reward that is necessary to make R&D privately profitable. IP rights reduce competition from copies or unauthorized use, thereby enabling rights holders to charge more for innovations. Both subsidies and strong IP

12. See generally Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in THE RATE AND DIRECTION OF INVENTIVE ACTIVITY 609-25 (1962). For a comprehensive survey of the field, see Paula E. Stephen, *The Economics of Science*, 34 J. ECON. LITERATURE 1199-1235 (1996).

13. See Charles I. Jones & John Williams, *Too Much of a Good Thing? The Economics of Investment in R&D*, 5 J. ECON. GROWTH 65, 80 (2000); Edwin Mansfield, Mark Schwartz & Samuel Wagner, *Imitation Costs and Patents: An Empirical Study*, 91 ECON. J. 907-18 (1981); Nancy Galini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, in 2 INNOVATION POLICY AND THE ECONOMY 63-65 (Adam Jaffe, Joshua Lerner & Scott Stern eds., 2002).

rights also can reduce wasteful copy-cat R&D by increasing its cost if decisions to subsidize R&D or to grant IP protection are based on novelty.¹⁴

The dilemma arises because both policies also create costs that can offset their innovative benefits. IP protection reduces the likelihood that inventions will be maximally exploited to produce economically useful products.¹⁵ If someone seeks to make use of the information arising from an innovator's R&D, the act of applying the new information imposes no costs on the original innovator. And, because no costs are imposed when an idea finds a new use, the socially efficient price of using information—that is, the price that maximizes the social benefits that new knowledge creates—is zero. However, if the price of using knowledge is zero, the creator of the knowledge may not be able to recover the cost of creating it. By allowing the creator to charge for (or to deny) the use of new knowledge, IP policy reduces the social benefits that can be derived from the discovery.

Strong IP protection also can inhibit innovation for technologies in which innovations are sequential—that is, some useful applications of one piece of knowledge depend upon the creation of other knowledge.¹⁶ For example, a British report on patent policy examined the use of genetic information to create effective new malaria drugs.¹⁷ Over thirty plausibly valid patents apply to genetic information that might be used to create a malaria vaccine. An innovator must obtain a license for all of these patents before introducing a malaria vaccine. According to the Commission, “although the malaria vaccine is unlikely to be of significant commercial value, holders of intermediate patents often put an unrealistically high value on their technologies.”¹⁸ The need to obtain all of these licenses on reasonable terms is a substantial barrier to entry.

Both IP policy and subsidy programs also have significant implementation costs. One cost arises from the process of evaluating the novelty of the creator's idea, as in determining whether an innovation deserves a patent or whether a grant proposal is meritorious. Another is the cost of en-

14. Galini & Scotchmer, *supra* note 13, at 53-62 (analyzing the relative merits of IP, *ex ante* grants, and *ex post* prizes as means to encourage private R&D).

15. For a thorough analysis of the advantages and disadvantages of intellectual property, see FRANÇOIS LÉVÊQUE & YANN MÉNIÈRE, *THE ECONOMICS OF PATENTS AND COPYRIGHTS* (2004), available at <http://www.bepress.com/leveque/>.

16. For a more thorough discussion of cumulative innovation, see Galini & Scotchmer, *supra* note 13, at 65-69.

17. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, *INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY*, 2001-02, at 143-44, available at http://www.iprcommission.org/graphic/documents/final_report.htm.

18. *Id.* at 144.

forcement. For IP, enforcement costs arise from using courts to penalize infringers. For grants, enforcement costs arise from complex accounting rules that assure accountability in spending public funds.¹⁹

Whether the benefits of stronger IP rights offset the costs is an empirical question that turns on, among other things, the responsiveness of innovative efforts to prospective financial rewards. IP protection is most likely to produce net social benefits if: (1) innovative effort is highly sensitive to financial rewards; (2) multiple complementary but independent innovations are not likely to be needed to create a valuable commercial product; (3) the nature and scope of IP rights are relatively transparent, thereby minimizing the need for costly litigation to resolve disputes; and (4) the social payoff for innovation is high.

For innovators who are motivated solely by the profitability of commercial applications, subsidies and intellectual property protection are substitutes because they both increase the financial incentive to undertake R&D. The profitability of an R&D project is the difference between the net revenue derived from commercializing the results and the cost of the project. The expected profitability of a project is increased by either lowering its cost with a subsidy or strengthening the intellectual property right in the output that is derived from the R&D project.

In academic research, the goals of scholars may attenuate the substitutability between subsidies and intellectual property.²⁰ If the main goal of scholars is career advancement within the academic community, scholars lack a strong incentive to disseminate the product of their research to those outside of academe who would find commercial uses for it. If subsidies are the only policy for promoting scholarly research, researchers will seek to win as many grants as possible, will focus their energy on research productivity, and will not pursue commercial exploitation of their research outputs. Only if scholars do seek financial reward will granting them IP rights in their research output encourage commercial uses of scholarly research.

Until fairly recently, government programs to subsidize R&D typically did not have a coherent, parallel policy about intellectual property that was derived from subsidized projects. Prior to 1980, each federal agency that

19. For a description and analysis of these accounting rules, see Roger G. Noll & William P. Rogerson, *The Economics of University Indirect Cost Reimbursement in Federal Research Grants*, in CHALLENGES TO RESEARCH UNIVERSITIES 105-46 (Roger G. Noll ed., 1998).

20. For a detailed discussion of the economics of academic research that contains the analytical basis for the argument of this paragraph, see Richard R. Nelson, *The Simple Economics of Basic Scientific Research*, 67 J. POL. ECON. 297-306 (1959).

subsidized R&D developed its own rules regarding IP rights arising from its sponsored research. Some agencies required that research results be the property of the government. This practice was common in defense research. Other agencies required that researchers place research outputs in the public domain, while still others insisted that the researcher grant IP rights to the government. Publications were a major exception. Researchers who wrote books and articles and private publishers of scholarly books and journals could profit from publications that were derived from federally financed research.

The old system drew three criticisms.²¹ First, the patchwork of procedures among agencies increased the complexity of managing IP from federal research. Second, policies created an artificial distinction between patents and copyrights, which became more important with the rise of academic computer science. Third, universities and research institutions were thought to lack an incentive to find commercial applications of their research.

In 1980, the federal government passed the Bayh-Dole Act to solve these problems.²² Bayh-Dole allows recipients of federal grants to obtain IP rights from work supported from federal funds in return for facilitating commercial uses of these rights. Giving IP rights to scholars and their employers creates the opportunity for financial gain if discoveries are commercialized, and thereby could cause research to find wider commercial application. But giving scholars a commercial interest in their discoveries also could deflect attention from more important (and even more commercially significant) fundamental discoveries that cannot be protected by intellectual property. For example, scholars can receive patents for creating new chemicals or discovering new genomic information, but not for characterizing a naturally occurring chemical or discovering a new physical property of matter. If financial gain motivates basic research, allowing researchers to have IP rights could shift research in favor of the former.

Notwithstanding all of these arguments, the Bayh-Dole Act has not had much of an effect on universities. First, the Act has not caused a change in the allocation of research among science and engineering disci-

21. For a more detailed discussion of the nature and problems of pre-1980 federal IP policies, see Jerry G. Thursby & Marie C. Thursby, *University Licensing Under Bayh-Dole: What Are the Issues and Evidence?*, May 2003, <http://opensource.mit.edu/papers/Thursby.pdf>.

22. The next three paragraphs are derived from a comprehensive evaluation of the Bayh-Dole Act: DAVID C. MOWERY, RICHARD R. NELSON, BHAVEN SAMPAT & ARVIDS ZIEDONIS, *IVORY TOWER AND INDUSTRIAL INNOVATION: U.S. UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT* (2004).

plines and, within disciplines, research priorities among fields of research. The most important factor affecting the allocation of faculty across research areas is the federal budget for basic research.²³ Second, although the Act created a new financial incentive to find commercial applications of university research, it has had no significant effect on the extent to which universities commercialize research outputs. In most industries, patents and licenses are not regarded as important in the innovative process.²⁴ Publications, conferences, consultancies, student employment, and informal contacts with faculty account for most technology transfer, with patents and licenses being relatively unimportant.²⁵ Third, while over 200 universities have technology transfer offices,²⁶ in most cases these offices have had little impact. Technology transfer offices in leading research universities have licensed hundreds of patents that are a major source of income. In 2004, eighteen universities received more than \$22.5 million from licenses, and three received more than \$65 million; however, among all universities with licensing offices, median licensing income is around \$750,000.²⁷ The precise costs of these offices are not reported, but the median number of FTE employees is four and the median expenditure for legal fees (not including the costs of infringement suits) is around \$500,000.²⁸ Considering that universities typically share licensing income with faculty, it is likely that most universities experience a net loss from their technology transfer offices.

C. Political Impediments

The organization of electoral systems, legislatures, and the bureaucracy can introduce inefficiencies into the design and implementation of an R&D program. The design of political institutions creates incentives that work against focusing R&D policy on inducing socially desirable but privately unprofitable R&D. By definition, an efficient R&D policy should not be much concerned about projects that researchers would undertake

23. Linda R. Cohen & Roger G. Noll, *Universities, Constituencies, and the Role of the States*, in CHALLENGES TO RESEARCH UNIVERSITIES 40-46 (Roger G. Noll ed., 1998).

24. Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson & Sidney G. Winter, *Appropriating the Returns from Industrial Research and Development*, in 3 BROOKINGS PAPERS ON ECON. ACTIVITY 793-98 (1987).

25. Wesley M. Cohen, Richard Florida, Lucien Randazzese & John Walsh, *Industry and the Academy: Uneasy Partners in the Cause of Technological Advance*, in CHALLENGES TO RESEARCH UNIVERSITIES 178-82 (Roger G. Noll ed., 1998).

26. AUTM U.S. LICENSING SURVEY: FY 2004 13 (2005), <http://www.autm.net/events/File/FY04%20Licensing%20Survey/04AUTM-USLicSrvy-public.pdf>.

27. *Id.* at 25.

28. *Id.* at 13, 21.

anyway, regardless of government policies, but instead should focus on projects that researchers otherwise would not pursue. In short, policy ought to be evaluated on the basis of the incremental innovation it creates, not the fraction of all innovations that are subsidized. Unfortunately, the government is not likely to be inclined to orient R&D policy in this way for three reasons: the political intolerance for failed projects, the influence of distributive politics (the “pork barrel”) on project selection, and the short time horizon of government due to the frequency of elections.

1. *Optimal Failure*

One political impediment to efficient government R&D arises because an optimally designed R&D program is likely to support many failures. Whether an R&D program will succeed in producing useful innovations is inherently uncertain, which is perceived as a cost to private innovators. Hence, the failure rate will be higher among borderline projects that government policy hopes to induce. A program that has a high incidence of failure is vulnerable to attack on the grounds that it is inefficient, and supporters of such a program face a difficult task in convincing constituents that a program is effective. Hence, both elected officials who support an R&D program and civil servants who implement it have an incentive to support some projects for which the probability of commercial success is high and that are likely to be privately supported regardless of policy. Precisely this phenomenon has arisen in the federal Small Business Innovation Research (SBIR) program, where SBIR grants for R&D in small firms have had no statistically significant effect on R&D effort or employment among firms that receive grants.²⁹

2. *Pork Barrel*

Another political source of inefficiency in R&D programs arises because elected officials are rewarded for bringing government expenditures to their constituency, even when projects have little intrinsic merit. Public R&D subsidies are prone to pork barrel incentives that arise from a systematic attempt to reward the constituencies of elected officials who support the program.³⁰ An example of the prosaic pork barrel in R&D is the use of “earmarking” expenditures for specific projects in appropriations

29. For a more comprehensive analysis of these points concerning the SBIR program, see Scott J. Wallsten, *The Effects of Government-Industry R&D Programs on Private R&D: The Case of the Small Business Innovation Research Program*, 31 RAND J. ECON. 674-92 (2000).

30. See THE TECHNOLOGY PORK BARREL (Linda R. Cohen & Roger G. Noll eds., 1991) (containing several examples of large-scale commercial R&D projects that yielded negative net benefits but nonetheless persisted because of their pork barrel effects).

bills. Earmarks represent the alternative to selecting R&D projects from among competing proposals on the basis of their merits, including both technical novelty and potential societal impact, as assessed by people with technical expertise in the proposed line of research.

A special problem in R&D is that the same political forces also create an incentive for elected officials to keep the economic exploitation of new knowledge within the jurisdictions that support its creation. Examples are the Cooperative Research and Development Agreements (CRADAs) that were initiated after the passage of the Stevenson-Wydler Act in 1986. This Act allows federal government research organizations to undertake joint R&D projects with private partners in which the private partners obtain commercialization rights to the research results.³¹ CRADA rules limit eligibility for these programs to U.S. firms.

Another consequence of the incentive to deliver political benefits is the incentive to avoid harming organized interests. R&D programs risk loss of political support if they “pick winners”—that is, among competing applicants, pick a few entities to receive subsidies while rejecting others. If the latter outnumber the former, the net effect on the political support for the program is likely to be negative. For example, the federal programs in communications satellites and photovoltaic energy were prematurely terminated not because they were failures, but because their success threatened some large, politically influential firms.³²

3. *Impatience*

The third distorting effect of political institutions arises from frequent elections.³³ The electoral cycle creates an artificially short time horizon for subsidy programs. Elected officials are motivated to seek political benefits within the time horizon of the electoral cycle. Typically, commercial R&D projects have a very long gestation period, in some cases twenty years or more. Consequently, elected officials who create a new R&D program are unlikely to be able to claim credit for its results, which typically accrue

31. See Linda R. Cohen & Roger G. Noll, *Feasibility of Effective Public-Private R&D Collaboration: The Case of Cooperative R&D Agreements*, 2 INT’L J. ECON. OF BUS. 223-40 (1995) (discussing the rise and fall of the CRADA program).

32. Linda R. Cohen & Roger G. Noll, *The Applications Technology Satellite Program*, in THE TECHNOLOGY PORK BARREL, *supra* note 30, at 149-78; William Pegram, *The Photovoltaics Commercialization Program*, in THE TECHNOLOGY PORK BARREL, *supra* note 30, at 77-96.

33. For a complete discussion of the effect of election cycles on the time horizon of elected officials and R&D policies, see Linda R. Cohen & Roger G. Noll, *The Political Discount Rate* (Stanford Inst. for Econ. Policy Research, Discussion Paper No. 209, 1990).

after their political career is over. A short political time horizon biases projects with very long-term payoffs, which works against supporting long-term R&D projects.

III. APPLICATIONS TO HESC RESEARCH

The potential impediments to effective R&D laid out in the preceding Part apply to hESC research in four ways. First, political polarization creates uncertainty and costly delay in implementing the program. Second, political pressures sacrifice merit in favor of pork barrel spending as a criterion for support. Third, the political process favors projects with short-term commercial payoff at the expense of more fundamental, long-term projects with much larger expected future payoffs. Fourth, the quest for geographic economic advantage can lead to an inefficient bidding war across jurisdictions.

A. Political Controversy and Policy Uncertainty

As discussed in Section II.A, hESC research is an intensely polarized policy issue. Continuing political controversy causes uncertainty in the durability of hESC policy over the long investment horizon of a research program, and in so doing increases the risks faced by organizations that receive grants from the program. Uncertainty arises because agencies that support hESC research and organizations that undertake it are likely to experience continuing challenges to their procedures and decisions. Ongoing challenges to the program create legal costs and highly bureaucratized procedures to assure accountability. These challenges come from many sources. One is litigation that seemingly expresses concerns about program design, but that in practice is intended to delay, minimize or even prevent hESC research from taking place. Another is continuing political pressure to seek legislation or to pass initiatives that limit, redirect or destroy the program.

1. Litigation

In California, two lawsuits were filed soon after Proposition 71 passed to prevent CIRM from making any grants.³⁴ These lawsuits claimed that Proposition 71, the initiative measure that created California's stem cell program and CIRM, unconstitutionally delegates spending authority to a body that is not adequately controlled by elected officials. The cases were

34. *People's Advocate v. Indep. Citizens' Oversight Comm.*, No. HG05 206766 (Cal. Super. Ct. May 12, 2006), available at <http://www.cirm.ca.gov/pressreleases/pdf/2006/04-21-06.pdf>.

consolidated, and plaintiffs lost at trial,³⁵ but the appeals process is still under way. A victory for the plaintiffs would kill CIRM by eliminating its process for making grants, but such an outcome always has been regarded as unlikely.

In June 2006, another lawsuit was filed to prevent CIRM from making grants to the University of California on the grounds of conflict of interest arising from the fact that CIRM's governing body includes nine members who are University of California employees.³⁶ While focused on the University of California, the complaint raises the same general issues about the structure of CIRM that were raised in the previous case, and so is likely to suffer the same fate.

Despite the dubious legal merits of these challenges, they have imposed substantial costs and delays on the California program. Until the litigation is resolved CIRM is unable to sell bonds to finance its grants, and meanwhile much of the early effort of CIRM's leadership has been devoted to fighting these lawsuits and seeking other sources of funds to enable it to launch a much smaller grant program.³⁷ Thus, as of this writing, litigation already has delayed full operation of the program for fifteen months, and a reasonable expectation is that the delay will be two years or even more.

2. *Political Resistance to Peer Review*

Some elected officials, especially those who are unfamiliar with research programs, are wary of making grants through a competitive process in which decisions are based on peer review. Reflecting this wariness, the California state legislature is considering a State Constitutional Amendment (SCA 13) to require open public records and meetings in making grants.³⁸ The amendment is a work in progress, so its ultimate form, if it passes, is uncertain. Its history, though, sheds light on the political envi-

35. See Press Release, California Institute for Regeneration Medicine, Court Upholds Constitutionality of Stem Cell Program; Judge Sabrow Declares Proposition 71 Constitutional in Its Entirety (Apr. 22, 2006), available at http://www.findarticles.com/p/articles/mi_m0EIN/is_2006_April_22/ai_n16131786.

36. See Joint Complaint for Declaratory Injunction Relief, Nat'l Tax Limitation Found. v. Westley (June 23, 2006), available at <http://www.lldf.org/Prop71.fu.Complaint-Rev3.pdf>.

37. For documentation of the effects of the lawsuits on CIRM's activities, revenues, and expenditures, see CIRM Home Page, <http://www.cirm.ca.gov> (last visited Aug. 25, 2006).

38. For progress of the bill, see California State Senate, Official California Legislative Information, http://info.sen.ca.gov/cgi-bin/postquery?bill_number=sca_13&sess=CUR&house=B&site=sen (last visited Aug. 25, 2006).

ronment in which a state constructs a basic research program. The original version of the bill would have required open records and open meetings for all aspects of the CIRM grant-making process, preventing blind peer review of research projects. The bill has been watered down, preserving blind peer review, but imposing the following requirements:

[A]ny working or advisory group that is charged with reviewing and recommending medical research projects for funding shall produce a written summary that shall be a public record of the reasons for recommending or not recommending any project for funding as well as how each project recommended for funding will benefit residents of California. The working or advisory group shall hold an open session to allow public comment on its decision prior to submitting any recommendation to the [Independent Citizens' Oversight Committee].³⁹

The parallel is to require that grant proposals to the National Science Foundation (NSF) be subjected to public reviews of recommendations by referees and decisions by the NSF disciplinary panels, and that scientific researchers and disciplinary panels predict the ultimate societal benefits to be derived from each research project. Obviously, these requirements would substantially lengthen the delay and cost in making grants, increase the difficulty in finding scholars who are willing to referee proposals and serve on advisory groups, and generate a substantial volume of useless paperwork as basic researchers project plausible uses for their work decades in the future.⁴⁰

The response of the California legislature to the passage of Proposition 71 illustrates both a short-term and a long-term problem for constructing state analogues to the basic science agencies of the federal government. The short-run problem is the absence of experience and knowledge concerning basic research, and the properties of an effective process for deciding which projects to pursue. Presumably this problem will diminish as states gain more experience with such programs, but in the interim it can make these programs far less efficient—and far less attractive as sources of funds for top researchers—than need be the case. The long-term problem is that in controversial areas, like hESC research, opponents of the

39. S.C.A. 13 § 8(c)(2), 2005 S., Reg. Sess. (Cal. 2005), available at http://info.sen.ca.gov/pub/bill/sen/sb_0001-0050/sca_13_bill_20050531_amended_sen.html (last visited Aug. 25, 2006). The Independent Citizens' Oversight Committee (ICOC) is the governing body of CIRM. The role and composition of the ICOC are discussed in Section III.B.

40. For an apocryphal perspective on this onerous process, see Roger G. Noll, *Einstein's Interoffice Memo*, 309 SCI. 1441, 1490-91 (2005).

research are given the opportunity to forge alliances with proponents who rigidly adhere to the principle that all government decisions ought to be transparent but that have the effect of undermining the effectiveness of the program.

3. *Federal Policy Uncertainty*

The constraints on hESC research imposed by the federal government are another source of uncertainty for state-sponsored programs. While President Bush issued a public statement prohibiting granting agencies from spending federal funds on any unauthorized hESC research, the legal requirements emanating from the President's statement remain unclear. Federal agencies have interpreted the President's statement as requiring the development of accounting procedures to carry it out. Like other rules regarding expenditure of federal funds, the penalty for a violation is Draconian, involving repayment of the grants that somehow were used for hESC research and loss of eligibility for future federal support. Thus, potential recipients of grants from both the federal government and state agencies that sponsor this research need to be virtually certain that their system satisfies all subsequent authoritative federal auditors that the President's directive has been respected. Otherwise, the potential risk of accepting state hESC grants is huge compared to the likely benefit of financial support from them.

How potential recipients of hESC research grants answer these questions is important not only to institutions undertaking research, but also to a state that is supporting hESC research. If a research institution is found to violate the federal rules, its punishment is very likely to be financially devastating and to undermine its ability to perform state-supported projects, which in turn would thwart its ability to serve as an economic magnet for biotechnology firms in the state.

Unfortunately, the practical meaning of the federal directive is far from clear, and the federal agencies that support research that is most likely to have common inputs with hESC research have, understandably, been reluctant to stick their necks out by issuing clarifying regulations. The National Institutes of Health (NIH), the main federal sponsor of biomedical research and thus by far the most important entity for implementing the President's ban, has stated: "Scientists who receive federal funds and study both federally fundable and non-federally fundable human embryonic stem cells must charge research costs for study of non-federal

lines only to non-federal sources of funding.”⁴¹ While all agree that direct expenditures on prohibited hESC research cannot come from federal funds, other issues about potential indirect support remain unresolved. According to the same guideline: “Federal policy is clear that no federal funding may be used, either directly or indirectly, to support human embryonic stem cell research outside the criteria established by the President on August 9, 2001,” and goes on to state that indirect costs should be divided between federal projects and prohibited stem cell research projects according to the principles of OMB Circular A-21.⁴² But these instructions are far from definitive.

Most importantly, the legal status of the President’s directive is unclear. Notably, the President has not issued an Executive Order on the matter, forcing agencies to attempt to implement a vague policy that was set forth in a speech, not a carefully crafted legal document that has gone through the standard vetting process among relevant federal officials. Because the directive is not an Executive Order, it was not published in the Federal Register. Thus, the outcome of an attempt by the federal government to enforce the directive is far from clear. Moreover, the President’s directive covers all federal expenditures, not just NIH grants, so that while NIH auditors probably are limited to enforcing the directive as it was embellished by the NIH, other agencies are not so constrained, and have not issued guidelines that set forth their interpretation of the directive. In particular, agencies that support students directly through fellowships, work-study grants, and student loans have been silent.

A few examples convey the importance of the gray areas and, therefore, the uncertainties facing potential recipients of state grants. Can a student who holds an NSF graduate fellowship or a government-guaranteed student loan work in a lab that undertakes prohibited hESC research, or would this represent the expenditure of federal funds in support of prohibited research? If a university buys equipment with federal funds, can this equipment be used on prohibited hESC research as well if it is not fully utilized on federally-supported projects? Can such equipment be used for prohibited hESC research after the grant has expired, full title to the equipment has passed to the university, and the equipment has been fully

41. National Institutes of Health, Stem Cell Information Frequently Asked Questions, <http://stemcells.nih.gov/info/faqs.asp> (last visited Aug. 25, 2006) (addressing how to assure that federal funds are not spent on prohibited stem cell research).

42. *Id.* For the Circular A-21 text, see Office of Management and Budget, Circular A-21: Revised 5/10/04, http://www.whitehouse.gov/omb/circulars/a021/a21_2004.html (setting forth the basic policies and procedures that recipients of federal grants must use to determine the reimbursable costs of federally sponsored research).

depreciated? If universities use indirect cost recovery from federal projects to finance seed grants, as many do, are projects involving prohibited hESC research eligible for these grants? Can administrative personnel who supervise expenditures from federal grants also oversee expenditures on hESC research if any part of their salaries is included in the entity's indirect cost rate? If a journal publishes an article reporting the results of prohibited research, can the costs of the university library in subscribing to that journal be part of the indirect cost pool for federal grants? Can a building be used partly for federally funded research and partly for hESC projects if the university incorporates a portion of the building, but not all, in its indirect cost pool?

Circular A-21 states that accounting procedures for separating costs between federal and non-federal projects must assure that federal projects do not cross-subsidize other activities. NIH has adopted the same principles for segregating costs between allowed and prohibited research. But creating accounting safeguards against cross-subsidization is not the same as creating safeguards to guarantee that no federal funds are used even indirectly for prohibited projects. The principles behind A-21 are that the federal government should not pay more than the stand-alone costs of a project and that joint costs of multiple projects can be allocated among federal and non-federal funds. For example, federal auditors do not care if a scholar uses a computer that was purchased from a federal grant to read e-mail, to surf the internet, or to work on other research projects as long as the federally-financed work is undertaken as promised. The President's directive seems to say that a scholar could not use this computer to write a paper on prohibited hESC research. And, while students with NSF fellowships can work on research projects that are not paid for by the federal government, the President's directive seems to ban them from working in a lab that conducts prohibited hESC research.

The optimal response of a research institution to all of these unresolved issues is not necessarily to be as safe as possible from federal reprisal. Complete separation of state-sponsored hESC research from all other activities at the university—the kind of “walling off” that arises in firms that engage in government contracting in order to avoid running afoul of procurement rules⁴³—is quite costly because it prevents a research institu-

43. *See, e.g.*, OFFICE OF THE UNDERSECRETARY OF DEFENSE FOR ACQUISITION, REPORT OF THE DEFENSE SCIENCE BOARD TASK FORCE ON DEFENSE ACQUISITION REFORM 3 (1993) (suggesting that a major problem in defense procurement has been the tendency of private firms completely to separate work for the government from other commercial work, thereby preventing synergies among product lines as well as economies of scale in production).

tion from capturing economies of scale and scope, and because it creates barriers to information sharing and intellectual synergies among closely related research projects. Thus, both research institutions and state governments may prefer to take some risks about how the federal directive ultimately will be interpreted in order to make their research programs more efficient.

States probably should be more willing to take such risks than individual institutions for three reasons. First, a state that successfully takes more risks will obtain more research output per dollar spent, and thereby be more likely to achieve both the scientific and economic objectives of the state program. Because the state, but not research institutions, values the economic spillover effect of the research program, it will place more value on accepting risks. Second, the state is not likely to view some federal funds at stake in undertaking state-sponsored hESC work as having the same economic spillover benefits as hESC research. If so, the state will place less significance in the continuation of this support than will the institutions that receive this support, and be more willing to risk losing it. Third, the state presumably will support projects in a portfolio of institutions, not all of which are likely to be found to be out of compliance—especially at the same time. This portfolio effect will cause the state to perceive the average risk per project to be lower than the risk of a state-supported project that a research institution perceives.

For these reasons, tension may develop between the protocols that the state recommends for complying with federal rules and the protocols research institutions prefer. Likewise, less prestigious institutions are likely to be less risk averse than more prestigious institutions simply because they have less to lose. If so, they can develop a cost advantage over more prestigious competitors, causing a relatively larger share of grant money to flow to projects with a lower probability of success.

The Bush Administration is not likely to resolve the ambiguity in federal rules. Likewise, the attempt by Congress to change the President's policies was vetoed, and Congress is not likely to pass further legislation that limits and/or clarifies the President's ban. Consequently, the clarification of the federal directive most likely will emerge from court cases in which either opponents of hESC research file *qui tam* lawsuits against research institutions or research institutions appeal decisions by aggressive federal auditors.

Compounding the uncertainty of federal policy is the strong possibility that the President's ban will not survive the Bush presidency. Many politicians, including early Republican candidates for the 2008 Presidential nomination Bill Frist, Rudy Giuliani, John McCain, and Mitt Romney, fa-

vor lifting the President's ban, indicating that they support at least some limited role for hESC research in federal R&D policy.⁴⁴ Because a speech created the current federal ban, the next President can equally easily dismantle it. The odds favor lifting the federal ban early in 2009.

If states and research institutions believe that the ban will be lifted, their incentives regarding state-sponsored research are affected. If the NIH begins to treat hESC as just another research tool, NIH immediately will become the dominant player in this research. With a \$30 billion annual budget, NIH quickly can dwarf the spending of all state programs, relegating the latter to relatively unimportant fringe programs. State political leaders, then, can ignore the issue and thereby avoid compromising themselves to the polarized politics of hESC research. At the same time, if states and research institutions could quickly implement a research program, they would get a head start on research centers in states without a program. The empirical issue is whether the leading researchers in the field are likely to locate in states with active programs to obtain a two- to three-year head start in hESC research.

B. Pork Barrel

As discussed in Section II.C.2, all policies are in danger of being seriously distorted by the forces of distributive politics. Programs are especially susceptible to pork barrel spending if they involve authorizations or appropriations bills that fund specific activities. In the research budget, specific projects for which funding arises from a provision in legislation are called earmarks. Both federal research agencies and the President's annual budget frequently criticize the tendency of Congress to bypass peer review and competitive bidding as the means for making research grants or selecting among proposals for new research facilities.⁴⁵

44. Frist and McCain voted for the Specter-Harkins Bill, and Giuliani supports stem cell research. See *Potential Presidential Candidates' Plans for Cancer Research*, DES MOINES REGISTER, July 30, 2006, at 15A, available at <http://desmoinesregister.com/apps/pbcs.dll/article?AID=/20060730/NEWS09/607300355/1056>. Romney supports hESC research, but opposes cloning to create new stem cell lines. See Scott S. Greenberger & Frank Phillips, *Romney Draws Fire on Stem Cells: Opposes the Use of Cloned Embryos*, BOSTON GLOBE, Feb. 11, 2005, at A1, available at http://www.boston.com/news/local/articles/2005/02/11/romney_draws_fire_on_stem_cells/. George Pataki has not taken a clear position, while Senators Allen, Brownback and Hegel voted against the bill to lift the ban.

45. See, e.g., OFFICE OF MANAGEMENT AND BUDGET, ANALYTICAL PERSPECTIVES: BUDGET OF THE UNITED STATES GOVERNMENT, FISCAL YEAR 2006 63 (2005), available at <http://www.whitehouse.gov/omb/budget/fy2006/pdf/spec.pdf>.

Despite the presence of earmarks in research appropriation bills, the R&D budget has been less distorted by distributive politics than many other areas of federal spending. Estimated R&D spending through earmarks in the 2005 federal budget was \$2.1 billion out of over \$130 billion, or less than two percent.⁴⁶ The best examples of pork come from construction projects—federal buildings, rivers and harbors projects, sewage treatment plants, transportation infrastructure, and military bases. Projects to support end-stage commercial development also have been distorted by distributive politics. Examples of projects that were continued far longer than they should have been, largely for pork barrel reasons, were the Supersonic Transport/National Aerospace Plane, the breeder reactor, and the space shuttle.⁴⁷

The design of a research program affects the extent to which it is influenced by distributive politics. To minimize pork barrel effects, the first important design requirement is that projects be selected by the agency, not by the legislature. The second important design requirement is that the enabling legislation requires peer review by experts as a mandatory part of the project selection process. The third important design requirement is that the ultimate selection of projects be made by people who do not have strong connections to any particular group that is a candidate to receive funds.

The agency that best exemplifies a design that minimizes the influence of distributive politics is the National Science Foundation (NSF). Though on occasion facilities expenditures by NSF are earmarked, nearly all of the NSF's budget is authorized and appropriated according to broad categories of research. Proposals are then subject to peer review, and project selection goes through specialized expert panels, the NSF professionalized bureaucracy, and the National Science Board. The primary distributive influence in this process is the community of scientific researchers. While some have claimed that this process is biased in favor of established researchers and research institutions, it is difficult to imagine any other method for awarding a large number of grants on the basis of merit.

The NIH is designed in a similar fashion to the NSF, with one major exception. Unlike the NSF, NIH-sponsored government laboratories, rather than university researchers, undertake a significant share of the re-

46. *Id.* at 61, 63.

47. See Jeffrey S. Banks, *The Space Shuttle*, in THE TECHNOLOGY PORK BARREL, *supra* note 30, at 179-216; Linda R. Cohen & Roger G. Noll, *The Clinch River Breeder Reactor*, in THE TECHNOLOGY PORK BARREL, *supra* note 30, at 217-58; Susan A. Edelman, *The American Supersonic Transport*, in THE TECHNOLOGY PORK BARREL, *supra* note 30, at 97-148.

search that is supported from the NIH budget. Likewise, the Department of Defense, the Department of Energy, and the National Aeronautics and Space Administration, which along with NIH and NSF are the most important supporters of federal research, also spend a substantial portion of their budgets in their own research laboratories. The advantage of in-house research is that administrators can more easily direct R&D into specific activities that are high priority for the agency but not necessarily high priority for external institutions. The disadvantages are, first, that internal research is less likely to be closely linked to commercial application (as compared to business R&D) or education (as compared to university R&D), and second, that funding decisions are influenced by the desire to keep the agency's labs financially healthy.

NIH also has another manifestation of distributive politics: the National Institute for Alternative Medicine (NIAM). NIAM is a form of earmark: elected political officials have set aside part of the NIH budget for research that, by scientific consensus, has no serious prospect for creating important new fundamental knowledge or significant therapeutic advances.

The structure of the California Institute for Regenerative Medicine (CIRM) as created by Proposition 71 provides an interesting and largely unprecedented example of an agency that was constructed to be influenced by the practical significance of research, but protected against pork barrel influences.⁴⁸ At first glance, CIRM appears to be especially susceptible to the influence of distributive politics, partly because its goal is to develop commercial products and partly because CIRM was created by a ballot initiative. Because initiatives are costly, well-organized interests are the primary source of ballot measures. These sponsors are likely to take advantage of a policy vacuum from a slow-to-respond legislature to place measures on the ballot that, from the perspective of a majority of the voters, are better than the status quo, but still far from the policies that centrist voters would prefer and would vote for if given the opportunity.⁴⁹ Plausibly some beneficiaries of the program—biotechnology firms, university researchers in biological sciences, and venture capitalists who specialize in

48. See California Secretary of State, *Text of Proposed Laws – Proposition 71*, in CALIFORNIA OFFICIAL VOTER INFORMATION GUIDE 147 (2004), available at <http://www.cirm.ca.gov/prop71/pdf/prop71.pdf> [hereinafter *Proposition 71*].

49. See Thomas Romer & Howard Rosenthal, *Bureaucrats versus Voters: On the Political Economy of Resource Allocation by Direct Democracy*, 93 Q. J. ECON. 563-87 (1979); see generally ELIZABETH R. GERBER, *THE POPULIST PARADOX: INTEREST GROUP INFLUENCE AND THE PROMISE OF DIRECT LEGISLATION* (1999).

biotechnology—were the forces behind the proposition and designed CIRM as a program to enrich themselves. In reality, this did not occur.

Proposition 71 was written by real estate developer Robert Klein, who had no direct stake in the program other than as an advocate of hESC research. Financial support for the proposition was broadly based, and did not include significant contributions from researchers.⁵⁰ Some California biotechnology and venture capital (VC) firms donated to the campaign for Proposition 71, but of these only people from the VC firm Kleiner Perkins were among the largest donors. Likewise, among disease advocacy groups only the Juvenile Diabetes Fund was a large contributor. Some major donors, including two who contributed over \$1 million each, were from outside California, and therefore could not receive direct financial payoffs from the program.

Proposition 71 created CIRM's administrative framework. CIRM was designed to enable industry and disease advocacy organizations to be influential but not dominant.⁵¹ The governing board, the Independent Citizens' Oversight Committee (ICOC), has twenty-nine members who are selected to represent a variety of constituencies: nine from universities (five of whom are from UC campuses with a medical school), four from other research institutions, ten from patient/disease advocacy organizations, four from commercial life sciences enterprises, and two (the chair and vice chair) without portfolio. The distribution of these members among interests is diffused to avoid significant political influence by anyone. The chancellors of the five UC campuses with medical schools designate who will represent them on the ICOC. The Governor, Lieutenant Governor, Controller, and Treasurer (all elected offices) each appoint one person from a university, a research institute, and a life sciences company, and two people from a disease advocacy organization. The Speaker of the Assembly picks the representative for mental health, and the President Pro Tempore of the Senate picks the AIDS advocate. The twenty-seven ICOC members so selected then pick the chair and vice chair. The initial appointees to the ICOC included twelve representatives from universities. The remaining members were divided among industry, research institutes, foundations, and patient advocacy organizations. A few disease advocates

50. See Roger G. Noll, *The Politics and Economics of Implementing State-Sponsored Embryonic Stem Cell Research*, in *STATES AND STEM CELLS* 39 (Aaron D. Levine ed., 2005), available at http://region.princeton.edu/media/pub/pub_xtra_19.pdf (containing details about the contributors to the Proposition 71 campaign).

51. The number, qualifications, and selection process of members of the ICOC are set forth in chapter 3, article 1, section 125290.20 of Proposition 71. See *Proposition 71*, *supra* note 48.

were from either business or academe, but most were from disease advocacy organizations.

Beneath the ICOC are three working groups: one for reviewing grant proposals (Scientific and Medical Research Funding), one for reviewing facilities proposals (Scientific and Medical Research Facilities), and one for standards (Scientific and Medical Accountability Standards). About a third of the membership of each is from the ICOC, and each includes the ICOC Chair and representatives of disease advocacy groups. The working groups “are purely advisory and have no final decisionmaking [sic] authority . . .”⁵² Final decisions about grants and standards are made by the ICOC using majority-rule voting.

The Scientific and Medical Research Funding Working Group has twenty-three members, including seven disease advocates from the ICOC and fifteen scientists who are “nationally recognized in the field of stem cell research.”⁵³ Only the fifteen scientists are involved in evaluating the scientific merit of proposals.⁵⁴ The same procedures for peer review and technical assessment are applied to basic research, therapy development, and clinical trials.⁵⁵

The Scientific and Medical Research Facilities Working Group has eleven members, six of whom are also members of the Research Funding Working Group and four of whom are “real estate specialists” who must not have any financial interest in the construction of any facility that is funded by CIRM.⁵⁶ Since Proposition 71 does not spell out clear procedures for making decisions about facilities grants, it remains to be seen whether these grants will be decided on the basis of peer review and merit. The facilities projects are limited to non-profit institutions, i.e., universities and research institutes. The basis for evaluating facilities proposals is not as clearly spelled out or structured as the procedures for research grants.

The structure of the ICOC presents one way to deal with the dilemma of expertise versus self-interest. Barring all people with a self-interest in hESC research would sacrifice expertise in allocating resources. CIRM attempts to resolve this by having a very large decision-making body representing many interests, some of which are likely to conflict on at least some issues, to dilute the ability of any one group to control allocations in

52. *Id.* § 125290.50(e)(3).

53. *Id.* § 125290.60(a)(2).

54. *Id.* § 125290.60(c)(1).

55. *Id.*

56. *Id.* § 125290.65(a)(2).

a self-serving manner. An interesting distinction between CIRM and federal research agencies is that, while it is structured to give academic scientists a great deal of influence, it also gives disease advocates direct participation in evaluating proposals and making grants.

Unlike other institutions, CIRM will not undertake research in-house. By contrast, the New Jersey hESC program establishes a new state research institution, jointly operated by two state universities, to undertake the research.⁵⁷ The New Jersey structure likely will be more responsive to legislative priorities, for better or for worse, because the entity that undertakes the research is government-owned. Federal laboratories, even if they are managed by universities, often are more responsive to legislative priorities than other university funded research facilities and other independent research organizations.

C. Short-Term Payoffs

Another problem facing state sponsored hESC programs is that R&D projects with potential commercial applications may be over emphasized at the expense of more fundamental, long-term projects with larger expected payoffs. As discussed in Section II.C.3, the necessity to seek re-election causes elected officials to seek short-term results for which they can claim credit to their constituents at the next election. The short time horizon of elected officials favors projects promising near-term commercial payoffs. The largest immediate benefit would arise from subsidies for the last stages of commercialization rather than fundamental research. An example is to underwrite clinical trials of new therapies derived from hESC research, with the idea that somebody else (perhaps in another state) will pay for the fundamental research that leads to the treatment that will be tested in the clinical trials.

CIRM overcomes this problem by removing the legislature and the governor from the appropriation of funds for CIRM and decisions about the allocation of the research budget. The only mechanism for political influence is through the appointment of members to the ICOC, but because membership is dominated by representatives of research organizations and disease advocacy groups, elected officials are not likely to have much influence over their appointees should they press for less promising projects with more immediate payoffs.

57. See State of New Jersey Commission on Science & Technology, Stem Cell Institute, <http://www.state.nj.us/scitech/stemcell/institute> (last visited Aug. 25, 2006).

D. The Quest for Geographic Advantage

State government officials, because they represent citizens and businesses within a state, have a political incentive to design programs so that as much of the benefit of the program as possible accrues within the state. The desire to design state programs to obtain an advantage over other states is a form of distributive politics because its political purpose, like pork barrel expenditures, is to deliver benefits to constituents. In one way, the quest for geographic advantage can be more conducive to inefficiency than standard pork barrel influences. State funded pork barrel projects create some losers within a state (entities that do not receive grants and contracts), and partially counteract the political benefit of delivering uneconomic projects to favored constituents. Those harmed by the pursuit of geographic advantage are mostly residents of other states, who are not part of the constituency of a state's elected officials.

The quest for geographic advantage can lead to either greater subsidies or more IP rights than are necessary to induce socially optimal R&D. State R&D expenditures that give a state an economic advantage over other states deliver both political and economic benefits. The economic benefits are the new knowledge and products emanating from the program, and the redistribution of wealth from other states. The program has no effective political cost because prospective grant applicants who are denied support for worthy projects are firms and citizens of other states. This problem is likely to be more severe among states than in the federal government. The federal government is much larger than any state, and the system of geographic representation in Congress prevents one state's congressional delegation from gaining an economic advantage for their state by channeling expenditures to it. While nations engage in international competition for research-intensive industries, this competition is less of a factor in federal decisions than interstate competition is likely to be in state programs. The U.S. is substantially more dominant in world R&D than any state is in national R&D, so that the U.S. has less to gain or lose in the relocation of industry from changes in its R&D budget. Moreover, international agreements limiting subsidization as an instrument for biasing the flow of trade constrains the federal government, but not individual states.

If the federal ban on hESC research does not survive the Bush Administration, the opportunities for a state to obtain geographic advantage by initiating its own program will be circumscribed. While the California program is at a scale that might have conferred such an advantage, litigation against CIRM has delayed the program. If a significant number of CIRM projects cannot begin until, say, summer 2007, and federal support

begins in summer 2009, the ability of CIRM to create a substantial first-in advantage for California is certainly limited.

IV. THE INTELLECTUAL PROPERTY REGIME

As discussed in Section II.B., IP policy allocates the commercial benefits of the results of R&D, and so can be used to create incentives for researchers to undertake projects with commercial potential and then proactively seek to transfer these results to commercial interests. Because states historically have not been extensively involved in supporting R&D with a commercial objective, they currently are in a position similar to that of the federal government before the passage of Bayh-Dole. States currently have no coherent policy regarding IP derived from state-sponsored research. Consequently, states that have enacted or are considering enacting a stem cell research program also must design an associated IP policy.

This section examines the development of IP policy in California, where both CIRM and political leaders have embarked on a process of developing a state IP regime that differs in important ways from federal IP policies under Bayh-Dole and CRADA. Even if federal IP policy is not optimal, creating state IP policies that conflict with federal policy is not a good idea for two reasons. First, a different state IP regime will generate substantial administrative costs for organizations that receive support from both state and federal sources. Second, California's proposed IP program is smaller than the federal program and less generous to grant recipients. Consequently, these proposals, if adopted, would discourage the best researchers from accepting grants from CIRM rather than federal agencies. This section explains the basis for these conclusions.

CIRM announced its policies regarding intellectual property rights in the results of research that it sponsors in non-profit institutions in February 2006.⁵⁸ These policies were provisional, and could be amended on the basis of public comment submitted in July 2006.⁵⁹ The proposed policy requires that grant recipients give twenty-five percent of royalty incomes in excess of \$500,000 from intellectual property that is derived from CIRM projects.⁶⁰ This proposal differs from the federal program created by

58. CIRM, INTELLECTUAL PROPERTY POLICY FOR NON-PROFIT ORGANIZATIONS (2006), <http://www.cirm.ca.gov/policies/pdf/IPPNPO.pdf> [hereinafter IPPNPO] (approved by the Indep. Citizens' Oversight Comm. Feb. 10, 2006).

59. See Meeting Agenda, IP Task Force Subcommittee of the Independent Citizens' Oversight Committee to the California Institute for Regenerative Medicine (July 14, 2006), <http://www.cirm.ca.gov/meetings/2006/07/07-14-06.asp>.

60. See IPPNPO, *supra* note 58, at 19.

Bayh-Dole, which involves no sharing with the federal government. Policies regarding for-profit grant recipients will be announced later.

The appropriate IP regime for CIRM has been the subject of intense public scrutiny and political debate over the extent to which the state should design an IP regime that enables it to recapture its expenditures on CIRM. The state can seek to recoup its expenditures on CIRM either directly through licensing the IP from CIRM's projects or indirectly by requiring firms that produce commercial products from CIRM projects to sell these products at discounted prices in California.

The pressure for local advantage and short-term payoffs can distort a state's policies regarding IP arising out of the research that it sponsors. Advocates of hESC research sought public support by claiming that it will generate therapeutic benefits to the public and financial payoffs to the state. These claims may have created unrealistic expectations about the immediate economic and financial benefits to a state that are likely to arise from IP that is derived from hESC research.

As discussed in Section II.B, the principle policy of the federal government regarding IP rights from federally sponsored research is the Bayh-Dole Act of 1980. Although Bayh-Dole generally has not had much of an effect on the commercialization of university research, it has caused several leading universities to establish technology transfer offices that generate substantial income for the universities from the research results of their faculty. Nevertheless, even among the successes, university revenue from licensing is much smaller than research expenditures. For example, in 2000, the University of California system spent almost \$2 billion on research but received only \$74 million in licensing income.⁶¹ Nationally, in 2003, the last year for which data are available, all colleges and universities received about \$1 billion in licensing income, but spent over \$40 billion on research, \$20 billion of which went to biological and medical research.⁶² These facts should give pause to state officials who see a potential financial bonanza in the IP arising from state-sponsored hESC research. Judging from recent royalty data, the licensing income from patents derived from stem cell research is likely to be a small fraction—less

61. For a summary of the revenues from the most effective university licensing programs, see Herb Brody, *The TR University Research Scorecard: Patenting and Licensing at U.S. Universities is Going Strong. Biotech in Particular Gets High Marks*, 104 *TECH R.* 81 (2001), available at <http://www.technologyreview.com/articles/01/09/scorecard0901.asp>.

62. NATIONAL SCIENCE BOARD, 2 *SCIENCE AND ENGINEERING INDICATORS 2006* 5-55 tbl.5-28, A4-4 tbl.4-3, A5-6 tbl.5-5 (2006), available at <http://www.nsf.gov/statistics/seind06/pdfstart.htm>.

than five percent—of the costs of that research. Moreover, because these projects are likely to have a long gestation period, the revenue from licensing is not likely to be substantial for many years.

State universities risk political backlash against successful commercial ventures that arise from their research. One potential form of backlash could arise from a belief that neither universities nor the state should seek to charge state businesses to use the product of research that was funded partly by taxes that were paid by those same businesses. Another possible backlash could arise from the view that, regardless of revenues, state universities should never sell rights to their IP to entities outside the state. Still another potential backlash could occur from those who believe that generating revenues from IP is a fine idea, but that the state, not the university, should be the beneficiary.

In California, some state political officials believe that hESC research is potentially a huge source of revenue, and favor assigning all or part of the IP rights to research supported by CIRM to the state. For example, the original version of the proposed constitutional amendment that the California legislature is debating sets forth an objective for California to recover from royalties all of the expenditures it has made through CIRM.⁶³ Others have proposed that CIRM keep some of the royalties to fund further research after the money from the bond issue has been spent.⁶⁴ Because CIRM has funds for a ten-year program, these proposals assume that after ten years royalties will be large enough to recover or replace an average annual expenditure of \$300 million. These beliefs likely will prove to be unrealistic, even if the state were to capture all of the royalties. Moreover, even if such revenues were feasible, it would be bad policy to try to capture them.

Allocating the royalties to CIRM to finance more research after the bond funds are spent creates an earmarking opportunity ripe with the problems associated with earmarks discussed in Section II.C. Legislating a particular use of a designated component of state revenue is a permanent earmark. The optimal amount of state support for hESC research, or indeed any area of research, bears little relation to whether the research un-

63. See S.C.A. 13, 2005 S., Reg. Sess. (Cal. 2005), available at http://info.sen.ca.gov/pub/bill/sen/sb_0001-0050/sca_13_bill_20050531_amended_sen.html. The most recent mark-up deleted this and other provisions regarding the state's rights to IP from CIRM. See S.C.A. 13 (June 8, 2005), available at http://info.sen.ca.gov/pub/bill/sen/sb_0001-0050/sca_13_bill_20050608_amended_sen.html.

64 For a summary and analysis of proposals for CIRM's IP policy, see CAL. COUNCIL ON SCI. & TECH., INTELLECTUAL PROPERTY INTERIM REPORT 33-35 (Aug. 2005), available at <http://www.ccst.us/ccst/pubs/ip/ip%20interim.pdf>.

dertaken in the first few years generates a bonanza of royalty income. The amount of state-sponsored hESC research a decade hence should be based on the opportunities for useful research and the availability of grants from other sources that are available at that time. hESC research could be highly successful and could generate enormous royalties, but opportunities for further useful research might not be as promising as research in other areas a decade hence. If so, the state should not create a financial incentive for researchers to continue to plow a field with low productivity. Likewise, the U.S. is three presidential administrations away from the day that CIRM funds run out, and the ban against federal support for hESC research is unlikely to remain in place through all three. If a future administration relaxes the rules regarding federal hESC research, the case for state support will be weaker. Thus, if the state lays claim to any royalty income, it would be better not to earmark it.

The proposal that royalties ought to be used to recover the initial cost of CIRM or finance CIRM in the future would create another problem that would undermine its success. If the state seeks to capture the equivalent of \$300 million annually in royalties from CIRM projects, most likely all royalties would have to go to the state. If all royalties go to the state, institutions that receive grants have no financial incentive to commercialize the IP that arises from CIRM grants, especially given that they can profit from IP rights derived from other research. Thus, implementing this goal likely will require that either CIRM or another state agency actually assumes responsibility for acquiring the IP rights and then licensing them. Because the state does not have the connections to or knowledge of the biotechnology industry that are possessed by research institutions, this approach likely will be less effective in actually producing either commercial products or royalties.

If grant recipients are the best institutions for licensing the IP that their research produces, they must be compensated for that effort. In fact, the advantage of making these institutions responsible for technology transfer is that they already have in place a set of institutions and internal procedures for implementing the system of research exploitation that was created by Bayh-Dole. Because Bayh-Dole is in place, research institutions and individual researchers anticipate that they, not the state, will be the beneficiaries of IP rights. As a result, if states claim a substantial fraction of the royalties from innovations arising from CIRM projects, they will create a disincentive for the best researchers to seek research support from CIRM grants instead of federal or private sponsors. The proposed CIRM policy runs the risk of making the best researchers reluctant to give up some of their potential royalties by taking CIRM grants.

Still another problem is that the advances for which IP is sought cannot usually be traced to a specific research grant, but instead are the product of many projects from many sources over a long period of time. If all rights are assigned to the research institution, tracking down all of the sponsors that were involved in creating it is not a problem. But if the state claims rights to revenues from IP arising from CIRM-sponsored projects, research institutions face the considerable problem of separating the independent sources of an innovation among sponsors. Because this can be very difficult, even impossible, to accomplish, a policy to pay some royalties to the state will create still another disincentive to accept CIRM grants.

Universities and research institutes can incorporate state-supported hESC research into technology transfer systems they already have in place with relative ease. However, by doing so they could run afoul of the ban on using federal funds for supporting hESC research. Because the cost of technology transfer offices is paid out of royalty income from federally sponsored research projects, the federal government might decide that these offices cannot be used to commercialize IP rights from state-sponsored hESC research.

Notwithstanding this problem, states should not attempt to differentiate hESC research from other biomedical research with respect to IP rights. Doing so will bias decisions of both researchers and their organizations about what kinds of research to pursue, and will create additional implementation costs for the program. The most reasonable solution is to mimic the policies of the federal government and to allow universities to combine their federal and state IP commercialization activities. State-sponsored hESC research is not a good vehicle for waging a battle against the form and spirit of Bayh-Dole, even if such a battle is warranted.

V. CONCLUSION

States have entered the business of sponsoring hESC research because of the current political controversy over hESC research. Some are jumping into a domain of policy in which they have little direct experience—financing basic research in universities and other independent research centers, and perhaps commercialization projects (therapy development and clinical trials) involving for-profit entities. This area of policy is difficult to implement efficiently and is all the more difficult because these research programs are narrowly focused and highly controversial.

States embarking on these programs should not try to be very innovative in creating agencies and policies to make grants and oversee IP rights.

These programs will not succeed if they ask grant recipients to act differently than they are required to act by other, much larger sources of funds. As an illustration, Stanford University receives as much revenue in a year as CIRM is likely to spend on external grants over a decade. Thus, CIRM cannot expect to have much leverage over either Stanford or the entities that support it. Any attempt to change the way that California research organizations do business with an annual expenditure of only \$300 million is doomed to failure.

Nevertheless, in the short term, CIRM's program will substantially increase expenditures on stem cell research not only in California but in the entire nation. As long as the program is not regarded as a source of substantial financial risks and administrative costs to research organizations, CIRM could jump-start this area of research and shorten the wait for the new knowledge and therapeutic applications from hESC research by a few years. In so doing, it could give California's research universities and medical research centers a head-start in this research, thereby enabling them to maintain, if not enhance, their international leadership in biomedical research. Thus, California will maximize the benefits to society and the state by making CIRM's IP and accountability policies parallel those applying to federal grants, thereby minimizing the disincentives to California research organizations from participating in the program. CIRM is reasonably well designed to carry out an effective R&D program with decisions about grants made mostly on the merits. If the state wants the program to succeed, it should not impose further restrictions on the agency.

