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

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Abstract

California's initiative to create the California Institute for Regenerative Medicine (CIRM), which sponsors human embryonic stem cell research within the state, has been 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 implementing 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 by political leaders and the public about the short-run therapeutic results and financial payoffs to this research. This essay explores these problems and discusses the extent to which the structure of CIRM is likely to lead to an effective response to them.

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Research on human genetics and cell biology periodically has given rise to intense, highly polarized debates about whether such research should be permitted or, if so, whether it should be financed by government. From the eugenics movement early in the 20th Century,[1] through the debate in 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 stem cells 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 have established or are considering programs to support this research. This essay 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).

Present State and Federal Policies

The federal government operates under two policies that restrict HESC research. First,

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1. Daniel J. Kevles, *In the Name of Eugenics*, Cambridge: Harvard University Press, 1985.

2. Roger G. Noll and Paul A. Thomas, "The Economic Implications of Regulation by Expertise: The Case of Recombinant DNA Research," in *Research with Recombinant DNA*. National Academy of Sciences, 1977.

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. The Dickey Amendment prevents the use of federal funds to extract stem cells from embryos, but does not prohibit further research on stem cells that were extracted using funds from other sources. Second, in 2001 President Bush directed federal agencies 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 severely inhibiting the most promising HESC research projects.[5]

The President's policy directive is controversial, even among Congressional Republicans. In May 2005, the Castle-Degette Bill, which would allow federal funds to be used on new stem-cell lines, passed the House of Representatives by a vote of 238-194.[6] The bill is pending in the Senate as the Specter-Harkin Bill (S-471), where it has 41 announced sponsors and co-sponsors.[7] Meanwhile, over 30 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

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3. First enacted as P.L. 104-99, Sec. 128, and renewed each year in appropriations bills.

4. The President's policy is at www.whitehouse.gov/news/releases/2001/08/20010809-2.html.

5. See testimony in *Stem Cell Research: Hearing before Senate Special Committee on Aging, 109th Congress (2005).*

6. See http://www.house.gov/castle/Castle%20DeGette%20ESCR.html.

7. See http://www.congress.gov/cgi-bin/bdquery/z?d109:S.471:.

8. The discussion of state legislation for and against stem cell research was compiled from

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 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 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 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 the legislation.

The motives for state-sponsored HESC research programs are diverse. Most obvious is a philosophical disagreement with the President. Others are motivated primarily by the practical objective of seeking effective treatments for several important and heretofore incurable diseases. Still others see the absence of federal support as creating the opportunity to gain strategic

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grassrootsconnection.com/state_stem_cell_resources.htm, www.ncsl.org/programs/health/genetics/embfet.htm, and www.ncsl.org/programs/health/genetics/geneticsDB.cfm.

9. See http://www.abcnews.go.com/Politics/wireStory?id=1574877.

advantage for a state's higher education and biotech industries, to cash in on royalties from patents arising from the research, or 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 effectively without causing a political backlash is difficult. Many problems stand in the way of establishing an effective program, but this essay focus 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) troublesome issues 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 essay discusses the underlying economics and politics that shapes state responses to these issues, and then examines how California has dealt with these issues.

The Economics and Politics of R&D Programs

This section summarizes the key economic and political factors that influence the performance of all R&D policies. These are the salience and controversial nature of the research among the general population, the mixed effects of the main policy instruments that are used to cope with the tendency of a market economy to under-invest in research, and the political impediments to effectively managing a commercial R&D program.

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 or 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 became less threatening and then 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 effort subsequently fell roughly in 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

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10. For more details about federally sponsored research after the cold war, see Linda R. Cohen and Roger G. Noll, "Research and Development after the Cold War," in *Commercializing High Technology: East and West*, Judith B. Sedaitis, ed. Roman and Littlefield, 1997, and Roger G. Noll,"Federal R&D in the Antiterrorist Era," in *Innovation Policy and the Economy* 3, Adam B. Jaffe, Josh Lerner and Scott Stern, eds., MIT Press, 2003.

treatment 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 to this research among a significant minority of the population. Various public opinion polls, stating the issue in different ways, report fractions 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 has created intensely polarized politics: a clear majority who support stem-cell research because it promises to create effective therapies is pitted against a large minority who want to stop this research. Intense polarization means that battles are never won because losers do not accept defeat. The rise of programs to support HESC 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 policy paralysis that it creates.

R&D as a Public Good

The product of research is information, which is a public good in that once knowledge has been created 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

11. For a summary of these polls, see http://www.pollingreport.com/science.htm.

12. The classic reference about the economics of research is Kenneth J. Arrow, "Economic

rivalrous in that if one person consumes a hamburger, a second person can not 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 it might be used without violating its IP rights.

These features of new knowledge lead to socially inefficient investment in creating fundamental new information, but can lead to socially inefficient over-investment in "copy-cat" R&D that seeks to "invent around" the original discoverer's intellectual property rights by creating the closest thing to a copy that is sufficiently different that it is non-infringing.[13]

The presence of these inefficiencies creates a policy dilemma for officials. Under-investment in R&D can be reduced by subsidizing it and by strengthening intellectual property (IP) rights. Both increase an innovator's net financial reward from R&D. Subsidies reduce the

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Welfare and the Allocation of Resources for Invention," in *The Rate and Direction of Innovative Activity*, New York: National Bureau of Economics Research, 1962, pp. 609-25. For a good survey of the field, see Paula E. Stephen, "The Economics of Science," *Journal of Economic Literature* 34 (1996), pp. 1199-1235.

13. See Charles I. Jones and John Williams, "Too Much of a Good Thing? The Economics of Investment in R&D," *Journal of Economic Growth* 5 (2000), pp. 65-85; and Edwin Mansfield, Mark Schwartz and Samuel Wagner, "Imitation Costs and Patents: And Empirical Study," *Economic Journal* 91 (1981), pp. 907-18; and Suzanne Scotchmer and Nancy Galini, "Intellectual Property: When is it the Best Incentive Mechanism?" in *Innovation Policy and the Economy*, *Vol 2*, Adam Jaffe, Joshua Lerner and Scott Stern, eds., Cambridge: MIT Press, 2002, pp. 51-78.

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 rights also can increase the cost of copy-cat R&D if decisions to subsidize or grant IP protection are based on novelty.

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.[14] Useful applications of new information do not cause the cost of creating the information to be higher; however, if the price of using knowledge is efficiently priced at zero, the creator of the knowledge can not 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. For example, a British report on patent policy examined the use of genetic information to create effective new malaria drugs.[15] Over 30 plausibly valid patents apply to genetic information that night 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

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14. For a thorough analysis of the advantages and disadvantages of intellectual property, see François Lévêque and Yann Ménière, *The Economics of Patents and Copyrights*, Berkeley Electron Press, 2004, at http://www.bepress.com/leveque/.

15. *Integrating Intellectual Property Rights and Development Policy*, Commission on Intellectual Property Rights, London: 2002, at http://www.iprcommission.org/, pp. 143-4.

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."[16] 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 enforcement. For IP, enforcement costs arise from using courts to penalize infringers. For grants, enforcement costs arise from complex accounting rule rules that assure accountability in spending public funds.[17]

Whether the benefits of stronger IP rights offsets the costs is an empirical question that turns, among other things, on the responsiveness of innovative effort 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 to innovation is high.

Because subsidies and IP have similar effects, they should be regarded as substitutes. In the case of academic research, however, the goals of scholars may attenuate the substitutability

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16. *Ibid.*, p. 144.

17. See Roger G. Noll and William Rogerson, "The Economics of University Indirect Cost Reimbursement in Federal Research Grants," in *Challenges to Research Universities*, Roger G. Noll, ed., Washington: Brookings Institution, 1998.

between subsidies and intellectual property. 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 if their research outputs.[18] If scholars do seek financial reward, then granting them IP rights in their research output will encourage commercial uses of scholarly research.

Prior to 1980, each federal agency developed its own rules regarding intellectual property rights arising from its sponsored research. Some agencies required that research results be the property of the government (the common practice in defense for national security reasons). Others required that research outputs be placed in the public domain. A major exception was publications. Researchers writing books and articles and private publishers of scholarly journals could profit from publications that were derived from federally financed research.

The old system drew three criticisms. 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. Bayh-Dole allows recipients of federal grants to obtain IP rights from work supported from

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18. See Richard R. Nelson, "The Simple Economics of Basic Scientific Research," *Journal of Political Economy* 67 (1959), 297-306, and Stephen, *op. cit.*

federal funds in return for facilitating commercial uses of these rights.[19] 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 can not 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 basic research is motivated by financial gain, 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 affected the allocation of research across disciplines and topics. The most important factor affecting the allocation of faculty across research areas is the federal budget for basic research.[20] Second, the Act has not affected the extent to which university research finds commercial use. In most industries patents and licenses are not

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19. The next three paragraphs are derived from the comprehensive evaluation of the Bayh-Dole Act: David C. Mowery, Richard R. Nelson, Bhaven Sampat and Arvids Ziedonis, *Ivory Tower and Industrial Innovation: U.S. University-Industry Technology Transfer Before and After the Bayh-Dole Act,* Stanford: Stanford University Press, 2004.

20. Linda R. Cohen and Roger G. Noll, "Universities, Constituencies, and the Role of the States," in Roger G. Noll (editor), *Challenges to Research Universities,* Brookings Institution, 1998, pp. 31-62.

regarded as important in the innovative process.[21] Publications, conferences, consultancies, student employment and informal contacts with faculty account for most technology transfer, with patents and licenses being relatively unimportant.[22] Third, while over 200 universities have technology transfer offices, in most cases these offices have had little impact.[23] Among leading research universities, these offices have licensed hundred of patents that are a major source of income. In 2004, 18 universities received more than $22.5 million from licenses, and three received more than $65 million; however, among universities with licensing offices, median licensing income is around $750,000.[24] 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.[25] Considering that universities typically share licensing income with faculty, it is likely that most universities experience a net loss from their technology transfer offices.

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21. Richard C. Levin, Alvin K. Klevorick, Richard R. Nelson and Sidney G. Winter, "Appropriating the Returns from Industrial Research and Development," *Brookings Papers on Economic Activity* 1987 (3), pp. 783-831.

22. Wesley M. Cohen, Richard Florida, Lucien Randazzese and John Walsh, "Industry and the Academy: Uneasy Partners in the Cause of Technological Advance," in Noll, *supra*, pp. 171-99.

23. *AUTM U. S. Licensing Survey: FY 2004,* Association of University technology Managers, 2005, available at www.autm.net/events/File/FY04%20Licensing%20Survey/04AUTM-USLicSrvy-public.pdf.

24. *Ibid.*, p. 25.

25. *Ibid.*, pp. 13, 21.

Political Impediments

The organization of electoral systems, the legislature 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 would be undertaken anyway, regardless of the policies of government, but instead should focus on projects that otherwise would not be undertaken. 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, government is not likely to be inclined to orient R&D policy in this way for three reasons.

Optimal Failure. One political impediment to efficient government R&D arises because an optimally designed R&D program is likely to support many failures. The ultimate success of R&D in producing useful innovations is inherently uncertain, and this uncertainty is perceived as a cost to private innovators. Hence, the failure rate will be higher among borderline projects that policy hopes to induce than among purely privately financed projects. A program that has a high incidence of failure is vulnerable to attack on the grounds that it is inefficient. Supporters of a program face a difficult task in convincing constituents that a program is effective if it has many failures. 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 commercial success is very likely and that are likely to be privately supported regardless of policy. Precisely this phenomenon apparently has arisen in the federal Small Business Innovation Research (SBIR) program, where the net effect of SBIR grants on R&D in small firms is not statistically

significantly different from zero.[26]

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.[27] An example of the prosaic pork barrel in R&D is the use of "earmarking." Earmarks are specific projects that are written into appropriations bills. Earmarks represent the alternative to competitive awards based on merit.

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. An example is 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.[28]

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26. 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," *Rand Journal of Economics* 31(2000), pp. 674-92.

27. Linda R. Cohen and Roger G. Noll, *The Technology Pork Barrel*, Washington: Brookings Institution, 1991, contains several examples of large-scale commercial R&D projects that yielded negative net benefits but nonetheless persisted because of their pork-barrel effects.

28. For a discussion of the rise and fall of the CRADA program, see Linda R. Cohen and Roger G. Noll,„"Feasibility of Effective Public-Private R&D Collaboration: The Case of Cooperative

CRADA rules limit eligibility for these programs to U. S. firms.

Another consequence of the incentive to deliver political benefits is the incentive not to do harm to 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.[29]

Impatience. The third distorting effect of political institutions arises from frequent elections. 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. The effect of this short political time horizon is to create a bias against projects with very long-term payoffs, which works against supporting long-term R&D projects.

Applications to HESC Research

The preceding section applies to HESC research in four ways. First, political polarization creates uncertainty and costly delay in implementing the program. Second, political pressures arise to sacrifice merit in favor of pork barrel as a criterion for granting support. Third, politics favors projects with short-term commercial payoff at the expense of more fundamental, long-

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R&D Agreements." *International Journal of the Economics of Business* 2 (1995): 223-240.

29. William Pegram, "The Photovoltaics Commercialization Program," and Linda R. Cohen, "The Applications Technology Satellite Program," in *The Technology Pork Barrel*, *op. cit.*

term projects with much larger expected future payoffs. Fourth, the quest for geographic economic advantage can lead to an inefficient bidding war across jurisdictions.

Political Controversy and Policy Uncertainty

Due to continuing political controversy, agencies that support HESC research and organizations that undertake it are likely to experience continuing challenges to their way of doing business, creating legal costs and highly bureaucratized means to assure accountability. These challenges come from many sources. One is litigation that seemingly states 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 or destroy the program.

In California, two lawsuits were filed to prevent CIRM from making any grants.[30] These lawsuits claimed that Proposition 71 was an unconstitutional delegation of spending authority to a body that is not adequately controlled by elected officials. In both cases, plaintiffs lost at trial,[31] but the appeals process is still under way. A victory in either case would kill CIRM by eliminating its process for making grants, but such an outcome always was regarded as unlikely. Despite the dubious legal merits of these challenges, they have imposed substantial costs and delays on the California program. Much of the early effort of CIRM's leadership was devoted to

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30. *People's Advocate v. Independent Citizens Oversight Committee* and *California Family Bioethics Council v. California Institute for Regenerative Medicine*, Consolidated Pleading Cal. No. HG05 206766, decision at www.cirm.ca.gov/pressreleases/pdf/2006/04-21-06.pdf.

31. See www.findarticles.com/p/articles/mi_m0EIN/is_2006_April_22/ai_n16131786 .

fighting these lawsuits, and in the interim CIRM was unable to sell bonds and to spend more than a token amount on grants, delaying the program by up to two years.

Meanwhile, the California state legislature is considering a state constitutional amendment that would require open public records and meetings in making grants.[32] The amendment is a work in progress, so its ultimate form (if it passes) is uncertain; however, its history sheds light on the political environment in which a state constructs a basic research program. The original version of the amendment would have required open records and open meetings for all aspects of the CIRM grant-making process, which would have prevented blind peer review of research projects. The bill has been watered down, and now it would preserve blind peer review, but it would impose the following requirements.

> "any 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 ICOC."[33]

The parallel is to require that grant proposals to the National Science Foundation be subjected to

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32. Updated reports on the progress of the bill can be found at the state legislature web site at info.sen.ca.gov/cgi-bin/postquery?bill_number=sca_13&sess=CUR&house=B&site=sen.

33. At info.sen.ca.gov/pub/bill/sen/sb_0001-0050/sca_13_bill_20050531_amended_sen.html.

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 increase 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 of their work decades in the future.[34]

The response of the California legislature to the passage of Proposition 71 illustrates both a short-term and long-term problem for constructing state analogs 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 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.

The constraints on HESC research that have been imposed by the federal government are still another source of uncertainty for state-sponsored programs. While President Bush issued a public statement requiring that no federal funds be spent on any unauthorized HESC research, the legal requirements that have been created by this statement are unclear. Federal agencies have

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34. For an illustrative example of the latter, see Roger G. Noll, "Einstein's Interoffice Memo." *Science* 309:5740 (September 2, 2005), pp. 1490-1.

interpreted the President's statement as requiring that they develop accounting procedures to carry it out. Like other rules regarding expenditure of federal funds, the penalty for violation is repayment of the grants that somehow were used for HESC research and loss of eligibility for future federal support. In short, the penalty is Draconian. Thus, potential recipients of grants from the federal government that might apply for grants from state agencies that sponsor this research will need to be virtually certain that their system satisfies all subsequent authoritative federal auditors of their activities that this federal directive has been respected. Otherwise, the potential cost of accepting state HESC grants is huge compared to the likely magnitude of financial support from them.

How potential recipients of HESC research grants answer these questions is important not only to the institution undertaking research, but also to the state that is supporting federally prohibited HESC research. If an entity is found to violate the federal rules, it is very likely to be devastated both financially and as a research center, thereby undermining its ability to perform the state-supported projects and, more generally, to serve as an economic magnet.

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 NIH 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."[35] While all agree that direct

35. The NIH's statement about how to assure that federal funds are not spent on prohibited stem cell research are at stemcells.nih.gov/info/faqs.asp#both.

expenditures on prohibited HESC research can not 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 Cicular A-21.[36] 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, so that agencies are attempting 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 grey 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

36. The circular is posted at www.whitehouse.gov/omb/circulars/a021/a21_2004.html.

research, or would these 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 it 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 depreciated? If universities use indirect cost recovery 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 HESC research if any part of their salaries are 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 a portion of the building (but not all) is incorporated in the indirect cost pool of the university?

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 institutions 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 rules[37] – is potentially quite costly, because it prevents a research institution 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 government may prefer to take some chances 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, all else equal, will obtain more research output per dollar spent, and thereby be more likely to achieve both the scientific and

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37. 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. See, for example, *Report of the Defense Science Board Task Force on Defense Acquisition Reform*, July 1993, Office of the Undersecretary of Defense for Acquisition, p. 3.

economic objectives of the state program. Because the state, but not research entities, value the economic spillover effect of the research program, they will place more value on accepting risks. Second, some federal funds at stake in undertaking state-sponsored HESC work are not likely to be viewed by the state 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 average risk per project perceived by the state to be lower than the risk perceived by each institution.

For these reasons, tension may develop between the protocols recommended by the state for complying with federal rules and the protocols research institutions would prefer. Likewise, less prestigious institutions are likely to be more risk-taking 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.

Most likely, the Bush Administration is not likely to resolve the vagueness in federal rules. Because of the polarization of opinion about HESC research and the natural desire of congressional Republicans not to pick a fight with their President, Congress is not likely to pass a law that either lifts the ban or establishes rules that produce clear answers to the questions about prohibited activities that were posed above. Moreover, even if such legislation does pass, the President has said he will veto it. Consequently, the practical meaning of the federal directive, if it ever is made clear, most likely will emerge from a long series of court cases in which either

opponents of HESC research file *qui tam* lawsuits against research institutions or research institutions appeal decisions in the field by aggressive federal auditors.

The last political factor to be taken into account is the likelihood that the current ban will not survive the Bush presidency. Most politicians who are regarded as likely to run for the presidency in 2008 support at least some limited role for HESC research in federal R&D policy, including many Republicans. Because the federal ban was created through a speech, it can equally easily be dismantled. 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 National Institutes of Health (NIH) begin to treat HESC as just another research tool, NIH immediately will become the dominant player is this research. With a $30 billion annual budget, NIH quickly can dwarf the spending of all state programs, and in so doing relegate the latter to relatively unimportant fringe programs. State political leaders, then, can avoid exposing themselves to the polarized politics of HESC research by ignoring it. At the same time, if states and research centers can get a research program up and running quickly, they can 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.

Pork Barrel

All policies are in danger of being seriously distorted by the forces of distributive politics. Pork barrel programs, in particular, are federal expenditures on projects that are selected in substantial measure on the basis of the extent to which they increase the wealth of specific,

narrow constituencies. Elected political officials and their agents in agencies that pick projects have an incentive to use expenditures to gain support or to reward past support from groups on the receiving end of grants and contracts.

Some programs are designed to encourage the pork barrel influence. These programs typically involve authorizations or appropriations bills that fund specific activities. In the research part of the budget, these are 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.[38]

Despite the presence of earmarks in agency research budgets, 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.[39] 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 program, the breeder reactor program, and the space shuttle.[40]

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38. See, for example, Office of Management and Budget, *Analytical Perspectives: Budget of the United States Government Fiscal Year 2006,* 2005, p. 63.

39. *Ibid.*, p. 61, 63.

40. See Cohen and Noll, *The Technology Pork Barrel, supra.*

The design of a research program affect the extent to which it is influenced by distributive politics. The first important requirement is that projects are selected by the agency, and not by the legislature. The second important requirement is that the enabling legislation requires that peer review by experts is a mandatory part of the project selection process. The third important 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). Whereas 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 then 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 how funds could be awarded by merit without giving a large proportion of the money in this way.

The National Institutes of Health (NIH) are designed in a similar fashion to the NSF, with one major exception. Unlike NSF, NIH laboratories undertake a significant share of the research that is supported from the NIH budget. Likewise, the Department of Defense, the Department of Energy, and the National Aeronautics and Space Administration also spend a substantial portion of their budgets on 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. But 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 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 design of the California Institute for Regenerative Medicine provides an interesting example of an agency that was constructed to be influenced by the practical significance of research, but protected against degeneration into pork barrel.[41] CIRM potentially could suffer from the influence of distributive politics. CIRM was created by a ballot initiative, and 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.[42] Plausibly some beneficiaries of the program, which are bio-

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41. The text of Proposition 71 is at www.voterguide.ss.ca.gov/propositions/prop71text.pdf.

42. The seminal work on the initiative is Thomas Romer and Howard Rosenthal, "Bureaucrats versus Voters: On the Political Economy of Resource Allocation by Direct emocracy," *Quarterly Journal of Economics* 93 (1979), pp. 563-87. For a recent treatment with many examples, see Elizabeth R. Gerber, *The Populist Paradox: Interest Group Influence and the Promise of Direct Legislation*, Princeton: Princeton University Press, 1999.

technology firms, university researchers in biological sciences, and venture capitalists who specialize in biotechnology, were the forces behind the proposition and designed CIRM as a program for enriching 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. While the initiative obtained considerable financial support from biotechnology and venture capital firms, the financial support for the proposition was much broader than this – and did not include any significant participation by researchers.[43] Some of the major donors to the campaign for Proposition 71 were from California biotechnology or venture capital firms, but of these only people associated with VC firm Kleiner Perkins were among the largest donors. Likewise, among disease advocacy groups only the Juvenile Diabetes Fund was a large contributor. Several major donors, including two that contributed over $1 million each, were from outside California, and therefore could not receive direct financial payoffs from the program.

Proposition 71 set up the CIRM, which was designed to enable industry and disease advocacy organizations to be influential but not dominant. The governing board is called the Independent Citizens Oversight Committee (ICOC), which has 29 members who are selected to represent a variety of constituencies: nine from universities (five of which are from UC campuses with a medical school), four from other research institutions, ten from patient/disease

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43. For details about the contributors to the Proposition 71 campaign, see Roger G. Noll, "The Politics and Economics of Implementing State-Sponsored Embryonic Stem Cell Research," in Aaron D. Levine, *States and Stem Cells,* Policy Research Institute for the Region, Princeton University, 2005, at region.princeton.edu/media/pub/pub_xtra_19.pdf.

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 that have 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 27 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. Several disease advocates 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, one for reviewing facilities proposals, and one for 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 authority..."[44] Final decisions about grants and standards rests with the ICOC.

The Scientific and Medical Research Funding Working Group has 23 members, including seven disease advocates from the ICOC but fifteen scientists who are "nationally recognized in the field of stem cell research."[45] Only the fifteen scientists are involved in evaluating the

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44. Section 125290.50(e)(3).

45. Section125290.60(a)(2).

scientific merit of proposals.[46] The same procedures for peer review and technical assessment is applied to basic research, therapy development and clinical trials.[47]

The Scientific and Medical Research Facilities Working Group has eleven members, six of which are also members of the Research Funding Working Group and four of whom are "real estate specialists" who can not have any financial interest in the construction of any facility that is funded by CIRM.[48] Proposition 71 does not spell out clear procedures for making decisions in either case, so it remains to be seen whether these, two, 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 is one reasonable 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. Here the solution is to have a very large organization that represents many interests, some of which are likely to be conflicting on at least some issues as a means of diluting the ability of any one interest to control allocations in a self-serving manner. The 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.

A final feature of CIRM is that it will not undertake research in-house. By contrast, the

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46. Section 125290.60(c)(1).

47. *Ibid.*

48. Section 125290.65(a)(2).

New Jersey HESC program establishes a new state research institution, jointly operated by two state universities, to undertake the research.[49] The New Jersey structure is likely to be more responsive to legislative priorities, for better or for worse.

The Quest for Geographic Advantage

The political sources of a desire to obtain geographic advantage are similar to the political sources of pork barrel expenditures, but in one way are even more conducive to inefficiency. Pork barrel projects create some losers within a state, which partially counteracts the political benefits of delivering uneconomic projects to favored constituents, whereas 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. 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 balancing of representation mitigates the tendency of each state's congressional representation trying to advantage their state through federal subsidies. While nations engage in international competition for research-intensive industry, 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, the federal government (but not a state) is further constrained by international agreements that

49. See announcement at www.state.nj.us/scitech/stem_intro.html.

limit subsidization as an instrument for biasing the flow of trade.

Because the federal ban on HESC research is unlikely to survive the Bush Administration, the opportunities for a state to obtain geographic advantage by initiating its own program are circumscribed. While the California program is at a scale that might have conferred such an advantage ($300 million is about ten percent of total federal biomedical grants to California institutions), the litigation against CIRM has delayed the program. If CIRM projects can begin, say, in summer 2007, and federal support begins in summer, 2009, the ability of CIRM to acquire a substantial first-in advantage for California is certainly debatable.

Short-Term Payoffs

Another problem facing state-sponsored HESC programs is that R&D projects with commercial interest may be over-emphasized at the expense of more fundamental, long-term projects with larger expected payoffs. The necessity to seek re-election causes elected officials to seek short-term results for which they can claim credit to their constituents. 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.

The Intellectual Property Regime

In February 2006, CIRM announced its proposed policies regarding intellectual property

rights in the results of research that it sponsors in non-profit institutions.[50] Final policies will be adopted after these proposals are reviewed, and policies regarding for-profit grant recipients will be announced later. The proposed policy requires that grant recipients give 25 percent of royalty incomes in excess of $500,000 from intellectual property that is derived from CIRM projects. This proposal would cause CIRM's IP regime to differ from the federal program as created by Bayh-Dole, which involves no sharing with the federal government.

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 either directly through licensing the IP from CIRM's projects or indirectly through requirements on firms that produce commercial products from CIRM projects to sell these projects at discounted prices in California.

The pressure for local advantage and short-term payoffs can distort a state's policies regarding IP arising from the research that it sponsors. Advocates of HESC research sought public support by claiming that it will bring therapeutic benefits and financial payoffs. These claims might create unrealistic expectations about the prospect that the IP from HESC research can be used to bring immediate economic and financial benefits to a state.

As discussed above, the principle policy of the federal government regarding IP rights from federally sponsored research is the Bayh-Dole Act of 1980. Although the jury is still very much out on whether the net effect of these changes has been positive, the one obvious result is that several leading universities have established very effective technology transfer offices that

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50. "CIRM Intellectuial Property Policy for Non-Profit Organizations," available at www.cirm.ca.gov/policies/pdf/IPPNPO.pdf.

generate substantial income from the research results of their faculty. Nevertheless, even among the successes, revenues from licensing are much smaller than research expenditures. For example, in 2000 the University of California system spent almost $2 billion on research but received $74 million in licensing income.[51] Nationally, all colleges and universities now receive about $1 billion in licensing income, but spend about $40 billion on research and $20 billion on biomedical research.[52] These facts should give pause to state officials who see a potential financial bonanza in the IP arising from state-sponsored HESC research. The licensing income derived from stem-cell research is likely to be a small fraction – less than five percent – of the costs of that research, and is likely not to be substantial for many years.

Some state universities have experienced political backlash against successful commercial ventures that arose from their research. One form of backlash arises from the belief that universities should not seek to charge state businesses to use the product of research that was funded partly by taxes that were paid by those same businesses. A similar backlash is the view that, regardless of revenues, state universities should never sell rights to their intellectual property to entities outside the state. Still another form of backlash is the view that generating revenues from intellectual property is a fine idea, but that the state, not the university, should be the beneficiary. Adherents of this position believe that the university's budget should be cut by

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51. See www.technologyreview.com/articles/01/09/scorecard0901.asp for a summary of the revenues from the most effective university licensing programs.

52. U. S. National Science Foundation, *Science and Engineering Indicators 2004* and *Academic Research and Development Expenditures: Fiscal Year 2003*, both available at thee NSF web site, www.nsf.gov.

an amount equal to its income from its research properties.

In California, some state political officials believe that HESC research is potentially a huge source of revenue for the state, and favor assigning all or part of the IP rights to research supported by CIRM to the state. The proposed constitutional amendment that is being debated by the California legislature sets forth an objective for California to recover from royalties all of the expenditures it has made through CIRM. Others have proposed that CIRM keep some of the royalties to support further research after the money from the bond issue is spent. 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 are likely to prove to be highly unrealistic, even if the state captures all of the royalties. Yet 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 problem. 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 undertaken 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 that are available then. 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 of 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 idea that royalties can recover the initial cost of CIRM or finance CIRM in the future faces another problem. If the state seeks to capture the equivalent of $300 million annually from royalties, most likely all royalties would have to go to the state. If all royalties go to the state, institutions that receive grants will 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, to implement this goal is likely to 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 and knowledge of the bio-technology industry that is possessed by research institutions, this approach is not likely to be very effective in actually producing 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 accept CIRM grants, rather than grants from 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 can not 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 relatively easily incorporate state supported HESC research into the technology transfer system that they already have in place. One potential problem is that 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 from royalties from federally sponsored research projects, the federal government might decide that these offices can not be used to commercialize IP rights from state-sponsored HESC research.

Notwithstanding this problem, states probably should not attempt to differentiate HESC research from other bio-medical 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.

Conclusion

States have entered the business of sponsoring HESC research because of an unusual contemporary political controversy. States in which most people oppose the President's policies on stem-cell research 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 at best, but is all the more difficult because these research programs are narrowly focused and highly controversial.

The best advice to states that are embarking on these programs is not to 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 behave a great deal differently than they are required to behave from other, much larger sources of funds. As an illustration, Stanford University receives as much revenues in a year as CIRM is likely to spend on external grants over a decade. The lesson here is that CIRM can not expect to have much leverage over either Stanford or the entities that support it. Any attempt to change the way that research organizations do business with an annual expenditure of $300 million is doomed to failure.