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The Politics and Economics of Implementing State-Sponsored Embryonic Stem-Cell Research

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Abstract

Human embryonic stem cell research has become both controversial and salient as a political issue. Limitations on federal support for this research that were announced by the President on August 9, 2001. These limitations have given rise to several state-sponsored research programs, most notably the $3 billion program enacted by California voters as Proposition 71 in November 2004. This essay examines the problems that states face in implementing a successful basic research program. Some of these problems are shared with other research projects having commercial potential, such as a the danger of "pork barrel" effects and the problem of accommodating confidential peer review, which is necessary to obtain candid assessment of research proposals, with the special problems associated with this program: a narrow focus (which really is an example of the otherwise inefficient practice pf "earmarking" government research expenditures), an unresolvable state of bitter public and political controversy, and an unrealistic perception by political leaders and the general public that this research will produce substantial short-run therapeutic results and financial payoffs. This essay examines these problems in detail and evaluates the extent to which the organizational structure of the California Institute for Regenerative Medicine is likely to be an effective response to these problems.

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The appropriate scope of research on human embryonic stem cells (HESC) is a highly polarized science policy issue that has led divergent policies among states and the federal government. The federal government operates under a presidential directive to prohibit the use of federal funds to support HESC research except on stem-cell lines that were developed before the directive was issued.[1] Because of contamination and other problems with these lines, the federal policy is widely regarded as severely inhibiting HESC research. Meanwhile, led by California's program to spend about $300 million annually for ten years, several states are establishing state-sponsored research programs to support HESC research, while Louisiana and South Dakota have passed legislation that bans HESC research and other states severely restrict such research or are considering bans.[2]

The motives for state-sponsored HESC research programs are diverse, ranging from

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

2. In the six months after the California initiative, smaller state research funds were passed in Connecticut ($10 million annually) and New Jersey ($6.5 million annually), and several others considered such legislation, including proposals in New York and Pennsylvania to spend $100 million annually. See grassrootsconnection.com/state_stem_cell_resources.htm and www.ncsl.org/programs/health/ genetics/embfet.htm for continuing updates about the status of state legislation for and against stem cell research.

philosophical disagreement with the values underpinning the President's position, to practical desires such as seeking effective treatments for several important and heretofore incurable diseases, gaining strategic advantage for a state's higher education and biomedical industries, cashing in on royalties from patents arising from the research, or reducing state spending on medical care.

As the California experience reveals, setting up a functioning research program is not easy. Establishing an effective state program requires overcoming substantial political and organizational problems. While spending a great deal of money is easy, spending money effectively without causing a political backlash is difficult. Moreover, opponents of HESC research do not go quietly in the night once legislation establishes a program. Instead, they continue to use all means at their disposal – litigation, political participation, and public demonstrations – to stymie implementation of the program.

The purpose of this essay is to describe some of the primary obstacles to implementing a successful HESC research program in the current legal and political environment. While many potential pitfalls stand in the way in establishing an effective program, I focus on a few that I believe are especially important. These are: (1) the uncertainties associated with federal policy and politics; (2) the difficulties associated with using government grants, contract and loans to attract industry by promoting developmental research; (3) the organizational challenges in creating a merit-based method of providing financial support within the institutional constraints of a government contracting agency; and (4) the troublesome issue of the assignment of the intellectual property rights arising from state-sponsored research projects.

Whereas none of these problems is insurmountable, state governments have little or no

experience in dealing with them, and as a result may be prone to make mistakes in designing such a program. Moreover, when programs are thrust upon a state through a ballot initiative, as occurred in California in 2004, unprepared state officials are likely to find themselves tasked to deal with these problems on a fast time schedule, further increasing the probability of a serious mistake in program implementation. In California, the otherwise very sophisticated and thorough Proposition 71 that created the California Institute for Regenerative Medicine (CIRM) really only dealt with items (2) and (3) above. Because of mandatory deadlines in implementing the proposition, the state was given approximately six months to solve problems (1) and (4). Moreover, opponents launched a constitutional attack on the proposition's solution to problems (2) and (3) that certainly has a non-zero probability of success. This litigation, if successful, would prohibit any research program (not just the HESC program) from creating a management structure that resembles the structure of the principle federal agencies that support basic research. This structure was carefully constructed to minimize the influence of interest-group politics. The remainder of this essay fleshes out these issues and makes suggestions about how to avoid the major pitfalls.

Background: The Politics and Economics of R&D Programs

To set the stage for the four major institutional design issues in implementing a state-sponsored HESC research program, this section summarizes the key economic and political factors that influence the performance of R&D policies. An important feature of national politics is that government research programs rarely achieve high political salience, and so rarely are created and sustained because of widespread grassroots support for them. Most scholars who

study the issue agree that the federal government never has had a coherent technology policy, but 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 in and/or profit from 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 participation in an arms race – continued large expenditures on R&D that was related to national defense for the purpose of maintaining military superiority over a competing great power. In the late 1980s, as the Soviet Union reformed itself, become less threatening, and then collapsed, support for defense-related R&D waned. As a result, in every major area of R&D except biological sciences, real federal R&D expenditures declined, and the federal government's share in U. S. R&D effort subsequently has fallen roughly in half.[3]

Another area of relatively high political salience in the United States is health care. Although the widespread interest in health policy is less directly tied to R&D than is the case for defense, nonetheless the high salience of health care has sustained substantial growth in federally

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3. For more details about federal research expenditures since the end of 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.

supported research in biological sciences since the demise of the Soviet Union. Thus, HESC research is one category of practically significant basic research in biological sciences that derives residual support from the widespread beliefs that science is useful in creating more effective treatment for illnesses and that the federal 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 the presence of a salient political issue among a significant minority of the population that strongly opposes this research. Whereas a largely (but not exclusively) religion-based opposition to the validity of many areas of scientific inquiry is an enduring presence on the political scene, it very rarely has taken the form of organized opposition to undertaking research. And even the targeted opposition of the past, such as against research on nuclear energy, recombinant DNA, and animal experiments, has not enjoyed as intense, widespread support as the attack on HESC research.

The immediate implication of the sources of salience of HESC research is an underlying unusual feature of its politics: intense polarization in that a relatively large number of people who place high priority on all forms of research that holds promise of creating effective new treatments pitted against a smaller but still large number of people who accord equally high salience to adopting policies that would prohibit this research. Intense polarization of this form means that battles are never won because losers will not accept defeat. The rise of state programs to support HESC research, and the reaction of its opponents to use numerous legal and political means to stop it, illustrates what is likely to be a long-term characteristic of this policy arena.

Long-term polarization is an unusual feature of HESC research, but in addition this work also will be affected by the standard set of economic and political factors that are common to all government-sponsored research programs. Some of these features arise from the unusual economics of R&D, and others reflect distortions arising from distributive politics than can occur in all policy arenas.

The key economic fact about research is that its product is information, which is an example of a public good in that once new 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 the information.[4] By contrast, ordinary economic goods are rivalrous private goods in that, say, if one person makes and consumes a hamburger, a second person who also wants to consume a hamburger must bear separately the costs of making one. Moreover, information is difficult to privatize in that, even in the presence of strong intellectual property rights, the creation and exploitation of new knowledge gives other clues that enable them to draw inferences about the new knowledge and how it might be used without violating those property rights.

These features of new knowledge generally 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 reproduce knowledge discovered but protected by others and to "invent around" the original discoverer's intellectual property rights by creating the closest thing

4. See Paula E. Stephen, "The Economics of Science," *Journal of Economic Literature* 34 (1996), pp. 1199-1235.

to a copy that is sufficiently different that it is non-infringing.[5] The presence of these inefficiencies creates a policy dilemma for officials.

Like other public goods problems, one solution to under-investment in R&D is to subsidize it. Unlike most public goods, under-investment in R&D also can be ameliorated by strengthening intellectual property (IP) rights. Both increase the financial rewards to R&D oriented towards breakthrough innovations, the first reducing the expected financial reward that is necessary to induce R&D effort and the second by reducing competition through copying. Strong IP rights also increase the cost of (and thereby reduce the incentives for) copy-cat R&D, as can subsidy programs if they are based on the novelty of the proposal and if the amount of subsidy is available is sufficiently low that only the most novel projects can be supported. Both of these policies create a dilemma because they also impose costs.

IP protection generates both social benefits and social costs because it simultaneously increases the incentive to produce new knowledge while it reduces the likelihood that inventions will be maximally exploited to produce economically useful products.[6] Most fundamentally, the

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5. See Kenneth Arrow, "Economic Welfare and the Allocation of Resources for Invention," in *The Rate and Direction of Innovative Activity*, New York: National Bureau of Economics Research, 1962; 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.

6. 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

incremental cost of allowing people to make useful applications of new information is zero; however, if the price of using new knowledge is efficiently priced at zero, the creator of the knowledge can not recover the cost of creating it. On the one hand, IP law in essence privatizes a public good, enabling the creator to charge for (or to deny) its use, thereby creating an income stream that may recover or exceed the innovator's cost of creation. On the other hand, either requiring that people either pay for the right to exploit the knowledge or allowing a holder of intellectual property to prevent others from exploiting it reduces the social benefits that can be derived from a discovery.

Strong IP protection also can inhibit innovation more than it encourages it if the nature of the underlying technology is complex, so that innovations are sequential – that is, substantial improvements in the ultimate utility of one piece of knowledge is conditional upon the creation of other pieces of new knowledge. As an example, a British commission report on patent policy provided the example of the use of genetic information to create effective new malaria drugs.[7] Over 30 distinct and plausibly valid patents apply to genetic information that potentially could come into play to create an effective vaccine against malaria. According to patent law, a researcher must obtain a license to all of these patents before undertaking research on creating 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

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Electron Press, 2004, at http://www.bepress.com/leveque/.

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

value on their technologies."[8] The difficulty of obtaining all of these licenses on reasonable terms is a substantial barrier to entry in vaccine research.

Both IP policy and subsidy programs necessarily also create significant implementation costs. One cost arises from the process of evaluating the novelty of the information, as in determining whether an innovation deserves a patent or whether a grant proposal is meritorious. Another is enforcement cost. Another cost of both approaches is enforcement costs. For IP, enforcement costs arise from the use of the courts to penalize those who infringe. For subsidies, enforcement pertains to accountability in spending public funds.[9] Enforcement costs in grant programs arise from mandatory use of more complex accounting rules than private entities normally would adopt for their own purposes regarding how grant money can be spent, backed up by the threat of court proceedings and the loss of further eligibility for contracts if the rules are violated. Holding fixed the total expenditure on these policies, one can devote more dollars to assessment and enforcement (thereby sharpening the incentive to undertake R&D on the most valuable projects), but at the expense of spending fewer dollars on R&D and more on assessment and compliance.

Whether the beneficial effect of stronger IP rights offsets the harmful effect is an empirical question that turns, among other things, on the responsiveness of innovative effort to the additional financial reward that is created by granting IP rights. The conditions under which

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8. *Ibid.*, p. 144.

9. 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.

IP protection is most likely to produce net social benefits are: (1) innovative effort is highly sensitive to financial rewards; (2) multiple 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, and demand for the innovation is not particularly responsive to price at prices that are likely to emerge.

Because subsidies and IP serve similar purposes, they can be regarded as substitutes. In general, a higher level of subsidy requires less strong intellectual property rights to achieve the same increase in the incentive for commercial R&D. In the case of academic research, the goals of scholars attenuate the degree of substitutability between subsidies and intellectual property. If the primary goal of basic researchers is career advancement within the scholarly community, they have no direct incentive to disseminate the product of their research to those who would find commercial uses for it. If only subsidies for fundamental research are available, the incentive of researchers is to attract as many grants as possible, and if the criteria for making grants is past and potential scientific achievement, scholars will focus all of their energy on research productivity, and not on potential for commercial exploitation.[10]

Prior to 1980, each federal agency developed its own rules and procedures for assigning intellectual property rights arising from their sponsored research. In many cases federal agencies required that the results of research be either the property of the government (the common practice in defense for national security reasons) or placed in the public domain. A major

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

exception was publications, which were allowed to be copyrighted. Thus, private publishers of scholarly journals and researchers writing monographs could profit from publications that were based on the results of federally financed research.

The criticism of the old system was threefold: it led to a patchwork of procedures the unnecessarily increased the complexity the university's faced in managing their intellectual property; it created an artificial distinction between patents and copyrights, which became more important and more arbitrary with the rise of academic computer science; and it blunted the incentive for universities and research institutions to attempt to find commercial applications of their research.

The primary policy instrument that the federal government has used to create an incentive to commercialize new research knowledge is the Bayh-Dole Act of 1980, which allows recipients of federal research grants to obtain and to commercialize IP rights from work supported from federal funds.[11] Giving IP rights to scholars who produce fundamental research and their employers creates the opportunity for financial gain if discoveries are commercialized, and thereby could cause scholars to redirect their research towards socially more important problems and to put forth greater effort to disseminate their discoveries to commercial entities.

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11. For a comprehensive evaluation of the Bayh-Dole Act and other policies that have encouraged universities and other basic research institutions to seek IP rights and facilitate commercialization of their discoveries, see 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. This book casts doubt on whether the Bayh-Dole Act has produced economic benefits.

But the effect of giving scholars rights to commercialize their discoveries also could deflect their attention away from more important fundamental discoveries that can not be protected by intellectual property to lines of research in which results are eligible for intellectual property protection. 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 the prospect for financial gain is a significant factor motivating basic research, then granting IP rights to the former but not the latter will cause a shift in research in favor of the former. Whether this switch is socially desirable depends on the relative amount of social benefit that is likely to be derived from this different fields of basic research. As with commercial R&D, the task of policy makers is to address this issue, and to seek a proper balance or trade-off among these conflicting effects of IP protection.

The effects of the Bayh-Dole Act have not been fully documented, especially its effects on the allocation of effort among different fields of research. But two aspects of its impact have emerged from the research literature. The first is that the Act probably has not had a major effect on the extent to which university research is commercialized. The reason is that licensing intellectual property is not the primary means by which knowledge is transferred from universities to business. Instead, publications, conferences, consultancies and employment of students still account for most technology transfer to business. The second is that Bayh-Dole has caused many universities to set up technology transfer offices that license IP to business. Among the leading research universities, these offices have become a significant source of income, although most universities that receive federal grants do not obtain much revenue in this fashion.

Thus far, this summary of the underlying economics of R&D has abstracted from political factors that also affect program performance. The underlying economics of new information apply as much to political jurisdictions as to individuals: it is socially inefficient, but politically beneficial, to contain the economic exploitation of new knowledge within the jurisdiction that supports its creation. An example is the rules surrounding the Cooperative Research and Development Agreements (CRADAs) that were initiated in the late 1980s, whereby federal government research facilities could enter into joint R&D projects with private partners and the private partners, in return for their contribution to the R&D, obtain the rights to exploit the research results.[12] CRADA rules limited eligibility for these programs to U.S. firms.

Elected officials are of necessity responsive to their constituencies over others, and so seek to base policy decisions on the basis of localized economic benefits. If contiguous jurisdictions use R&D policy to create a market advantage for businesses within each jurisdiction, the result can be both stronger IP protection and larger subsidies than are needed to induce the socially desirable amount of R&D effort. In this case, the programs serve more to redistribute wealth from citizens in general to the beneficiaries of the program than to induce broadly beneficial technological progress.

Politics also can work against focusing R&D policy on inducing socially desirable but privately unprofitable R&D. By definition, a socially desirable policy would not be much concerned about projects that would be undertaken anyway, regardless of the policies of

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

government, but instead would 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. For three reasons, government is not likely to be inclined to orient policy in this way.

First, an optimally designed public R&D subsidy for commercial R&D 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 the borderline projects that policy hopes to induce than among purely privately financed projects. But 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 on R&D in small firms due to SBIR grants is not statistically significantly different from zero.[13]

Second, elected officials are rewarded in part on the basis of the amount of money that is spent on projects within their constituency, regardless of the merits of the project. Like all expenditure programs, public R&D subsidies are prone to "pork barrel" incentives – a systematic

13. 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.

attempt to reward the constituencies of the elected officials who support the program.[14] Federal policies reflect this incentive in the growing use of "earmarking" in the R&D budget. Earmarks are specific projects that are written into appropriations legislation. Earmarks represent the alternative to competitive awards based on merit.

Another consequence of the incentive working on elected officials to deliver benefits to organized groups of constituents is the incentive not to do harm to organized constituents. As a result, 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, government programs in advanced communications satellites and photovoltaic energy were prematurely terminated not because they were failures, but because their success threatened to disadvantage some very large and politically influential firms.[15]

Third, the frequency of elections creates an artificially short time horizon for subsidy programs. Elected officials derive more political benefits from projects that provide payoffs within the time horizon of the electoral cycle. The effect of the short political time horizon is to create a bias in R&D programs against projects with very long-term payoffs, which works

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14. 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 were supported largely because of their pork-barrel effects.

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

against supporting projects with a long gestation period.

Applications to HESC Research

The preceding discussion of the economics and politics of R&D apply to HESC research in four ways. First, political polarization about the validity of HESC research is likely to create significant uncertainty and delay, and thereby vastly increase the implementation costs of the program. Second, at each stage of the R&D process political pressures will seek to sacrifice merit in favor of pork barrel as a criterion for granting support. Third, politics will tend to favor R&D commercially interesting projects 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 a bidding war across jurisdictions. The remainder of this paper will discuss each of these problems.

Political Controversy and Policy Uncertainty

Due to continuing political controversy, agencies that support HESC research and organizations that undertake are likely to experience continuing challenges to their way of doing business, leading to legal costs to defend themselves and highly bureaucratized means to assure accountability. These challenges can come from many sources. One is litigation that, on the surface, raises issues concerning implementation of the program, but that in practice is intended to delay, minimize or even prevent HESC research from taking place. Another is continuing political pressure, as opponents of HESC research and their representatives seek legislation to limit or destroy the program.

In California, two lawsuits have been filed to prevent CIRM from making any grants,[16] and the California Supreme Court has ruled that these cases must proceed to trial. These lawsuits seek to declare Proposition 71 to be an unconstitutional delegation of spending authority to a body that is not adequately controlled by elected officials. A victory in either case would kill CIRM by eliminating the process set up by Proposition 71 for making grants. Much of the early effort of CIRM's leadership is to fight these lawsuits.[17]

Meanwhile, the California state legislature is considering a state constitutional amendment that would require open public records and meetings in making grants.[18] The amendment is a work in progress, so its ultimate form (if it passes) is uncertain; however, its history sheds interesting light on the political environment of the states in trying to construct any 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 gradually been watered down, and now it would preserve blind peer review, but impose the following requirements.

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16. *People's Advocate v. Independent Citizens Oversight Committee*, Cal., No. S131655; 3/23/05; *Californians for Public Accountability and Ethical Oversight v. California Institute for Regenerative Medicine*, Cal.No. S131677

17. Bob Egelko, "State Supreme Court Refuses to Hear Challenge to Stem Cell Research Program," *San Francisco Chronicle*, March 24, 2005, available at sfgate.com/cgi-bin/article.cgi?f=/c/a/2005/03/24/BAGFIBTQC71.DTL&type=science.

18. 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.

> "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."[19]

The parallel here would be to require the issuance of public reviews of grant proposals by the disciplinary panels in the National Science Foundation that recommend funding actions to the NSF administration and, ultimately, to the National Science Board, and that such panels predict the ultimate societal benefits to be derived from each basic research proposal.

The California legislature 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 the nature and purpose of 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

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

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 the President has 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 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 a state's 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. Thus, states have an interest in setting forth minimum standards for compliance with the federal rules.

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."[20] While all agree that direct 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.[21] But these instructions are far from definitive.

Most importantly, the legal status of the President's directive has not been determined. 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 federal officials who implement extramural grant programs. And, 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

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20. 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.

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

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 research, or would these represent the expenditure of federal funds in support of prohibited research? If a university buys equipment with funds from a federal grant, 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 and full title to the equipment has passed to the university? If universities use indirect cost recovery to finance seed grants, 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 are sufficient to assure that federal projects do not cross-subsidize other

projects. NIH has adopted the same principles for segregating cost responsibility between allowed and prohibited research. But the issue of accounting safeguards against cross-subsidization are not clearly the same as preventing all federal funds from being used for prohibited projects. The principal behind A-21 is that the federal government should not pay more than the stand-alone costs of a project. 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 promised federally-financed work also is undertaken as promised. But 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 does seem to ban them from HESC research.

Note that the optimal response to all of these unresolved issues is not necessarily to be as safe from federal reprisal as possible. Complete separation of state-sponsored HESC research from all other activities at the university – the kind of "walling off" that has arisen among firms that engage in government contracting in order to avoid running afoul of procurement rules[22] – is potentially quite costly, not only because it prevents a research institution from capturing economies of scale and scope, but also because it creates barriers to information sharing and

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22. 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.

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 the 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 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 of the 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 federal support for it, 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 out of compliance – especially at the same time. Thus, the portfolio effect will cause the average purely statistical risk per project as perceived by the state to be lower than the risk as 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 vagueness in federal rules will not disappear soon. Because of the polarization of opinion about HESC research, Congress is not likely to be able to legislate rules that produce clear answers to the questions about prohibited activities that were posed above. Likewise, federal research agencies are not likely to issue clear answers to these questions because by doing so they will become targets for congressional investigations and lawsuits challenging their regulations. Instead, the practical meaning of the federal directive is most likely to be derived 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.

If this prediction of a slow, painful process of clarifying the federal prohibition turns out to be accurate, an important policy instrument that is available to a state is to defend its research institutions against these attacks. States could establish plausible interpretations of the federal rules and methods for assuring compliance, and then provide litigation insurance for a grant recipient that complies with these rules. This policy would reduce the extent to which fear of litigation harassment would deter the participation of research institutions in the state program.

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.[23]

Despite the presence of earmarks in the budgets of agencies that support research, in reality the R&D budget has been less distorted by distributive politics than many other areas of federal spending. For example, the 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.[24] 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 strongly distorted by distributive politics. Examples of developmental projects that were continued far longer than they should have been, despite poor performance and largely for pork barrel reasons, were the Supersonic Transport/National Aerospace Plane program, the breeder reactor program, and the space shuttle.

The design features of a 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

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

24. *Ibid.*, p. 61, 63.

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 does a significant share of the research that is supported from its budgets. Likewise, the Department of Defense, the Department of Energy and the National Aeronautics and Space Administration, the other most important supporters of R&D, also spend a substantial portion of their budgets on their own research laboratories. The advantage of substantial in-house research activity 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 that are likely to place more weight on the likely scientific impact of a project. But the disadvantages are, first, that extramural 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 decisions are likely to be influenced by the desire to keep the agency's own labs financially healthy.

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

The design of the California Institute for Regenerative Medicine provides an interesting example of a structure that was constructed to be influenced by the practical significance of research, but protected against degeneration into pork barrel.[25] The potential for a strong influence of distributive politics was present in this program because it was created by a ballot initiative. Because initiatives are costly, well-organized interests are the primary source of ballot measures, and 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.[26] One possibility was that some beneficiaries

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

26. 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.

of the program, which are bio-technology firms, university researchers in biological sciences, and venture capitalists who specialize in biotechnology, would be the forces behind the proposition and would design CIRM as a program for enriching themselves. In reality, this did not occur.

Proposition 71 was written by a real estate developer, Robert Klein, who had no significant 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.

Table 1 lists all the major donors to the campaign for Proposition 71. Several donors were from California biotechnology or venture capital firms, but of these only people associated with VC firm Kleiner Perkins were among the very largest donors. Likewise, only the Juvenile Diabetes Fund among the disease advocacy organizations was a large contributor. An interesting feature about this list is that several major donors are from outside California, and therefore could not possibly receive direct financial payoffs from the program. Examples are Gordon Gund of Princeton, New Jersey, and the Stowers Institute for Medical Research in Kansas City, both of which contributed $1 million to the campaign.

Proposition 71 set up the CIRM, and it 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), and has 29 members who are selected to represent a variety of constituencies: nine from universities (five of which must by UC campuses with a medical school), four from research institutions, ten from a patient/disease

advocacy organization, and four from a commercial life sciences enterprise, which leaves two (the chair and vice chair) without portfolio. The appointment of these members is highly diffused so as 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 another 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.

Table 2 shows the original composition of the ICOC. This list includes twelve representatives from universities. Thus, the ICOC is heavily influenced by universities, but not in control of them. The remaining members are divided among industry, research institutes, foundations and patient advocacy organizations. Several disease advocates are from either business or academe, but most are from disease advocacy organizations.

Beneath the ICOC are three working groups: one for reviewing grant proposals, one for reviewing proposals for facilities, and one for medical accountability standards. These working groups "are purely advisory and have no final decisionmaking authority..."[27] The ultimate decision about both grants and standards rests with the ICOC. Moreover, each working group draws about a third of its membership from the ICOC, including the ICOC Chair and representatives of disease advocacy groups.

The Scientific and Medical Research Funding Working Group has 23 members,

27. Section 125290.50(e)(3).

including seven disease advocates from the ICOC but fifteen scientists who are "nationally recognized in the field of stem cell research."[28] Only the fifteen scientists are involved in evaluating the scientific merit of proposals.[29] The same procedures for peer review and technical assessment by the scientist methods is applied to basic research, therapy development and clinical trials.[30]

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.[31] 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.

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28. Section125290.60(a)(2).

29. Section 125290.60(c)(1).

30. *Ibid.*

31. Section 125290.65(a)(2).

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 New Jersey HESC program establishes a new state research institution, jointly operated by two state universities, to undertake the research.[32] 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 be manifest in either greater subsidies or more IP rights than are necessary to induce socially optimal R&D. This problem is likely to be more pronounced among states than in the federal government for two reasons. First, 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. Second, while nations engage in international competition for research-intensive industry, this competition is less of a factor in federal decisions than interstate

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

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

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 much larger expected future payoffs. The necessity frequently to seek re-election causes elected officials to seek short-term results for which they can claim credit to their constituents, which favors supporting projects promising near-term commercialization. In addition, to the extent that state economic advantage plays a substantial role in implementation, 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. Of course, this effect is partially mitigated by the tendency of commercial bio-technology to locate near university research centers. Nevertheless, political incentives work to cause the division of expenditures to focus on short-run employment and investment effects, and these are strongest for end-stage projects.

This problem can be manifest either more generous subsidies for large, established entities at the expense of new, smaller ones, or as a reluctance to make rewards in highly

competitive areas for fear of being accused of picking winners. For basic research, this bias means spreading support more evenly among universities, non-profit research organizations, and commercial enterprises than is warranted by the merits of proposals. For commercialization research, this bias means emphasizing established biomedical firms (with many employees and stockholders) over start-ups. The pork barrel incentive also could mean restricting clinical trials to within the state or to firms that will manufacture HESC treatments in the state, even though both make delivering the final product more expensive. Moreover, in bio-technology, innovators and manufacturers are more likely to be separate companies than in the pharmaceutical industry in general, so that this bias also mans favoring large, integrated companies over specialized R&D entities, which are the most likely to locate facilities around major centers of basic research.

The Intellectual Property Regime

The pressure for local advantage and short-term payoffs can distort a state's policies regarding intellection property rights arising from the research that it sponsors. Proponents of HESC research have sought support by claiming that it will bring both therapeutic benefits and financial payoffs to a state. These claims run the risk of raising unrealistic expectations about the prospect that intellectual property rights in the results of 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 expressed in 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 generate substantial income from the research results of their faculty. Nevertheless, for the vast majority of colleges and universities, technology transfer is not an important source of income, and in many cases the costs of obtaining patents and establishing a technology transfer operation have substantially exceeded the revenues. Moreover, 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.[33] 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.

In some cases, state universities have experienced political backlash against successful commercial ventures that arose from their research. One form this backlash has taken is the expression of 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 almost opposite form of backlash is that generating revenues from intellectual property is a fine idea, but the state, not the university, should be the beneficiary. The implication of this position is that the university's budget should be cut by an amount equal to its income from its research properties.

In California, some state political officials believe that HESC research is potentially a

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

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. Proposition authorized a $3 billion bond issue for a ten-year program of research, so the implicit assumption of this proposal is that royalties from CIRM projects will be very large.

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, this proposal not only assumes that the royalties will be large, but that they will begin soon enough to display an average annual expenditure of $300 million.

Both of these ideas are likely to prove to be highly unrealistic, even if the state captures all of the royalties. Yet even is this were feasible, it would be a bad policy in any case.

Allocating the royalties to CIRM to finance more research after the bond funds are spent raises a form of the earmarking problem. Legislating a particular use of a designated component of state revenue is a permanent earmark. The optimal amount of state-sponsored funding for HESC research, or indeed any fairly narrow 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 research in this area a decade hence should be a considered political judgement that is based on the opportunities for useful research that are available in the future. One can imagine circumstances in which HESC research is highly successful and generates enormous royalties, but opportunities for further useful research are not as promising as research in other areas. In this case, it would be a mistake to create a large financial incentive for researchers to

continue to plow a field of low productivity. Likewise, we are one or two presidential administrations away from the day the CIRM funds run out, and the likelihood that the directive against HESC research will remain in place forever is surely less than certain. If a new administration relaxes the rules regarding 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 face another problem. If CIRM or the state expects to capture the equivalent of $300 million annually from royalties, most likely this will require that nearly all royalties go to the state. If so, institutions that receive grants will have no financial incentive to commercialize the IP that arises from CIRM grants. Thus, to implement this goal is likely to require that either CIRM or another state agency actually assume responsibility for acquiring the IP rights – typically, patents – and then licensing them. Because the state does not have the kind of connections to and knowledge of the biotechnology 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 having these institutions be responsible for technology transfer is that the best research institutions already have in place a set of institutions and internal procedures for implementing the system of research exploitation that was created by Bayh-Dole. But because Bayh-Dole is in place, both research institutions and individual researchers anticipate that they will be the beneficiaries of IP rights, not the state. As a result, if states were to claim a substantial fraction of the royalties from innovations arising from CIRM projects, they would in so doing create a disincentive for the best

researchers to accept CIRM grants, rather than grants from NIH or private sponsors.

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 could 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 federal restrictions on using federal funds for supporting HESC research. Here the issue is whether someone in the federal government will decide that royalty income from IP that was the result of federally funded research is part of the "federal funds" that can not be used to support HESC research. Because technology transfer offices are paid in part from the royalties from past 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. Thus, the most reasonable solution is to

mimic the policies of the federal government and to merge the IP activities regardless of the source of the funds. State-sponsored HESC research is not the best 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.

Table 1: Contributors to California Proposition 71

Major Donors (≥$10,000)

Name	*Company*	*$ Amount*
Dick Allen	Dima Ventures	25,000
Gerson Bakar	Filbert Management	50,000
John Garland Bowes	Self-Employed	48,817.08
Sergei Brin	Google	100,000
Brook and Shawn Byers	Kleiner Perkins	710,000
Castle and Cook		150,000
Leslie Charles	Writer/Producer	20,000
Thomas Coleman	Dowing Development	14,000
J. Taylor Crandall	Oak Hill Capital	100,000
Ann and John Doerr	Kleiner Perkins	974,645
William C. Edwards	Not Employed	10,272
John Friedenrich	Bay Partners	10,000
Michael D. Goldberg	Jasper Capital	50,000
John D. And Marcia Goldman	Willis Insurance	25,000
Michael B. Gordon	Meritech Capital	175,000
Gordon Gund	Gund Investment	1,000,000
Brad and Jill Grey	Brillstein-Grey Entertainment	25,000
Eric Greenberg	Innovation Investments	25,000
Robert M. Halperin	Retired	10,000
F. Warren Hellman	Hellman and Friedman	11,000
J. S. Housing Capital		10,000
Juvenile Diabetes Research Fund		500,000
Joanne Kagle	Not Employed	500,000
Kick Law Firm		25,000
Robert N. Klein II	Klein Financial	1,330,756.44
Kevin Kline	Actor	10,000
Steven Krausz	US Venture Partners	25,000
Laurie and Joseph Lacob	KPCB	1,000,017
Steven L. Merrill	Self-Employed	51,041.90
Diane D. Miller	Silverado Winery	11,500
Claire & Noel Perry	Self-Employed	250,000
Barry Porter	Clarity Partners	10,000
George Rathman	Nuvelo	50,000

John S. And Robina Riccitiello	Not Employed	25,520
James and Julie Rooney	Gilead Sciences	30,000
William J. Rutter	Synergenics	50,000
James and Virginia Stowers, Jr.	Stowers Institute for Med. Res.	1,000,000
David Taran	Divco West Properties	25,000
James Tong	Charter Properties	100,000
Jan S. Tuttleman	Tuttleman Family Foundation	25,000
William Unger	Mayfield Venture Capital	50,006.75
Jamie Morse von Heidegger	Monarch International	10,000
Wick-Fisher	Trust	50,000
David and Danielle Zucker	Zucker-Netter Productions	10,000
Janet and Jerry Zucker	Cures Now	55,054.10

Major Loans

Name	*Company*	*$ Amount*
Ann and John Doerr	Kleiner Perkins	1,000,000
Michael B. Gordon	Meritech Capital	100,000
Robert N. Klein II	Klein Financial	1,580,000

Other Large Donors ($1,000 to $10,000)

Name	*Company*	*$ Amount*
Paul Berg	Stanford	2,500
Hoard Birndorf	Nanogen	2,000
Alexandra Bowes	Not Employed	1,000
Margaret Boyer	Artist	4,000
Andrew Brechman	Writer	1,250
Joseph Calahan, Jr.	Calahan Property	5,000
Jamie Constance	Retired	5,000
Jean Douglas	Not Employed	1,000
Michael Dovey		2,500
William H. Draper	Draper International	1,000
Lisa Feintach	Physician	2,000
K. Hovinanian Companies		1,000
Howell Capital		1,000
IF Hummingbird Foundation		1,000
Barbara F. Isger	Retired	7,500
Deepak Kamra	Canaan Partners	1,000

Robert S. Kaplan	Goldman Sachs	2,000
Arthur Kern	Retired	5,000
Gary Lauer	E-Health	2,000
Michael P. Lazurus & Laura F. Kline	Weston Presideo	5,000
Gordon Litwin	Ansall Zaro Grimm & Aaron	1,000
Allen Mendelson	Latham and Watkins	2,500
Julie Newhall	Not Employed	1,000
P&A DMF		5,000
Mary Houle Phillips	Not Employed	2,000
Jing Poon	Asia Standard International	1,000
Mary Dell Pritzlaff	Not Employed	2,500
Project ALS		1,000
Steve Rattner and Maureen White	Quadrangle/DNC	5,000
Robert Reiner	Rob Reiner Productions	5,000
Peter Rosenthal	Self-Employed	1,000
Ray Rothrock	Venrock	2,500
Harry J. Saal	Self-Employed	1,000
Richard and Maryann Schall	Retired	1,000
Jennifer Smith	Not Employed	1,000
Eliot Spitzer	Attorney General NY	1,000
Stanton, Inc.		1,000
Maryanna G. Shaw Stockholm	Not Employed	1,000
Lubert Stryer	Retired	1,000
Basil R. Twist, Jr	Pachamama Alliance	5,000
Roger Walther	Tusker Corp.	1,000
John Weeden and David Davies	Retired	1,000
Wild Horse Entertainment		2,500
A. & M. Winner	Charitable Trust	5,000
Diane B. Wilsey	A. Wilsey Properties	5,000

Source: Official campaign finance records of the Secretary of State of California, available at: cal-access.ss.ca.gov/Campaign/Committees/Detail.aspx?id=1260661&session=2003.

Table 2: Composition of Independent Citizens Oversight Committee for the California Institute for Regenerative Medicine

Name	Affiliation	Position
David Baltimore	President, Caltech	University
Robert Birgeneau	Chancellor, UC Berkeley	University
Keith Black	Neurosurgeon, Cedars-Sinai	Research Institute
Susan Bryant	Dean, UC Irvine Medical School	UC Med. School
Micael Friedman	President, City of Hope	Research Institute
*Michael Goldberg	Managing Director, Jasper Capital	Life Science Business
Brian Henderson	Dean, USC Medical School	University
Edward Holmes	Dean, UC San Diego Medical School	UC Med. School
David Kessler	Dean, UCSF Medical School	UC Med. School
*Robert Klein	Klein Financial Corp.	Chair
Sherry Lansing	Chairman, Paramount Pictures	Advocate (cancer)
Gerald Levey	Dean, UCLA Medical School	UC Med. School
*Ted Love	CEO, Nuvelo	Life Science Business
Richard Murphy	President, Salk Institute	Research Institute
Tina Nova	CEO, Genoptix	Life Science Business
Ed Penhoet	President, Moore Foundation	Vice Chair
Philip Pizzo	Dean, Stanford Medical School	University
Claire Pemeroy	Associate Dean, UC Davis Medical School	UC Medical School
Phyllis Preciado	American Diabetes Foundation	Advocate (diabetes II)
Francisco Prieto	American Diabetes Foundation	Advocate (diabetes I)
John Reed	CEO, Burnham Institute	Research Institute
Joan Samuelson	Parkinson's Action Network	Advocate (Parkinson's)
David Sewell	ALS Association and MLS Society	Advocate (ALS/MLS)
Jeff Sheehy	UCSF Aids Research Institute	Advocate (AIDS)
Jonathon Shestack	Cure Autism Now	Advocate (autism)
Oswald Steward	Reeve Research Center UC Irvine	Advocate (mental health)
Leon Thal	Professor Neuroscience, UCSD	Advocate (Alzheimer's)
*Gayle Wilson	Director, Gilead Sciences	Life Science Business
James Wright	American College of Cardiology	Advocate (heart disease)

*Indicates donor or affiliated with donor.

Source: CIRM at www.cirm.ca.gov/icoc/.