

Proposition 71: Vulgar Democracy in Action
AAAS Annual Meeting
Symposium on Stem Cells and Society: Assessing a Grand Challenge
February 17, 2006

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In 1947, when Congress passed legislation to create the National Science Foundation, President Truman vetoed the bill because it insulated the administration of the proposed agency from direct Presidential control. At issue here was not a simple question of turf or the exercise of power, but a fundamental principle of democratic governance: that publicly funded programs must be ultimately accountable to the public via democratically elected officials. In the decades since Truman's veto, as the nation's investment in research has grown from a few tens of millions to about sixty billion dollars, this principle has never seriously been challenged. Indeed, it is precisely this accountability that has allowed the publicly funded research enterprise to maintain its political legitimacy, productivity, and growth through such crises as the Tuskegee experiment and the death of Jesse Gelsinger, and which has stimulated a considerable beneficial evolution of scientific norms in such areas as protocols for human subjects' research, the treatment of laboratory animals, and the role of gender and ethnic diversity in clinical trials. Democratic accountability, that is, is good for science.

So, in the summer of 2004, when I first read the language of Proposition 71, the "California Stem Cell Research and Cures Act," I was floored. Written and promoted by a coalition of patients' advocates and research interests from the academic and private sector, Proposition 71 was of course a response to President Bush's draconian restrictions on publicly funded embryonic stem cell research. But it was a response that was as extreme in its own way as the President's actions. Proposition 71 would create a new stem cell research institute, funded by public monies raised through a bond issue, that was effectively insulated from all public accountability through a variety of mechanisms, including the creation of a state constitutional right to conduct stem cell research, a ten-year funding entitlement that "shall not be subject to appropriation or transfer by the Legislature or the Governor for any other purpose," and a provision that allowed legislative amendment to the initiative only after three years, only by a 70% supermajority of the California legislature, and only "to further the purposes of the grant and loan programs created by the measure."

Most troubling of all were the proposed mechanisms for accountability, particularly as embodied in the Independent Citizen's Oversight Committee, whose stipulated membership was made up almost entirely of people whose interests were in some way served by goals of embryonic stem cell research. There was absolutely nothing independent about this committee at all. In summary, as I wrote in an LA Times op-ed in October 2004, "Proposition 71 would put stem cell research out of the reach of

democracy—in a move that would seriously undermine the unwritten social contract that exists between government and science in this country.” Conservative political theorist Francis Fukuyama, writing in the *Wall Street Journal* on the same day, was less restrained, asserting that “Prop 71 is a bad idea, not because stem-cell research is morally wrong, but because it represents a huge, self-dealing giveaway of money from cash-strapped California taxpayers to a small group of institutions and companies that will remain largely unaccountable.” A similar position was taken by the Center for Genetics and Society, a California-based NGO with liberal leanings.

Now of course I recognize that questions of political accountability and the governance of science can hardly stack up to the promise of curing disease. Indeed, at one point prior to the election I found myself in the compromised position of having to debate on a radio program one of the promoters of Proposition 71, a Hollywood director named Jerry Zucker, who, if I recall correctly, had a child with diabetes. No doubt I came off as an ivory tower esthete willing to place abstract principle above the alleviation of a child’s suffering.

And indeed, buoyed by a major promotional campaign promising both significant economic and health benefits for the state, and riding the coat-tails of California’s vote for presidential candidate John Kerry, who in fact used the stem-cell controversy as a campaign issue, Proposition 71 gained a 59-to-41 percent majority and became the law of the state. In the process, supporters of Prop. 71 had outspent opponents by about sixty-to-one.

Perhaps it is not surprising, then, that serious scrutiny of Proposition 71 did not begin until the initiative became the law. Three weeks after the election, the *New York Times*, which had supported Prop 71 on its editorial page prior to the election, ran a news story raising questions about governance. By early December, California Democratic State Senator Deborah Ortiz, who chaired the Senate Health Committee and had been a strong supporter of the initiative, began to voice serious misgivings about provisions relating to oversight, conflict of interest, transparency, intellectual property, and the ethical treatment of women who donate eggs for research. On March 17, 2005, Ortiz and Republican colleague George Runner introduced legislation and a state constitutional amendment to redress what they saw as flaws in Prop 71. The legislation would have placed a three year moratorium on multiple egg donations for research, prohibited payments other than reimbursement for egg donations, and required periodic “performance audits” of the California Institute for Regenerative Medicine (CIRM), the research institution created by Prop 71. The constitutional amendment specified strict conflict-of interest requirements for ICOC and CIRM, required open meetings except for scientific peer review panels, and specified measures to ensure both affordability of treatments funded under the initiative, and return of a share of intellectual property revenues to the state. The language of Prop 71 neither assured nor disallowed implementation of these provisions, but in May the ICOC voted unanimously to oppose the constitutional amendments, stating, through a press release, that it “will make it extremely difficult, if not impossible, for scientists to do their jobs, and it will delay critically needed medical therapies.”

The legislation, whose bipartisan supporters included both Planned Parenthood and the California Catholic Conference, ultimately passed both houses of the California legislature before being vetoed by Governor Schwarzenegger last September. Senator Ortiz also decided not to try to put the constitutional amendment on last November's ballot, opting instead to seek concessions directly from the ICOC that would meet her concerns.

Meanwhile, a coalition of fiscal conservatives and religiously motivated stem-cell research opponents pursued litigation to stop the implementation of Proposition 71. While one suit seeks to block action based on the argument that stem cell research violates the rights of embryos, two other suits claim that various provisions in the Proposition are unconstitutional, including exemptions from state conflict-of-interest laws, and the placing of state funds into the hands of an agency that is not under state control. One of the litigants, a non-profit called "People's Advocate," has for years been a powerful voice for the use of public initiatives to reduce public spending in California. It is only slightly ironic, I suppose, that they are now suing to block a public initiative that enables public spending. In any case, while these suits are not expected to be successful in the end, their interim impact has been to prevent the sale of the bonds that would finance the research activities of the CIRM, significantly slowing the institute's start-up process.

The response of leaders of CIRM and ICOC have been fairly predictable, and include an insistence that Prop 71 provides all the necessary provisions and protections to ensure that fiduciary and ethical responsibilities are met, continual reminders that science needs to be free of political constraints, and repeated suggestions that those who would seek to delay the implementation of Prop 71 are consigning sick people to prolonged suffering. For example, in a July 11 press release responding to the lawsuits, CIRM President Zach Hall said, in its entirety: "California's medical research scientists are poised to move ahead and join scientists in South Korea and elsewhere on the forefront of stem cell research. Unfortunately, we are prevented from doing so by special interests whose sole intentions are to thwart the voters' overwhelming endorsement of the science."

I needn't say more about South Korea, but I'll return to the issue of voting for science later. First I want to point out that the politics of implementing Prop 71 should be familiar to anyone who watches the evolution of scientific norms in the U.S., although the process here has been rather compressed. We've seen these dynamics play out in issues ranging from the ethics of human subjects research and animal experimentation to the role of AIDS activists and feminists in influencing research priorities and conduct, to the adoption of appropriate policies for scientific misconduct. First scientists and science advocates claim that there is no serious problem, that the scientific enterprise can police itself and should not be interfered with by non-experts, and that criticism or interference will simply slow the advance of knowledge. Then, under pressure from outside groups and elected officials, the science community negotiates and gradually adapts to a new set of norms and priorities, and finally, those who previously resisted change begin to take credit for having made the changes. This dynamic is only human, I suppose, and is

certainly not limited to science. But since science holds such a privileged place in our society, and since the conduct of science can reasonably claim protection from most types of political interference, I think one can observe a tendency to exploit this privilege and over-apply this claim for autonomy when faced with legitimate problems of governance.

Be that as it may, in June and July of 2005 various ICOC subcommittees approved what were delightfully termed “policy enhancements” that began to respond to concerns of Senator Ortiz’s and others about conflict of interest and insufficient transparency. And in a meeting last Friday, February 10, the full ICOC approved policies aimed at protecting the autonomy and health of women who donate eggs, and providing a mechanism for sharing intellectual property revenues with the state. “These policies are representative of the ICOC’s commitment to ensuring that CIRM-funded research is conducted under the highest levels of public oversight and transparency,” ICOC Chairman Robert Klein said. Senator Ortiz and the ICOC appear still to differ on the strength of ethical and health protections that ought to be ensured for potential egg donors, and Ortiz has introduced a bill that would maximize such protections. Nevertheless, the policies adopted by the ICOC have significantly responded to many of the concerns raised about Prop 71. So the conscious and explicit effort of the authors of Prop 71 to make the initiative immune from political oversight was not entirely effective. Concerned elected officials, the press, and public interest groups compelled, in the formative stages of the initiative’s implementation, a greater degree of responsiveness than I had anticipated.

But, over the longer term, a huge problem remains, and it is not likely to be addressed by the ICOC, by legislators, or by litigation, and this is the question of independent oversight. Now, I want to be clear that I am not talking about simple questions of financial conflict-of-interest here, although according to recent critiques by the Center for Genetics and Society and the *Sacramento Bee*, rules against such conflicts are still insufficiently strong. The more serious problem, however, is also more subtle.

My perusal of the ICOC member biographies suggests that at least 23 of the 29 members have reasons to support embryonic stem cell research from either scientific, institutional, intellectual, financial, or personal perspectives. Most Notably, ICOC Chairman Klein, whose mother has Alzheimer’s and whose son has diabetes, was the principle author and advocate for Proposition 71, and he donated more than \$3 million to the advocacy campaign for the initiative. The qualifications for the chair, which are stipulated in Proposition 71, sound to me suspiciously like a job ad that is wired for a particular candidate: “Documented history in successful stem cell research advocacy . . . experience with state and federal medical legislative processes that must include some experience with medical legislative approvals of standards . . . direct knowledge and experience with bond financing . . .” and so on. Perhaps there is more than one person who fits the bill, but only Klein was nominated by the four government officials—including the governor—empowered to do so by Prop. 71.

Now, compare the make-up of the ICOC with the Human Fertilization and Embryology Authority (HFEA) in the UK, which, among other functions, licenses and monitors all human embryo research conducted in the UK. Quoting from the HFEA website: “To

ensure that the HFEA has an objective and independent view, the HFE Act requires that the *Chair, Deputy Chair and at least half of the HFEA Members* [emphasis added] are neither doctors nor scientists involved in human embryo research . . . HFEA Members bring to the HFEA a broad range of expertise, from medicine to law and religion to philosophy.”

In stark contrast, oversight of CIRM is in the hands of a leader—Mr. Klein—and a group—the ICOC—with little if any critical distance on the enterprise. Rather, they share an interest in moving the science ahead as quickly as possible, both within the laboratory and the marketplace. And remember that the decisions of this group are, by law, insulated from any intervention, oversight, or amendment by elected officials. The prospective dangers of this arrangement derive from a homogeneity of interests informed by irrational exuberance. Proposition 71 provides 3 billion dollars in research funding over ten years for California stem cell researchers. If, during the expenditure of these funds, ethical transgressions occur in the treatment of donors or research subjects, if the promises made in promoting the initiative do not pan out, if scientists funded under the proposition engage in misconduct, if tragedies of the Jesse Gelsinger sort should occur, then, even if the ICOC is able to see clearly what is happening and act decisively and appropriately, it will have zero political or moral legitimacy precisely because its interests are so closely aligned with the research enterprise that it oversees. Moreover, in my view, and consistent with what we know about decision processes, this insular homogeneity of interests can act to cloud judgment and thus increase the possibility that such problems will occur in the first place. Where is the scientific commitment to institutional skepticism that can challenge hidden assumptions and biases? It is absent, and absent by design.

The authors of Proposition 71 clearly saw political openness as a threat to their scientific and medical ambitions. Yet such openness, while often inconvenient, inefficient, and sometimes even highly unpleasant, has been the bedrock of scientific accountability, and thus legitimacy and consistent public support, in the United States in the years since President Truman’s veto of the original NSF bill.

Now of course I understand the obvious response to these sorts of considerations, a response that has been made on numerous occasions by the advocates of Proposition 71. The people support it. They voted for it. What could be more democratic? As a joint statement last March by ICOC chair Klein and Vice Chair Ed Penhoet asserted, the vote for Prop 71 was “not only an expression of hope, but also a vote of confidence that the Prop 71 initiative contains sufficient governance, oversight and accountability mechanisms . . . The voters of California sent a clear message: they entrusted the Institute’s governing board, which is comprised of 29 prominent Californians—leaders in academia, science, medicine, research, patient advocacy, and business—to move forward with the work ahead.”

California voters were bombarded with 25 million dollars worth of promotional promises about how Prop 71 would lead directly to both the cures for terrible diseases and the creation of great wealth. The idea that they were also supposed to be casting a vote of

confidence for the governance regimes surrounding embryonic stem cell science strains credulity to the breaking point. Of course public figures of Klein and Penhoet's sophistication well understand that representative democracy is in part aimed to address a huge weakness of direct democracy—the reality that voters cannot be experts on the intricacies of all policy matters. Thus our system assigns responsibility for formulating broad policies to elected officials, allows time for extended public deliberation about these policies through the legislative process, and assigns policy implementation and oversight to experts and bureaucrats who are accountable to elected officials who are themselves accountable to voters. The idea that an up-or-down vote on Proposition 71 represents a meaningful exercise in democratic engagement with the governance of science is nonsense. In the lexicon of philosopher of science Philip Kitcher, the Prop 71 vote was an exercise in “vulgar democracy.”

I hope I am being clear here that one major long-term danger resulting from this process is a danger to science in general, and embryonic stem cell research in particular. Of course I understand that Proposition 71 itself was a response to what many perceived as a threat to science coming from the Bush Administration. But there is a huge difference here. As ill-conceived and politically motivated as the President's stem-cell-research restrictions may be, they were publicly aired, debated fiercely in public fora, and are open to reversal subject to the will of voters and their elected officials. Similarly, stem cell advocates in California should have worked through the legislative process to advance their cause. While this process may be ungainly and inefficient, in the end it would afford the legitimacy, accountability, and long-term sustainability that both science, and the society that supports and benefits from science, deserve.