Appropriate Collaboration between Industry and Government in the Development of an AIDS Vaccine

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On August 22, 1986, as part of its response to the AIDS epidemic, the Public Health Service (PHS) invited U.S. industrial firms to collaborate with the government in the development of an AIDS vaccine. The framework for the collaboration was outlined in a PHS document entitled, "AIDS Vaccine Development: Private Sector/ Government Collaborative Efforts."[1] This document identified the resources the government is prepared to make available to industry, including patents, facilities, data, and assistance with clinical trials. The overall aim of the PHS proposal was to establish a formal framework for coordinating existing government and private efforts and to foster industry participation in the search for an AIDS vaccine.

An example of private sector/government collaboration is provided in the human trial of an AIDS vaccine approved by the FDA in August 1987.[2] The vaccine, named "VaxSyn HIV-1," is the product of a joint effort between a company called MicroGeneSys and investigators at the National Institute of Allergy and Infectious Disease (NIAID). The collaboration here was quite extensive, with the investigators at NIAID doing the groundwork of isolating a gene for a particular HIV protein which was in turn cloned by MicroGeneSys in order to produce sufficient protein to test as a vaccine. The laboratory animal tests of the product were conducted jointly. The initial trial of the vaccine in humans will be conducted by the NIAID. It is noteworthy that despite such intimate collaboration, it is MicroGeneSys that holds the patent for VaxSyn HIV-1. Though it will pay royalties to the federal government should the vaccine ever be marketed, MicroGeneSys will retain—as patent holder—substantial control over distribution of the vaccine.

In order to facilitate this kind of collaboration, there has been a call—in the government and private sectors—for the removal of scientific, technical, legal, and financial "obstacles" to the involvement of industry in the effort against AIDS. That is, beyond provision of technical and scientific assistance of the type outlined in the PHS document, there have been propositions to remove legal and financial obstacles through the revision of tort liability laws, the provision of government funding for private sector research, the enactment of favorable purchasing agreements between pharmaceutical firms and state governments, and so forth. These changes have been defended, in part, by pointing to the unorthodox threat posed by the AIDS epidemic.

This threat, however, should not lead to incautious tampering with impediments to private sector development and marketing of an AIDS vaccine. Legal and, to some extent, financial obstacles exist precisely because the interests of the private and public sectors are very different. This is not to say that removal of such obstacles is inherently inappropriate. Rather, unbalanced and unstructured removal may be misguided. Certain additional regulations, unaddressed in current proposals, will be required if a sensible national AIDS vaccine policy is to be assured.

In general, we believe that a significant degree of public control over this private sector endeavor, well beyond that afforded by existing frameworks for collaboration, should be required. Such public control will serve the important function of bringing a vaccine to

market in the most reasonable, equitable, and efficient manner possible. Although the government has traditionally relied on the market to accomplish these objectives, the distinctive scientific and policy concerns related to an AIDS vaccine force a re-evaluation of this reliance.

For government assistance to be most effective in vaccine development, we believe that important reciprocal obligations on the part of the private sector must be instituted. Legislative initiatives to foster AIDS research—such as a proposed Senate bill and recent California legislation—should provide for more specific governmental access to experimental lots of developed vaccines, control of patent rights, and regulation of distribution and pricing schemes. Such government rights, we will argue, are justified both by the current models of private/public collaboration and by the overriding public interest in ensuring a wide and effective distribution of an AIDS vaccine.

AIDS Vaccines: Development and Evaluation

The biology of HIV is such that several significant scientific and technical obstacles must be surmounted, including uncertainty about how to establish protective immunity through vaccination and how to reproduce HIV infection in animal models. These and other problems considerably complicate vaccine development.[3] A variety of products have been considered as possible AIDS vaccines, including: 1) non-pathogenic infectious HIV; 2) killed HIV; 3) purified natural virus proteins; 4) genetically engineered subunit proteins; 5) infectious recombinant viruses; and 6) so-called "anti-idiotypes."[4] The first three alternatives have received relatively little consideration, in part because they have the dangerous potential of transmission of HIV infection.[5] Consequently, development of a vaccine has thus far been largely directed towards using recombinant DNA technology to introduce portions of the viral genome from the so-called "env domain" into bacteria, yeast, or mammalian cells in order to produce large amounts of pure HIV protein efficiently. Recombinant technology has also been used to insert portions of the env gene into other relatively innocuous viruses in order to create vaccine consisting of a virus expressing an HIV protein on its surface.[6] In both of these types of vaccines, the idea is that the HIV protein would stimulate a host immune response directed against it and thus protect against future HIV infection. Research to develop an effective vaccine along these lines is proceeding along many fronts concurrently.

The necessity for a vaccine against HIV was appreciated relatively early in the AIDS epidemic. Even in advance of its availability, some authors outlined a pathway for evaluation of a vaccine.[7] Specifically, an evaluation protocol would likely involve the following steps: 1) preparation of the vaccine in sufficient quantity and purity; 2) testing in animals to see if the vaccine results in antibodies able to neutralize HIV *in vitro;* 3) testing in non-human primates to establish the ability of the vaccine to protect against subsequent challenge with HIV; 4) testing in a small group of humans (members of AIDS risk groups or others) to evaluate short term safety and immunogenicity (a phase I trial); 5) determination of ideal dose and spacing of the vaccine through larger safety and immunogenicity trials (phase II); and 6) determination of protection against HIV infection through large scale efficacy trials (phase III).[8]

A phase III trial would ordinarily be of the randomized, double-blind, controlled type. Such a trial would involve assembling a group of subjects (approximately 1,000–2,000) who met certain essential criteria and who consented to participation. Subjects would be randomized into two sub-groups and would be given either the vaccine under investigation or an alternative. Initially, the alternative would be a "dummy" vaccine with no activity against HIV; subsequent trials of newer vaccines, however, would involve comparison of the new vaccine with previous ones instead of with placebo. Trial participants would be followed in an effort to detect a significant difference in protection from HIV infection between the two groups. Such a difference would form the basis for the assertion that a given vaccine was effective.

Rationale behind Private Sector/ Government Collaboration

The idea of collaboration between the government and the private sector is not new and finds ample precedent, for example, in the defense industry. The precedent for a joint effort with respect to AIDS has been set by previous collaboration in the remarkably speedy development and implementation of an HIV screening test to protect the nation's blood supply.[9] The federal government is also facilitating industry efforts to develop AIDS drugs.[10] For example, in developing AZT, the only agent so far approved for the treatment of AIDS, Burroughs Wellcome Corporation benefitted not only from a direct collaboration with the National Cancer Institute, but also from favorable legislation in the form of the Orphan Drug Act and from highly expedited FDA approval.[11]

One reason for fostering private sector/government collaboration is that collaboration helps avoid a wasteful duplication of efforts and so helps increase overall efficiency. Such a gain in efficiency is not always realized, however; in some cases, industry advances are considered secret, are not revealed, and hence do not obviate duplication. A relevant example of this problem may

be seen in the case of a feline vaccine that has been developed by Norden Laboratories for a virus related to HIV. Not unpredictably, the manufacturing process of this vaccine is considered by Norden to be a trade secret.[12] An additional example is provided by the research surrounding AZT; as we shall see, this research was initially hampered by business considerations on the part of Burroughs Wellcome. Hence, under the proposals for collaboration, the exchange of ideas and technologies is largely one-way, from government to industry.

There is, however, a more important reason to foster collaboration between the government and industry: a mutual benefit that arises from the different expertise to be found in the two sectors. The government has unrivalled scientific resources that can be marshalled to address the problem of developing and testing an AIDS vaccine. The comparative advantage of the private sector, on the other hand, will be in the actual manufacturing, marketing, and distribution of the product.[13] In the case of VaxSyn HIV-1, for example, MicroGeneSys has acquired a patent as a result of a collaborative effort. Yet, it is unlikely that this patent has been yielded to MicroGeneSys in exchange for a scientific contribution that government scientists could in all probability have made on their own; rather, MicroGeneSys has been yielded the patent because of the important marketing and distribution services, unavailable within the government sector, that it can provide. Indeed, this type of contribution is viewed as essential in the PHS document. The PHS proposal requires that companies "define fully the scaling up from research quantities through pilot lots to final production quantities up to FDA approval and marketing of the vaccine, including . . . a plan for marketing the vaccine, which will provide for delivery of the product at a reasonable cost, taking into account limitations on availability and distribution, including the availability and cost of insurance."[14]

Two Models for Collaboration

Currently, there are two legislative models for private/public collaboration in the development of an AIDS vaccine: 1) a federal proposal, Senate Bill 1220, and 2) existing California legislation, found in the California Health and Safety Code. These models provide for a more extensive interaction between industry and the government than the type outlined in the PHS document, and they therefore direct most of their attention towards those aspects of industry contribution that are essential to the *development* and *marketing* of a vaccine. The two programs illustrate some of the options available to government policy makers. As they are designed to function in very different contexts, at different levels of government, these models highlight different aspects of the vaccine development problem. But given the urgency of the problem in California, it is not surprising that this state has moved ahead of the federal government.[15]

The recently enacted California bill provides a funding program for development, clinical testing, and guaranteed sale of the vaccine.[16] The bill begins with an acknowledgment of the catastrophic dimensions of the AIDS problem and then notes the "uncertain profitability and perceived and actual marketplace risks and disincentives" in the development of an AIDS vaccine. It is to this last point that the legislation directs its principal focus: "Without state intervention to assure minimal profitability of an AIDS vaccine, inadequate incentives may exist for the private sector to commit resources and expertise to the accelerated development of an AIDS vaccine."[17] The bill outlines what amounts to a government subsidy for three central areas of vaccine development and distribution. First, by codifying existing California law, the bill limits liability for vaccine manufacturers for injuries due to the vaccine. Second, it appropriates $6 million for private firms to conduct clinical trials of a vaccine. Third, it guarantees that the state will purchase 500,000 units of the vaccine at $20 per dose. Thus, the bill does not address the issue of scientific collaboration—a concern properly focused on by federal regulations—but, instead, addresses other serious concerns of vaccine manufacturers: liability, development costs, and profitability.

In recent years, the scientific and corporate communities have been disturbed by large liability judgments against pharmaceutical manufacturers.[18] The state-created liability cap in California aims to alleviate what many view as the greatest disincentive to production of a vaccine. (Alternatively, the federal government could, through statutory changes, preempt state law tort judgments altogether with respect to certain types of vaccines.) In seeking relief from the California legislature, Brian Cunningham, vice-president and general counsel for Genetech, a California pharmaceutical concern, complained that "manufacturers are held liable for injuries caused by a vaccine even though they were not negligent in designing it . . . In these circumstances . . . the legal system has run amok."[19] The bill rewrites drug tort liability for an AIDS vaccine essentially by restricting so-called "strict product liability," a legal doctrine that means that a manufacturer is liable for any injuries caused by a product, even if the product is made properly. The statute does not limit liability, however, for failure to warn of *known* defects. This liability limit applies only provided that the trial judge finds as a matter of law that the AIDS vaccine was a so-called "unavoidably dangerous drug." This latter requirement is defined by the legislation in a manner that essentially tracks a 1985 California Court of Appeals decision,

Kearl v. Lederle Laboratories;[20] the criteria involve, briefly, that the proposed vaccine offer an "exceptionally important benefit" with but "temporary or insignificant inconvenience" and with no more than essential risk of harm. For purposes of the legislation, it is presumed that any AIDS vaccine approved by the FDA would satisfy the "exceptionally important benefit" criterion. This statutory limit on liability is a manifestation of the desire of the California State government to facilitate industry participation in vaccine development. In so doing, the government is advancing certain benefits to industry. But this interaction between industry and government is unbalanced.

In lieu of conventional tort liability, the legislation mandates an "AIDS Vaccine Victims Compensation Fund" which would provide compensation for medical costs, lost wages, and pain and suffering damages, so long as the total bill per person does not exceed $550,000. The Fund will be funded by a surcharge, not to exceed $10 per unit, on the sale of an approved AIDS vaccine in California.[21] In addition, the legislation establishes a committee to determine the contribution of manufacturers to the compensation pool.[22] The legislation precludes recovery only in the case of 1) comparative negligence of the claimant; 2) negligent conduct by the manufacturer in producing the vaccine; or 3) injuries during a clinical trial.[23]

Assuming that the Fund is financed by the maximum permissible surcharge and an equivalent contribution per unit by the manufacturers, $20 would be raised per unit. If each harmed individual received damages of $550,000, the maximum allowed, the Fund could finance one such claim per 27,500 innoculations, a not unreasonable estimate of adverse consequences likely to arise.[24] A question is raised, however, regarding how individuals will be compensated should the incidence of adverse effects be an equally reasonable 1 in 10,000. This type of epidemiological uncertainty illustrates the difficulty in using a compensation fund to make proper allowances for injuries caused by a new vaccine.

The compensation fund program aims both to expand the base of recovery for injury as the result of an AIDS vaccine and also to limit the liability of manufacturers.[25] Although neither goal is perfectly achieved, it is clear that a firm benefitting from the limitations on liability will reduce its overall costs. Such a limitation thus not only provides an incentive for companies, but it also presents the possibility of a windfall for them. Liability judgments and settlements can constitute a significant element of a firm's expenses; without these, the dollars that would otherwise be spent will become potentially large profits.[26]

The two other elements in the legislation also provide significant benefit to manufacturers. The legislation provides for a state subsidy to California companies for clinical trials. The statute notes that the grants are necessary because profit-making corporations are "not eligible for most of the existing public funding sources." These grants would therefore encourage research by the private sector. Any company which receives a grant and which ultimately "sells, delivers, or distributes" an FDA approved vaccine must reimburse the state for the full amount of the grant.

Finally, the law guarantees a minimum market for an FDA-approved vaccine. The state assumes that at least 175,000 persons will be vaccinated with three units of vaccine each and guarantees the purchase of 500,000 units. If this minimum sale is not met, the state will purchase the difference at not more than $20 per dose to reach the 500,000 guarantee.

The second legislative model for public/private collaboration is a pending U.S. Senate bill.[27] Inasmuch as the Senate bill provides for a less detailed program, the California model suggests several areas that should be addressed by the Senate bill or additional federal legislation. As it stands, the Senate bill provides for no detailed program and instead delegates the responsibility for formulating national AIDS research funding policy to a scientific coordinator in consultation with a seven member National Acquired Immunodeficiency Board.[28] The coordinator, who will be appointed by the director of NIH, must be one of the directors of a national research institute. The Board is to consist of scientists and knowledgeable members of the general public, including at least one member who is infected with HIV. The coordinator and the Board may "encourage and coordinate research" by private industry and "exchange" information with private concerns. This broad appropriations bill leaves most of the details for any collaboration program to these experts and does not itself place any limits on their discretion.

The Senate bill would operate in tandem with existing federal regulation of patent rights in inventions created either with federal assistance[29] or by the government alone.[30] Broadly, government research is either conducted by government employees, in which case the government holds the patent, or by private firms with federal money, in which case the private contractor may generally elect to retain the patent. Both frameworks have figured in AIDS-related research.

For example, in its effort to produce and market a test to detect HIV antibodies, the government issued non-exclusive, royalty-bearing licenses to qualified firms.[31] Here, government scientists had invented the techniques necessary to develop and detect HIV antibodies and private industry was needed to mass produce and market the technology. In a notice soliciting proposals for HIV test development, the PHS emphasized that desirable firms would have the ability to mass produce the test and "to package, market and distribute

[the product] in a nationwide marketing system at a reasonable price."[32] The government, through the PHS, retained control of the patent and, in a broad sense, set the pace for the development and distribution of the technology. This program has been credited with quickly safeguarding the nation's blood supply.[33]

In contrast, the effort to develop AZT involved a collaboration between the government and Burroughs Wellcome in which the government provided scientific and financial assistance and the company retained the patent rights. This arrangement followed existing federal regulations which provide a preference for private control over collaborative developments,[34] a preference which has been strengthened under the Reagan administration.[35] The government, however, is able to use the patent royalty-free for its own purposes. In exceptional circumstances—notably, cases wherein the government feels that action is necessary to minimize inefficiency or to protect the public health—the government retains the right to take control of the patent and the product.[36] There is no record of these so-called "march-in rights" being exercised in the area of drug development in the past 20 years, however, and it is unclear what standards would, in practice, be applied for making the decision to exercise these rights. Thus, although the government would have the power to take the patent on a product, analogous to its rights in eminent domain, such a move could likely only be made in the face of hearings and litigation—adding additional time to the already lengthy process of development. In practice, the government has avoided disrupting the incentives of the free market on the presumption that new products will thus reach the public more quickly and with the justified concern that such disruption would jeopardize future collaboration. Moreover, the government is not at present in a position to produce and distribute such products; this is, as we have seen, the major reason for collaboration in the first place.

The collaboration with private industry is a major component of the Senate bill which is generally designed to "provide a comprehensive program of education, information, risk reduction, training, prevention, treatment, care, and research concerning acquired immunodeficiency syndrome."[37] This integrated approach is significant in at least two respects. First, the drafters recognize that there is no single solution to the AIDS epidemic. Rather, as the history of venereal disease in this country has shown, any policy response must rely upon a comprehensive approach including research, education, and treatment.[38] Second, because the bill encompasses so many different approaches and policies, much of the actual implementation is by necessity delegated to experts and to local organizations. The bill envisions participation of "local government and public and private non-profit entities (including community-based organizations)."[39] The federal government simply assumes a guiding role.

Policy Recommendations

In the collaboration to develop an AIDS vaccine, government will provide enormous advantages to industry in a number of diverse areas, such as scientific assistance, financing, and tort reform. To maximize the effectiveness of this assistance in bringing a vaccine to general use, private industry should cede a certain amount of control to the central authority of the government. Government control of the process of AIDS vaccine development is essential in two broad phases of that development: 1) research and testing, and 2) distribution and sale. No revisions in current contract or patent law are required for this. Rather, our proposals build on the existing legislative framework of government regulation of collaboratively developed technology. In addition, recognizing that the existing and proposed legislative initiatives neglect the necessary reciprocal obligations of industry in return for government concessions, we propose that several such obligations be made explicit. These obligations are necessary to: 1) facilitate the formulation of a coordinated national AIDS policy; 2) ensure that the public receives a fair return for the benefits it extends to industry; 3) reduce the potential for time-consuming litigation or administration contests; and 4) align policy decisions with scientific exigencies.

The goal of the first phase of AIDS vaccine development, efficiently formulating and testing a candidate AIDS vaccine, can be compromised by the way the private sector functions in a number of ways. Especially in the initial post-development period, when supplies of an AIDS vaccine will certainly be limited, decisions regarding access to the vaccine for research purposes should not be left to the private sector. Here, motives of self-interest can conflict with appropriate use. The experience with AZT is telling. Burroughs Wellcome, though it consulted with federal officials, ultimately had control over what further scientific studies involving AZT were conducted and by whom.[40] Burroughs Wellcome was criticized by both legislators and scientists for its reluctance to test AZT in combination with competitors' products, presumably for fear that an alternative therapy would prove superior to AZT.[41] In contrast, the company did test combinations of products when the other drugs were of their own manufacture.[42] Because firms have a rational economic interest in not helping their competitors, this type of competition between firms cannot easily be remedied by market forces and requires the intervention of a governmental mediator capable of setting priorities and ensuring that market forces do not conflict unduly with the social good.

In the case of an AIDS vaccine, moreover, restriction of research is an especially troubling possibility. Research on AIDS vaccines is rapidly proceeding along many scientific fronts in many government and industry settings. Candidate vaccines will therefore be available for evaluation concurrently. Proper scientific evaluation of these vaccines will require comparison amongst the alternatives in randomized clinical trials. There must be unrestricted access to vaccine for this purpose.

Because government assistance has proved instrumental in industry development of a vaccine, the government should have the right to control access to the vaccine for research purposes. Such control would form part of the concessions of the firm in exchange for the favorable treatment received. In responding to criticisms of its AZT distribution policy, a Burroughs Wellcome official emphasized that the company had difficult choices to make and that it made them in good faith.[43] This response assumes that it is proper for a pharmaceutical firm to make such allocation decisions in the first place and so misses the broader point: It is essential that public health and scientific decisions regarding AIDS research—and, in this case, AIDS vaccine distribution and use—be removed from the private sector. Major national health policy should not rest on the judgment of a few select firms.

Various individual firms and government research facilities should not only be assured a supply of a competitor's product for testing and development, they should also have access to data and ideas generated in the search for an effective vaccine. In this regard, the policy of awarding exclusive patents to private firms should be re-evaluated. Companies receiving government assistance should make information regarding their AIDS vaccine project accessible to the government and to other firms participating in collaborative efforts. This would effectively decrease wasteful duplication of efforts and accelerate development of an effective vaccine.

With respect to access to information, it is important to distinguish research in which there is a proprietary interest from that which is routinely published without any restrictions on use. In the case of published research, the government and, more generally, the public receive a benefit from the increase in scientific knowledge. If discoveries regarding AIDS vaccines are patented, this important benefit is lost to the public. Preservation of this benefit would be facilitated by an explicit articulation of reciprocal obligations within collaborative agreements.

The second phase of AIDS vaccine development will involve distribution of a vaccine shown to be effective. Once again, experience with AZT points to a variety of problems that arise when private firms are allowed to make decisions regarding a pharmaceutical product in short supply. As with decisions regarding research projects, Burroughs Wellcome had final say in which p tients (e.g., AIDS patients suffering from pneumocys pneumonia versus other types of patients) received drug.

Use of an initially scarce vaccine will likely be problem, especially since it will be needed most urgen by those at highest risk of infection: highly sexually tive individuals (such as prostitutes) and intravenc drug abusers—two groups that have traditionally be difficult to reach. But reaching these groups is necessa not only for reasons of fairness; it makes epidemiol ical sense to attempt to stem the epidemic by vaccinati those at high risk. Legislation must ensure that priv. sector distributors have the obligation of reaching hi risk groups as well as their traditional consumer ba Alternatively, manufacturers could provide free vacc to the government to be used by public health offici

Also at issue is how much of the population to v cinate. Should the vaccine be targeted for risk groups for general use? Regardless of the type of product p duced, private firms will likely desire a widespread c tribution in order to boost sales and profits. But government may well have an interest in preventing perfluous vaccination of the population which mi unnecessarily increase the risk of injury. The liabil problems connected with an inappropriately large eff must also be considered—aptly illustrated by the pr lems arising in the swine flu program.[44]

Beyond questions of overall research coordinati and distributional fairness, the basic issue of price equ is especially important in the case of an AIDS vacci Firms ordinarily seek to recover the cost of manufact and some profit. In fact, when Burroughs Wellcome v criticized for its pricing policy for AZT (abc $7,000–10,000 per patient per year), it responded t it was forced to account for its development costs.[45] this sense, a research firm is gambling; the pay-off fr a successful product has to be large enough to acco for the costs of unsuccessful products. What is sign cant about the models of public/private collaborati described above is that they eliminate much of the r justification for pricing. Especially in the case of C fornia, the manufacturer faces very reduced risk in veloping a vaccine since certain development costs well as production level are guaranteed for any vacc ultimately approved by the FDA.[46]

In our free market economy, it is presumed t firms, motivated by the search for profits, will devel and market goods to meet a demand. In the case o medication, however, such a policy is problematic. T high a price may put an enormous burden on those w cannot afford the treatment. Motivated by such a c cern, New York and Massachusetts have both recer inaugurated programs to subsidize the cost of AZT those unable to afford it.[47] At the federal level, the S

ate recently appropriated $30 million to pay for AZT for low-income AIDS patients.[48] Neither the federal nor the California legislation guarantees that an AIDS vaccine would not be excessively priced in response to demand—thus yielding undue profits for manufacturing firms.[49] The government could find itself in the unhappy position of subsidizing the purchase of an AIDS vaccine after having already subsidized the development and manufacture. There needs to be a mechanism for regulating the pricing of the vaccine to prevent such an eventuality. Such a mechanism is provided by allowing government control of the price as part of the obligation of industry in exchange for the benefits advanced by government. Given the desire of pharmaceutical firms to be seen in a favorable public light, the government should not underestimate the power of moral suasion in the marketplace. Publicity concerns may well motivate firms to set reasonable prices. Nevertheless, government review of the price charged for a collaboratively developed vaccine should be part of any agreement between the government and industry.

Sensible National AIDS Vaccine Policy

In the effort to develop and market an effective AIDS vaccine, the government and the private sector have a relationship of mutual dependence. Both have special expertise. The government, through the legislature, administrative agencies, and courts, acts as the proponent of the collective good. It is the appropriate and expert source of central planning of large scale projects in the national interest.[50] And the government, with its enormous resources and highly developed national research institutes, is a rich source of basic scientific data and technology; to date, no private firm has been able to produce a significant AIDS-related drug or technology without its assistance. Industry, however, also has a special expertise—an expertise in production and marketing ordinarily not available within the government sector—that is needed in the venture. Private firms are expert in taking a product from the theoretical to the practical stage in the market.

But along with different expertise, government and industry have different interests—for which an effective policy must properly account. In the case of an AIDS vaccine, governmental bodies have the public health as a paramount consideration; the government has the obligation to ensure fair and medically proper distribution of an AIDS vaccine. Private industry, by contrast, is generally driven by self interest.

The Senate bill provides for a national AIDS coordinator, but unless the bill provides for further enumerated powers it will be difficult for the coordinator to make the type of forced allocations—especially during the nascent stages of any given vaccine technology—that will be necessary for effective policy coordination. This is not to say that the Advisory Board will not eventually institute obligations on the part of the benefitting firms and develop national standards; rather, there is no legislative mandate in this bill to oblige the Board to do so. In the effort to develop a vaccine, it is essential that a clear program be outlined at the outset. Something may be learned from the clarity and specific nature of the California bill. Once collaboration begins on a grand scale, it will be more difficult for the federal government to institute broad policy objectives without appearing to prejudice the interests of any involved firms. Indeed, in the incipient stages of collaboration, the government essentially has bargaining power with interested firms, power which can be used to serve the public interest.

The California bill articulates several important policies that should be extended nationally. Particularly with regard to government financing for clinical trials, the Compensation Fund, and price guarantees for experimental vaccines, we believe that the California bill provides a model for federal and other state legislation. These provisions address one of the central problems in vaccine production: the high risk character of these investments. By limiting some of the downside risk for firms—but *only* within the framework of responsible government control and proper industry behavior—the search for an AIDS vaccine is facilitated.

The California legislation and the proposed Senate bill have their strengths, but, as we have seen, they provide an inexact solution to the complications in allocation, pricing, and distribution that arise from the way in which the private sector functions. Both legislative models share the feature of eliminating risks and costs to drug manufacturing firms without extracting reciprocal obligations. A balance must be struck between adequate incentives to gain industry participation and appropriate safeguards to ensure the public good. Ignoring this balance makes little economic or policy sense and, indeed, presents a significant hazard for a legitimate and coordinated national AIDS policy.

References

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12. See D.P. Francis and J.C. Petricciani, *supra* note 7, and also a letter from L. Wetzler and M.E. Seiff, "AIDS Vaccine and the Private Sector," *New England Journal of Medicine* 314: 1511–1512 (1985). The problem of competition and secrecy is not restricted to the private sector; incentives for secrecy also exist for public sector scientists; see D.R. Forsdyke, "An Ethical Dilemma" (letter), *Nature* 332: 200 (March 1988).

13. See R. Neustadt and H.V. Fineberg, *The Epidemic that Never Was: Policy Making in the Swine Flu Scare,* New York: Vintage Books, 1983, for a discussion of a previous case of collaboration in a vaccine program.

14. Fed. Reg. 30130, August 22, 1986, at p. 30131. The need for such manufacturing and distribution expertise was identified even earlier in a report released in 1985 by the Congressional Office of Technology Assessment: U.S. Congre Office of Technology Assessment, *Review of the Public Hea Service's Response to AIDS,* Washington, D.C.: U.S. Co gress, OTA, February, 1985.

15. California has also moved ahead of the federal g ernment in drug approval, recently passing legislation to p mit bypassing of FDA review of new drugs; Session La under AIDS, California Health and Safety Code, Chap. §26679.5 (1987). See also K. Bishop, "California Acts Speed AIDS Drug Testing," *The New York Times,* Septemb 30, 1987, p. A18.

16. California Health and Safety Code, chaps. 1.14 a 1.15 (1986).

17. California Health and Safety Code, chap. 1.1 §199.45(o).

18. For example, see J.L. Mills and D. Alexander, "T atogens and 'Litogens,' " *New England Journal of Medici* 315(19): 1234–1236 (1986); and, for analysis of proposals revamp vaccine liability law, see: E.W. Kitch, "The Vacci Dilemma," *Issues in Science and Technology* 2: 108–1 (1986).

19. P.M. Barnes, "Will an AIDS Vaccine Bankrupt t Company that Makes It?" *Science* 233: 1035 (1986).

20. 172 Cal. App.3d 812.

21. California Health and Safety Code, chap. 1.1 §199.50(O). On the federal level, a vaccine injury compens tion program was recently established to provide no-fault surance to provide compensation in the case of injury or dea arising from the administration of certain childhood vaccin The program will be funded by an excise tax levied on t covered vaccines; see 42 U.S.C. §300aa-10 *et. seq.,* P.L. 10 203 (1987).

22. California Health and Safety Code, chap. 1.1 §199.50(n)(3).

23. See Mariner and Gallo, *supra* note 3, for an analysis the significance of this gap in coverage for manufacturers a for patients.

24. For example, with widespread inoculation for swi flu, the unexpected incidence of a severe complication kno as Guillane-Barré Syndrome was determined to be 1 105,000; see Neustadt and Fineberg, *supra* note 13 at 100

25. See Mariner and Gallo, *supra* note 3, for further an ysis of this point.

26. T. Moran, "Products Liability Law and Pharmaceu cals: New Developments and Divergent Trends," *Food, Dr and Cosmetic Law Journal* 43 (Jan. 1988): 33–53. Sometim liability judgments can exceed the profit made on a prod altogether; see, L. Bosy "Drug Makers: Courts Treating Like Insurers," *American Medical News,* Oct. 10, 1986, p.

27. S. 1220, introduced May 15, 1987. Passage of this b has been stalled by party and political divisions; see "Congr is Stalemated Over AIDS Epidemic," *Congressional Quarte* December 5, 1987, p. 2986–2988.

28. Public Health Service Act §408(b), §409(A)(b), as pr posed. In a similar vein, Congress recently established the N tional Vaccine Program directed by a national coordinator a an Advisory Committee, to coordinate the development, d tribution, and licensing of vaccines for certain infectious d eases; see 42 U.S.C. §300aa-1, *et. seq.*

29. 35 U.S.C. §§200–210, and implementing regulatio at 37 CFR 401 (1987).

30. 45 CFR §§6–6.4.

31. 49 Fed. Reg. 18900, May 3, 1984.

32. 49 Fed. Reg. 18900, at 18900.

33. L.K. Altman, "Blood Supply Called Free of AIDS," *The New York Times,* August 1, 1985, p. A1.

34. 35 U.S.C. §§200–210. See also Rosenberg, *Patent Law Fundamentals* §12, (2d. ed. 1987). Notably, the regulations have rigorous confidentiality requirements to preserve the marketability of a patent for a private firm. The only area in which the government routinely opts to take control of the patent is when national security concerns are involved; see 35 U.S.C. 2 sec. 202(f) and also Rosenberg, *op. cit.,* at §12.01.

35. 48 Fed. Reg. 16254, April 15, 1983.

36. 35 U.S.C. §203(a)–(d).

37. S. 1220, introduction.

38. See A.M. Brandt, *No Magic Bullet,* New York: Oxford University Press, 1987, for an excellent consideration of the history of venereal disease in the U.S.

39. S. 1220 §2403(a).

40. See E. Eckholm, "AIDS Drug Decision is Expected Today," *The New York Times,* September 24, 1986, p. A15, and J. Molotsky, "U.S. Approves Drug to Prolong Lives of AIDS Patients," *The New York Times,* March 21, 1987, p. A1.

41. The company maintained that this was in order to free up available AZT supplies for the treatment of patients. See P.M. Boffey, "Experts Find Lag On Testing Drugs in AIDS Patients," *The New York Times,* April 12, 1987, p. A1.

42. P.M. Boffey, *supra* note 41.

43. T.E. Kennedy, "Borroughs Wellcome's Efforts to Get Retrovir to AIDS patients" (letter), *The New York Tim* May 9, 1987, p. A30.

44. See R. Neustadt and H.V. Fineberg, *supra* note 13

45. See P. Weinraub, "Panel Says New AIDS Drug M Cost Too Much," *The New York Times,* March 11, 1987, A24. See also E.H. Thomas and D.M. Fox, "The Cost AZT," *AIDS and Public Policy Journal* 2(2): 17–21 (198

46. Even for vaccines not ultimately approved by the FD firms can still reap a valuable financial benefit, conducti research and paying overhead at government expense.

47. See "State Health Department to provide AZT," *New York Times,* July 21, 1987, p. B4; and J. Foreman, "St to Give Anti-AIDS Drug to Needy Patients," *The Bost Globe,* December 4, 1987, p. 13; not surprisingly, in Mas chusetts, the $728,000 necessary for the program was suppli by a grant from HHS.

48. "Fund Voted for AIDS Treatment," *The New Yo Times,* May 1, 1987, p. A18.

49. See A. Pollack, "High Cost of High-Tech Drugs Protested," *The New York Times,* February 9, 1988, p. A

50. See A.M. Brandt, "Polio, Politics, Publicity, and D plicity: Ethical Aspects in the Development of the Sa Vaccine," *International Journal of Health Services* 8(2): 25 270 (1978) for a discussion of the (problematic) role of go ernment intervention in the historical case of the developme and trial of the Salk polio vaccine.