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The Protective Oversight of Biotechnology

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THE MANAGEMENT OF BIOTECHNOLOGY is arguably becoming one of the most consequential problems of international security ever encountered. Knowledge of fundamental life processes has progressed to the point that extensive human intervention in the course of natural evolution has apparently become feasible, not only to determine particular outcomes but to redirect the process itself. One can credibly imagine the eradication of known infectious diseases. One can also credibly imagine the deliberate or inadvertent creation of new disease pathogens dramatically more virulent than those that have naturally evolved. One can similarly imagine both therapeutic and destructive applications affecting basic features of cognitive, emotional, and reproductive activity. Hundreds of millions of lives might be enhanced, salvaged, manipulated, degraded, or terminated, depending on how the same basic knowledge is applied. Little of that potential has yet been accomplished, but none of it can be dismissed as impractical fantasy.

Unfortunately, the capacity to alter basic life processes is not remotely matched by the capacity to understand the extended implications. For the foreseeable future, moreover, that imbalance in the state of comprehension is much more likely to accelerate than to diminish. It is not realistic to expect that the current momentum in fundamental microbiology will extend to the many other disciplines necessary to assess the evolutionary process as a whole. As a result, the human species is relentlessly acquiring power far in excess of its vision and is thereby posing monumental problems of prudential judgment—problems that it is not yet conceptually or institutionally equipped to handle. Those are the stark facts of the situation.

In current public discussion of the subject, fear of terrorism has been a particularly prominent theme, especially in the United States in the aftermath of the anthrax letters. That concern does reflect a circumstance of obvious importance. Any individual or organization dedicated to destruction but capable of undertaking only small-scale operations might plausibly choose advanced biotechnology as the instrument of choice. There would be very appreciable practical difficulties and risks involved, but an especially virulent pathogen might in principle induce a disease epidemic sufficient to disorganize an entire society or degrade an entire economy. Otherwise, a small-scale clandestine operation could accomplish genuinely massive social destruction only by the use of nuclear explosives, whose effects would be more localized, and the fissile material required is currently much more elaborately protected than is biotechnology. Biotechnology is one of only two technologies that truly deserve the label *agents of mass destruction*, and it is by far the more accessible of the two.

For all its natural prominence, however, the threat of terrorism is not the exclusive or even the primary source of danger. As a practical matter, terrorist organizations forced by their nature to evade detection cannot independently generate the fundamental science required to perpetrate acts of mass destruction—as distinct from acts of mass sensation. At least the basic knowledge required would have to be extracted from the legitimate research community, and the people involved would have to have been trained within that community. At the moment there is very little organized protection against the diversion of legitimate science to malicious purpose, but more robust protection can be and almost certainly will be devised. In doing so, it will be necessary to address the deeper problem of inadvertence.

Precisely because the rate of fundamental discovery, especially in molecular biology, is far outrunning the

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more integrated science required to assess the extended social effects, there is considerable danger that legitimate scientists pursuing compelling research ideas will initiate chains of consequence they cannot visualize and do not intend. The most widely noted illustration of that problem was the mousepox experiment in Australia,[1] where researchers seeking to develop alternatives to toxic pesticides unintentionally transformed a mild pathogen into a lethal one and demonstrated a potential method for doing that to yet more dangerous pathogens. In general, the extensive and necessarily open process of medical and agricultural research is regularly producing knowledge that could be exceedingly dangerous as an unavoidable by-product of knowledge that could also be compellingly beneficial. Given that situation, protective standards of prudence will have to be developed for their own sake within the legitimate research community. That is the first, the most important, and the most promising line of defense against deliberate maliciousness. If that line of defense is not constructed, nothing else will be effective, and literally everyone will increasingly be in lethal danger.

The relevant biomedical research process is very extensive and globally distributed. More than a million scientific articles are published every year, and seminal results are generated in all parts of the world. Information necessarily flows rapidly among leading scientists, and knowledge of fundamental developments also transfers rapidly to those in training. Given that situation, it seems obvious that adequate measures of protection would have to be globally devised and globally enacted.

Not surprisingly, however, regulatory practice, such as it is, has been dominated by political tradition rather than scientific reality. Current regulation of biotechnology is conducted primarily by national governments and is principally concerned with the localized containment of virulent pathogens, the safety of research scientists and subjects, the treatment of patients, and the preparation of commercial products such as drugs and vaccines. There have been as yet only embryonic efforts to organize prudential judgment at the level of basic research regarding the extended implications of the knowledge to be generated. The legitimate fear of interfering with the process of scientific discovery has minimized oversight at that level. In areas considered to be relevant to weapons application, however, national governments have imposed security classification and are actively exploring the destructive application of biotechnology under the justification of "threat assessment."[2] That practice is intensifying suspicion among the many governments already inclined to be suspicious of one another.

In broad outline, the requirements of managing advancing biotechnology are not difficult to discern. The hard part, actually, is taking the problem seriously enough to be willing to examine the fairly obvious answer. It can be presumed that inherently dangerous areas of biological research will have to be subjected to a much more systematic process of prudential oversight than is yet practiced in any country. That will have to be done globally and therefore will have to be globally formulated and globally implemented.

The basic method of prudential oversight will have to be based on enforced transparency and informed peer review. In areas of research capable of having massive consequence, it is truly a vital matter to bring independent, adequately informed, and broadly representative scrutiny to bear. No individual or research team, however competent, honorable, and patriotic, should carry the burden or be given the authority to make research decisions that might put an appreciable fraction of the human species at risk without subjecting themselves in advance and throughout the course of their work to the discipline of independent oversight.

The judgments required in such an oversight process cannot be entirely derived from any set of general guidelines, although refined and harmonized research standards would be an essential feature of the process. Valid judgments about the balance of benefit and danger in any specific instance can be made in detailed context only by people capable of understanding not only the scientific issues in question but also the social consequences. That implies a mix of scientists and public representatives who are not directly involved in the research in question.

While the review process would be conducted at the local or national level in most instances, the oversight system as a whole would have to operate through an international oversight body of extraordinary credibility. That credibility would have to be established not only by the quality of the individuals but also by a highly refined specification and limitation of their powers. They would be charged with licensing and monitoring all specific research projects of especially dangerous potential as well as all the individuals and research facilities involved in those projects. They would determine and implement the rules under which the results of those projects are disseminated. In order to justify that degree of authority, it would be narrowly limited to an appropriately restricted set of people, institutions, and projects. In order to protect against the misuse of the authority conferred, there would be exacting legal determination of its scope, limits, and associated responsibilities.

The licensing and review provisions have precedent in current national regulatory practice. The entire arrangement constituted on an international basis has no close precedent, however, and there are many who would summarily declare it to be impossible for that reason. Perhaps in the end it will be, but in that case the consequences are likely to be very dire indeed. If one is determined to be a

hardheaded realist in this situation, it is prudent to anticipate some response commensurate with the magnitude of what is at stake. Active international oversight is the prime candidate. Whatever the eventual outcome, it presumably will have to be seriously explored.

PRACTICAL CONSIDERATIONS

The most immediate and most probable form of deliberate threat that might emerge from biotechnology is reasonably judged to be substantially less than the aggregate effects of naturally occurring infectious disease and not fundamentally different in terms of the problems of protective reaction that are posed. Human societies are currently absorbing on the order of 10 million deaths each year from known infectious diseases, a substantial proportion of which could be prevented if the public health practices of the advanced societies were extended to the developing world.[3] Using basic preventive techniques of vaccination, personal hygiene, active surveillance, isolation, and contact tracing, smallpox was declared globally eradicated in 1980 even though there was no effective therapy. Monumentally infuriating as it would be, that effort could be repeated if a standard form of smallpox were to be reintroduced.

Similarly, the infectious disease generated by a new coronavirus in 2002 was effectively contained within a year by a largely improvised epidemiological response that demonstrated fundamental improvements in the global public health system.[4] Diseases such as malaria and polio have been nearly eradicated in the more advanced societies, and even the more intractable HIV has been better contained in those societies. In principle, with enhanced disease surveillance, global propagation of advanced public health practices, and protocols for rapid epidemiological reaction, the natural occurrence of infectious disease and the scope for deliberate initiation could both be simultaneously and dramatically reduced. The social and economic benefits of natural disease reduction would alone justify the effort.

Even for agents such as anthrax that can be disseminated in prepared aerosol form much more widely than ever occurs naturally, the basic methods of public health protection can in principle be effective. Wild strains of anthrax and most other bacteria susceptible to aerosol propagation can be effectively treated with antibiotics if exposure is detected before onset of the disease.[5] Since that interval is typically short and can be as little as a single day for those subjected to high doses, not even the most advanced of the current public health systems could undertake a completely protective reaction, but the requirements of a reasonably effective response are not inherently infeasible.[6] In principle, the immediate threat of bioterrorism or biowarfare can be treated as a public health problem.

Unfortunately, however, maliciously applied biotechnology has strong potential over the longer term to overwhelm any feasible elaboration of public health protection or medical treatment. If a highly contagious agent such as influenza or the viruses that cause measles or the common cold were to be made more lethal and if any of these were simultaneously released at a number of transportation nodes throughout the world, it is doubtful that any feasible response could contain the devastation that would probably occur. If critical bioregulators that control emotional, cognitive, and reproductive functions were stealthily propagated by an infectious agent in a manner that imposed some delay on the manifestation of the ultimate effects, then nefarious global manipulation might occur before the effects were identified, and it is questionable whether the ensuing race for reversal could be decisively won. For looming dangers of this sort, prevention is certainly the preferred and probably the only feasible option for meaningful protection. Since it is impossible to know how much time there might be to organize a protective arrangement and since development of that effort itself is likely to require a considerable amount of time, it is prudent to assume that prevention is in fact an immediately urgent problem.

It is also prudent to assume and important to realize that, as initially noted, legitimate research activities are necessarily the primary locus of protection. Whatever terrorist organizations or belligerent governments might do, they cannot independently duplicate the fundamental scientific capacity of the global biomedical and agricultural research community. Meaningful protection against destructive application of biotechnology ultimately depends on the standards set and the procedures applied by those who are the source of consequential knowledge.

At the moment, the legitimate research community is in the very earliest stages of recognizing the problem and has not yet generated any broadly agreed scheme for dealing with it. Most practicing scientists at the leading edge of relevant research quite literally are not thinking about the possibility of destructive application and are naturally reluctant to acknowledge the problem. Many of them are assertively resistant. Recent reports issued by the National Academy of Sciences in the United States and by the Royal Society in Great Britain do identify the danger in general terms, but neither has advanced a plausibly effective scheme for controlling it.[7] The British government has a more advanced system for regulating biomedical research than does the United States, or as yet any other country, but even that system is not explicitly focused on the social consequences of fundamental knowledge. And, of course, it does not extend beyond British jurisdiction. It provides legal precedent and a ba-

sis of experience for oversight procedures that might be applied but is not yet a complete model. No national government or international organization has suggested or attempted to develop a protective oversight arrangement on the global scale that would be necessary.

Moreover, the embryonic state of oversight is not the extent of the immediate problem. There is also an issue of perverse reaction. In the aftermath of the 2001 terrorist attacks, the U.S. government dramatically increased the level of expenditure directed to biodefense purposes—from an estimated $414 million in 2001 to more than $7.5 billion projected for 2005.[8] The mandated effort features an array of activities designed to prevent, detect, and control the outbreak of disease—most of which are obviously prudent and unlikely to be controversial. The program also includes, however, a major expansion of basic research on the biological agents of greatest immediate danger: more than $1.7 billion in the National Institutes of Health's budget for FY2004, on the order of $300 million in the Department of Defense's budget for basic and applied research, and roughly $750 million in comparable categories of the new Department of Homeland Security's budget. Research efforts sponsored by DoD and DHS—over one-third of the $2.75 billion total—are subject to security classification, and there is some suspicion that especially sensitive projects will be undertaken under "black program" rules completely opaque to virtually all of the legitimate scientific community.[9] As best can be judged, neither the detailed planning nor the actual execution of this overall effort will be subjected to policy oversight or independent scientific review, although some individual projects might be.

With no assurance of comprehensive transparency or documented accountability, the expanding exploration of dangerous biotechnology that will be generated by the spending surge is virtually certain to generate international suspicion.[10] Indeed, the United States would consider a corresponding effort in any other country to be definitive evidence of an illegal offensive weapons program, a glaring double standard that even the staunchest allies are unlikely to endorse. In the public record of deliberations that generated the American program, there is no indication that anyone seriously considered or systematically addressed the consequences of widespread emulation. It is intuitively evident, however, that secretive national programs operating under conditions of unresolved national suspicion on the basis of inherently open fundamental science run a very substantial risk of both stimulating and justifying the threats they are claiming to defend against.

That danger is substantially compounded, moreover, by the separate exploration of biotechnology for supposedly nonlethal application that is currently being conducted under the supposition that nonlethal effects are inherently more benign. Again there is no indication in the public record of consideration of these programs that the opposite possibility has been seriously considered, but it is nonetheless intuitively evident there is such a possibility. If the idea takes hold that attitudes, behavior, and reproductive capacity might be manipulated for national advantage, vehement objections can be expected to arise well before the actual capability is mastered, and those might well rival or exceed objections to lethal application. Biotechnology has the potential to engage the depths of personal emotion and the fundamentals of social legitimacy more powerfully than any of the technologies that have historically been used for belligerent purposes. The sense of threat and the political reaction generated might readily outrun even the very imposing reality.

ESSENTIAL FEATURES OF PROTECTIVE OVERSIGHT

Since historical experience is not an adequate guide for the unprecedented situation created by the accomplishments of biotechnology, effective response to the problems posed will ultimately depend on productive imagination. Presumably, the idea of protective oversight will not be the exclusive result of a suitably vigorous competition in applied imagination, but it is the most apparent contestant at the moment. As a means of stimulating discussion, it makes sense to visualize a comprehensive oversight arrangement, even if it is currently considered impractical and even if the ultimate response proves to be different.

If the central provision of a protective oversight system is the imposition of independent judgment on all highly consequential research activities without exception, then the critical first step is to specify the criteria for inclusion in a manner that can be widely accepted as rational and equitable. If the oversight process is too inclusive, it would blur the sense of extraordinary danger on which its justification rests. If it is not inclusive enough, it would be considered inequitable, arbitrary, and ineffective by the scientists directly affected. It is very difficult to draw lines that can plausibly command respectful compliance, and even the most dedicated effort to do so might not succeed.

Nonetheless, the best chance of establishing a viable definition of danger would arguably be based on the intrinsic properties of pathogens that determine the capacity for spontaneous propagation from one person to another, or more generally from one host to another. Those are the features that make a disease transmissible. Unfortunately, those determining features have not been definitively identified, nor has the resulting capacity for spon-

taneous transmission been systematically measured for the pathogens of most immediate concern. The relevant parameter that appears in standard epidemiological models implicitly combines properties of the pathogen itself and those of the social circumstances under which it propagates.[11] The current models typically use average values, moreover, which obscure variations that would be quite important in determining inherent danger. Nonetheless, despite these impediments, the concept of intrinsic transmissibility offers a reasonable conceptual basis for defining extraordinary danger. If large numbers of people are to be subjected to a lethal or otherwise nefarious effect in a short period of time, that would have to be done by means of a transmissible pathogen. It is intuitively reasonable to impose organized scrutiny on those lines of research that might combine transmissibility with lethality or with some other highly consequential effect. That approach would exclude many lines of research of extraordinary consequence to individual organisms, but it would allow a narrower focus on social consequence.

The basic purposes of the institutional arrangements that would implement the oversight process are a matter of debate as yet unresolved even among those interested in the idea. Preventing the deliberate or inadvertent creation of more lethal or objectionably more manipulative pathogens than those currently known is generally presumed to be the essential core objective, but there are differing views on whether that can or should be the exclusive purpose. An arrangement narrowly focused on that objective would be generally less demanding than one that also had constructive public health objectives. The narrower arrangement would also be predominantly negative in character, however, and would not provide positive incentives to induce compliance.

Since there are compelling reasons to pursue inherently dangerous lines of biological research for constructive reasons—the exploration and development of protective measures—there is an argument for assigning that mandate to the same set of arrangements designed to prevent destructive application. Those who argue against that combination of purpose warn of conflict of interest as well as the greater burden and expense involved. Those who argue for it note the inseparability of the purposes in question and the importance of balancing interest as well as the role of positive incentives. Both versions of the arrangement would require formal legal instruments and dedicated financing, but the constructive formulation would undoubtedly generate a larger, more expensive, and more consequential organization.

Whatever blend of preventive and constructive measures might eventually emerge, it is evident that the effectiveness of an oversight arrangement would depend on individual judgments made in the detailed context of specific lines of research and would therefore have to be more of a distributed process based on accepted norms than a hierarchical process based on authority. Although legal authority would almost certainly be required to reinforce the relevant norms and to justify public expenditure on active oversight procedures, in the end preventive and constructive protection necessarily depend on the judgments made by practicing scientists. The essential effect of an organized oversight arrangement is to formulate and activate the consciousness of those individuals.

These considerations suggest a tiered process, where the level of danger determines the scope of oversight required:

- *local consultation*, where the potential effects in question are reasonably judged to be worthy of attention but limited in character;
- *national consultation* for research involving the most dangerous of the currently known agents—a limited selection of the most transmissible of the currently listed agents; and
- *international consultation* for work with the potential to create agents significantly more consequential than those currently known.

Such a system would tolerate variations in local judgment for most lines of work as long as established oversight procedures were followed. It would seek to harmonize judgments for the more threatening of the current pathogens—plague, for example, and the viral hemorrhagic fevers—but would accept national jurisdiction. It would impose international oversight over work on smallpox or any line of research that might exceed the danger of the smallpox pathogen. In order to do any work in the highest category of danger, individuals and research facilities would have to be licensed according to internationally agreed standards, and each specific project would have to be approved in advance. In instances where research results prove to be more dangerous than anticipated at the initiation of the project, the appropriate level of oversight would be applied as soon as that became apparent.

An oversight system of that sort or any other protective arrangement worthy of the name would necessarily involve substantial extension of existing legal rules and regulatory design. Local, national, and international peer review bodies would need detailed information on which to base their judgments, and researchers would need reliable reassurances that the information they provided would not be misused. Individual freedoms and proprietary rights and national security concerns would have to be balanced against global security and public health interests under circumstances where categorical rules cannot be applied.

Very little of the necessary specification of interest has

yet been determined. Even in advance of that specification, however, there is a strong presumption that any effective arrangement would have to depend on procedures for deriving appropriate standards from case experience—that is, from specific research projects that are submitted for approval and judged in terms of the balance of benefit and danger posed. At the moment those review procedures that are being applied have restricted coverage, are not explicitly focused on the broad questions of social consequence, and are not generating an organized record of judgment prior to formal publication.[12] As a result, it is impossible to determine at the leading edge of the research process what the current state of danger actually is, how it is evolving, and what judgments are being made. Human societies are poised to recognize sensational danger when it emerges but are not currently organized for detailed anticipation or systematic prevention. As result, they are tolerating a substantial risk of inadvertent destructiveness.

UNDERLYING PRINCIPLES

Fortunately, the essential foundation for more organized and more effective protection is well established. The norm against destructive use of biotechnology is among the strongest and most broadly accepted of all human standards. It is formulated in the Hippocratic Oath, which has been the foundation of medical ethics since ancient times. It is legally stated in the 1972 Biological and Toxin Weapons Convention (BWC). It is reflected in prevailing social attitudes in all parts of the world. Any credible preventive effort can reasonably expect to evoke universal resonance extending across virtually all political and cultural divisions.

Not so fortunately, however, the natural strength of the fundamental norm is currently being undermined by undisciplined speculation about bioterrorism and undocumented allegation of offensive biological weapons programs. It is prudent to be concerned about both forms of threat. It is not prudent and indeed perverse to speak of such threats as if they were inevitable and by implication tolerable.

The vital objective of prevention ultimately depends on setting and actively reinforcing not only the norm but also the practical expectation that the destructive use of biotechnology will not be tolerated under any circumstance for any reason. Biotechnology can and must be separated from weapons application absolutely and without exception. Speculation about rogue violation of that rule does not provide valid grounds for exception, nor would a credible indictment. Under a fully developed protective arrangement, any actual violation by any person, organization, or country would be swiftly and decisively eradicated, by force if necessary, but that would involve police action or conventional military operations, not the countervailing use of biological agents. The status of the norm, including the capacity for enforcing it, depends primarily on clarity and legitimacy. Any perceived ambiguity, permissiveness, or inequity diminishes that status.

Not so fortunately as well, the status of the norm is also threatened by truly ominous ambivalence about the institutional location and hence the operating rules of protective activities. In the United States at the moment, the public health and the national security establishments are both actively responding to the new sense of threat. Both are mandated to do so by a political process that has neither recognized nor resolved the tension between their distinctive traditions. A collision of conceptual and institutional paradigms is occurring, and there are likely to be many battlegrounds—prominent among them the new Department of Homeland Security that is struggling to be coherently born.

"Paradigm" is admittedly a troublesome word loaded with profound but maddeningly mysterious connotations. In this instance, however, it has reasonably clear and undeniably important application. The public health establishment is dedicated to defense against naturally occurring infectious disease and has learned in the course of its encounters the importance of prevention, of global collaboration, and of the open sharing of information. The enemy in question does not calculate but displays far more intricate and less readily penetrable strategy than is used by organized human enemies who do calculate. Infectious disease operates on a global scale and is advantaged by barriers imposed on public health jurisdiction. Timely and extensive sharing of information across all jurisdictional boundaries is vital for protective reaction, and there is no risk whatsoever that active pathogens will benefit from the interception of shared information.

In contrast, national security establishments are dedicated to defense of national territory against calculating enemies whose operations are much less intricate and much more exposed to decisive defeat or evasion if they can be accurately detected. National security establishments have a politically and geographically more limited focus of concern, and they have learned to sequester information as one of their most fundamental commitments. They are extremely reluctant to share information beyond national jurisdiction and even within it, lest the information in question be intercepted and used against them.

Particularly with regard to the handling of information, the potential intersection of deliberate and natural threat drives both the public health and the national security establishments outside the scope of their traditional concerns and their habits of operation. If open research and

disease control information can be deliberately exploited and if secret threat assessments can indirectly generate a public health catastrophe, then each of the sectors confronts an unfamiliar, unwelcome, but ultimately unavoidable problem. Presumably, that situation requires a judicious blend of the respective traditions, but the implications of that presumption have barely been examined and have certainly not been worked out with the degree of global consensus that would be required to implement them.

Nonetheless, even at the outset of serious consideration, there are some guidelines that suggest themselves. Since the fundamental enemy in question is infectious disease and since human intervention is only a complicating factor, albeit a very important one, there are strong reasons to make transparency the dominant operating standard, not only because information from the fundamental research process cannot be sequestered as a practical matter but also because actively enforced transparency offers the only realistic basis for systematic prevention. That in turn strongly implies that all biological research ought to be removed from all national security establishments and should be organized under public health jurisdiction as a global standard. If the norm precludes any destructive application of biotechnology, then there is no legitimate reason to conduct fundamental research under national security jurisdiction and no comparative advantage in doing so. The legitimate requirements of defending military personnel against infectious disease can be addressed by dedicated agencies operating within the public health sector.[13] Although the specifics may vary, the protection of military personnel is not fundamentally different from the protection of civilian populations, and no categorically preferential standard should be applied. Any threat assessment having to do with the exploration of existing or potential pathogens should be done for global benefit and not for national advantage.

That said, national security interests of the United States and all other countries as well clearly dictate that under the looming threat of terrorism and other forms of rogue behavior, the practice of transparency has to be subject to some restriction. Transparency cannot realistically mean unrestricted access. What it might realistically mean is more difficult to determine, but the natural implication is that access to information with extremely dangerous potential will have to be restricted to people professionally qualified to have it and that a new social contract will have to be formulated with those people whereby access is accompanied by active assurance of responsible use, including monitoring of relevant personal activities. That is an unpleasant but probably unavoidable implication that will have to be applied on a global scale. Since national identity is not a viable criterion for controlling access to biotechnology, professional identity will have to be used instead. Such an arrangement might be called qualified transparency.

Under a qualified transparency regime, whatever scope is allowed for national security classification or for proprietary restrictions on information would have to be subordinated to the basic principle of global public health jurisdiction, and the burden of proof would have to be imposed on anyone arguing for exemption or amendment of qualified transparency rules. Moreover, any restrictions on dissemination that are allowed for national security or proprietary reasons could not be so categorical as to prevent either the independent oversight of research projects or the communication of research results vital for public health purposes.

If information about a dangerous pathogen variation were to be withheld, for example, until countermeasures had been prepared, that provision would presumably have a reasonable time limit, and the countermeasures would be made generally available. Undoubtedly, a great deal of contentious discussion would be generated by serious examination of those principles as well as many other predictably unwelcome implications. And admittedly, even the most adroitly designed and most assiduously practiced oversight arrangement that might result would not guarantee prudential judgment in all instances and would not preclude deliberate evasion. Actively organized oversight would substantially improve the current state of protection, however, and can be considered a necessary foundation for any yet more extensive arrangement. Since the underlying circumstances will almost certainly prove to be relentless, so also will be the idea of protective oversight.

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9. For a history of "black" programs and government policy, see Foerstel HN. *Secret Science: Federal Control of American Science and Technology*. Westport, Conn: Praeger; 1993, particularly chapter 2, "National Security Controls on Science." DHS and DOD can choose to classify work being done under contract at any point. For example, see "FAQ: Detection Systems for Biological and Chemical Countermeasures, RA-03–01." Available at: www.bids.tswg.gov/HSARPA/bids.nsf. Also available at: www.hsarpabaa.com/solicitations/KeithWard.pdf. In a recent government presentation it is stated: "The goals under this solicitation are currently unclassified. In the future, the DHS may choose to classify the performance of detection systems developed under this initiative. Bidders to this RA will need to include a plan to handle SECRET level material by the end of Phase I." It is reasonable, too, to assume that some of the activities of NBACC described by Lt.Col. Korch will also be classified (see www.cbwtransparency.org/archive/nbacc.pdf).
10. In a recent report issued by the U.S. National Academy of Sciences, for example (Harrison SC, et al. Discovery of antivirals against smallpox. *Proc Natl Acad Sci U S A* 2004;101(31):11178–11192), the authors argue for an expanded research effort to identify the molecular dynamics of the disease agent, the variola virus, in order to develop effective therapies against it. In a single sentence they acknowledge concern for misuse of the knowledge that would be generated (p.11190), but they declare that issue to be outside the scope of the report.
11. The standard SIR model (Susceptible-Infected-Recovered) was elaborated in Anderson RM, May RM. *Infectious Diseases of Humans: Dynamics and Control*. Oxford: Oxford University Press; 1991. The parameter, R_0, which represents the disease transmission rate, is assumed to be constant. R_0 is intended to be the average number of additional disease cases caused by each initial case. That parameter, the authors admit, "combines many biological, social, and environmental factors, and . . . is thus rarely amenable to direct measurement. Indeed, it will often be that the best way to assess transmission rates is to infer them indirectly from data on population-level processes. . . . ."
12. Oversight of recombinant DNA work is done by Institutional Biosafety Committees (IBCs) at the local level and by the Recombinant Advisory Committee (RAC) at the national level, according to procedures described in the *NIH Guidelines*. There is as yet no method for IBCs to harmonize their biosafety judgments with each other or with the RAC.
13. Research into exotic diseases has long been important for the U.S. military because of its global presence. However, transfers from military-sponsored to public health–sponsored research are not unprecedented: The CDC was created from what was a military tropical disease research center.

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