

Human Subjects Research for Biochemical Antidotes

A journal author believes human subjects should be used in research on biochemical weapons or their antidotes.

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London AJ. Threats to the common good: biochemical weapons and human subjects research. *Hastings Cent Rep.* Sept-Oct 2003;33:17-25.

With the specter of biochemical warfare upon us—if not from credible threats then certainly from the popular press and imagination—the debate has begun on the ethics of human subjects research to create effective antidotes and countermeasures.

In his article "Threats to the Common Good: Biochemical Weapons and Human Subjects Research," Alex John London explores how we, as a society, can justify human subjects research to develop countermeasures against biochemical weapons [1]. In this era of anthrax mailings, sarin gas releases, and threats of attacks with smallpox and other infectious diseases, London points out that "a bulwark...must be mounted...within the very bodies of military and civilian personnel" in the form of vaccines and other medical treatments [2]. The ethical rub is, of course, deciding who will assume the risk associated with creating and testing those treatments for the benefit of all. London employs the concept of "the common good" as an approach to making that decision.

London contextualizes his discussion within the current climate of homeland security and examines the role of informed consent in an environment of rising patriotism and nationalism. He worries that in prioritizing public well-being we may be less vigilant in our protection of individuals and their liberties.

Actions taken for the common good are based on practical arguments with instinctive and wide-reaching appeal. Their claims build on the normative foundation that an individual's well-being and interests can be subverted, in some circumstances, to the community interests. The risk is that such appeals can function independently of other moral theories and political sympathies.

Building on the foundation that an individual's interest may be subverted to a common cause, London posits a threshold for this restriction of personal liberty; namely, that the common good is indeed in danger. Then he places a practical constraint on common good actions—the subversion of individuals' rights cannot be a graver danger than the initial threat to the common cause. He points out that arguments for action in the interest of the common good do not suggest that civil liberties are unimportant, but rather that they lose some priority when society is threatened.

The key to understanding when civil liberties may be limited for the common good is first determining how to define the common good, so we can understand when it is threatened. Secondly, we must understand the threat posed by limiting individual liberties so that it can be weighed against other dangers. In pursuit of this goal, London takes up 2 different interpretations of the common good—the "corporate conception" and the "generic interests conception." Within the corporate conception, actions in the "common good" are those actions taken in the *interest of community survival*, where the community is a unique entity with distinct interests that, at times, may conflict with an individual's interests. Setting threat to community survival (extinction of the community) as the necessary, or what London calls "triggering condition," creates relative intolerance for disregarding individual interests in the name of the community.

Once this condition has been met, however, there are few safeguards to protect individual liberties.

Within this "corporate conception" framework, pandemic infectious disease such as HIV infection in sub-Saharan Africa might trigger common good actions. Other "'organic, noncontagious'" [3] illnesses such as cancer and heart disease would not qualify as triggering conditions—they threaten individuals' well-being but not survival of a society. There is no societal imperative to undertake medical research into treatments and cures for these types of diseases. Individuals, then, have to take up this research, and participants have to be fully informed of the risks of the research and derive some personal benefit (because there is no societal benefit) before consenting to be research subjects.

London finds a number of flaws in the corporate conception of the common good, pointing out that, if interpreted strictly, it would permit no action to be taken in the community interest unless the entire community's survival were threatened; thus it would ignore problems that affect only a portion of the community such as drug use or poverty. On the other hand, a lenient interpretation of threatened community survival permits more frequent intrusion on civil liberties and might force vulnerable populations to accept significant sacrifice in the interest of the community, eg, the internment of the Japanese Americans during WWII.

The lenient conception of the common good might also lead to the promotion of apartheid or prohibition of peaceful succession or mass emigration to protect community survival. Within a community, members might argue that the community dissolution presents a graver threat than the societal practice of racial segregation or overriding individuals' freedom to emigrate. Although the corporate interpretation of the common good offers rationale for subjugating individuals' rights to community needs (when societal survival is threatened), it provides no framework for how to appropriately and fairly curtail individual rights.

If we apply the corporate model of the common good to the case of medical research, only research that bolstered the survival of the society could be pursued, research into, for example, stemming the spread of infectious diseases. Within the corporate vision, individuals' interests are pitted against societal interest. In the case of human subjects research on biochemical weapons and their antidotes, society has an interest in undertaking these investigations, but no individual has a clear interest in participating in these trials unless that individual feels, what London calls, a sense of "foolish altruism" or subscribes to patriotic ideals of civil service that include possible personal sacrifice in the name of harmful medical research.

The corporate conception would then permit this type of research to protect the society's survival without safeguards to protect individual trial participants. Under this model, informed consent functions to help individuals who volunteer to participate in trials balance their interests, eg, altruism, with personal safety. This suggests that there would be no upper limits on the risk we allow individuals to assume in medical trials as long as it was balanced against threatened societal survival.

After rejecting the corporate conception, London turns to a second definition of the common good, the "generic interests concept." Here "common good" is defined as "the shared basic interests of each in being able to develop and exercise their basic intellectual and affective capacities and to pursue significant relationships with each other" [4]. Because all individuals in the society share these interests, they are societal interests.

Under the generic interests model, action for the common good is triggered by a need to support or promote the basic shared interests of individuals. These common good actions are curbed when the action deprives individuals of other shared and basic interests. Whereas in the corporate concept the controversy centers on when the triggering condition has been met, in the generic interests model the triggering condition is easily met. The focus is then shifted to whether actions taken for the common cause present more of threat to individual liberties than the initial threat. For example, we could all agree that we have a shared interest in highway safety. Seat belt laws and speed limits could be instituted to protect this shared interest, but these policies must be balanced with our shared interest in autonomy.

Within this framework the interests of individuals are not pitted against societal interests. The generic interests model approaches conflicts over the common good by weighing the individual interests involved and trying to guarantee all parties basic rights without one party losing out completely to benefit another. The success of a community is defined, in part, by how well it supports individuals' pursuits while also preventing individuals from infringing on others' basic rights. Under this model, society must take responsibility for righting many societal problems but is significantly

constrained in how this might be done with respect for all individuals.

Under the generic interests model, human subjects research is assessed by the benefits it offers trial participants as well as possible benefits it might offer future patients. Medical research is necessary, that is to say, society has an obligation to engage in such research because all people share an interest in being healthy and avoiding harm and suffering. London points out that since biological and chemical weapons do exist and society has an interest in possessing antidotes against these weapons, this research should be done.

In adopting the generic interests model, London recognizes that all individuals have basic rights which they cannot be deprived of even in the face of societal extinction. He argues, however, that we might allow some individuals to assume high risks because we, as a society, have a vital interest in pursuing this research. Trial participants would have to volunteer and be fully informed of the risks and how the risks have been minimized. London claims that the risk society allows these trial participants to assume might be comparable to the average risk encountered on a daily basis by public servants such as police officers and firefighters. Although London leans towards allowing human subjects research with biochemical weapons or their antidotes, he doesn't answer the question of how we determine who will be the guinea pigs of such trials.

London cautions that such trials should not be allowed to take place without oversight by an independent body. Finally London addresses questions of guarding the information such trials would produce. He points out that creating effective antidotes to biochemical weapons may initiate a cycle of research on increasingly effective antidotes against increasingly infective and damaging weapons. He states that such research must take place in an open and public forum to ensure public accountability and protect community interests, allowing secrecy to shroud these research trials only if it is necessary to protect the efficacy of the antidotes.

References

1. London AJ. Threats to the common good: biochemical weapons and human subjects research. *Hastings Cent Rep.* Sep-Oct 2003;33:17-25.
[View Article](#) [PubMed](#) [Google Scholar](#)
2. London, 17.
3. Jonas H. Philosophical reflections on experiments with human subjects. *Daedalus* 98. 1969;2:221. Cited in: London AJ. Threats to the common good: biochemical weapons and human subjects research. *Hastings Cent Rep.* Sep-Oct 2003;33:17-25.
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4. London, 21.

Questions for Discussion

1. Is government-sponsored research that might harm healthy human subjects ever ethical?
2. How might research for antidotes and countermeasures to biochemical weapons be construed as offering benefit to the individual research subject?
3. London suggests that society might allow research subjects to accept risk comparable to that encountered "on a regular basis by members of professions that are dedicated to ensuring public safety, such as police officers or fire fighters." Should human research subjects in biochemical weapons research trials receive compensation for themselves and their families and insurance commensurate with that of a public safety professional?

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