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cc: "George Whitesides (E-mail)" <gwhitesides@gmwgroup.harvard.edu>,
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Subject: DSB/TRAC bio report - some amendments re Strategic Reserve - R-306
Fcc: /jm/DSB, /jm/JL, /jm/PUB
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Mon Jun 25 15:30:57 EDT 2001 RE: I am working on some language that would unify the idea of strategic reserve with what FDA is already contemplating, reserving some antibiotics for last-ditch compassionate use. >>>

The Texts I have are:
If these are totally obsolete, please advise in the light of my suggested amendments.

CURRENT TEXTS: A) There are also a range of other, more specialized, problems that plague the development of medical products for biodefense. For example: if, in a government-sponsored program to develop antibiotics, a company develops a new, broad-spectrum antibiotic, active against antibiotic resistant organisms, and of a new class, it will wish to commercialize it as rapidly as possible to take maximum commercial advantage of a proprietary product. From the vantage of availability and affordability large-scale commercial production is clearly desirable. From the vantage of strategic defense, it may be desirable or necessary to hold this drug in reserve, and to forbid large-scale commercial use in conventional medicine, in order to have reserve capability against a sophisticated biological threat. There are many similar examples in which government objectives in sponsoring research and corporate objectives in undertaking it may not be in alignment, or in which the government itself may have to resolve contradicting objectives.

B)

In addition, there are other important themes related to contingency preparations that need to be examined. For example, should we develop a concept of Reserve Medical Technology? Can and should the U.S. government ever require that certain therapies be held off the market or kept in secrecy to have a new capability to respond to a biological attack? It is especially if secrecy also prevents the development of the doctrine, training, and operational effectiveness of certain antibiotics and anti-infectives by minimizing their use and holding them in reserve to respond to outbreaks of dangerous disease or BW attack. Any such policy, however, will be difficult to administer effectively without a sound analytical base and substantive acceptance by the medical community and the public. >>>>>>>>>>>

These are somewhat repetitive. My suggested texts are:

A) A range of other arcane problems plague the development of medical products for biodefense. For example: if, in a government-sponsored program to develop antibiotics, a company develops a new, broad-spectrum antibiotic, active against antibiotic resistant organisms, and of a new class, it will wish to commercialize it as rapidly as possible to take

maximum commercial advantage of a proprietary product. From the vantage of availability and affordability large-scale commercial production is clearly desirable; and this provides the necessary incentives for investment in costly clinical trials needed for NDA approval by FDA, and general marketing.

It is already evident that this approach is at odds with public needs for backup reserves needed to cope with antibiotic-resistant infections. Many suggestions are already afloat to regulate some specialized new antibiotics, so they will be available for compassionate use, when all else would fail. The same concept can be applied to the establishment of a reserve capability against a sophisticated biological threat. There are many similar examples in which government objectives in sponsoring research and corporate objectives in undertaking it may not be in alignment, or in which the government itself may have to resolve contradicting objectives.

B) Other important themes related to contingency preparations also need to be examined. For example, should we develop a concept of Reserve Medical Technology? In fact, genomically-informed targetting is likely to generate many times more candidates for good drugs than the pharma industry can afford to put through the NDA hoop. Government should then regulate and subsidize second tier agents to a point, short of where they qualify for NDA, but are available for controlled compassionate or analogous strategic reserve applications. As these are unlikely to offer much financial return to the developers, front end subsidies may be needed to take them out of the standard market economy, and maintain them under government control. Such policies of restraint, whether for rare medical emergencies, or for large scale disasters, will need a sound analytical base and substantive acceptance by the medical community and the public.

Revise ad lib!

Josh