Bio Terror Bible

EXPOSING THE COMING BIO-TERROR PANDEMIC

BIOTERRORBIBLE.COM: In the aftermath of man-made bio-terror generated pandemic, the government and media will be feeding the public any number of different scapegoats allegedly responsible for the pandemic that will likely kill millions.

While some scapegoats (see below) are indeed plausible, it is much more likely that the live pathogens or agents responsible for the pandemic will likely be dispersed via A) chemtrails by government airplanes or drones, B) by the U.S. Postal Service via Tide detergent samples, C) by the government and medical establishment via tainted vaccines, or by D) the portable petri dish commonly known as the Trojan condom.

Bio-Terror Scapegoats: Africa, Agriculture (Food & Animals), Airports & Air Travel, Al Qaeda, Bio Labs, Bio-Terrorism Is Easy, Bio-Terrorists (Bio-Hackers), Black Market, Bugs & Insects, Censorship / Lack Thereof, Domestic Terrorists, Exotic Animals (Zoonosis), Government Ineptitude, Mail-Order DNA, Mexico, Missile Shield Failure, Mutation, Natural Disaster, No Clinical Trials (Vaccines), and The Monkeys.

Title: FDA Acts To Speed Bioterror Medicines
Date: March 31, 2002
Source: UCLA

Abstract: Responding to the threat of anthrax and other forms of chemical and biological terrorism, the Food and Drug Administration adopted new rules yesterday that will speed the approval of drugs that could protect people from attacks.

In a major change from past practice, the agency said that in some unusual circumstances it would allow companies to base their new drug applications on animal testing alone when assessing whether a drug is effective. Previously, a drug's effectiveness had to be tested on humans before the FDA would give its approval and allow it onto the market.

"The terrorist attacks of last fall underscored the acute need for this new regulation," said Lester M. Crawford, the FDA's deputy commissioner. "Today's action will help make certain essential new pharmaceutical products available much sooner -- those products that because of the very nature of what they are designed to treat cannot be safely or ethically tested for effectiveness in humans."

The new rule, which was first proposed in 1999 and took on a new urgency last fall, was likened yesterday to the FDA's landmark decision a decade ago to approve new HIV and AIDS drugs that had not been fully tested by previous standards. At that time, the FDA concluded that its standard review process was standing in the way of making potentially lifesaving drugs available to infected people.

Some consumer advocates said yesterday that they are wary of the animal-testing rule, contending that its use could expand to other less pressing concerns -- just as the FDA's "fast track" approval process for AIDS drugs was later used for many other medications.

But Janet Woodcock, director of the FDA's Center for Drug Evaluation and Research, said use of the new rule, which the agency considers "urgently needed," would be limited.

Woodcock said the FDA has "been struggling in a number of cases to persuade applicants to go forward" with drugs to treat biological, chemical and nuclear attacks. "When they couldn't ethically do human trials, it has been very difficult to move forward," she said. "This rule addresses that obstacle."

She said that it would still take a year or more for companies to design, undertake and complete their animal studies, and that she "would not expect a flood of products based on the rule. But it does provide a path, and some companies will respond."

The new standard will only be allowed when tests of a drug's effectiveness on humans would be unethical. Some vaccines have been approved without full human testing, but traditionally, drugmakers conduct human trials to determine whether a medication is more effective than a placebo by giving some patients the medicine and some an inactive pill.

It is considered unethical to expose a test subject to a potentially lethal or permanently disabling agent, making it impossible to test a drug's effectiveness against biological, chemical and radiological threats.

Woodcock called the new rule "narrowly drawn," saying that it would usually require two or more animal tests, and that it could be invoked only when all other FDA testing standards are inappropriate. In the text of the new rule, the agency estimates that it will be applied infrequently, probably less than once a year.

Woodcock said that in most cases, drugmakers would still have to prove that their products were safe in humans. That determination, she said, can generally be done without exposing patients to unethical risk.

The FDA has already approved one drug for use against bioterror attacks, the antibiotic Ciprofloxacin, which was widely used among victims of a series of anthrax attacks last fall. That drug, also used to treat a variety of other infections, received accelerated approval for use against inhaled anthrax in 2000 based on both animal tests and human studies of how it behaved in the bloodstream.

Sidney Wolfe, of the consumer advocacy group Public Citizen, questioned why the new rule is needed if Cipro could be approved without it, and voiced concern that it could be abused by the FDA and industry. "There's been a lot of slipping and sliding in the past on this kind of speeding up the review process," he said.

Drug and biotechnology industry spokesmen welcomed the new rule yesterday, calling it an important advance.

"This is a very important and valuable development because it offers some consistent rules for how products will be evaluated," said Michael Friedman, a former acting FDA administrator who now helps coordinate the drug industry's bioterrorism efforts for the Pharmaceutical Research and Manufacturers of America.

"That's been the big difficulty for years: You have diseases that are untestable in humans," he said. "There are medicines out there that we have every expectation would be effective against anthrax, for example, but there's been no consistent way to test them."

Friedman said that the new rule did not, however, mean that testing would speed ahead. He said another pressing problem is the limited number of rhesus monkeys available to test for the bioterror drugs. While the new rule allows testing in a range of laboratory animals, monkeys are most like humans in the ways they respond to drugs and have traditionally been the standard for assessing the effects of a new medication.

According to Steve Lawton, chief lawyer for the Biotechnology Industry Organization, the new rule is an "absolutely appropriate and necessary tool to combat terrorism." He said that a recent BIO conference on bioterrorism was "packed with an extraordinary number of young companies working in the lab to find products against anthrax and other biological agents."

He predicted that the ability to avoid the costly and time-consuming process of conducting human clinical trials would likely make the drugs more attractive to venture capital companies. "It's a terrific combination of patriotism and opportunity," he said, "and there are a lot of people out there ready to respond" (UCLA, 2002).

Title: In Search Of Antiterror Drugs
Date: June 3, 2002
Source: New York Times

Abstract: In an effort to come up with drugs and vaccines to protect people against biological, chemical or nuclear attacks, the Food and Drug Administration adopted new rules last week that will allow it to approve some medicines without requiring clinical trials to determine their efficacy in humans. The agency will rely instead on animal tests and other measures to determine if the substance is likely to be effective.

That could leave the American public in an uncomfortable position. Should a devastating attack occur or be imminent, people could be betting their lives on unproven remedies, with no assurance that they will really work in humans. Even so, the new policy seems the best way to proceed in an age of terrorism. There is simply no ethical way to conduct the clinical trials that are traditionally required to prove a drug's efficacy.

The problem is not that the drugs or vaccines themselves cannot be taken. They can be and will be given to human volunteers in the traditional tests that are designed to demonstrate that a substance is safe for human consumption. Rather, the problem arises at the next step, when the effectiveness of the medicines would have to be tested by exposing human volunteers to lethal agents like smallpox, nerve gas or intense radiation.

In a practical sense, it would be hard to find many volunteers eager to test an experimental vaccine against, say, the Ebola virus, by potentially subjecting themselves to a gruesome death should the vaccine fail. But practicalities aside, the F.D.A. has concluded that it would be unethical and unsafe to conduct such trials. The risks to the volunteer would be very high, and the possible benefit, in the absence of a terrorist attack, would be nonexistent.

The agency will rely instead on animal testing buttressed by whatever supporting data is available. The agency expects that potential drugs and vaccines would be tested in more than one animal species unless there is a single species deemed especially good for predicting human effectiveness.

The agency's carefully drawn rules also require that the pathways by which a drug and a germ operate in the body are understood well enough that reasonable predictions can be made. But none of this is foolproof. As the F.D.A. acknowledges, "There are countless examples of treatments with favorable effects in animals that did not prove effective in humans."

Even consumer advocates who serve as watchdogs over the F.D.A. agree that the new rules make sense. They simply urged that the rules be sparingly applied and not become a loophole to weaken the drug approval process. The F.D.A. swears it will move cautiously and estimates that the new rules might be invoked only once every three years. If that proves the case, the real problem might not be too many approvals, but too few new medicines to cope with terrorist attacks (New York Times, 2002).