sensitivity of the animal model in detecting a "rare event" like carcinogenesis (cancer-producing potential). As a result, the massive doses can "stress the test organism, tending to make extrapolation calculations extremely uncertain." In other words, the doses are so abnormally high, much higher than would be prescribed for human patients, that data from animal testing are often grossly distorted.

2) The ability to extrapolate test data from animal models to humans is very uncertain, and even from rodents to species other than humans. "Therefore, such comparisons introduce potential errors in extrapolation to humans," warns Brusick.
3) Since animal testing is so costly and time-consuming, the drug company is unable to assess its results by trying to reproduce them. This point is especially relevant for drugs with borderline characteristics since test results often fluctuate widely.
4) No tried-and-true method exists to help the toxicologist or researcher extrapolate his animal test results to the human population. This is directly attributed to our "poor understanding of the factors which enter into the etiology of cancer in mammals," according to Brusick.[17]

Inadequacy of Animal Models

The FDA claims that its animal-testing regulations exist to protect the public. But since there is no animal model that accurately reflects human physiology, marketing a drug tested only on animals as a solution to human medical ills is almost impossible. A case in point are drugs for rheumatoid arthritis. Although new drugs that may halt or reverse the progress of rheumatoid arthritis can possibly be developed, drug companies cannot or will not try to develop them since there is no valid animal test for such drugs.

This point was made early in 1983 by one of the nation's leading experts on rheumatoid arthritis at a meeting of more than 100 arthritis specialists. "The cost of seeing one of these new compounds through development . . . is $50 million to $100 million," said Dr. Israel Jaffee, professor of medicine at Columbia University. "To start from scratch . . . not knowing if something will work, is a risk that no drug company is willing to take. The main reason is that there is no animal . . . that reproduces rheumatoid arthritis."

[17]Ibid.

Drug companies must conduct years of animal testing in the development of a drug before it comes to market as a "safe" and effective drug. But without an accurate animal model, says Jaffee, commenting on the futility of rheumatoid arthritis drug development, you could do "five years of testing and still end up with something that is totally ineffective."

Nonetheless this kind of situation does not deter the drug companies from using animals to test drugs. Although there is no animal that reproduces rheumatoid arthritis, aging animals can develop osteoarthritis, a deterioration of the bone or cartilage. Doctors now have discovered a method of creating an arthritic-like condition in animals, called "adjuvant disease," an inflammatory illness similar to rheumatoid arthritis but it is unlikely to have the same causes and just as unlikely that any drug developed from these animal tests will have a beneficial effect on humans.

The reluctance of the biomedical community to actively pursue non-animal alternatives perpetuates the crippling pain suffered by three out of every 100 American adults and 150,000 children. In some instances the very agency, FDA, which has developed regulations designed to protect the human community, delays the providing of quality care.

Alternatives

1. Molecular Approach:

Brusick has outlined a molecular approach to drug testing, which avoids the use of animals and utilizes *in vitro* (out of the living animal) techniques:

NON-ANIMAL IN VITRO TESTING **[negative]** **LIMITED HUMAN USE APPROVED**

[positive results]

COMBINED IN VITRO/ IN VIVO TESTING **[negative]** **HUMAN USE APPROVED**

[positive]

DATA ANALYSIS

HUMAN MONITORING ON POPULATIONS ALREADY EXPOSED

STANDARD EXPOSURE LIMITS ESTABLISHED