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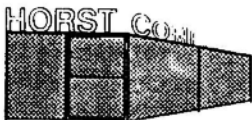
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RESEARCH

How Safe Is "Safety First"?

The Tragedy Behind LD₅₀

By Nedim C. Buyukmihci, VMD

Virtually anything that is ingested by, injected into or applied onto humans (or which may accidentally come into contact with them) is "safety" tested annually by using millions of various nonhuman animal species annually. This includes therapeutic agents such as antibiotics, personal hygiene preparations, cosmetics, household cleaners and industrial solvents. The same holds true for products used in the environment such as pesticides, fertilizers and machine lubricants.

There are several parameters used in testing these substances: chronic toxicity, carcinogenicity, teratogenicity and acute toxicity. I will address two of the methods used in the latter category.

Acute toxicity testing almost always is associated with extreme suffering because of the very nature of the tests used. Anesthetics or analgesics are *not* used. Two of the ways in which a substance is evaluated for its acute effects are the lethal dose 50% (LD₅₀) and the eye irritancy (Draize) tests. Surviving animals are killed after the tests.

The LD₅₀ typically involves the administration, by injection or forced ingestion, of various doses of the material to groups of animals. Two or more species of animals, and as many as several hundred each, may be used for every substance tested. The dose at which 50% of the animals die is called the LD₅₀ and is expressed as the amount of the material per unit of body weight. Sometimes the material is not very toxic and the animals die from the volume of the material forced into their stomachs. The animals that die, often after agonizing illness, may be considered the lucky ones. Those that become sick and do not die, suffer longer. Depending on the material tested, the animals may have severe abdominal pain, muscle cramps, convulsions, vomiting,

diarrhea, gastrointestinal ulcers with bleeding, loss of kidney function or other painful conditions.

LD₅₀ is only a statistical value

The problem with this test, besides its inhumanity, is that the numbers generated are meaningless. The LD₅₀ is only a statistical value, valid only for the exact conditions under which it was derived and only for the animals in which it was determined. Changes in ambient temperature, level of stress, or amount of food or water, for example, can alter the LD₅₀ by 10 times or more. Furthermore, the LD₅₀ changes drastically from one species to another or even from one strain to another of the same species. The LD₅₀ of a substance in rabbits or rats is in no way an indicator of the acute toxicity of the substance in a human being. Drug interactions, a common problem in the clinical setting, are not addressed by this test. Moreover, a number indicating 50% mortality has minimal clinical relevance. A minimum lethal dose or a maximum tolerated dose (in humans) would have much more meaning to the practicing physician.

In the Draize eye irritancy test, any compound that might intentionally or accidentally gain access to the eye is tested by being placed onto the eyes of conscious, restrained rabbits. The animals are observed for several days for adverse reactions. There may be no reaction or irritation may range from minor to severe. In the worst situation, the cornea may ulcerate and perforate. Because the cornea is one of the most sensitive tissues in the body, rich in nerve endings, irritation or ulceration produces considerable pain. The rabbits usually are restrained in stocks which hold the animals by the neck and prevent them from rubbing their eyes. Therefore, they cannot mitigate the

discomfort or pain.

Are the tests really necessary?

For some substances tested using the Draize method, notably those containing acids or strong bases such as lye, the results could easily be surmised; no tests are necessary. For others, the material already may be known to be safe and further testing is not necessary. In other cases, there may be little correlation between what happens in the rabbit and what happens in the human, the rabbit's eye often being much more reactive than the human's.

From a scientific and human safety perspective, results from the LD₅₀ and Draize tests largely are irrelevant, unpredictable and potentially dangerous since people react differently from other animals to many substances. In addition, this type of testing can never predict individual or familial tendencies for adverse reactions. For example, the antibiotic chloramphenicol is relatively safe in nonhuman animals but causes death from aplastic anemia in susceptible humans. The amount necessary to do this in some individuals is so small that even the tiny amount applied through eye ointments can be fatal.

Ironically, products still are manufactured and distributed for human use even though they are demonstrated to be toxic

to nonhuman animals. For example, during "safety" testing of the artificial sweetener saccharin, rodents developed cancer. Despite this, the test results were, in essence, ignored, and the product was marketed, albeit with a warning label. Therefore, perhaps thousands of animals suffered and were killed for a trivial, nonessential product and the data generated were pre-empted by economic interests.

In another example, a nail-polish remover containing acetonitrile, which was tested on nonhumans, was released for use and resulted in the death of a human child.

It would be more pragmatic and reliable to gain data from the numerous unplanned human exposures to various substances. Physicians deal daily with accidental poisonings or exposure of the eyes to chemicals. The data generated by these observations would help us predict what another person might expect and develop treatment measures.

What is the solution to the problem of safety testing? There is no easy, universally acceptable answer. Federal agencies, such as the FDA and EPA, do not require nor encourage the LD₅₀. Many companies are modifying the LD₅₀ and other tests to reduce the number of animals used. They are safe and reasonable alternatives to those tested on nonhuman animals. Much, if not most, safety testing is done on prod-

ucts designed to improve existing ones. Whereas this normally would be appropriate in a free enterprise system, the fact that animals must suffer and die as a result makes it unconscionable.

What can you do?

What can you do to reduce the pain and suffering involved in "safety" testing? Alert others to the truth behind the products. Substitute cruelty-free alternatives. Alert your local market and ask them to carry alternative products. Whereas food co-ops traditionally have been open to this, a need exists for exposure in the large grocery chains. Make the pledge to use cruelty-free products whenever possible. With increased economic pressure, there will be increased efforts by large companies to develop cruelty-free products.

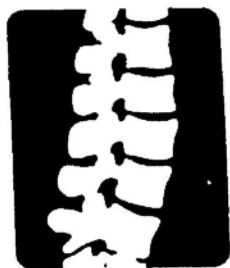
From a moral perspective, toxicity testing using nonhuman animals cannot be condoned. The animals are living, feeling creatures capable of suffering in ways similar to ^{human} ~~man~~. They have lives and interests independent of ours. There are no morally significant differences between them and us. ■

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