CASE STUDY
When reliability and validity are not enough: the case of animal experimentation

You doctors are lucky because you can bury your mistakes.

Animal experimentation (mainly on rats and mice) has a long tradition in medicine. It is conducted in private and public laboratories, for example, at universities (perhaps at *your* university). Its purpose is, amongst other things, to discover new drugs to treat diseases or to study the effects of certain chemicals on human beings (for example, toxicity tests). The practice does not enjoy broad consensus; on the contrary, it is subject to increasingly harsh criticisms, principal among which is that animal experimentation is based on a reductionist scientific model where rodents, dogs, cats, monkeys or pigs are considered to be biological replicas of the human body. But this is to ignore the numerous differences (in metabolism, genetics, physiology, immunology, and so on) between one species and another. In other words, it is as if a sociologist, in order to study hierarchies or power relations in organizations, used as his model . . . a beehive.

Anti-vivisectionist criticism does not banally condemn the simplification of a phenomenon, given that the reduction of complexity is a cognitive, as well as practical, necessity due to the limits of our reasoning capacity. The criticism is instead centered on the implausibility of the animal model. This conclusion has also been recently reached by the so-called 'official science,' well-represented by three of the most prestigious international scientific journals (see *British Medical Journal*, no. 328 of 28 February 2004; *New Scientist*, vol. 182, no. 2436 of 28 February 2004; *Nature* of 10 November 2005, the most scientifically accredited journal in the world, which until recently never accepted any criticism of the animal model). Thus gaining ground in official science, as well, is the conviction that no species can serve as a reliable biological model for another species (as regards both toxicity tests and pharmacological research). Indeed, if medical knowledge were based on laboratory rats, thalidomide would be considered safe; alcohol would be regarded as no more toxic for the liver than sugar; tuberculosis would not be considered a dangerous disease because rats are little affected by it; smoking would not be deemed responsible for lung cancer; and we would not consider it necessary to include vitamin C in our diet. A recent example is the case of vitamin E. For many years, this was promoted and sold as boosting fertility and enhancing the nervous and muscular system. Today it is agreed that vitamin E is indispensable only for mice, not for human beings: in fact, if mice are deprived of it in their diets they suffer severe debilitation; instead, its absence from human diet does not cause significant damage.

Is that all? Is it 'only' a problem spanning ethics and science? Not at all. It is also an extremely serious problem in medicine and health care. According to Claude Reiss, the French molecular toxicologist and emeritus director of the CNRS of Paris, the reductionist culture that guides the testing of pharmaceutical products on animals (the expression 'this product has been clinically tested' on packaging is well known) has been responsible in France for the hospitalization of 1.3 million

people due to the harmful effects of medicines, and for the deaths of 200,000 people every year around the world. Likewise in the United States 100,000 Americans die every year because of adverse reactions to drugs, all of them considered innocuous after being tested on animals. From an epidemiological and statistical point of view, medication-caused pathology is the fourth or fifth (according to the year) most frequent cause of death. In 1998, *AIMA*, one of the most important scientific journals in the world, published two studies documenting that 52% of the medications marketed in the USA cause severely adverse reactions: death, risk of death or permanent disability. From this one deduces that however many preliminary tests have been carried out, the first really valid result is obtained when the drug is administered to volunteers and human patients in clinical trials.

This example clearly shows that the concepts of reliability and validity alone do not take us very far. These laboratory tests are certainly reliable (according to the paradoxical and perverse logic of reliability: see Carmines and Zeller). Despite this, many doctors certainly do not consider all these victims as proof that animal experimentation does not produce valid results. Also, as research on medical errors (Shulman, Singer, Goldstone and Bellingan, 2005; Koppel, 2005) shows that the method of discovering medical errors strongly affects the types of errors identified. For instance, a patient's chart states the diagnosis and the medications proposed. If an incorrect (different from that prescribed) medication or dose has been administered, this will not be apparent on the chart. It can, however, be seen by looking at the patient's physical condition, or by observing or interviewing the nurses.

Reviewing patients' medical records (charts) reveals types of errors, including those 'potential errors' that may have been averted (i.e. by a pharmacist or a nurse before the drug was administered). In addition, if the diagnosis is wrong, the process of chart review has probably been faulty. On the other hand, observation of the patient may reveal other errors not ascertainable from chart reviews, but it will miss errors prevented by nurses or pharmacists.