

Subject: FR Notice Comments - 72FR23832: Draft Five-Year Plan

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Comments: Research methods that do not use animals have been advancing medical knowledge since ancient times, and are still in use today. These include autopsy studies and clinical research, which involves the observation of human patients. Epidemiology, which is the study of the incidence of disease within a population group, has been around since the 1600s. The development of sophisticated technology in recent years has enabled epidemiologists to maintain large databases of information and analyze the data quickly, with pinpoint accuracy.

A couple of the most commonly used non-animal product safety tests include:

Murine Local Lymph Node Assay (ILNA), a method for assessing the allergic contact dermatitis of chemicals. The peer review panel concluded that the

ILNA is a valid alternative to currently accepted guinea pig test methods, and that the ILNA reduces the number of animals required for testing and eliminates animal pain and distress.

Corrositex, an in vitro (test tube) method for assessing the dermal (skin) corrosivity or burn potential of certain classes of chemicals using a collagen matrix barrier as a kind of artificial skin.

Emerging technology has had a tremendous effect on the development of non-animal research methodologies, and the innovative techniques and procedures that are now defining the frontier of medicine would fill an encyclopedia. Today, these technologies are providing physicians with a whole new level of information that they can use to ensure more accurate diagnoses of illnesses in a patient and an appropriate treatment program. Some of the highlights which represent only a tiny fraction of the non-animal advancements made in recent years include:

- Interactive computer simulations that predict how a particular drug will affect a person's respiratory or circulatory system.
- Data mining techniques that analyze drug information databases to find previously undiscovered applications for pharmaceuticals that have already been studied.
- Diagnostic imaging technology, including magnetic resonance imaging (MRI), positron electron tomography (PET), computer-aided tomography (CAT) and ultrasound.
- Mathematical modeling, in which computers simulate parts of the human body as mathematical equations.
- Lasers, which have a wide range of applications in medicine, including eye surgery, the treatment of skin disorders, and as a replacement for the scalpel in many types of surgery.
- New DNA chip technology that can be used to differentiate clinically distinct cancer types and discover clinically important tumor subtypes.
- Acoustic microscopy, which demonstrates internal conditions using sound waves without requiring dyes.

A wealth of innovative technologies are on the horizon, too. Research using stem cells, the Human Genome Project and the Human Proteome Project all hold the promise of cures that we would never have discovered using animal models. As we understand more how genes are involved in disease, we will be able to test potential drugs to see what effect they have on the DNA that comprises the gene. In the emerging field of pharmacogenomics, scientists can employ a "gene-to-drug" strategy to predict a person's response to a given drug before exposure to the drug and customize therapies to meet explicit genetic criteria.
