curate than the MST . . . but his findings were not published! "Nobody listened to us, nobody believed us," said Perkins to Michael Marten, a journalist sponsored by an animal rights organization.[13]

Dr. Walter Hennessen has also decried the bureaucratic inertia in adopting available technology to replace monkey tests. "It seems remarkable that after the accumulation of much evidence by which experts recommended the abandonment of a monkey safety test, . . . (the MST) is still required unchanged by national control authorities."[14]

Artificial Vaccines: Quality with Morality

The most promising technique to date and one which may totally eliminate the use of animals in vaccine production and testing is the artificial vaccine.

Synthetic vaccines of various types are now being produced in a number of laboratories, including the Scripps Clinic's Research Institute. The first synthetic vaccine developed there was for foot-and-mouth disease, an animal plague still prevalent on every continent except Australia and North America. Three billion doses of conventionally produced vaccine, administered annually, are required to control it. Success at Scripps in producing an artificial vaccine against all three varieties of this disease has tremendous implications for the control of other viral diseases, including cancer.

Thus, artificial vaccines can be specifically targeted for a given disease, can be inexpensive to produce with computer imaging techniques and recombinant DNA technology, can eliminate the possibility of pathogenic contamination and, since no live virus is present, can eliminate entirely testing on monkeys for effectiveness or virulence of prepared batches.

E. DRUG DISCOVERY AND DEVELOPMENT

History

The history of drug development has involved the relationship between a drug's structure and its activity. Early scientific belief held that if the structure of a drug determines its activity, drug development should concentrate on the synthesis of chemicals according to certain chemical laws that could determine their structure. In the 19th century, both the scientific and medical establishments expected results from this concept.

In 1877, Thomas Lauder Brunton, eminent British physician and pharmacologist, stated that therapeutics would become rational, with physicians predicting the pharmacological action of any drug from its chemical structure. In 1889, he predicted that physicians would have an arsenal of drugs, arranged in order of their comparative strength, which could affect any physiological function and disorder. He believed that this could be "rationally" achieved without the use of animal models to verify the structure/activity relationship. But success in drug discovery was not due primarily to this reasoning, and by the end of the 19th century, the belief that chemical structure determined specific activity began to weaken.

Drug research activity intensified in the 15 years following World War II after the discovery of sulfonamides and the antibiotics. But in the last 13 years, there has been a decline in this momentum. One in about 2,000 newly synthesized chemicals reached the consumer 20-30 years ago; today the rate has fallen to one in 8,000-10,000. Why?

The mandates of the FDA have had a significant influence, resulting in a tightening of drug evaluation studies in the sixties and seventies. The watchdog role of the FDA, and the thalidomide and other disasters, resulted in many new tests being required, including studies of chronic toxicity, fetal toxicity, mutagenicity and carcinogenicity.

Consequently, it now costs $50-60 million to develop and market a new drug; this amount includes the cost of developing unsuccessful drugs as well. And in addition, each marketed drug involves taking the lives of 3000 to 4000 animals.

Because of the time required to market a new drug there has been a tendency in the United States to curtail preliminary research. Lately, however, manufacturers of pharmaceutical products have felt pressure from technological and cost factors to make use of the newest developments involving the causes and mechanisms of disease. The new field of molecular biology has been the source of significant contributions, especially in the areas of toxic, mutagenic and therapeutic chemical effects.

With the development of the electron microscope, nuclear magnetic resonance measurements, X-ray diffraction analysis, and recombinant DNA technology, scientists now have the submicroscopic tools to "see" and manipulate inner cell mechanisms. And, with the aid of the computer, it is now possible to determine the three-dimensional structure of

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[13]Ibid., p. 47.

[14]Hennessen, W., *Developments in Biological Standardization*, (1979) 45: p. 170-171.