PHARMACOLOGY

Drug Makers vs. Review

Legal definitions of "old" and "new" drugs are the central issue in a Pharmaceutical Manufacturers Association suit against the Food and Drug Administration.

➤ WHETHER DRUGS long in use with Government approval will need to go through a process of reapproval by the Food and Drug Administration is being tested in the courts.

The Government contends that the efficacy and safety of such drugs as cortisone, resperine and sulfathiozole must be redetermined.

A suit by the Pharmaceutical Manufacturers Association (PMA) has been filed against the Food and Drug Administration in Wilmington, Del., where many drug manufacturers are under court jurisdiction.

More than 40 members of the PMA, whose drugs are affected, are the plaintiffs.

The suit, in effect, argues that the new regulations require too much research and paper work, and that the effectiveness and safety of a drug in use since 1938 should not necessarily be at stake.

PMA officials hold that the new regulations do not always relate to the public safety, and that the reason for the legal action is an attempt to clarify their meaning.

PMA says it is not trying to castigate FDA. The actual age of the drug's discovery has nothing to do with the suit, but the legal definition of a new drug definitely needs clarification.

A drug can be 25 years old, in constant use, yet if new discoveries have shown it to be dangerous or ineffective, PMA will comply with the FDA amendment to its old rules.

In the case of many "old-new" drugs, however, the drug manufacturers feel that more research and paper work are unnecessary.

In 1947, for example, one drug company may have obtained a new drug application, obtained a patent, and obtained a license to manufacture a drug which had passed all required tests. Then in 1960 another drug company may have asked permission of FDA to manufacture the drug without further research and paper work, and FDA may have said that this was all right.

Now under the new regulations, FDA appears to be asking the second company to go back and make a new application, containing complete reports on the efficiency and safety of the drug.

The burden of such requirements is on the time of research scientists in the drug companies, PMA contends. Their scientists should be doing new research, not rehashing old research and reporting old findings, drug officials believe.

Commissioner George P. Larrick, head of the FDA, opened the way for the suit in a statement on April 14, PMA points out, when he told a Pharmaceutical Manufacturers Association meeting that the FDA welcomes legal action if it is to clear up honest differences of opinion.

The drugs affected by the controversy could number as many as 3,000, FDA says. Many of these drugs were considered safe and became "old" drugs before the Kefauver-Harris drug amendment went into effect Oct. 10, 1962.

The latest date for new drug application has been set for Oct. 10, 1964, and the drug manufacturers are trying to avoid overall compliance with the requirement.

• Science News Letter, 86:94 August 8, 1964

BIOCHEMISTRY

Deoxyadenosine Form May Give Key to Life

➤ THE SIMPLEST possible chemicals have been joined together to form the most complex compound yet made under conditions believed to represent those of primitive earth.

The synthesis of deoxyadenosine is a step toward understanding how life on earth originated, since the compound is present in deoxyribonucleic acid, the hereditary material of all living cells. The synthesis was accomplished by Drs. Cyril Ponnamperuma and Patricia Kirk of the U.S. National Aeronautics and Space Administration's Ames Research Center, Moffett Field, Calif.

The chemicals they used to form deoxyadenosine are likely to have been present on the primordial earth due to action of lightning, ultraviolet light or atomic radiation. Other scientists have previously shown that adenine, a purine, and deoxyribose, a sugar, can be synthesized under primitive conditions.

Now, Drs. Ponnamperuma and Kirk have found that these two compounds will combine to form deoxyadenosine when the cyanide radical is present and the mixture put under ultraviolet light. The cyanide radical, CN, is related to the deadly poison potassium cyanide.

Adenine and deoxyribose will also combine in ultraviolet light in the presence of ammonium dihydrogen phosphate, which is related to widely used fertilizers.

The adenosine was identified both by paper chromatography and by the radiation given off from the radioactive carbon in the adenine.

The scientists also found evidence indicating that ionized magnesium can replace the cyanide radical in the formation of adenosine. They are now studying this further, since magnesium is extensively involved in biological processes.

Drs. Ponnamperuma and Kirk reported their work in Nature 203:400, 1964.

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