

or capsule to pass through the body undissolved, with no medical effect whatsoever;

- 6) **Deterioration.** Some drugs, if improperly produced, can deteriorate to ineffective or toxic substances. The widely used antibiotic tetracycline, if dispensed in relatively acidic capsules, slowly transforms into a deadly kidney poison. Without appropriate — and costly — safeguards, this kind of problem can occur;
- 7) **Absorption.** How well a medicine is absorbed into the body depends on many factors, including how rapidly it dissolves, the nonactive ingredients used, stability in digestive juices, and how it reacts with food in the stomach.

The Dangerous Effects of These Differences

Here are some specific examples from medical journals that also received some attention in newspapers.

A few years ago, it was discovered that while Chloromycetin (brandname) is a very powerful and effective antibiotic for certain infections, all the generic equivalents of chloramphenicol (chemical name) would not do the job, no matter *how* much was given to patients.

Digoxin (generic name) is used by millions of Americans to help their hearts beat more forcefully. In 1974 the Food and Drug Administration discovered that some manufacturers' digoxin varied so much in absorption rate from batch to batch, that patients could get dangerously high or low amounts from the same dosage. The FDA also noted that Lanoxin (brandname) had no such problem. It was a little more expensive, but it worked, unlike its cheaper counterparts.

Alan Tasoff, MD, writes of his experiences as an Air Force doctor in Thailand in 1972: "Struggling to overcome a penicillin-resistant gonorrhea epidemic among airmen — of the magnitude of twenty new cases per day — we were armed with an Italian-manufactured tetracycline, purchased in massive quantities by Congress. The drug was chemically equivalent — in the judgment of consumer groups — to brandname drugs. The failure of this drug to dissolve in the alimentary tract was known to all physicians prescribing it, but supplies had to be consumed before a replacement could be made available. The ultimate cost to the airmen involved was chronic, intractable urethritis and prostatitis."

Two Branches of the Government Say All Drugs Aren't Equal

With all the controversy surrounding this question, the United States Senate Health Subcommittee asked the Office of Technology Assessment (OTA), an agency of Congress, to study the whole problem of prescription drug bioequivalence (whether chemically equal drugs will be equally available in the body, therefore allowing them to have an equal effect).

The OTA set up a Drug Bioequivalence Study Panel, and asked Dr. Robert M. Berliner, dean of the Yale University Medical School, to be its chairman. After months of intensive study, the panel released its report in July 1974. Among its findings were:

"Current standards and regulatory practices do not assure drug bioequivalence for drug products."

"Present . . . guidelines do not insure quality and uniform bioavailability for drug products. Not only may the products of different manufacturers vary, but the product of a single manufacturer may vary from batch to batch or may change during storage."

"The problem of bioinequivalency in chemically equivalent products is a real one."

The Food and Drug Administration has so far identified 193 categories of drugs, including thousands of different products, as having known or strongly suspected equivalence problems.

The People Say They Don't Want Prescription Drug Substitution

In a democracy, what the people think counts. So it's important to know the findings of the national and two state surveys on the relative importance of drug cost, quality, effectiveness, safety, and bioequivalence. 2,532 people were surveyed all across America, and 1,149 people were questioned in California and Wisconsin.

Seventy-one percent of the people questioned nationally believe the physician, not the pharmacist, should determine which drug product a patient takes. (In the state surveys, the percentage was 75.)

In the state surveys, people placed far greater importance on effectiveness and safety of prescription drugs than on their cost or speed of relief. In fact, cost was last by a decisive margin.

Over 70% in the national poll said they didn't want substitution of generic drugs for those prescribed,

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