

is still used over the world. In some instances there are good reasons to use combined preparations.

In the world of antibiotics, combinations are used to broaden the coverage in individuals when you don't know what you are dealing with and it is an emergency situation. Another use is to delay the emergence of resistance to one of the drugs. This is commonly used in tuberculosis, or to achieve an effect, a so-called synergistic effect, when the effect of the combination is greater than the addition of the properties of the two agents.

Actually, however, except in tuberculosis and one form of heart disease, use of drugs in combinations are really not essential.

Senator NELSON. When Dr. Miller, representing the USP testified here he said that the USP does not list any combination drugs in the belief that since drugs administered separately give the physician greater control, there is no good reason for listing combination drugs.

You say basically the same thing except in reference to cases in tuberculosis and rare infections of the heart where combinations are of value; is that correct?

Dr. KUNIN. Well, we must make a distinction between the combined use of drugs and the fixed combination of a drug in one package.

Senator NELSON. I was referring to the fixed combination. Is that what you are talking about?

Dr. KUNIN. In tuberculosis they don't use the fixed combination. I am sorry if I implied that. There are drugs used in combination, but they are used separately. There is no fixed combination there, necessarily.

Senator NELSON. Do you see any value in the fixed combination drugs appearing in one capsule?

Dr. KUNIN. No.

Senator NELSON. For any disease that you know of?

Dr. KUNIN. No. I will give you an example from an advertisement if you wish. Urobiotic—by the way, it took me only 10 minutes to pull these out. These are available so easily in all the medical journals that one doesn't have to work hard to find these examples.

Here is one called Urobiotic, which is a combination of oxytetracycline, a tetracycline derivative, which is an excellent drug, glucosamine, which is simply an excipient and a sulfonamide, and a material to turn the urine red. The dose of oxytetracycline is very low, 125 milligrams. This is lower than we would customarily use. It does have sulfonamide, 250 milligrams. It might work. But this would be an unnecessary combination, perhaps not as effective as the tetracycline Terramycin component all by itself, and so I think this is an example of a fixed combination that has no place in the market.

(The advertisement referred to follows:)