

offer the medical profession the most *unbiased* information on all forms of therapy.

May I digress for a moment here and say that the information I am offering today is not something I have just decided on. I should point out that I offered some of this information to the Food and Drug Administration twice in 1963. Had some of my suggestions been adopted then, or had those that were adopted been enforced, an ad such as the one I have exhibited could never have been printed to mislead today's prescribing physician.

Now, let me reinforce my testimony with another ad from the same issue of *JAMA* from which I obtained the Anarase ad, and but a scant 14 pages away from it. Please keep in mind that most physicians will accept this ad at face value simply because it is in *JAMA*; they assume it has been screened for absolute accuracy (Exhibit D).

This ad is for Mandelamine, a chemical to use against infections in the urinary tract (kidneys and bladder). This ad uses five published references to support its claims. Although the ad cites the first reference for one purpose, it is of interest to note that another, important, part of that first reference is not only omitted, but is even contradicted in the ad.

In the ad it is pointed out that an acid urine is essential for the antibacterial activity (of Mandelamine). The ad goes on to say that maximum efficiency of the drug occurs at pH 5.5 or below. I am sure members of this committee understand the terms acid and alkali; the letters pH followed by a number being a specific indication of whether something is acid or not—in this instance we are considering urine. Normally, most people on an average diet will produce urine with a pH of 6, or slightly acid (7 being the neutral dividing point between acid and alkali). When we eat an excess of proteins, it tends to make the urine more acid; while vegetables and citrus fruits do the opposite, that is, make the urine alkaline or with a pH greater than 7).

Now you might possibly remember that at the beginning of my statement I mentioned it was possible for a drug to fail in its intended effect because of improper environment. The use of Mandelamine illustrates what I meant; if the drug is not used in a very acid environment, it has no therapeutic effect. This, in turn, is not only a waste of money for the patient but could be even more dangerous than the original infection since an ineffective drug allows the infection to grow and become worse.

To come back to the ad, the first reference used in the ad to support the company's claims not only *stresses* the need for acidifying the urine, it specifies just how acid the urine must be. The original article, indicated by reference number 1, says the pH must be "less than 5." This is *very* acid, and more often than not must be achieved by adding another chemical (e.g., methionine, ammonium chloride, lysine) or forcing the patient to drink a great deal of cranberry juice or take large doses of Vitamin C. In other words, to use this drug without making equally sure the patient's urine is very acid is not only likely to be ineffective but could even be considered negligent.

Now look at the ad again. The ad states that maximum efficiency occurs at pH 5.5 or below. The ad does not hesitate to use reference 1 to support some of its claims, but it evidently does not agree with that same reference when it comes to acidifying the urine. While it may not seem much in the way of numbers, there is a great deal of physiological difference in a pH of 5.0 or below and 5.5. Actually it is as if the acid strength were doubled when the lower figure is used. If the reference's claims for how acid the urine must be is correct, then the doctor who reads only the ad will wrongly feel he is doing a proper job if his patient's urine reaches an acidity of pH 5.5, as the ad says. Thus, by following the ad alone, the doctors may well prescribe an ineffective drug. What is flagrantly missing from the ad is the fact that the doctor must monitor his patient's urine—at the very least once a day—in order to achieve and maintain the proper pH.

In another portion of this same ad, where the effectiveness of this drug is boasted about, it is important to note the "fine print" statement that in a true scientific sense actually discredits the very claim the ad is making. The ad admits, almost as an aside, that those who benefited most from Mandelamine also received greater amounts of antibiotics for greater periods of time. How can you honestly measure the effect of one drug when other drugs were used at the same time? And, with certain antibiotics, especially ones used most often to treat the identical urinary infection for which Mandelamine is recommended, it is best to have an alkaline urine—one that would render Mandelamine completely ineffective.