

### A Presumption Of Guilt

The American system of jurisprudence is based on the assumption that a person is held innocent until proven guilty. Not so with physicians. A Department of Health Education and Welfare (HEW) Memorandum on Maximum Allowable Cost Regulations on Drugs is printed elsewhere in this issue. It addresses itself to a serious problem, for as public money is spent, some control must be exercised to assure that it not be spent without reckoning. The HEW regulations as approved incorporate every conceivable foolish and reprehensible feature that such a plan could possible incorporate. Reasonable alternates will be presented on a future occasion.



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The little village of Chelm, in Poland, is known allegorically as the classic example of well-intentioned foolhardiness. Its Elders took themselves most seriously as they went about improving their daily lot. For instance, they were most concerned about the sexton sullyng the pure-white snow covering the ground, as he walked from door to door to wake the inhabitants for their morning prayer. So, the Elders met in consultation and deliberated for seven days and for seven nights at the end of which they had come up with a Memorandum on Improved Techniques for the Preservation of White Snow. From then on, four men would carry the sexton from door to door so his shoes would not touch the snow.

The Elders of Chelm must have emigrated to the United States, and have probably settled in Washington, D.C. Their descendants are probably responsible for the HEW Memorandum that supposedly would save the American people as much as 89 million dollars. (Sic! How did they figure it out that closely?) They must have simply forgotten to remember the cost of planning, supervising, monitoring, auditing and administering this newly born brain-child, who like his many brothers and sisters, may well end up spending more than he would be earning. They have also failed to include the cost of physicians' time required to go through HEW manuals to check whether a prescription is included in the allowable list of drugs, as well as the time and energy required for finding acceptable substitutes.

The foolishness of the plan is based on the presumption that physicians are suspect a-priori, and that they, more so than bureaucrats, are likely to misuse and abuse such programs. They can be kept honest only if every one of their steps is closely supervised by upright clerks, staunchly defending the public and the republic against its enemies, the physicians. This is a ridiculous, if ineffective, insult aimed, perhaps, innocently, at the majority of the medical profession.

The plan as presented is not only foolish and short-sighted but also arbitrary and high-handed. The included drugs and the maximum prices "would be determined by a Pharmaceutical Reimbursement Board composed of five HEW employees." These Board members are not physicians, yet, they would determine which drugs might be dispensed by physicians and which might not. This Board also has the power to grant or not to grant informal hearings to persons or organizations that object to its rulings, "if the Board *feels* it will aid in the final determination. The granting of such a hearing is completely discretionary with the Board."

The arbitrariness and high-handedness of these regulations are not even hidden in vague language. Its anti-professional attitude is indicated through the non-professional composition of the Board. Such officials cannot possibly understand that drugs that have the same biochemical formula are not necessarily equivalents in biological activity. Impurities and different production tolerances can make even one batch of the same manufacturer somewhat different from others. Basic differences exist sometimes in biologic activity of the same biochemical compound when produced by different manufacturers, some in foreign countries that have looser governmental regulations on quality control than those in the United States.

Almost every practicing physician has encountered cases of adverse drug reactions that have been corrected by using the same drug, but of a different manufacturer. This is one important reason for prescribing by specific rather than by generic names. Gastrointestinal X-rays have shown that swallowed pills and capsules occasionally pass the entire length of the tract without dissolving. Regardless of potential biological activity or biochemical composition, these drugs are obviously useless. Such secondary considerations as solubility and ease of absorption are not necessarily the same even if the basic compound is. They are of crucial importance, however, and have important bearing upon the outcome of therapy and the cost of cure. Huge amounts of aqueous Penicillin had already been acquired by certain VA hospitals when Procaine Penicillin was introduced. Many VA patients had to continue receiving several such injections per day when one could have done the job. This type of unnecessary suffering and widespread waste is likely to become the rule rather than the exception, as these regulations are enforced.

The time has come to do something about such foolishness. These regulations are now in force. No individual physician can afford to ignore them without peril to himself or to his patients. Medical societies must assume the responsibility of adopting measures to reject these and similar encroachments on the judgment of physicians. The Council of the Wayne County Medical Society should seriously consider the possibility of recommending to the AMA House of Delegates non-compliance with these regulations. The advisability of implementing local non-compliance similarly deserves close and careful evaluation.

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