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## FRUITLESS NUMBERS GAMES

"At least five," stated one of the group.

"No, no! There could be no more than two," said another.

"You're both wrong," exclaimed a third. "I'm sure that there could be at least five archangels and as many as twenty ordinary type angels!"

With only a bit of imagination and paraphrasing, the above represents the sort of absurdity that took place in arguments among certain theologians during the middle ages. In discussing the attributes of angels, a common point of dispute was how many such spirits could dance at the same time on the head of a pin.

We are reminded of that story every time we hear comments about the so-called "drug lag." Some say it involves this many drugs, while some others say it's half that number and yet others will say it's twice that number. Moreover, at other times, the issue will be argued not in terms of numbers of drugs but in terms of time; for example, that new drug introductions in the United States are a certain number of months behind one country or another with comparable controversy as to whether that estimated time period is overstated or understated.

Statistics pertaining to new drug introductions are very valuable and serve many useful purposes. However, we are of the opinion that their use or application in an effort to prove or disprove the so-called "drug lag" is unfortunate. In our opinion, the question of whether or not there is a drug lag is academic. What really matters is what has been the effect, if any, on health care in the United States.

But it seems that everyone wants to play "the numbers game" in one form or another. Industry representatives and academicians have been doing so repeatedly for at least the past five years. Even the present Commissioner of the Food and Drug Administration seems to have slipped—if not fallen—into that same morass.

In an article over his byline, which appeared in the January 30 issue of the *Journal of the American Medical Association*, FDA Commissioner Donald Kennedy addresses the subject under the title "A Calm Look at 'Drug Lag.' " He starts out by appearing to reject the numbers approach, but then proceeds to draw upon it himself in his effort to defend FDA's record. Predictably, the Pharmaceutical Manufacturers Association, as the principal critic of FDA's performance in the processing of new drug approvals, gave the article poor marks in its initial reaction. And, since Dr. Kennedy chose to buttress his position using the statistical approach, such criticism may have been deserved.

Our own personal view is that a drug lag does exist, and this fact should be conceded without further dispute. But we also believe that—with regard to this subject—it is senseless to haggle over numbers.

In the area of new drug approvals, the drug regulatory process is intended to keep from the market any and all agents until an appropriate determination has been made as to each agent's safety and effectiveness. Hence, the only questions that matter are twofold:

(*a*) Has FDA permitted drugs to be marketed that lack sufficient proof of safety and effectiveness?

(*b*) Has FDA unduly withheld drugs from the market for which adequate evidence has been provided as to their safety and effectiveness?

Whether such agents are permitted to be marketed in some foreign country or another is irrelevant and should not be a factor in assessing either FDA performance or the appropriateness of the drug armamentarium available to health-care practitioners for treating patients in the United States. The sooner everyone can get away from playing the numbers game, the sooner we shall be able to make a meaningful assessment of where this nation stands with respect to the adequacy of drugs approved for marketing.