November 25, 1974

Mr. William Rubin, Editor
Internal Medicine News
12230 Wilkins Avenue
Rockville, MD 20852

Dear Mr. Rubin:

I make reference here to your very emotional and especially positioned editorial in the November 1, 1974 issue of Internal Medicine News. You produce indeed some great publications that we all enjoy.

But, as you rail against the competence of various distinguished bodies in and out of government to pass judgment on medical issues, did you ever stand back and consider the appropriateness of a person with your competence and with your position with drug company-supported journals, passing such firm judgments on medical and scientific issues and serving as a major source of information and attitudes in the profession.

Right or wrong judgments, sometimes the picture is just a little amusing.

Cordially,

Henry Blackburn, M.D.

HB:jp

blind pc: C. Klimt c pc of article.

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Editorial Comment

Who Evaluates Drugs?

BY WILLIAM RUBIN, *Editor*

The dignified manner in which the Senate Watergate Committee went about its work and the awesome solemnity of the House Impeachment Panel hearings made us forget for a while that Congressional hearings often are shameful displays of irresponsibility. Having watched them since the McCarthy hearings in the forties, I thought I was more or less inured, but I found the Nelson subcommittee hearings on the oral antidiabetics (reported on this page) completely outrageous.

The hearings were set up to show that the Food and Drug Administration, because of drug industry influence, was remiss in not banning or at least restricting the use of oral antidiabetics. An array of carefully selected witnesses expanded on this theme, working from the premise that the University Group Diabetes Program (UGDP) study in 1970 was holy writ. Except for the lonely voice of Dr. Robert Bradley, no one attending the hearings—and certainly no one reading about them in the newspapers—would have known that there was any question about the validity of the study, or that any criticisms had been voiced over the past three-and-a-half years.

A portion of a report we ran in the January 1, 1971, issue of INTERNAL MEDICINE NEWS is pertinent at this point:

> In what will hardly be recorded as one of American medicine's finest moments, diabetologists continued their brawl over the use of oral agents in the treatment of diabetes, leaving practicing physicians as confused as they were last June when the University Group Diabetes Program was first reported.
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> From the very first the controversy over the UGDP study has been marked by vociferous criticism and tight-lipped reticence—sometimes by the same expert. The entrenched positions taken by both sides in the controversy, the unedifying spectacle of experts questioning not only the competence but the integrity of their opponents, leads to some concern over how—and if—the question can ever be resolved.

The controversy is far from resolved, but as tempers cooled the criticisms of the study impressed practicing physicians as having more validity than the rebuttals. We haven't taken a poll, but I think it would be fair to say that the great majority of diabetologists who were not involved in the study do not accept its conclusions. One of the witnesses at the hearing decried the fact that "physicians in general don't believe the UGDP," and attributed this disbelief to the repudiation of the study by respected diabetologists.

In a world I confess I no longer fully understand, physicians were criticized at this hearing for basing their treatment of diabetes on their own clinical experience plus the opinion of acknowledged experts in the field. Maybe it would be better to have medical treatment specified by FDA regulators, but I hope I never need the services of a physician who works this way.

The hearings contributed to the numbers game that seems to go on all

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Hearings the Place to Evaluate Drugs Responsibly?

(Continued from page 1)

/ picked up the estimate that the deaths of
e unnecessarily hastened by the use of oral
ɔn't need any support for this estimate; it will
nd accepted as gospel by writers who won't
: the number came from.
l the astounding news from one of Senator
ug industry promotion had caused ignorant
ɔle a year in the United States with something
s (ADR). While we were still boggling at that
ıg to "at least" 140,000 ADR deaths a year.
come from? From extrapolation. You know
ou? You start out with a finite study on one
ıowned teaching hospital. You find out how
:s that could be attributed to the drugs they
fact that by definition this hospital gets more
ush aside the observation that many of the
ɪn terminally ill and had been kept alive only
at difference does it make if physicians will
ɔr their patients when there is no other alter-

nany people are admitted to hospitals each
hat's admitted to the hospital, not just to the
ratio: the number of people admitted to all
f people in this one study as the number of
tion is to the number of ADR deaths in this
ɔlation.
show that the actual number—if it can be
ɔt closer to 2,000-3,000 than to 140,000, and
accidental poisoning rather than misuse of
ɔ using them by the drug industry, but don't

: long-range deleterious effects, but this new
· diabetics" will have direct and immediate
al reports of the UGDP study, physicians will
g difficulties because they stop taking their

, and the newspaper coverage they generate,
ıg-industry bias. This doesn't bother me; the
ght its own battles. What does concern me,
of this bias is the premise that most doctors
l by the drug industry.
ınder duress—that I have met an occasional
nature's noblemen, and we have all worried
:ian still treating patients when we feel he
et, but most physicians aren't really stupid.
lical school on a football scholarship, and
d to the Senate but it won't get you through

your Boards. Pollyanna and I feel that by and large physicians try to do the best thing for their patients.

Dr. Schmidt, FDA commissioner, is counting on a study being conducted by the Biometrics Society to validate the original UGDP study. Setting up another prospective study of oral antidiabetics would pose difficult logistical and ethical problems—if you believe a treatment is harmful or simply of no benefit, how can you place patients on that regimen?—but at this late date another argument over how many angels can fit on the head of a pin is not going to convince many practicing physicians.

Anybody who has studied science recognizes and appreciates the need for, and validity of, statistical studies. We know that what an accountant in Passaic, New Jersey, tells Neilsen he watches on TV is the right way to determine what the rest of us will watch, and a quarter of a century or so ago I could have made a stab at defining the statistical basis of the quantum theory. Physicians, though, have a special problem. Statistical niceties notwithstanding, they deal with people, not numbers, and people usually don't behave the way numbers say they're supposed to.

The point was made again and again at the hearings that the best way to treat maturity-onset diabetes is by diet, and that oral antidiabetics should only be used when dietary measures won't work. Who will argue with that contention? This statement is akin to the oft-repeated dictum, "Pregnant women should take drugs only when they are necessary." (No one ever tells us who should take drugs when they aren't necessary.)

As we seem to be heading into an era when medical practice will be dictated by bureaucrats subject to demagogic pressures, I have a suggestion on how to improve the delivery of health care and alleviate the shortage of physicians in one fell swoop. Congress should pass a law saying that:

¶No one will be overweight, and everyone will eat properly and exercise regularly and in moderation. (The statute will naturally define "properly," and "moderation.")

¶No one will be permitted to smoke.

¶No one will be allowed to drink any alcoholic beverage.

¶No one will be permitted to breathe polluted air, drink contaminated water, or be exposed to hazardous chemicals.

¶No one can drive an automobile faster than 40 miles an hour, and then only when belted up in a car built to minimize hazards.

¶No one shall be trapped in a job he hates, have an unhappy marriage, have parents who abuse him, or have aggravating children.

¶And, oh yes, if in spite of adhering to all of these clauses anyone does have to consult a physician, he or she shall, under penalty of law, get any prescription filled, take medication in the exact amounts and at the exact times specified by the physician, and shall otherwise follow the doctor's instructions exactly.

I solicit your help in adding other provisions to this proposed good-health statute. When we collect all the suggestions, we will have the bill drawn up and see if we can find a friendly congressman to introduce it.