

From the EDITOR



Dr. Wulf H. Utian, consultant in women's health and reproductive endocrinology, has served as Editor-in-Chief of *Menopause Management* since its inception in 1988. The Arthur H. Bill Professor Emeritus of Reproductive Biology and Obstetrics and Gynecology, Case Western Reserve University School of Medicine, he is also Consultant, Obstetrics, Gynecology and Women's Health Institute at the Cleveland Clinic, and Executive Director of The North American Menopause Society (NAMS). He is Chairman of the Advisory Board of Rapid Medical Research, Cleveland. He received his medical degree from the University of Witwatersrand, Johannesburg, South Africa, and his PhD from the University of Cape Town, South Africa, and is a Fellow of the Royal and American Colleges of Obstetricians and Gynecologists, as well as the International College of Surgeons. In 2007 he earned the DSc(Med) degree from the University of Cape Town, its highest degree and only awarded 11 times in over 100 years.

A pioneer in Women's Health issues and menopause research, in 1967 he established the Groote Schuur Menopause Research Clinic in Cape Town, the world's first such clinic. He was one of the three original founders of the International Menopause Society in 1976, of which he is Honorary Past President, and founded the North American Menopause Society in 1989.

He is the recipient of numerous national and international awards and research grants, and is still an active investigator with multiple grants. Dr. Utian has written over 200 papers related to the reproductive system in women and has authored five books on menopause and its effects on women. He is editor of *Menopause: The Journal of The North American Menopause Society*.

McCarthyism is Alive and Well—This Time the Target is the Medical Profession

Are we to suffer the 1950s all over again? The anti-communist investigations and hearings conducted by Senator Joseph McCarthy in the 1950s led to a widespread social and cultural phenomenon that affected all levels of society and was the source of a great deal of conflict in the United States. Over the past few years there has been a concerted effort by certain members of Congress to expose "corruption" of health providers by the pharmaceutical industry. The supposed logic is that gifts of trinkets, minor office supplies or office lunches would act as a "subliminal inducement to prescribe high priced drugs."¹ Every health provider, by this argument, is therefore considered guilty by association. In response, medical organizations, the FDA, the Accreditation Council for Continuing Medical Education (ACCME) and Pharmaceutical Research and Manufacturers of America (PhRMA) itself have drawn up strict guidelines that apply to links between pharmaceutical companies and individual physicians, as well as between these companies and organized medicine, particularly those organizations providing continuing medical education (CME). It is now time for those of us on the CME-provider side of the equation to evaluate the controversy, and to speak up in defense of the overwhelming majority of individuals who are honest, and also on behalf of the scientific organizations that provide medical education.

Let me get to the "rotten apple" side of the equation immediately. Examples of inappropriate physician or researcher behavior have been uncovered and exposed, in which there was non-disclosure to institutions of payments to these individuals by drug companies for research or teaching activities, the amounts sometimes being quite extraordinary. Given the nondisclosure by these individuals to their institutions, or to scientific journals when papers were submitted for publication, I would accept without argument

that they failed the “smell test.” These individuals must be brought to account. Regarding CME providers, if they have been “fronts” for industry and have produced programs biased toward their supporters’ products (almost certainly the exception and not the rule), they too should be exposed.

But does the presence of a few rotten apples give license to Congress and the media to taint the whole barrel? Most certainly not!

There appear to be at least two major components to this controversy. First, as addressed above, there is the assumption that all individual practitioners can easily be “bought” by handouts. Second, it is assumed that experts or organizations will, for a price, present biased information to influence prescribing habits of physicians.

Are All Individual Health Providers and Experts for Sale?

I will address the question of the experts first. In any area of medical discovery and advancement there are relatively few genuine experts. Review their life histories, and inevitably their career paths have followed a similar track. An area of interest triggered their curiosity, usually early in their careers, and years of basic science and/or clinical research followed. An inducement to academic advancement is publication of peer-reviewed papers in the best journals possible, and, over time, they have become recognized as experts by their peers. In the sphere of drug discovery and development, they were likely to have worked with multiple products developed by many pharmaceutical companies conducting phase I through III randomized trials. In turn, they would also be involved with writing the scientific papers that report the results, which were ultimately published in peer-reviewed journals. Inevitably, these individuals would also be recognized as experts in their particular medical fields of endeavor by research-development departments in pharmaceutical companies, and were likely to have been invited to serve on drug-development advisory boards or, through their education divisions, on “speaker panels” for CME programs.

If these individuals were not the ones to be invited to share their expertise, who could serve as experts in their place? It is of no value to an expert advisory panel to have the blind leading

the blind. But according to the new conspiracy hunters, because of this association the expert participants are automatically considered to be bought or biased.

What About Organized Medicine?

The other group that is being considered easily bought is organized medicine itself—medical schools, academic centers, teaching hospitals and national and regional scientific organizations providing CME. The logic, we are to believe, is that if company X gives an unrestricted grant to one of the above, the CME teaching program produced would be “slanted and biased” toward the drug produced by that company.

This is truly a case of the pot calling the kettle black. *The New York Times* calls for “the medical profession to wean itself almost entirely from its pervasive dependence on industry money,” automatically assuming that the firewalls between nonrestricted educational grants and the educational programs produced are a mere façade, and that all professional organizations are easily bought.¹ Are we, in turn, to assume that articles in *The New York Times* favor only products marketed by companies that advertise in its pages, or that it would write negative articles about those that do not? Of course this seems to be a ridiculous assumption. Is there a Congressman or Senator who is not there as a result of huge financial donations by special interests? Do newspapers, TV and other media not survive by revenue generated by advertising? The truth could well be that the public is so cynical about the behavior of our politicians that it has lost trust in everything—or that our politicians, understanding the hard facts of their own world, assume that professionals like physicians are as easily influenced and biased as they may be by donated funds to support their special interests. And where are *their* firewalls?

By the above logic, it would appear that no individual, and no company or organization, is immune from bias.

Personal Experience

In the interest of transparency and full disclosure, let me use myself as an example. My career followed the path described above. Over 43 years

ago I became intrigued by the impact of oophorectomy on women of reproductive age, and what could be achieved by replacing exogenous hormones. Through the years I have investigated dozens of drugs produced by multiple pharmaceutical companies, published the results for many in scientific journals, lectured at meetings and medical institutions worldwide, have been invited to serve on multiple advisory boards and, yes, received honoraria for some of these (but peanuts by any measure). I was one of the founders of the South African Society for Inherited Disorders (SAIDA), the International Menopause Society and The North American Menopause Society, and assisted well over 20 other countries in the founding of national menopause societies. Does that make me a pharmaceutical salesman? Read my life's work and see just how critical I have been of the "hand that feeds me."²

During the course of those years it has been my honor and privilege to work closely with literally hundreds of dedicated researchers, teachers and committed clinicians with expertise in a wide-ranging spectrum of medical endeavors. Were some of them potentially rotten apples? Yes, but I can count them on my fingers. Without question, the overwhelming majority were dedicated to their work and the constituencies they represented, most specifically their patients.

The Tiger in the Room: Fringe Medicine

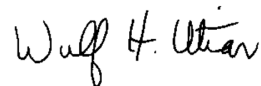
While the attention is on mainstream medicine, an entire industry is proliferating and profiting with a virtual absence of oversight. The marketers of so-called food supplements (including potent hormones like growth hormone and DHEA) and the compounders of "bioidentical hormones" use the Web and other advertising media to offer false assurances and indications to sell their services or their products. Conflict of interest is absolutely obvious. Here, indeed, is an area calling for scrutiny and demonstrating a major need for legislative oversight through the FDA and the Department of Justice.

A Plea for Caution

The New York Times calls for Congress to "pass legislation that would force all drug and medical device companies to report a wide range of pay-

ments through a national registry so that all conflicts are known."¹ This is most appropriate, although I would prefer it use the term "disclosure" rather than make the immediate assumption of "conflict." We should also remember that when the gross sum of a research grant is reported, this does not mean all that money lands in the pocket of the researcher. There are huge costs and overhead in conducting research. For the sake of emphasis, let me repeat that *The New York Times'* call for the medical profession to wean itself from industry-sourced financial support, automatically assuming that the firewalls between nonrestricted educational grants and the educational programs produced are a mere façade, and that all professional organizations are easily bought, is patently absurd.¹ Transparency is critical, but we cannot destroy the structure of medical education developed over decades because of the few who have betrayed the trust—not unless we have something truly concrete in mind as a replacement.

We do, indeed, live in very cynical times. But it is destructive and irresponsible to destroy the long-developed traditions in medical research and education by regarding all individuals and organizations receiving financial support for educational, clinical and research activities as automatically biased. We are all well aware of public scrutiny and the need for absolute transparency with full disclosure of all commercial interests, and the essential firewalls between unrestricted funds received and the education programs developed. By all means, expose and punish the few who cross the threshold. At the same time, give the FDA more teeth to monitor the production, marketing and conflicts of interest in the fringe areas of medicine. But please, members of Congress, do not throw out the baby with the bathwater.



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