



Center for Health Ethics
Health Management and Informatics
University of Missouri

David A. Fleming, MD
315 Clark Hall
Columbia, MO 65211

October 2004

The Ethical Use of New Drugs

The practice of medicine requires clinical judgments within the context of an inexact and very complicated science, the end result of which has profound implication for the welfare of patients. The ethical question for the practitioner is whether changing medications for the sake of research or other interests outside the patient can be justified for the sake of those interests, as long as the patient is at low risk for being harmed. My response to this question is that any clinical decision is ethically defensible only if it is reasonable to think that such a move is in the best interest of the patient, all other interests remaining secondary. When detailed about new and wonderful drugs it is difficult to justify a decision to discontinue therapy that is effective and without side effects, and replace it with one that is unproven and with unknown risks. The use of new drugs, by definition, is experimental and therefore places the patient at some risk. Above all, the physician must consider the patient's safety before agreeing to proceed.

The physician's first responsibility is to the welfare of their patient, even though safe participation in clinical research and the use of new treatments from time to time is necessary for the good of present and future patients. Physicians, as scientists, are sensitive to this need, as are drug companies. When being detailed about a new and promising drug separating truth from marketing hype is often difficult. Product information, though scientifically grounded, is often skewed in favor of the product being detailed and it may be difficult to reasonably predict the risks and benefits to be expected. Independent reading and review of the evidence, anecdotal feedback from colleagues, and the use of consultants, who are often more versed in the newer drugs, are often helpful in ensuring an unbiased and informed decision.

New products also come by way of clinical trials. Industry funded trials may offer promise and are not without scientific merit, but bias and conflict are unavoidable when the obvious interest of drug trials is in obtaining "good data" to support a product. Financial incentives for physicians to enroll patients also create a milieu of ethical peril when enrollment is driven by self-interest. Promising drug trials may also offer hope for patients with chronic illness when conventional therapies have failed, or patients volunteer to participate through a sense of altruism.

If a patient's instance company will pay for a new drug being considered the economic argument that neither the patient nor the health care system will be impacted also cannot be ethically supported. Though the burden of paying for new and expensive drugs is not born by either the patient or the health care system, to not consider cost and expense at all levels ignores the physician's obligation to maintain fiscal prudence in prescribing practices with respect to scarce resources and the rising cost of health care.

As physicians we have significant power to influence the thinking of our patients who often tend to decide based on the recommendations we make. They trust us to use our skill and knowledge primarily for their welfare when they come to us for help. When other incentives, such as financial gain or scientific curiosity, become a driving force for such recommendations the trust relationship is threatened because the primacy of patient welfare may no longer exist.

The art of medicine entails selecting wisely amongst a myriad of therapies, new and familiar, with the goal of serving the welfare of the patient above all other interests, including that of clinical research, the corporation, and society. Best practices derive from rational, evidence-based decision-making, balancing economic concern, diagnostic elegance, and therapeutic parsimony while putting aside self-interest. Patient welfare should therefore never be suborned even by well-placed desires for better science.

Prescribing new and experimental medication to patients may be ethically dubious unless sound evidence supports doing so or, in an altruistic sense, the patient freely chooses to take new or experimental therapy after being fully informed of the risks and benefits involved. Even then, doing so requires the highest level of concern and monitoring for the safety and welfare of the patient.