We are unaccustomed to seeing the juxtaposition of the words that are in the title of this editorial. Indeed, I first heard this combination of words used in March 2002 at a special conference sponsored by our Office of Health Policy and Clinical Outcomes at Thomas Jefferson University in Philadelphia. The conference, entitled “Preparing Medical Directors for Decision Making in the Genomics Age,” featured faculty members from varying fields who were helping to prepare managed care medical directors for the challenges of managing in a world characterized by the possible creation of genetically based customized pharmaceutical agents.

Paul Root Wolpe, PhD, a senior fellow at the Center for Bioethics at the University of Pennsylvania (Penn) and director of the program in psychiatry and ethics, was one of the featured speakers. In addition to his role at Penn, Dr. Wolpe serves as the first ethicist, Dr. Wolpe outlined his view of prophylactic ethics, and I believe the message is relevant to members of P&T committees in every sector. Allow me to first define our terms and then to draw examples from Dr. Wolpe’s presentation that I hope will resonate with members of P&T committees.

Prophylactic ethics is not simply about public relations. It is all about goals and objectives. Ethics, according to Dr. Wolpe, promotes public buy-in and support for the rapid technological changes faced by our society. Ethical action in biomedicine involves public relations and predicting pitfalls and problems. Preparing for these pitfalls and problems requires creative planning, openness, and responsiveness. Ultimately, it serves to clarify values and acceptable standards of behavior. Dr. Wolpe also believes that ethical issues in pharmacogenomics, in particular, can be broadly categorized into a number of areas that have the potential for harm, both to oneself and to society. Some potentially dangerous areas include discrimination, privacy and confidentiality, the environmental impact, and the problem of setting limits on human intervention. Let’s examine aspects of these definitions and their relevance to our readers.

The scientific leaders in the field of pharmacogenomics, including such giants as Francis Collins, MD, and Craig Ventnor, MD, have helped us to understand that, in the very near future, primary care physicians might be able to routinely perform genetic tests before writing prescriptions so that they can identify the possible poor responders. Although the science of pharmacogenomics is certainly beyond the scope of this editorial, our readers know that different individuals metabolize certain drugs in different patterns. There are now off-the-shelf tests available in many laboratories that could enable us to rapidly evaluate large populations of patients in terms of their metabolic status (i.e., that would enable us to identify both low and high metabolizers of particular chemical compounds). This patient-specific metabolic status might be governed by what are called single nucleotide polymorphisms, or SNPs for short (this is further discussed in Functional Genomics: Health Care Implications, February 2001 supplement, page 7). It is clear that there are ethnic variations in the frequency and type of polymorphisms present in many populations. My imagination conjures up a series of powerful and ethically complicated clinical challenges based on SNPs in different patient populations.

Imagine, for a moment, if we knew that members of a particular ethnic group were low metabolizers of, say, statin medications—or that members of another group were genetically wired, so to speak, to potentially suffer a higher rate of adverse drug reactions (ADRs) with certain classes of medications. The implications for a dramatic impact on everyday practice as well as, of course, on clinical trials and research are manifold.

Should your P&T committee routinely engage the services of nationally prominent bioethicists to create your prophylactic ethical strategy? Although this might be a bit farfetched and, no doubt, prohibitively expensive, the notion of prophylactic ethics is certainly on the minds of P&T committees every day. Beyond the futuristic scenario of screening particular patient populations are the more immediate needs to educate the public about the use of high-tech, high-cost, genetically derived agents that are already on the market. Of course, we need to distinguish between patient testing and genetically derived products already in the approval pipeline, but the educational issues are parallel. Prophylactic ethics might come in handy as we try to explain, for example, who may have access to Xigris and who may not (see Sepsis Segue, P&T, April 2002, page 170).

Finally, Dr. Wolpe outlined some additional ethical challenges in pharmacogenomics, including the danger of developing drugs targeted to specific individuals that might be dangerous if given to other people. The need for mandatory feedback for ADRs for SNP identification and smaller targeted trials, while beneficial, might cause us to miss even rarer ADRs. These are technical issues that would be very important to P&T committees that are overseeing clinical trials and ADR surveillance systems.

Although prophylactic ethics might not be a concern for every patient, the concept is broadly applicable. Leaders like Dr. Wolpe are helping us to focus our thinking and to carefully analyze our options—before they make sensational newspaper headlines. How is your P&T committee preparing for this brave new world of pharmacogenomics and custom-made, genetically based drug therapy?

As always, I am interested in your views. You can reach me at my email address: david.nash@mail.tju.edu. Dr. Wolpe’s email address is: wolpep@mail.med.upenn.edu.