Formularies run roughshod over key ethical considerations commonly viewed as important in American society. While these formularies can be defended, administrators, health care professionals, and managed care organizations must be sure to think through certain ideas about ethics in health care.
use of nonformulary drugs been restricted, but both generic and therapeutic substitution are frequently used when a practitioner fails to prescribe a formulary medication.

This strictness raises important ethical questions. In this paper, I explore the ethical aspects of the use of drug formularies by health care organizations.

**AUTONOMY**

The ethical principle of autonomy states that one's liberty of thought, choice, or action is not to be interfered with. In other words, it argues that rational individuals have a moral right to make choices for themselves without interference from others.

The right to autonomy is not without exception. Two ethically justifiable exceptions exist to the principle of autonomy. The first of these is referred to as the harm principle. The harm principle allows for one's autonomy to be overridden when the exercise of that autonomy may harm others. This exception prevents one individual from harming another simply because they have an autonomous right to do so.

A second exception to the principle of autonomy is weak paternalism. Weak paternalism allows overriding another's autonomy if the person does not appear to be autonomous, or if minimal intervention is necessary to determine whether someone is autonomous. Overriding the autonomy of children is an example of the application of this exception. Strong paternalism, not an ethically justifiable exception to autonomy, is the overriding of one's autonomy when one believes that another has made a wrong decision or one that will cause harm to themselves.

The concept of paternalism, or acting parent-like, has important implications in medicine. Medical paternalism involves the overriding of a patient's autonomy and is often justified ethically by invoking weak paternalism. For example, a patient must seek the counsel of a practitioner when a legend drug may be indicated because the patient is not autonomous (i.e., the patient lacks sufficient knowledge to make a rational or autonomous decision). Nonprescription drugs do not require the intervention of a practitioner because they can be safely and rationally used by the lay public.

Both prescriber and patient autonomy are at issue in the enforcement of drug formularies. Prescribers who either voluntarily (i.e., PPO agreement, hospital privileges) or are mandated to (i.e., staff HMO practitioner) adhere to drug formularies have their autonomy violated. Neither the harm principle nor weak paternalism—the ethically justifiable exceptions to autonomy—appear to apply. In fact, formularies would seem to override a prescriber's autonomy by invoking strong paternalism for having made what the formulary committee views as the 'wrong' decision, even though strong paternalism is not an ethically justifiable exception to autonomy.

Both the concept of generic substitution and therapeutic substitution would appear to restrict further the autonomy of practitioners. In many restricted formularies, prescribers do not have a choice as to whether they wish to have a generic or brand name product dispensed. Even more of an infringement on a prescriber's autonomy is the practice of therapeutic substitution. In this instance, a completely different drug entity, albeit usually from the same therapeutic class, is dispensed in place of the drug prescribed by the practitioner.

Patient autonomy is likewise infringed upon by the use of drug formularies. In mandatory formulary systems, patients do not have a choice as to whether they desire generic or therapeutic substitution. In some instances, a patient may even be unaware that a switch is made, especially with generic substitution, unless so informed by the pharmacist or unless they read the drug line on the prescription label.

Further, a patient may have made the decision to begin a medication, after consultation with their practitioner, on the basis of the side effect profile and other considerations of a particular medication. However, when a therapeutic substitution occurs, the patient will be receiving a medication different from that planned during the patient—prescriber consultation. Even drugs within the same therapeutic category may have slightly different side effect profiles, precautions, or other clinical considerations, which may alter a patient's choice of whether to take a particular medication.

The justification sometimes used for this action on the part of the patient's health care provider is that the patient lacks sufficient knowledge about prescription drug therapy, and medical professionals are therefore ethically justified in making the substitution for them according to the principle of weak paternalism. This argument appears to have less justification than that used for the restrictions placed on legend drugs. The issue is not one of diagnosis and choosing an appropriate medication; it is rather the right of the patient to be a full partner in their own treatment plan.

Generic substitution involves the interchange of one drug product for its generic equivalent. The decision to substitute is based on financial considerations, not therapeutic considerations, and as such the argument that a patient lacks sufficient medical knowledge has no basis. Similarly, therapeutic substitution occurs because a health care organization has chosen to limit the drugs it will carry on its formulary to decrease duplication and control inventory costs. Again, to invoke weak paternalism on the basis of lack of patient knowledge seems inappropriate.

**INFORMED CONSENT**

The ethical principle of informed consent requires that health care professionals inform patients about a procedure, drug, or research study, and receive their consent before beginning treatment. Informed consent can be thought of as an application of the principle of autonomy because—by assuring that a patient receives full disclosure and has the opportunity to choose or refuse treatment—patient choice is respected. Informed consent is comprised of five el-

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Disclosures: disclosure, understanding, competence, voluntarism, and consent.

Disclosures require health care professionals to fully inform a patient of what will be done to them, what the potential benefits and risks of the treatment are, and other pertinent information. The most common problem with achieving this element is determining how much disclosure is adequate. Three standards of disclosure have been used both legally and ethically to establish guidelines; unfortunately, all have drawbacks and none has emerged as the "gold standard."

The professional practice standard states that a health care professional should disclose to a patient that information about any "reasonably prudent professional" would disclose. The reasonable person standard argues that a health professional should disclose that information to a patient that any "reasonable person" would need to know to make an informed decision. Both of these standards establish a standardized disclosure based on either what an average professional would disclose or what the average person would need to know. However, neither standard permits variation in disclosure based either on the professional judgment of the health care professional or the individual needs of the patient. The subjective standard attempts to address these concerns by contending that the disclosure should be based on what an individual patient needs to know to make an informed decision. Unfortunately, even though this standard permits individualization of what is disclosed, it may lead to biased or incomplete information being provided to a patient.

The second element, understanding, requires that the disclosed information be in a form the patient can clearly comprehend. This element requires not only that the information be in lay language, but that it be simple enough for an individual with even a minimal education to understand. Language barriers, such as those in patients who speak English as a second language or do not speak English at all, present additional difficulties for health professionals trying to meet this element.

Competence, the third element, requires that individuals who ultimately will provide their informed consent be competent to provide such assent. The most obvious example of individuals who are not competent to provide informed consent are children. However, establishing competence in many other patients can be problematic. Patients suffering from Alzheimer's disease, mental illness, or emotional trauma may or may not be deemed competent. Often legal means are used to establish what is very much an ethical issue.

The fourth element of informed consent is voluntarism. Patients must give their informed consent in the absence of either overt or subtle coercion. Subtle coercion is often present when informed consent is sought. Providing monetary reimbursement to entice individuals to participate in a clinical drug study, or using a long-standing practitioner-patient relationship to coerce a patient to choose a particular therapeutic option, are examples of this type of subtle coercion.

The final element is consent. Once all the other four elements have been met, the patient still has the right to refuse a course of treatment. Their assent must be obtained to complete the informed consent process.

How does the principle of informed consent relate to the question of drug formularies? As the previous discussion of the five elements suggests, informed consent places a heavy ethical burden on the health care professional. We often think of this responsibility in terms of formal informed consent (i.e., a consent form administered before surgery or participation in a clinical drug study).

However, the most common application of informed consent is informal. Patient medication counseling, done millions of times each day, does not involve a standardized form, but is nevertheless a process by which informed consent is obtained. Patients are counseled, they ask questions, and ultimately, each chooses whether to accept a medication. This discussion, usually conducted to some extent by both the prescriber and pharmacist (and sometimes also by the nurse), includes very specific information about the use of a particular medication. In the case of therapeutic substitution, the initial counseling by the prescriber about a particular medication may differ from the subsequent information provided by the pharmacist, for a different drug, at dispensing. This can create a true sense of confusion on the part of the patient and may in some cases challenge the notion that the element of understanding has been achieved. This may especially be a problem with non-English-speaking patients, and those who have minimal education.

Achieving informed consent in cases of therapeutic substitution begins with communication of the substitution to the patient. A busy prescriber may fail to discuss a medication, even to the point of not providing the name of the drug, with a patient. If the pharmacist fails to inform the patient that a therapeutic substitution has occurred, the disclosure element of informed consent is not met.

Another problem with both therapeutic and non-therapeutic use of a generically substituted product may not in every case provide the same therapeutic effect in a patient that a non-English-speaking patient, even if highly educated, may lack clear understanding of the implications of substitution. This is even more of a concern for therapeutic substitution. Unlike a generic interchange, therapeutic substitution involves the actual exchange of different chemical moieties.

Finally, there is a question of voluntarism when formularies are enforced. Patients often do not realize that any substitution has occurred when they are hospital inpatients—and would not have a choice even if they did. In much the same way, ambulatory patients in a growing number of health
plans are forced to live by the provisions of a formulary coupled with generic and/or therapeutic substitution. Many patients understand that this is how their drug benefit will be administered when they choose a health plan, but many others do not. Further, patients may not have a choice among health plans that do not have drug formularies.

**BENEFICENCE/ NONMALEFICENCE**

Beneficence and nonmaleficence are complimentary ethical principles that place important responsibilities on health care professionals with regard to care of patients. Beneficence is an active process requiring a practitioner to act in such a way as to do good for their patient. Nonmaleficence, a more passive process, instructs that health care professionals take due care or practice in a way that will avoid harm to patients.

Like the ethical principles discussed previously, beneficence and nonmaleficence have application to the enforcement of drug formularies. The primary objective of drug formularies is to control costs. As a result, drug inventories are reduced and generic and therapeutic substitutions are employed. When a generic drug is interchanged, or when one drug is substituted for another in the same therapeutic class, less than optimal benefit may be achieved for the patient. A generic drug may not provide exactly the same benefit as the name brand drug prescribed. The therapeutically interchanged drug may have a slightly different side effect profile than the one originally prescribed. Consequently, achieving optimal therapeutic benefit with a minimum of untoward consequences may not be possible.

**FIDELITY**

Fidelity requires health care professionals to act in such a way as to demonstrate loyalty to their patients. A type of bond or promise is established between the practitioner and the patient. This professional relationship places on the health professional the burden of acting in the patient's best interest.

Drug formularies and generic and therapeutic substitution may not always ensure that practitioners meet this ethical obligation. By their very nature, formularies may violate this trust. They are fiscally-based entities, not ones that necessarily promote the empathetic nature of patient care.

**VERACITY**

Veracity is the ethical principle that instructs practitioners to be honest in their dealings with patients. The violation of veracity may be ethically justifiable (i.e., the use of placebos to act beneficently or nonmaleficently toward a patient), but the violation of this principle for non-patient-centered reasons would appear to be unethical.

Patients who are not informed about drug substitution, or who may in some cases even be misled about the use of a generic substitute, are victims of unethical behavior on the part of the practitioner.

**DISTRIBUTIVE JUSTICE**

Justice has a long history as an ethical principle. The Greek philosopher Aristotle defined justice as “treating equals equally and unequals unequally.” Today, when we think of justice, words such as fairness and equality come to mind.

Distributive justice refers to the equal distribution of the benefits and burdens of society among all of society’s members. We often think of distributive justice in terms of our health care delivery system. This principle is frequently used as a justification for providing health care as a right to all Americans.

The ethical principles discussed up to this point have indicated that the use of an enforced drug formulary may be unethical. Distributive justice, on the other hand, might lead one toward the opposite conclusion. Given the escalating cost of our health care delivery system, cost-containment measures—such as the use of drug formularies—may be necessary as a means of controlling costs. Getting our health care financial house in order is a benefit to all members of society. Money that is saved by controlling the use of drugs may ensure that more individuals have access to therapeutic interventions and other types of health care.

On the other hand, not all patients in the United States have their drug therapy controlled by a formulary. Affluent individuals are able to pay for their medications out-of-pocket and are not subject to the restrictions of a third party payer’s formulary. Nevertheless, a rapidly growing number of Americans will be subject to some type of formulary control. Further, some states have mandatory generic interchange laws for all patients, whether they are able and willing to pay for their medications out-of-pocket or not.

**CONCLUSION**

I have attempted to explore ethical considerations about drug formularies. These moral questions are important as managed care controls an increasing segment of our health care delivery system and formularies are used more widely.

Are drug formularies unethical? No, if viewed in the proper context. The thrust of this paper has been this: The inflexible nature of many drug formularies often means that optimal therapy for the patient is sacrificed for the sake of costs. The use of generic drugs and therapeutic substitution can often be accomplished with little or no impact on patient care. Problems arise in those instances where the rigid nature of a formulary places the patient in undue peril, provides less than the first-line treatment, or ignores the rights of patients to be informed about and choose the course of their treatment.

As we undergo dramatic change in the way in which our health care is delivered and paid for, we must remain cognizant of our ethical and moral responsibilities to our patients. Drug formularies can be a tool that produces positive results if health professionals remember that the first concern is to be true to their Hippocratic obligations.