PROPOSED PAYMENT CHANGES RAISE QUALITY, INNOVATION AND MEDICAL JUDGMENT ISSUES

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In 1990, a Florida woman is diagnosed as having ovarian cancer. After surgery and three months of combination chemotherapy, no trace of disease remains; however, because it was in an advanced stage, her oncologist recommends three additional months of treatment.

The woman feels healthy and sees no reason to further delay her plans to move by her daughter, who lives in Tennessee, once her physician says he can easily refer her to another oncologist in that state.

Once the woman moves, however, her new oncologist explains that one of the drugs she previously was taking is not approved by the FDA for the treatment of ovarian cancer and, in the state of Tennessee, is not reimbursable. If she wants to continue to receive it, she will have to pay for it out of her own pocket, and it is an extremely expensive drug.

"But I also have Medicare," she says. "Won't catastrophic insurance cover the cost once I meet the deductible?"

"Unfortunately, no," the physician replies. "The state Medicare intermediary won't pay for off-label drug use either, despite the fact that a number of physicians in other states have had considerable success in using this drug to treat your type of cancer."

The woman and the oncologist finally decide to resume her former treatment, but to substitute an FDA-approved drug for the nonreimbursable agent she had been receiving in Florida.

Two months later, the woman begins to experience abdominal pain. Biopsies reveal recurrent cancer. She files three malpractice suits: one against her Florida oncologist for not informing her that her treatment regimen could be affected if she moved out of state; one against her Tennessee oncologist for not providing the most effective cancer care; and one against the state Medicare intermediary for enacting discriminatory payment policies.

If the above scenario was fact and not fiction, this woman's attorney would, of course, have to prove that the change in treatment was responsible for the recurrence, that physicians are responsible for knowing variations in reimbursement policies, and a number of other legal points would have to be proved. Nevertheless, this "worse case scenario" presents some of the potential concerns and issues that are now being raised with regard to changes in chemotherapy reimbursement policy---changes that have profound implications for continued access to current agents, ongoing innovations in investigational drug treatment, and the prescription of therapy on the basis of physicians' medical judgment rather than the reimbursement policies of third-party payors.

NO MORE 'BUSINESS AS USUAL'

In the past, third-party payors have underwritten the cost of clinical trials for new chemotherapy drugs and, almost across the board, allowed payment for both investigational combinations of existing drugs and additional indications outside of the package insert uses initially approved by the Food and Drug Administration (FDA). However, times are changing. Cancer treatment is no longer a "sacred cow" in the eyes of either third-party payors or government.

Although oncology treatments of all types represent only a small proportion of insurance carriers' health care payments,* the volume of outpatient cancer treatment is increasing, investigational drugs carry increasingly expensive price tags, and the unbundling of inpatient chemotherapy and radiation therapy charges is attracting closer scrutiny of cancer treatment costs.

At the same time, third-party payors are facing intensive price competition from such new health care delivery systems as HMOs, and they are losing market share to large and small businesses alike who, in the face of 100 percent increases in employee health benefit costs, are opting for self-insurance as a better way to monitor and control employee health consumption.

The federal government also has a large say in reimbursement policy changes through the Medicare program. The proposed Medicare catastrophic insurance bill, which is in House/Senate conference, could result in physicians' medical judgments being challenged by private insurers and government agencies purely on the basis of reimbursement considerations.

One section of the bill that is of particular concern to physicians is the outpatient prescription drug program amendment, which transfers all of the program's costs for the elderly into a new federal program and provides a stop loss or reduced risk for senior citizens' out-of-pocket expenditures. However, cost estimates for the catastroph-

*"Study of Third-Party Reimbursement Procedures for the Association of Community Cancer Centers," Touche Ross & Co., Chicago, August 1987.

HOW THE BLUES ASSESS NEW TECHNOLOGIES

The following five criteria, used by the technology assessment group of the Blue Cross/Blue Shield Association to evaluate new medical technologies, can give oncologists and health policymakers an idea of the parameters by which pharmaceuticals may be judged in the near future.

1. The technology must have appropriate regulatory approval (in the case of pharmaceuticals, approval by the FDA).

2. There must be scientific evidence of the efficacy of the technology. The studies must be "well-designed," of "sufficient sample size," and appear in "peer review journals," Gleeson says.

3. Health outcomes must be positively affected. In the case of chemotherapy or other cancer modalities, "the intermediate outcome we're looking for is the effect on the tumor," Gleeson explains. "Has tumor growth been stopped?" In the long-term, she says, "we look at the palliative effect; whether or not length of life has been affected."

4. How does the new technology compare to existing technologies? Cost-benefit analyses are performed to see if the new technology truly does make inroads. "You're not going to pay for a Cadillac if a Ford will do it," Gleeson points out.

5. Improvements must be obtainable outside of the research setting. The Blues want to know whether or not clinicians will "achieve the same results," Gleeson explains. ■

phic insurance program already range from $3 to $12 billion, and there is considerable pressure to keep the program budget neutral. As a result, the conference committee is already considering such cost-limiting strategies as drug utilization review. The Senate version of the bill allows for retrospective review of physicians' prescribing practices to determine if they conform with "standard medical practice," and it empowers the Secretary of HHS to draw up a list of approved drug utilization indications based solely on criteria and standards established by the Health Care Financing Administration (HCFA). And, although it is no longer the intent of Congress to use FDA labeling as the basis for such a list of approved indications, professional medical associations and societies are concerned about the sources or references that ultimately may be used.

The American Medical Association (AMA) is strongly urging Congress to clearly define "standard medical practice," and it believes that the authority granted to the HHS and third-party payors should be curtailed. Providers are worried that if physicians' prescribing practices are challenged by carriers---not on the basis of the medical literature and sound medical judgment, but on the basis of reimbursement policy---patients' fair access to quality care will be seriously threatened. They also contend that such randomized judgments on the part of payors could lead to significant variations in reimbursement policies from state to state. In other words, a patient in Texas could receive a course of therapy that is not available in Massachusetts.

A PAYORS' REVOLT?

The cost-reduction pressures that insurers face are not going to disappear. If anything, the pressure to reduce costs is simply being shifted from the inpatient to the outpatient side of the equation. How are third-party payors responding? Blue Cross and Blue Shield is beginning to demand the type of efficacy, cost, and medical necessity information for chemotherapy agents that they use to evaluate other new technologies (see "How the Blues Assess New Technologies").

Another strategy of the Blues is to enforce contract provisions that require FDA approval, not only for new drugs, but for all new drug indications. According to Aleta Sindelar, a consumer safety officer with the FDA, if an insurers' contract "is limited to FDA approval, its my view that it's legally right to say the drug is approved." If the contract says that FDA approval is necessary for the indication, "that's different," she says, but her argument to carriers is that "contract specifics should be delineated." (See the sidebar for the formal views of FDA and HCFA on drug labeling.)

Nevertheless, contracts with purchasers can be modified. And Blue Cross and Blue Shield has clearly stated that unless it begins to receive documented evidence of the efficacy of new chemotherapy indications, payment for those uses may not be forthcoming. The Blue Cross/Blue Shield Association "does not [evaluate] and is not equipped to evaluate the eligibility of drugs for third-party payment," says Susan Gleeson, executive director, technology management. However, "the Blues are trying to create new incentives for drug manufacturers' to obtain FDA-appproval for promising new indications," Gleeson says, and to have package inserts revised accordingly. (See the short feature on page 19 for an indepth look at the time and costs involved in obtaining FDA approval for new package insert indications.) In addition, HCFA, through its reimbursement policy manuals, has already endorsed payment denials for off-label drug uses.

Cancer center administrators and oncologists can be assured that such a posture on the part of Blue Cross and Blue Shield has not gone unnoticed by other health insurers. A survey of the top 25 members of the Health Insurance Association of America (HIAA), representing 70 percent of all privately-insured lives, reveals "an overwhelming reliance (50 percent of the 18 responding carriers) on FDA approval as the minimum criterion for payment of cancer chemotherapy," according to Ronald Goodspeed, assistant medical director, CIGNA Corp., and the initiator of the survey.

PHYSICIANS AND LABELING

Rodger Winn, M.D., chairman of the CCOP connected with the University of Texas, M.D. Anderson Hospital and Tumor Institute, Houston, says that "if it comes to third-party payors only reimbursing for FDA-approved drugs and indications, that would be a terrible blow to patient care. Physicians don't use the package insert; they use current medical literature to assist in treatment judgment."

That view is substantiated by a survey of 200 practicing oncologists and hematologists, conducted in April 1987, which found that responding physicians' interest in and knowledge of package inserts was

seriously limited. In fact, most of the uses physicians' claimed were outside of labeled indications were actually FDA-approved uses and, similarly, most of the uses they believed to be unlabeled treatments were, indeed, FDA-approved indications.

The study also revealed that 65 percent of responding physicians use antineoplastic agents outside of FDA-approved indications. When physicians in the above group were asked how many patients they treat in this manner, the answers ranged from 1 to 5 patients per month (42 percent) and 6 to 10 patients per month (19 percent) for a mean average patient volume of 5.7 patients per physician. (See the article on page 21 about physicians' unlabeled use of common chemotherapeutic agents, and the cost implications of such practices if payment is denied.)

About 24 percent of physicians surveyed stated that they do not use products outside of package insert guidelines because (1) they believe patients should only be treated with approved standards of therapy (46 percent) and (2) they are afraid of the potential legal ramifications of such practices (21 percent). However, the majority of respondents (71 percent) said they were in the practice of using antineoplastic agents in an empirical manner when standard drug protocols failed (46 percent), as part of experimental drug protocols (17 percent), or when the current medical literature supported the efficacy of the drug (9 percent).

Forty-five percent of responding physicians maintain that if there is evidence of efficacy, products should be paid for by insurance providers. However, a similar number of physicians (40 percent) already indicate ongoing problems with third-party coverage of such uses and say that regulations are becoming increasingly stringent. Only 21 percent of responding clinicians believe that current payment policies for chemotherapy agents are fair.

PROVIDERS' CONCERNS

Increasingly stringent payment policies could have catastrophic effects on cancer centers, both hospital-based and freestanding, and on private oncology practices which, in particular, are already suffering from inadequate reimbursement levels.

Lloyd Everson, M.D., Community Hospital of Indiana, and a member of the ACCC board, believes that "every medical oncologist with a high-volume practice has had experience, on a case-by-case basis, of not getting reimbursed for drugs that are used in so-called 'off-PDR' applications."

Recently, according to Deborah Boyce, administrator of the Center for Cancer Treatment at Orlando (FL) Regional Medical Center, four staff oncologists shifted their entire chemotherapy outpatient practices from the private setting to the Cancer Center at the hospital, because of inadequate reimbursement. Trudy Graves, office manager for Hematology Oncology Associates of Central Florida---the group practice to which the four oncologists belong---explains that although Medicare Part B reimbursement usually covered the cost of chemotherapy drugs, payments for necessary medical equipment, such as Huber needles, syringes, and tubing, was either woefully inadequate or nonexistent. This was the major reason for moving patient treatment to the outpatient clinic, where overhead under Part A Medicare is currently reimbursed at more acceptable levels.

To date, neither the group practice nor the cancer center have experienced any significant payment delays or any payment denials for non-FDA approved indications. Any strategy by private insurers to do so would "simply be a road-block," Boyce says, but a threat that carries serious implications for the Center, which recently opened a new outpatient chemotherapy center and currently treats about 1,500 new cancer patients each year, 79 percent of which are privately insured.

Rick Perez, administrator, medical oncology, Rush Cancer Center, Chicago, IL, says the Center hasn't "encountered any problems on an outpatient basis with insurance carriers, except in the lack of reimbursement for oral or tablet form chemotherapy, which still is not covered." Another area of concern is with the time lags associated with payors' acceptance of new technologies. "We are still having reimbursement problems with implantable infusion pumps and the refillings for them," Perez says, "and they've been around for more than two years. Medicare, in specific, is very slow in implementing new payment policies."

Because of the high cost of chemotherapy drugs and new delivery technologies in the face of customary private insurance payment levels of 80 percent of charges, oncologists try to limit patients' out-of-pocket costs. For instance, the Central Florida group practice tries to limit patient charges to 10 to 20 percent above costs. But oncologists and cancer program administrators have limited opportunities to reduce costs or to formulate strategies to cope with the dramatic payment shortfalls that can be expected if FDA labeling is used as the basis for reimbursement.

George Bascom, M.D., an oncologist with the Platte Valley Medical Group, Kearney, NE, says, "Our overall profit margin is not high. We only have about a 10 percent markup on drugs, which doesn't leave much room to cut back." Everson adds that the current level of reimbursement for therapy and drug costs is "ludicrous. No oncologist would have a break-even operation on the basis of reimbursement. Most oncologists make up the

DRUG LABELING: TWO VIEWS

FDA'S VIEW:

The FDA has formally stated (*FDA Drug Bulletin*, April 1982) that unlabeled uses of an approved drug "may be appropriate and rational in certain circumstances and may, in fact, reflect approaches to drug therapy that have been extensively reported in the literature;" and, according to Thomas Holohan, M.D., medicine staff, Office of Health Affairs, FDA, "the use of an approved drug for an unlabeled indication does not *ipso facto* require the submission of an Investigational New Drug (IND) exemption."

HCFA'S VIEW:

The Health Care Financing Administration (HCFA), holds a similar view of drug labeling; namely: "labeling is not intended to circumscribe the use of that drug in the practice of clinical medicine (i.e, it does not regulate medical practice); and . . . [it] . . . is not considered to represent all medical scientific information regarding the use of a particular drug in all possible clinical circumstances" (*Medicare Claims Manual*, Sect. 2050.5, revised August 1987). ■

discrepancies between reimbursement and costs through laboratory, X ray, and other charges."

The entire burden can't be placed on insurers though. John Yarbro, M.D., Ph.D., professor of medicine and medical oncology, University of Missouri, has "an example of where physicians are going wrong." Yarbro was once told that an HMO advised its oncologists, who were under contract, that it would not pay for the delivery of chemotherapy for non-small cell carcinoma of the lung. When Yarbro was asked how he felt about that policy, he replied, "If you're going to identify what not to treat, that's a pretty good choice, because it doesn't prolong life, there are severe side effects, and it's expensive." That judgment also applies to irradiation of such tumors, he says. Yet, he points out, "the vast majority of these tumors get irradiated and the patients receive chemotherapy. As a result, a lot of people are receiving ineffective and costly treatments---costly not only in terms of dollars, but in regard to suffering and quality of life."

Bascom shares a similar concern about appropriate decisionmaking. He points to an NCI consensus development conference at which the participants decided that "there was no proof that adjuvent chemotherapy for breast cancer is effective in post-menopausal women. But," he adds, "60 to 70 percent of American oncologists prescribe it. Who's right?" Variations in physician practice patterns is a "significant issue," Bascom says. We can't expect insurance companies to give us a blank check for those variations. They're paying the bill and they have a fiduciary obligation to their prescribers."

We need consensus among practitioners and the best way is to have up-to-date treatment information readily available. For instance, Bascom says, "are patients who receive 5-FU and Leucovorin that much better off than those who are receiving 5-FU alone? These issues need to be examined; Leucovorin is a very expensive drug."

Laurens White, M.D., professor of medicine at the University of California, San Francisco, and president-elect of the California Medical Society, says that "you can't let physicians have free reign" in their treatment decisions, but there "should always be room for physician judgment. If there isn't, innovation is stifled." Along the same lines, he says, "a more flexible system of health care will occasionally be abused, and I don't promote that abuse, but if control mechanisms are so severe there is no potential for abuse, you markedly decrease the opportunities for innovation as well."

The bottom-line is that both variations in treatment practice and short-term "cookbook" approaches to payment policymaking, affect patients--they're the ones who have the most to lose. A lymphoma patient who suddenly cannot be reimbursed for his bleomycin and adriamycin "is going to be hit hard," Bascom points out, because of the cost. "I've always tried to prescribe the simplest and least expensive regiments," he notes, but the effect of payment denials will vary depending on the patient's regimen.

As the cost of chemotherapy keeps increasing and payment shortfalls increase, "physicians are getting much more careful about the type of drugs they provide, and they are substituting cheaper drugs which are effective, but to what degree?," White worries.

Everson says, "We've just begun to scratch the surface of new technology, but it's more expensive and, regardless of survival improvements or increases in patient benefit, if insurers and government won't pay for such treatments, they won't be administered."

"Even unproven regimens offer terminal patients hope," Winn of M. D. Anderson points out. "It is extremely difficult to deny such patients any kind of treatment and, thus, deny them hope. How can regulations include the need for hope and address the effect of treatment denial on the mental quality of life of cancer patients?"

THE TREATMENT IND RULE

Another part of the controversy is the FDA's publication, in 1987, of the Investigative New Drug (IND) Treatment Rule, which allows the use of unapproved drugs as treatment and not as part of a preapproved FDA protocol. The rule also permits the commissioner of the FDA to determine, on a case-by-case basis, whether the use of an investigational drug should be approved and, thus, eligible for third-party payment. Although the IND rule is meant to encourage continued innovation in cancer treatment, it may turn out to be the straw that breaks the insurance industry's long-time backing of investigational cancer drugs.

Goodspeed, in his HIAA survey, solicited reactions to what he calls "the unanswered question: Will most insurance contracts consider drugs in the treatment IND category as experimental?" The survey shows that "approximately 38 percent of respondents believe the new category of FDA approval will affect their decisionmaking regarding cancer chemotherapy payments," Goodspeed says. Eighty-three percent of respondents said they will not categorically approve payment for treatment INDs, but a significantly smaller percentage (67 percent) of those same respondents said they will not categorically deny payment. The majority of respondents (61 percent) indicate that "requests for payment will be handled by a review of each request with reference to policy or contract language and subsequent application of usual criteria." Goodspeed predicts that "the heterogeneity of health insurance companies as a group, and the variations in insurance contract language within a given company, are likely to lead to a diverse set of reimbursement decisions" on the part of insurers. (Further highlights of the HIAA study appear on page 14.)

The new rule has its detractors in both the insurance and provider sectors. Goodspeed of CIGNA points out that the new rule "exposes insurers to the reimbursement cost of investigational treatments in the phase II trial stage or even earlier." Therein lies the growing controversy because, at a time when insurers are being pressured by health care purchasers to find further ways to reduce costs, the IND rule could significantly increase the number of new drug applications for increasingly expensive agents. In point of fact, "the number of applications have increased, since the publication of the IND rewrite," says Sindelar of the FDA.

Another concern with the new rule, voiced by Charles Moertel, M.D., at an ACCC meeting last October, is its potential to turn "unproven drugs loose on the general public"---an action that he said will "unquestionably be damaging to the oncologist who is committed to participating in carefully controlled research trials." Moertel claims that the rule promotes efforts to "obtain third-party

payment for a nonresearch administration of costly drugs that have no established safety or effectiveness." In essence," he said, "it shifts the cost of new drug development from the stockholders of high-tech drug companies . . . to the back of an already overburdened health insurance industry." (See the Fall 1987 Issue of *JCPM* for a full transcript of Moertel's talk.)

THE SEARCH FOR SOLUTIONS

Without third-party payor support, chemotherapy research and development by pharmaceutical companies, clinical trials, and access to promising new cancer treatments are all subject to unacceptable constraints.

What steps need to be taken to ensure that the creation of and participation in high-quality clinical trials continue in this country, as well as ongoing chemotherapy research and development on the part of pharmaceutical firms? Goodspeed says that the Treatment IND category is "going to create a much greater need for up-to-date information to be provided to insurance companies," which will necessitate "the development of better information systems" to help third-party payors make fair, constructive payment policies for investigational drugs. However, he also predicts that it will be difficult to overcome current contractual barriers to such payments. In many instances, he warns, "policy provisions may be the ultimate decisionmaker---a situation that can only be overcome if insurers are employing a case management approach to patient care."

Yarbro and White advocate public education programs and the involvement of such consumer advocates as the Association of Retired Persons (AARP) and the Grey Panthers. "There must be some appeal to such groups," Yarbro says, "and to any others who have a substantial stake in good health care." But, he warns, it has to be a "dignified approach to tell persons who are interested in quality of care what attempts at cost-cutting are compromising quality."

But the bottom-line is that purchasers' interests drive the marketplace. It is the private purchasers of health care, Goodspeed points out, who are spending approximately $300 million per day on employee health benefits. "Open and accurate cancer therapy information needs to be provided to both insurers and purchasers of care on the local, state, and national levels."

One increasingly expensive portion of that health care bill is the result of new technology. Everson believes that the replacement of ineffective, low-technology therapy by effective, high-technology is a "natural process." However, he warns,

HIAA SURVEY

Twenty-five members of the Health Insurance Association of America (HIAA), representing 70 percent of all privately-insured lives, were surveyed about the criteria they use to make payment decisions for oncology services, and the typical sources of information they use to aid the payment decision process for oncology services. Eighteen of the 25 companies completed the survey for a response rate of 72 percent.

- Half of the respondents rely on FDA approval as the minimum criterion for cancer chemotherapy payment. Other frequently cited criteria include medical necessity (44 percent), safety and efficacy (28 percent), and acceptance by the medical community (28 percent). Cost was not listed as a criterion by any of the responding insurers.

- When respondents were asked to rank the information sources they most frequently used to assess how closely a treatment conforms to their criteria, once again, FDA approval ranked highest (see accompanying table), followed by local physician consultants, the National Cancer Institute, the American Medical Association, and the American Cancer Society Unproven Methods Service. Several respondents use reviews of the medical literature as a fourth line of information.

- In general terms, most health insurance companies make payment decisions with the aid and advice of physicians. Typically, a physician who is employed either full-time or as a consultant to the insurance company, will provide medical input as to appropriateness of treatment, safety and efficacy, and acceptance by the medical community.

INFORMATION SOURCES FOR CHEMOTHERAPY PAYMENT DECISIONS

Resource	Rank Score*	Not Ranked**
Food & Drug Administration	1.4	0%
Local physician consultant	2.9	0%
National Cancer Institute	3.4	0%
American Medical Association	3.9	0%
American Cancer Society (Unproven Methods Service)	4.2	11%
National physician consultant	4.2	61%
University Cancer Infoline	4.7	72%
ACCC	5.3	72%

* The lower the rank score, the higher the frequency of use as a resource

** Percentage of respondents who did not rank the resource.

"high-technology treatments that are promulgated and set up as new standards of therapy must be carefully and rigorously proven. Are they truly of benefit? I suspect," he says, "that when the answer is an unequivocal yes, consumers will demand those treatments and they will be paid for by government and insurers, but it's a complex administrative, legislative, and political process that medical and professional societies need to be involved in."

Goodspeed believes that "the appropriate medical society should develop a method of review and approval of therapeutic methods analogous to technology assessment." In his opinion, "it would be great if an organization could speak for cancer chemotherapy the way the American College of Physicians is attempting to address the issue of clinical efficacy."

Gleeson of Blue Cross/Blue Shield agrees. The Association "does not want to deal with making drug reimbursement policies," and "most insurers are not equipped to evaluate drug trials, but we will support agencies that tackle the problem. We have to have some kind of objective group to conduct and/or evaluate clinical trials for new applications."

In the absence of standards of medical care within the medical community, the U.S. Pharmocopeia Drug Information Index is beginning to examine the appropriateness of taking on that role. According to a statement it issued on November 25, 1987, 65 percent of physicians favor incorporation of PDI language in the draft of the Senate bill. (It should be noted, however, that at this time, the bill does not contain any reference to potential sources or references that should be used as the basis for determining reimbursable drug indications.) There may be some disagreement among physicians with regard to the timeliness of US PDI information, but the general consensus is that, at this juncture, it has the most up-to-date information on new drug uses and a number of involved parties want it to be included as a reference if approved indications are designated as part of the outpatient drug prescription amendment.

The Public Affairs Committee of the ASCO is "discussing reimbursement with major carriers, discussing a legislative approach with Senators and Representatives to get Medicare to cover clinical trials, which it currently does not; and to discuss situations whereby changes in Medicare coverage can be effected," says Karen Antman, M.D., chairman of that committee. She contends that if Medicare can be pursuaded to change some of its payment policies, other carriers will follow suit.

SUMMARY

The solutions are not simple; they cannot be short-term. Unlike the carriers' short-sighted payment strategy of "delay, deny, and decrease," cancer treatment costs are likely to rise faster and higher if effective existing therapies are curtailed and ways are not found to increase, rather than decrease, the timely introduction of new technologies. Quality of care issues are at stake. Patient survival, length of survival, quality of life, and access to effective treatment are issues that rest in the balance. Research has proven that quality of care increases and technology transfer takes place only if there is significant involvement in clinical cancer research. Clinical trials are the only sound, although incremental way, to improve survival rates and quality of life. Moreover, it has yet to be proven that clinical trials significantly increase costs of care. Certainly existing therapies, already proven to be of significant effectiveness, must not be curtailed, especially when medical practice shows their promise for new indications and in new combinations. Providers, pharmaceutical manufacturers, government, consumer advocates, payors, and purchasers must work together to see that data on the efficacy and promise of both new and existing drugs is disseminated quickly; they must find ways to cut current cancer treatment costs; and they must find effective ways to balance quality and cost concerns. Those goals will not be easily accomplished, but fair solutions are possible only if the concerns of all involved parties are weighed and judged under the light of one overriding concern: patient survival and quality of life. ■

In the Spring issue of the Journal, potential solutions to the issues raised in this article will be explored, with representative viewpoints from all concerned parties, from clinicians to purchasers of care.