Robert Henry: By way of introduction, Gary, give us the basic direction that you would like to take on today’s subject—the high costs of biologics—whether your focus is on the benefit design structures that are going to be fashioned in response to the cost of biologics or elsewhere.

Gary Owens: It is not uncommon for new and innovative technologies to be expensive compared with costs for an older technology. Keep in mind that technologies which were considered high in cost 15 years ago, are now considered either average or low cost. If the cost of a new surgical procedure 20 years ago was $10,000, it was considered astronomical. I can remember as a resident in the 1970s how we were admonished for using IV cephalosporin antibiotics, which then cost around $500 for 10 days per day of therapy.

However, that was a different era. All things are relative. Now, we are in an ongoing healthcare cost crisis. In 1996, we saw healthcare spending exceed $1 trillion in the United States. By 2005, the $2-trillion spending level had been eclipsed and, slightly after the end of the decade, we will have exceeded $3 trillion in annual healthcare spending, representing more than 18% of the gross domestic output. At that level, healthcare spending certainly gets everyone’s attention for a number of reasons. For one thing, somebody must pay for it. There are only 2 major sources of payment for healthcare in this country—the federal government, including state and local involvement in Medicaid, and private employers. And it is clear that these payors of healthcare are concerned about costs. The federal government is trying to balance the budget, while private employers face having healthcare become a larger and larger portion of their cost of doing business, making it more difficult for them to compete. Consequently, they are pushing the people who administer their benefits—e.g., health plans, PBMs—to find ways to control costs and keep premiums affordable. In some cases, this has meant changing benefits, implementing utilization controls on certain treatments, and identifying more efficient treatment patterns. We have brought many new ideas into the mix, including case management, disease management, patient education, and physician education. One of the areas that has come squarely into the spotlight is consumerism. The theory behind this is that if consumers have more of a stake in the issue, if consumers have to spend their own healthcare dollars on services, they will become wise purchasers.

I am a bit of a skeptic, however. For the most part, consumers do not have the knowledge required to know how to spend their healthcare resources wisely. Even healthcare professionals, such as physicians and managed care executives, do not necessarily have sufficient knowledge to help direct them in how to spend their resources on the most effective treatments.

Furthermore, you need to distinguish between 2 kinds of healthcare spending, those being discretionary healthcare spending and necessary healthcare spending. You as a consumer can readily decide when to take care of minor ailments, or when to have somebody look into a rash or check out a painful hip joint that you have been walking around on for the past 5 months, and when you need more aggressive attention than aspirin or another over-the-counter remedy.

Then there are life-threatening or chronic conditions that absolutely require care. Sometimes, the treatments for these diseases are exotic and specialized, and therefore, very expensive. Keep in mind, that
among patients in this category, 10% of the population will typically use 70% of the resources.

**Robert Henry:** Has this statistic increased over the past decade?

**Gary Owens:** When I first started in the business more than 25 years ago, there was the 80/20 rule, that is, 80% of the spending was done by 20% of the people. Today, half the population only spends about 3% of the healthcare dollar: the relatively young and healthy and also the ambulatory unwell who simply do not seek healthcare services for a variety of reasons. So we have 2 competing forces: on one side, half of the population spends almost nothing in healthcare resources, while the other spends a disproportionately large amount. About 10% of the population requires appropriate healthcare because their well-being and their quality of life depend on it. Unfortunately, the one-size-fits-all approach does not work when it comes to managing cost and creating consumer incentives for these very different populations. Each segment of the population has specific requirements because there are very different forces at work on these patients.

Employers are looking for ways to control costs, and one of the ways has been to ask consumers to pay more out of pocket. In theory, this works well, but as I have noted, there are populations where this practice can be counterproductive. Many biologic therapies cost between $10,000 and $40,000, and some are as costly as $250,000 per year. If a consumer is asked to pay 20% of a therapy that costs $25,000, that would be $5,000 per year. This often results in having some consumers either forego the treatment altogether or take Draconian steps to afford it.

**Robert Henry:** What disease states are driving this? Will patients with certain disease states receive healthcare benefits that cover the more expensive biologics because their employers have an incentive to get them well and return them to the productive workforce? Are there patterns emerging, or is this still all over the map?

**Gary Owens:** Trends are gradually emerging. Fifteen years ago, there were only a handful of high-cost biologic therapies that were targeted at things such as anemia, growth hormone deficiency, and some of the inborn metabolic errors such as Gaucher’s disease. Since the mid-1990s, we have seen high-cost biologic therapies emerge for rheumatoid arthritis, cirrhosis, and hepatitis C. In these disease instances, patients are often symptomatic, but they are most likely in the workforce. Hence, the availability of these meds may keep them as productive individuals.

Biologic therapy is now emerging for more common diseases such as asthma. Suddenly there is a shift. High-cost biologics are now targeted at a much larger segment of the population than they were 15 years ago. Furthermore, many of these patients are still perfectly capable of maintaining an active and productive lifestyle provided they are able to have access to these therapies. Again, some of the therapies range from $10,000 to $40,000 a year, and if patients do not have adequate coverage, they may find that access to them is limited.

Some of the [high-cost biologic] therapies range from $10,000 to $40,000 a year, and if patients do not have adequate coverage, they may find that access to them is limited.

**Robert Henry:** It appears to come down to the single issue of access. It strikes me that the high cost of biologics supersedes the ability of the free market system to accommodate the population at large. Because if you are patient A and you have a disease that requires immediate treatment with a biologic that’s going to cost $50,000 to $100,000 a year, and cost sharing is going to be prohibitive, then you’re not going to want to wait around for 7 to 8 years for the market to stabilize, because you won’t be around by then.

So, this is the kind of thing that tends to invite government involvement to remedy the situation. This can escalate to a point where the free market system fails and the government steps in to offer a remedy. Do you see this issue being resolved at the policy level?

**Gary Owens:** I think it can be resolved at a number of levels, and you’re absolutely right, the cost of some of these therapies is such that if one doesn’t have third-party coverage for all or mostly all of the therapy, you’re just not going to get that therapy; it’s that simple. Or you’re going to mortgage your future in order to get it, and even that can only provide a limited amount of treatment in some instances.

The temptation for legislative relief by way of mandates or other actions is always there; although I don’t know in what form that would come. One possibility is a form of price control on some of these therapies, which goes against the capitalistic, free market system.
It could come in the form of the FDA requiring manufacturers of these new therapies to demonstrate the relative value of the treatments to the system. But one main opportunity exists outside of legislative or regulatory remedy, namely, in benefit design.

The initial temptation to put biologics in a high-cost benefit bucket solved the problem only in the short term, and it may have created access barriers for patients.

Robert Henry: That is clearly the first place to start looking. The role of the payor in throwing a harness around this runaway stallion is still only partially utilized: so much power, so much potency for facilitating the treatment of diseases, so much life-saving potential.

Gary Owens: Exactly.

Robert Henry: All we have really done here is to run ahead of ourselves financially. The only vice is that science and the corporations funding the science have invented life-saving remedies that we have not yet figured a way to pay for. It is nothing more or less serious than that. Then front-and-center come the healthcare plan and the actuary models and the overall resource allocation models.

Gary Owens: Yes, and up to now, we have figured out a way to pay for them in a straightforward manner: add the cost of the therapy into the benefit program and ultimately charge the consumer, the employer, or the federal government for the costs of these new therapies. Unfortunately, continuing to do that leads to problems. And as you pointed out, the day of reckoning will come, if it has not already.

In most health plans, these biologic therapies were not really considered in their existing benefit designs. Benefit programs were often developed several years ago. There were relatively few injectable or infusible medicines, and most health plans offered a benefit that covered injections or infusions when prescribed by a physician in the health plan’s network.

As these treatments began to grow, it was clear that not all health plans were equal, not all of them cost the same, not all of them offered the same benefits to the consumer. Management of these products consisted of selecting certain products that could be used for their approved indications, and in some cases, off-label. So traditional medical management programs were put in place. One example of the early management controls imposed involved growth hormones. Treating children with short stature owing to pituitary insufficiency or chronic renal disease was considered appropriate. But it was not necessarily appropriate for the system to pay for growth hormone for somebody who wants to be a bit taller or do body building.

Thus, prior authorizations were put in place just to manage usage of these products. This obviously could not be done with every product. In 1990, there were only 20 biologics on the market. Now there are more than 300, and as many as 800 are expected by the end of the decade. So one quick temptation is to allow the problem to self-regulate: Create a unique group of products called the biologics, then create a new tier of benefits for them, allowing access to all the biologics a consumer needed plus a fixed dollar copayment or a percentage from coinsurance.

The downside was that 10% of the population have life-threatening or serious chronic diseases. It is not unheard of for a rheumatoid arthritis patient to have 2 or 3 other chronic diseases and be faced with a 20% coinsurance on a disease-modifying agent. Consequently, they have to turn down the new drugs and opt for traditional therapy because of the out-of-pocket cost. The initial temptation to put biologics in a high-cost benefit bucket solved the problem only in the short term, and it may have created access barriers for patients with resultant decreased quality of life and possibly increased downstream medical costs.

Robert Henry: How do healthcare plans avoid the knee-jerk reaction to control costs at all costs, falling back on the tired model of cost-minimization when experience has shown that cost-effectiveness is essential to long-term success?

Gary Owens: Health plans like to be able to apply cost-effectiveness and cost-utility models and comparative outcomes analyses in developing their coverage policies. That being said, these data are not currently available. In the absence of meaningful comparative outcome studies, health plans have been forced to take some cost-minimization strategies, because those are really the only things on which they have any hard data.

It is a stop-gap measure, but it was born of necessity, because the other option is to continue to absorb those costs, which health plans can do; however, when health plans absorb the cost of new therapies, eventually premiums increase in the next underwriting cycle.
**Robert Henry:** Yes, the cost point on the cost/quality/access triangle is out of kilter here. Seven years ago health-care plan margins were perilously low, and over the past few years they have improved. Has this given plans a cushion to offset the new cost demands of biologics?

**Gary Owens:** That cushion disappears very, very rapidly. In the health plan business, all things are relative. Somewhere between $0.80 and $0.85 of every premium dollar collected goes back out to cover health-care costs. And $0.10 to $0.12 of every premium dollar goes toward the health plan’s administrative load. What remains is the margin, and, as you can see, that margin is quite small. A small margin on a large number of dollars can still represent some significant amounts of money that can go into a health plan reserve or become profit; but remember, as healthcare cost increases are covered, the amount of money that must be kept in reserve, either from a state regulatory standpoint or insurance department regulatory standpoint, must increase.

So health plans must keep some reserve. If they do not, they become financially nonviable and incapable of dealing with downtimes or when their actuarial projections were incorrect. It doesn’t take very long to erode those reserves, and an ultimate outcome of increasing healthcare costs is to increase premiums. As premiums increase, fewer people are insured. Employers have second thoughts about providing healthcare coverage for their employees, especially small to mid-sized employers who may have to determine how to provide healthcare coverage for their employees and still have a sufficient margin to stay in business.

**Robert Henry:** Earlier in our conversation, we discussed the natural course of events attending new technologies, which raises its head here in hopes of offering a natural, unlegislated solution. Over time, these new technologies will decrease in cost, and people have to be patient and allow the market to settle, and the cost of biologic agents to decrease on their own after we have gone through the hurdle of initial high cost associated with discovery and development. Is there a consensus on the part of chief financial officers at healthcare plans as to when such a settling out of costs might occur?

**Gary Owens:** If it were most any other technology-driven business, I would agree that people are probably waiting for the proverbial light at the end of the tunnel. I recently purchased a laptop computer that is much more sophisticated and has more capacity than my previous laptop did 5 years ago. And it does it for less than half the cost. This is a perfect example of market forces and technology balancing new and improved technology with decreasing costs. Unfortunately, this paradigm does not fit medicine. New medical technology and medications continue to cost more, and as innovation builds upon innovation, the newer innovation tends to cost even more than the technology that is being replaced.

As healthcare cost increases are covered, the amount of money that must be kept in reserve, either from a state regulatory standpoint or insurance department regulatory standpoint, must increase.

**Robert Henry:** This brings me back to the core mission of American Health & Drug Benefits: the notion of collegiality, that the different stakeholders should combine forces to solve such problems rather than take adversarial, competitive stances toward one another. How can we—meaning we the stakeholders—make this system work to accommodate biologics?

It seems to me that this is one of those examples where healthcare really stands to make progress and capitalize on the extraordinary innovations that biologics represent. Sometimes you have to ask for less initially to get more in the long term. Are there examples of the kind of cooperation that I am talking about, that is, enlightened self-interest? Which payors or leaders—either individuals or institutions or private companies—have been the most visionary in this regard?

**Gary Owens:** Frankly, I think we are only on the edge of this ideal at best. All too often what occurs is exactly as you describe: Manufacturers get nervous about dwindling pipelines and having fewer products; payors react to increasing cost trends by deciding to put in management controls such as step therapy, or prior authorizations. Consumers and doctors often react negatively to increased controls, prior authorizations, and benefit designs that require high member out-of-pocket costs.

I agree with you that at some point people need to step up and say, “We need to look for a different way of doing this.” Although I have not yet seen it, I would applaud the manufacturer that brings its product to market with outcomes studies and economic data that
help place their product in the appropriate position in the value equation.

Now this, of course, is a double-edged sword, because if you happen to bring a product to market and it does not bring high value according to your studies, then you’re going to have a hard time getting people to pay for it. On the other hand, if you can show significant cost offsets or that the cost of your product produces a value that is unparalleled by the competing products in the same space, you have the opportunity to hit a home run.

I think the problem will be getting the parties to sit down and lay down their arms to solve this problem.

Robert Henry: Yes. That is what American Health & Drug Benefits is attempting to do—increase dialogue between the sometimes warring factions.

Gary Owens: Somebody must take the first step and take a chance that doing the right thing will ultimately be rewarding.

Robert Henry: When I attended the Institute of Medicine roundtables on evidence-based medicine this year, there was that sense that people sat down at the table together. The venue had been designed that way so that there was a time for FDA regulatory people to step up and present their ideas for implementing evidence-based medicine standards. There was a chance for industry pharmaceuticals to step up and present their vision. There was a chance for patient advocacy groups or the healthcare plans for the purchasers. And I liked the feeling that was generated there. It seems to be another example of this kind of form building, this bridges-across-the-water process.

Are the other examples of this conciliatory approach as opposed to having one sector dominate the healthcare debate and hope to solve the question all by themselves?

Gary Owens: I am not sure you have anybody out there looking to solve it all by themselves. I think too many are still protecting their territory and solving their own problems without giving thought to the other stakeholders’ problems.

Robert Henry: There has been a lot of movement in the past few years toward empowering the Agency for Healthcare Research and Quality (AHRQ) to become a center for comparative effectiveness, that is, making it the definitive center for evidence-based medicine standards. Do you consider this an example of healthy data clarification, or an attempt by one healthcare stakeholder group to solve the problem once and for all, as opposed to a collegial way of sitting down and sharing information?

Do you think this movement by the government to establish an evidence-based center is fraught with peril, as some fear, or can it help contribute to the dialogue that you hope to promote?

Gary Owens: If properly done, taking into account the viewpoints of all the stakeholders, including physicians, patients, health plans, employer groups, manufacturers of innovative products, to name only a few, with balanced, scientifically driven opinions, I think you could create a highly effective body. The challenge is to create a body that can simultaneously balance the needs of all those stakeholders.

Robert Henry: Yes. This would require approaching it as an art and not solely a science.

Gary Owens: True, not all of medicine is scientifically driven. A good physician must balance the scientific, personal, and artistic aspects of medicine to achieve the best outcomes.

Robert Henry: Well, this requires a certain amount of lobbying—for want of a better term—by each of the stakeholder groups to make sure that their point of view is heard. That would mean that each of the stakeholder groups would have to have access to a leadership community within AHRQ to make this work. And there remains another aspect to their effectiveness. Will AHRQ have sufficient funds to do this?

Gary Owens: Funds for AHRQ might double from 2007 to 2008, which is a good start, but probably only
5% of what is really needed to get real answers on evidence-based medicine. That of course brings up another related issue: the high cost of biologics. It becomes a lot easier to pay that bill if there is clear and indisputable evidence that biologics produce high-value outcomes.

Robert Henry: With so many of these disease states occurring in small populations, you cannot get sufficient numbers of patients to complete a randomized controlled trial to determine the effectiveness, safety, health-related quality of life, and performance perimeters. What trial designs do you look for when you are evaluating biologics to determine if you are getting a sufficient clinical return on investment? And to what extent do medical and pharmacy directors participate in this process?

Gary Owens: Medical and pharmacy directors must collaborate in the process of evaluating biologics, because some of these products are covered under the medical benefits and some by the pharmacy benefit. Some plans have crossover coverage. As you pointed out, we need large, longitudinal trials and trials in naturalistic settings to properly determine value. As soon as you introduce patients into a clinical trial, you have already created an artificial setting that does not always resemble the real world and does not always produce outcomes that can be duplicated in the population at-large. Studying large populations in naturalistic settings is probably the best way to evaluate the economics of these issues. We generally only have the FDA-required studies, which amounts to examining safety and efficacy. Cost-effectiveness is not evaluated; therefore, acquisition cost is all we have to work with. In other words, if the cost is too high, then utilization may need to be managed.

We do not have all of the pieces of this puzzle necessary to assign value to biologics. All we have is cost. And if the cost is high, drug utilization management often becomes restrictive.

Robert Henry: Permit me to offer an historical analogy. In the New World, pioneers such as Lewis and Clark sought new methods for understanding, exploring, and developing a new country. The same principle should be in place here. We have a new medical world before us in the form of biologics. It stands to reason that some innovators, both individuals and organizations such as healthcare plans, are going to boldly apply different approaches to a new entity, but this time in the form of benefit design methods, which brings me back to an old axiom: when you’ve seen one managed care organization, you’ve seen one managed care organization.

Gary Owens: Which still holds true, by the way.

Robert Henry: What then has been your observation industry-wise with regard to payor innovation in this brave new world of biologics? And can innovation occur, given the clamor for conformity to guidelines, especially where the technology is too new to allow for meaningful guidelines?

Medical and pharmacy directors must collaborate in the process of evaluating biologics.

Gary Owens: I think we are still waiting for the leaders to emerge. For the most part, however, most plans are exploring in their own unique ways. This is still a new enough problem that the solution has not yet manifested in an obvious fashion. Because this is a highly competitive business, it is difficult to be an early innovator and risk failure. Look at the incentive of the payor: If a health plan tries something radical and extremely pioneering and falls flat, it may have given away its competitive advantage for a significant period of time. It takes a health plan a long time to recover if it loses significant market share.

Robert Henry: Also true if a healthcare plan takes in all the sick patients who show up at their doorstep to get the liberal coverage benefits provided.

Gary Owens: However, if they truly come upon something innovative and can actually take care of these people and make a name for themselves, they win big. But it’s a big risk to take.

Robert Henry: It certainly is. I wonder if plans can try something on a small scale, so they don’t risk their entire portfolio.

Gary Owens: Yes. I think pilot programs are often the way. I think it behooves all of us who are in this business to keep our ears to the ground and continue to follow new trends and emerging ideas. Whenever somebody truly finds a solution in this business, it is quickly emulated.

Robert Henry: One of the other considerations is to look at how each medical group expresses its interest in the
utilization of these products. I think it’s safe to say that cancer and rheumatoid arthritis are the principal disease states affected by expenditures with biologics.

**Gary Owens:** Yes, the biggest growth area is oncology. Nearly half of all the new biologic therapies are targeted at cancer. Another big area is for diseases mediated through the immune system, such as rheumatoid arthritis, lupus, and Crohn’s disease. A host of other illnesses are also targets for biologic development, simply because the underlying disease mechanisms or the pathology is already understood.

**Robert Henry:** How are medical groups such as the American Society of Clinical Oncology and the American Society of Hematology expressing their desire to utilize the biologics? I ask this because we know that each stakeholder group exerts official pressure to increase access to drugs they find advantageous. Both of these societies came out strongly in favor of more liberal coverage than that determined by the Centers for Medicare & Medicaid Services.

**Gary Owens:** Yes. They have certainly made their position statement quite well known. They usually begin with position statements for their membership that outline how they believe the product should be used, followed by guidelines for the specific use of a product.

**Robert Henry:** So it begins with a dynamic tension between the stakeholder groups that tends to result in a given level of coverage.

**Gary Owens:** That is correct.

**Robert Henry:** In all of this, where is the value of patient knowledge in participating in the cost management aspects of this? I ask because we saw what happened in the wake of the article about rosiglitazone in the New England Journal of Medicine and the national furor that ensued from a meta-analysis that many regarded as being of less than conclusive worth. It is likely that the principal result was that patients refused to take their drug anymore. If patients are going to participate in the decision-making process, they have to know enough to be able to say this is what I want and this is what I do not want. What are the implications for biologics, which are far more complicated and probably less within the grasp of the lay public?

**Gary Owens:** Well, I think the lay public is very capable of commenting appropriately and intelligently. The problem is that the issues often hit the press so quickly that the public is provided with incomplete information. The public often will act on incomplete data when they appear to be positive for controlling a disease. It strikes me that many clinicians may also fall prey to oversimplification of the results of one study.

**Robert Henry:** Do you see opportunities or incentives for healthcare plans to institute more aggressive patient education programs? Is it worth their while professionally to try to educate the public sufficiently to engage in a dialogue with their payors and doctors about biologics?

**Gary Owens:** Yes, but we do not know who should be responsible for informing the public. Although it’s tempting to put the onus on health plans, they have limited resources and limited ability for outreach. And sometimes communications from the health plan are viewed by the public as self-serving. So they may be viewed with skepticism.

**Robert Henry:** This strikes me as an opportunity for a larger organization such as PhRMA to be a participant in patient education programs with the medical associations. I could see something at the higher levels of each of the stakeholder groups where the dialogue is further extended, for example, to patient advocacy groups and so on. Does that seem to be part of a reasonable patient education process?

**Gary Owens:** If you can create a patient education process that would be viewed as free of inherent bias and one that represents the viewpoint of multiple stakeholders in the process, then it will be thought of as a credible source of information to the public. The key there is that I think we still have to invent it.

**Robert Henry:** We have seen efforts from American Health Insurance Plans (AHIP) with regard to improving quality of care. So there is a desire and a willingness to become proactive on healthcare measures. The climate
Robert Henry: And it's the same with government. The FDA can be looked on as oppressively restrictive. Payors can be oppressively restrictive, instead of managers of resources. The purchasers can be looked upon as totally self-interested. The patients can be looked on as naïve and greedy for all the benefits of modern research, but not willing to pay for any of them. All the negative stereotypes could go on.

Gary Owens: So, we have to be careful not to vilify any sector. Every sector has valid reasons for doing the things they do. Depersonalizing the dynamic, it becomes a matter of addressing, aligning, and correcting, where necessary, the incentives driving each stakeholder group. These are not good or bad parties, just different participants to the process of care.

Robert Henry: I am interested in seeing if an appreciation for the right kind of financial strength of pharma and biotech of the manufacturing sector can emerge, because pharma is a resource that has grown out of a period of economic prosperity in the West over the past few decades to the point where we are able to produce the biologics that we have been covering in today's conversation. And that resource is finite. If it is hit too hard and treated in a totally adversarial way, it can disappear. And I don't mean to single out pharma as the sole sector requiring protection. Pharma has to be equitable and balanced and reasonable in its desires for profitability. And it has to be ultimately on fire with a desire to improve patients' care. And if everybody keeps their eye on that prize—the regulators in government, the payors, the purchasers, the patient advocacy groups—if everyone treats this as Operation Fair Share, then I think we can pursue this new world of biologics with a certain degree of patience, which is really hard to do when there is an immediacy toward patients wanting to get the best care to reverse the progression of their disease. Do you have any final thoughts for payors regarding how they should conduct their affairs strategically in benefit designs for biologics?

Gary Owens: Well, I think that has been the essence of this conversation. Ultimately payors will need to examine their benefit designs, how they are paying for value, or how they are assessing value. They are going to have to be willing to reassess their benefits, reassess how those benefits affect certain vulnerable populations and be willing to adjust those benefits as new information emerges.

This would help them direct the benefit design in such a way that we are neither wasting healthcare resources on inappropriate spending, and at the same
time, that we are not depriving patients of vital care. I think such changes will occur as a gradual process.

Robert Henry: There is one final question to that, Gary. Do you see an increase of communication within the corporate infrastructure of the average healthcare plan, that is, an increase of communication between the CEO, the medical director, the pharmacy director, and the CFO? Have you seen evidence of an increase in dialogue between these groups to arrive at a corporate consensus that will help them devise benefit designs?

Gary Owens: To a great extent, this dialogue has always been there, and we are seeing a continued process, where, in a successful managed care plan, all of the stakeholders in the plan are at the table. This is what makes a health plan successful—having open internal dialogue that flows across various stakeholders in the plan and breaks down the barriers of communication within the plan.

Robert Henry: Won’t it be nice when this harmony characterizes the entire stakeholder spectrum.

Gary Owens: We’re going to need it if patients are going to receive the awesome potential that biologics offer. This is a case of potentiality versus reality, and we are only just beginning to realize how to reap the harvest made possible through biologics.

For inquiries or comments, please e-mail editorial@AHDBonline.com.

AHDB Stakeholder Perspective

Value-Based Benefit—A Joint Effort

In the era of rising healthcare cost, it is easy for all stakeholders to point fingers at others and assign the “blame” for the high cost of care to any of the other stakeholders. For the system to advance, it will be important for all stakeholders to begin to grasp the complexity of providing healthcare to a growing population, a population that is rapidly aging and to a population that desires the latest and best that medicine has to offer. Simply put, we cannot afford to spend precious healthcare resources unwisely. We must design a system that neither wastes resources on new technology that is unproven, nor deprives patients of access to valuable new technology that has the potential to improve their clinical outcomes or their quality of life.

To do this, each of the stakeholders must be prepared to work collaboratively. Patients and providers will need to understand that without proper evidence of effectiveness—and in the future cost-effectiveness—access to some therapies may need to be limited, or simply not available, under insurance benefits. The concept of mandated benefits may need to be reconsidered at the legislative level as in states where there are significant mandates; the cost of health insurance typically exceeds those states where no mandates are available. Insurers will need to be willing to provide new benefit structures that allow relatively open access to treatments—no matter how costly—that are proven to be effective and cost-effective for the treatment of chronic illnesses.

Manufacturers of these treatments will need to show, by well-designed studies, the comparative efficacy of their newly created therapies relative to existing treatments. They will also need to show cost-effectiveness of their treatments in this new environment.

Finally, the purchasers of healthcare, the government, and private employers will need to understand how these new benefit packages are evidence-based, and how the covered therapies are providing value to justify future cost increases.

In short, it will be necessary for all involved stakeholders to stop looking to the others to solve the problem and work cooperatively to develop new benefits and products that meet the goal of providing access to timely and effective care, without wasting resources. This is a challenge that readers of American Health & Drug Benefits™ should be willing to embrace, as well as provide the leadership to accomplish it.