Our World Is Endogenous

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How important is personal health compared with other decisions we make every day? It is probably number one. Yet when it comes to other people, we generally make decisions about how healthcare is delivered based on a world outside of healthcare. Decisions are not made based on the needs we see right in front of us but on exogenous factors. In the world of scientific discovery and drug development, do researchers inside companies decide what products to pursue based on who wins an election? Do they ask a health plan or employer what new drug they are willing to fund for the future? No. The pipeline is filled with incentives driven by the healthcare needs of our society and of course an opportunity for profit.

Advances in healthcare come from years or even decades of scientific development. Historically some of our most valuable and novel agents have been unanticipated discoveries. Others have come from natural products such as plant and animal molecules. Now we are seeing the focus shift profoundly to targeted therapies and even an ability to change how we define a disease such as cancer or HIV.

The newest biologic agents in the pipeline offer tremendous opportunities in our search for ways to fight illness. Scientific researchers have found new ways to target products that improve effectiveness and lessen side effects. Sometimes even specific treatment paradigms are developed based on genetic markers, allowing for maximum effectiveness. Our challenge is getting these products to the right patient population at the proper time. We are even seeing the development of formularies that ultimately will be unique to each individual.

Now the bad news—all this innovation has a price (and the price often is quite large).

One need look back only a short time and remember the "epidemic" of AIDS and HIV infections. This was a taboo subject and frightening at best. Today HIV is readily described as an illness that needs to be managed. Who among us watching the course of HIV in the 1980s and 1990s would ever consider that this disease would or could be "managed"? This is nothing less than amazing. Just ask Magic Johnson, who since his retirement from professional basketball has headed a foundation to promote HIV/AIDS education and prevention.

> **New products enter the marketplace and we have to figure out the best ways to get them to the right person at the right time. Our system is ripe for innovation of our own making.**

How nice it would be if the development of products were timed to what we could afford. But that is not how it works. Advances in healthcare do have an expense direction. That direction is nearly always up. We know the cost and we know new advances are coming to market fast, yet it seems we often delay our response to these changes, no matter how profound they may be. Our current systems for defining these products, labeling them, delivering them to patients, billing for them, and even using them are antiquated. The evolution of new and expensive pharmaceutical and biologic agents is creating a near-revolution in healthcare. Our systems for this entire area of "specialty" need reformulation.

Specialty medications and all they encompass will force a sea change in the pharmacy benefit landscape. We are unable to really figure out whether these agents are part of a pharmacy benefit or a medical benefit. Sometimes we do one or the other based on some intricate back-office formula that does not really fit either. We do know that if we allow the copayment or other charges to increase too much, patients will not take or use the medicine. This failure serves no one. Finding the delicate balance with tools we use today has been a struggle. We just do not have it right yet.

Even worse, we sometimes cannot even describe what we have. The billing and labeling codes for specialty products are composed in strange ways because they do not fit our current coding models. Sometimes we need to link our pharmacy billing services with a medical office visit and/or treatment. This situation obligates us to create a complicated crosswalk that may be unique to our own billing organization. The problems escalate from there. A system is needed to allow these services to be described in a consistent way.

We have waited too long to get on with it. Some have pinned hopes on federal programs such as Medicare to define and organize specialty pharmaceutical agents. We look to our elected officials to answer our demands for a unified system, but they are driven by politics rather than the needs of patients. We seem to be waiting for someone else to tell us what is paid for and by whom. Our needs are now and we cannot wait for answers based on outside influences. Those of us who understand the changes best need to take the steps forward and create a new specialty paradigm. If we do not seize this opportunity to control who gets what when, then others with far less knowledge will make those decisions for us. The ambiguity will never leave us, but we can make choices based on what we know now.

Specialty healthcare products bring profound opportunities for us all. As we define how this benefit is to be administered, we need to use endogenous resources to create our future. We need to act together and act now. ajpb