Shaping the Future of Drug Development & Marketing Strategies

Payer perspectives

Two questions from patients about drug therapy—does it fix my problem? does it cause other problems?—suggest three new pharma strategies to address payers' priorities for improved results. These strategies are affected by payer perspectives as they shape the future of drug development and marketing strategies.

Elizabeth L Bewley
President & CEO
Pario Health Institute, USA

The US ranks 50th in the world in life expectancy and 46th in infant survival rates. Virtually all the statistics point in the same direction. Compared to other developed nations, health outcomes in the US are worse and costs are higher. US health outcomes and costs are unacceptable.

For example, the US ranked last out of 19 developed nations in a study of preventable deaths. Additionally, the US spends more than twice as much per person on healthcare as other developed nations do. In 2009, healthcare costs in the US will total about US$ 8,160 per person.

Medical Care Causes One of Every Six Deaths

Medical care is the direct cause of at least 17 per cent of all deaths in the US each year. These include 200,000 deaths caused by medical errors in hospitals, 99,000 deaths caused by Infections acquired in hospitals and 125,000 deaths caused by Adverse Drug Events (ADE). Total deaths from selected causes are 424,000 deaths.

This is equivalent to killing the entire population of the city of Miami every year. These numbers do not include all deaths caused by medical care. For example, they do not include deaths resulting from misdiagnoses. Additionally, many more people are injured by medical care than are killed outright. For example, a typical study concluded that ADE alone lead to 17 million trips to the emergency room each year, and 3 million admissions to long term care.

Payers want better results

Purchasers of healthcare have limited interest in the outcomes of clinical trials. They are paying for real people in real life, including people with multiple diseases. They expect medical care to enable these people to perform significantly better in day-to-day activities.

Healthcare is not individual-centric

Why doesn't the excellent medical research in the US result in better quality of care and longer life expectancy? The answer is deceptively simple. Healthcare in the US is not individual-centric (patient-centric). That is, care decisions often do not take into account whether they improve or degrade the patient's long-term well-being.

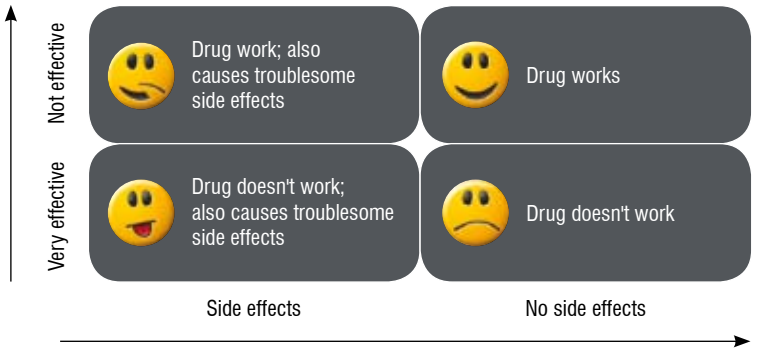
Four outcomes of treatment are common

As an example, consider what happens when a doctor prescribes a drug for a chronic condition. People are likely to have two questions about its impact on their health:

- Does it fix my problem
- Does it cause other problems?

These two concerns are mapped on the chart in Figure 1 and yield four possible outcomes. The first outcome appears in the upper right hand quadrant: the drug solves the original problem and ▶

Four outcomes are common



does not create any others. However, on average, 50 per cent of the people given a typical drug will fall in the bottom two quadrants—the drug does not work for them.

The second outcome appears in the bottom right-hand quadrant. Here, the drug does not solve the original problem. It also does not cause people any new problems. However, if their condition warrants treatment, and the treatment is not working for them, then presumably their health is likely to deteriorate. In addition, money spent here is wasted. It is not a desirable quadrant.

The third outcome appears in the bottom left-hand quadrant. Here, the drug does not solve the original problem. However, it does create new health problems. For example, more than 50 common drugs are known to cause significant weight gain in many people.

The fourth outcome appears in the upper left-hand quadrant. Here, the drug solves the original problem, but also creates new problems. It is a challenge to decide if gaining the benefits justifies tolerating the problems.

It is no longer acceptable to payers for pharmaceutical companies simply to develop a drug that is very helpful for, say, 48 per cent of the people with a certain disease. It is also necessary to be able to tell if any given individual is one of the 48 per cent who will be helped, or one of the 52 per cent who will not. Purchasers do not want to pay for the drug for the 52 per cent in this example who will not benefit from it and they do not want to expose those people to potential side effects.

Healthcare focuses on one quadrant

There are four well-populated quadrants on the chart. However, it is typical across the healthcare industry for professionals to talk and act as if the only quadrant is the one in the upper right: drug works, no serious side effects.

Thus, when they talk about engaging individuals more in their own care, they focus on coming up with the right incentives and penalties to drive 'compliance' or 'adherence'. That approach is not in the patients' best interests. The people who fall in the bottom two quadrants should not take the drug and many people in the upper left-hand quadrant should not either. Generally, well over half the people will be worse off if they simply do as they are told.

Better health would be achieved not by driving people to follow orders, but instead by helping them be better CEOs of their own health and healthcare. CEOs do not know everything. They rely heavily on experts. But what they do know is what questions to ask. In this case, these might include:

- What is this drug intended to do?
- How will we know if it is working for me?
- When will we know if it is working for me?

It is hard to be a successful CEO without good information. A logical question to ask is whether individuals get the information they need.

Doctors omit key facts when prescribing drugs

Archives of Internal Medicine reported on a study in which doctors agreed to be recorded during patient visits, prescribing drugs new to those individuals. Here are the percents of the visits in which doctors mentioned important information:

The reason for taking the drug	**87 %**
The name of the drug	**74 %**
Side effects	**35 %**

Given the volume of ADE, the failure to provide these facts consistently is disturbing. The person who is present 100 per cent of the time when a drug is administered is not the doctor. It is the patient. How can individuals help prevent ADE that can kill them if they are not even told the name of the drug they are supposed to be getting?

Healthcare often appears to be focussed on delivering treatments—e.g. writing prescriptions—rather than on improving health. Payers are increasingly intolerant of this disconnect.

Prescribing multiple drugs multiplies the problem

The problem of prescribing drugs without providing basic information gets significantly worse when there are more doctors and more drugs in the equation.

This situation arises frequently. More than 45 per cent of the people in the US have a chronic condition, and 81 per cent of people with serious chronic conditions see two or more doctors. About 20 per cent of people over age 65 take 10 or more different drugs each week.

Prevention provides the following example of healthcare's focus on delivering treatments instead of on improving health.

A woman in her sixties was prescribed several drugs. After she started taking them, she developed new symptoms,

so more drugs were prescribed. Then she developed more symptoms, so yet more drugs were added, and so forth, until she was taking thirteen drugs. She deteriorated significantly. She felt that she would be better off dead.

A pharmacist analysed her drug regimen and identified a number of drug interactions and potential side effects that were probably causing most of her symptoms. When she took this analysis to her doctor, he 'fired' her as a patient. The next eight doctors she went to refused to consider that the treatments might be causing many of her problems.

Stories like this are very common and usually end very badly. She was lucky: the tenth doctor agreed to change her treatment plan, based on the pharmacist's analysis. Several years later, she is healthy and active, and taking just three prescription drugs.

Payers are upset about the high costs and damaged lives that result when healthcare professionals act as if the only quadrant is the one in the upper right: drug works no serious side effects.

Pharmaceutical companies face lawsuits, bad publicity, fines and restrictive regulations. It is possible that many of these arise because people feel that the pharma company should have made it clearer that their drug results in four heavily-populated quadrants.

Identify in which quadrant an individual falls

Here are three ways a pharmaceutical company can help identify into which quadrant an individual falls when the doctor prescribes a drug they sell. These approaches range from pre-emptive to corrective.

First, many companies are already working to find genetic markers to identify which people are good candidates for a particular therapy and which are not.

Second, because companies cannot possibly do clinical trials to check every combination of real-world conditions, it may be very useful to work with integrated care systems (organisations that are responsible for providing everything from primary care to hospitalisation for their roster of patients) to mine their data about their patients. For example, while the drug treats one condition, it may be possible to tell whether people with specific co-morbidities (additional diseases) do especially well or especially poorly when they take it. While this data is not as pristine as clinical trial data, it is often a great deal better than nothing.

Third, it would be useful to apply the research concept of 'fast failure' to prescribing. That is, once individuals are taking a drug, how can it be determined very quickly whether it is actually helping them or hurting them?

Address polypharmacy

Polypharmacy, the overprescribing of multiple drugs, resulting in drug interactions and side effects, is very pervasive. In fact, one researcher concluded that it works best to assume that every symptom in the elderly is a side effect of drugs until conclusively proven otherwise. An industry-wide initiative could address polypharmacy.

A first step might be an awareness campaign directed towards doctors and patients. This initiative would need to go far beyond the usual admonitions to 'bring all your pill bottles to your doctor once a year.' It would need to provide practical recommendations for preventing, recognising and addressing polypharmacy as it is happening.

A second step might be a toll-free number and a website run by pharmacists. Individuals could list the drugs they are taking and the symptoms they are experiencing. A computer programme could analyse that particular drug regimen and highlight potentially serious drug interactions and known side effects that could be causing their symptoms. The output would be a printout individuals could discuss with their doctors.

Help individuals be better CEOs

The third strategy for pharma companies to meet the needs of payers is to help individuals be better CEOs of their own health and healthcare. Industry-wide efforts would be helpful, and so would checklists for doctors and patients specific to individual drugs. These could address such questions as, "How will I know if this drug is working for me?" This strategy means giving individuals the information they need to take more responsibility for the care they receive. Their lives may depend on it. ■

Pharmaceutical companies have a key role

Better results are likely if all players act as if the purpose of healthcare is to enable people to lead the lives they want.

Three strategies for pharma companies to respond to payers' priorities are:

- One, help identify into which quadrant an individual falls
- Two, help address polypharmacy (the over-prescribing of multiple drugs)
- Three, help individuals be better CEOs of their own health and healthcare.

AUTHOR

Elizabeth L Bewley has joined Pario Health Institute in 2008 after 20 years at healthcare icon Johnson & Johnson. Her work focusses on catalysing change so that healthcare becomes more individual-centric, and its goal becomes to enable people to lead the lives they want.