The Specialty Drug Price Debate:
Should Medtech Be Worried?

As prices for specialty drugs like oncologics soar, outrage is mounting over the cost of the new therapies, prompting a debate about their value. Could any of this spill over to medical devices?

by DAVID CASSAK

As we note in this month's *Perspective*, notwithstanding significant differences between the two industries, issues and debates that arise in the pharmaceutical industry often spill over to medical devices in time – sometimes appropriately so, sometimes not. (*See "Specialty Drug Pricing Pushback: Is this the Canary in the Mineshaft for Medtech?" in this issue.*)

So it's worth asking whether the controversy that has arisen in recent years about soaring drug prices for diseases like cancer, multiple sclerosis, and rheumatoid arthritis has any relevance for a medical device industry that has seen its share of cost scrutiny – albeit with nowhere near the vehemence that has attended, in particular, the debate over cancer drugs.

For the past several years, a wide range of people – from public policy makers to consumer groups to payors and providers – have complained, often loudly, about the enormous price tags that new specialty therapies come with these days. Outrage is hardly too strong a term for the reaction to the cancer therapies, for example, that extend lives for months but threaten to bankrupt institutional and sometimes personal finances.

In their defense, drug companies point to the high cost of developing new treatments and bringing them to market and to the value of prolonged lives as justification of the high cost of the new therapies. Indeed, on some fundamental level, the debate is as much about the value of prolonging life as it is about the cost of the drugs.

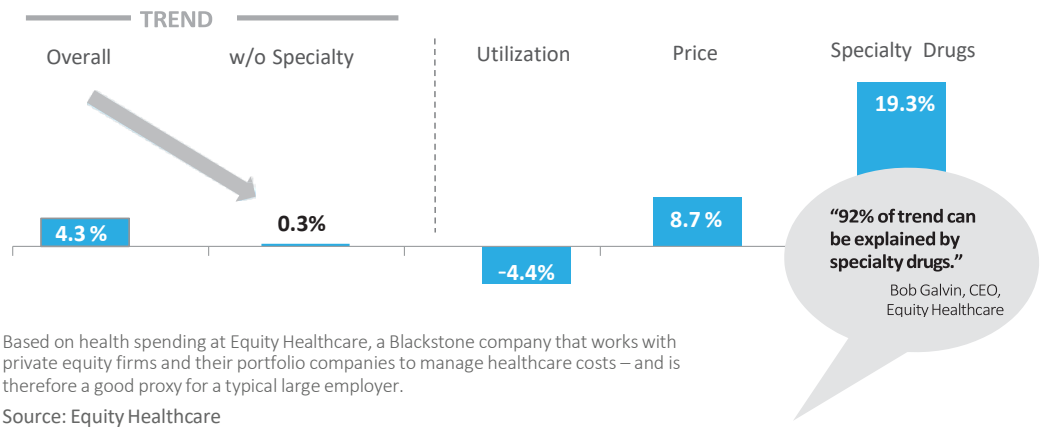
These kinds of debates have been going on for years, but recently two new initiatives, one at Memorial Sloan Kettering Cancer Center (MSKCC) in New York, the country's most prestigious provider of cancer services, the other from United Healthcare, the country's largest health insurer, have set out to try to get at the heart of the cost/value debate over cancer therapies. (The MSKCC program was featured in an article in *The Wall Street Journal;* the United Health program in *The New York Times*.) They are by no means alone: The American Society for Clinical Oncology has just released its "value framework" for determining the "net health benefit" of cancer therapies and the American College of Cardiology and the American Heart Association are moving along the same path, issuing their own "statement" on cost-value methodology.

The MSKCC initiative was powered by an analytical tool developed by Westport, CT-based **Real Endpoints** (RE), an analytics firm developing tools and services that provide transparency about drug attributes, assess comparative drug value, and help customers—an almost unique combination of payors, providers and biopharmaceutical companies—increase return on their pharmaceutical investment.

Does any of this matter for medical device companies? It's tempting to be of two minds about the significance of the specialty drug pricing debate for medtech. On the one hand, all of this is irrelevant because the roughly $130 billion cost of specialty drugs (with annual prices, for example, of $60,000 for most MS (multiple sclerosis) therapies, $175,000 for **Merck**'s *Keytruda* cancer therapy and $300,000 for **Vertex**'s cystic fibrosis drug *Kalydeco*) is significantly greater than spending on medical devices and therefore an obvious target for scrutiny by cost-conscious payors and providers (*see Figure 1.*) On the other: what happens to pharma has a way of drifting over to medical devices. The kind of scrutiny that we're seeing around specialty drugs – and perhaps more importantly, the empowered stance of payors and providers armed with new weapons in their battle over the cost of medical technology, whether drug or device – is a kind of canary in the mine shaft for medtech, which can expect to see similar, if not as high-decibel debates about the cost of medical devices.

Figure 1

Specialty Therapeuti Driving Growth in Health Costs
Medical Infl ti at Equity Healthcare



Based on health spending at Equity Healthcare, a Blackstone company that works with private equity firms and their portfolio companies to manage healthcare costs – and is therefore a good proxy for a typical large employer.

Source: Equity Healthcare

Real Endpoints' CEO, Roger Longman, has followed the pharmaceutical industry for more than 30 years and is widely considered one of the most acute, insightful analysts of the industry. (Disclosure: Longman co-founded Windhover Information Inc. with me.) We spoke with Longman recently to see what insights he could share about the whole specialty drug-price debate and its possible implications for medical device companies.

The MedTech Strategist: ***We in the device industry are seeing a lot about high drug prices and angry reactions from payors and health systems. Just recently Memorial Sloan Kettering released a tool that it said was going to help bring rationality to an irrational system of pricing cancer drugs. And as it turned out Real Endpoints' technology powered that initiative. What's going on?***

Roger Longman: Essentially this: drug costs never used to be a big part of the healthcare bill. Now they are. And the pain is so intense for drug purchasers that they are finally beginning to turn to an industrial purchasing approach. Just as when Boeing or GE buys parts, the industrial buyer of pharmaceuticals will assess the relative merits of the competitors, choose a few – and negotiate the best deal it can. To do so, a number of things have had to change: the willingness of providers to restrict themselves to a smaller set of drug choices; the willingness of payors and health systems to endure the blowback from angry doctors and patients; and a credible system for actually comparing drugs on an apples-to-apples basis.

MTS: ***This is far from the first time that we've seen public debates about the high cost of drugs – pitting payors/providers against drug companies. Why is this time different?***

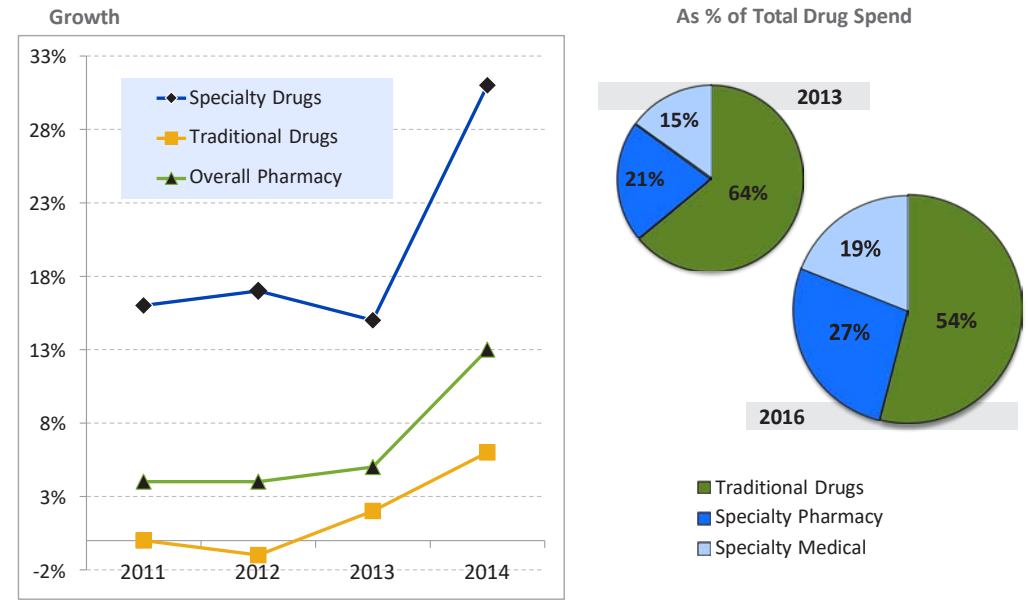
RL: For years, the purchasing decision-maker, the physician, has not been at risk for its cost, which has been the responsibility of the payor – the employer, the insurance company, government. Healthcare manufacturers have merely had to convince doctors that the new product has some advantage – an advantage that can be completely unrelated to its incremental cost.

But in the pharmaceutical world, three major things have happened to change this situation. First, drugs never used to be a big part of the total bill. Now they are – at many insurers more than 20% of the total expense (*see Figure 2*). Although in the past few months we've seen some cost-increases in other areas of medical care, the single biggest cause of cost increases are specialty drugs – the drugs for cancer, RA [rheumatoid arthritis], HCV [hepatitis C virus], HIV and dozens of other disease areas which are now the primary focus of the pharmaceutical industry's R&D.

Figure 2

Specialty Spend Rising Quickly

and will soon be almost 50% of total drug spend



SOURCE: Express Scripts Drug Trend Report; MarketScan Commercial Database; Express Scripts Analysis

Second, doctors, or their healthcare system employers, are increasingly taking risk for the quality and cost of care. If a drug costs more, it had better be clear that it delivers more healthcare value – in demonstrably improved outcomes or perhaps in lower total costs. One particular example: oncologists made an important fraction of their income from the buy-and-bill reimbursement process associated with infused cancer drugs: they'd buy an IV therapy, infuse it into the patient, and charge a mark-up for the drug plus an infusion fee calculated as 6% of the drug's price. That of course incentivized docs to buy higher-cost drugs: most people would rather get 6% of a big number than 6% of a small number. But more and more payors are adopting smarter rules around the practice (e.g., a set infusion fee regardless of the price of the drug) and more and more doctors are sharing risk for cost – that is, they can make more money by delivering good outcomes for less money.

And third, doctors realize that their patients are paying more and more of these bills. As co-insurance and co-pays increase, the financial burden grows on the consumer. We've all heard the stories of patients skipping drug doses to save money. Doctors are aware of this. And they're concerned.

MTS: **What was the effect of the hepatitis C drug *Sovaldi* on the discussion?**

RL: Huge. Industry-changing. The first thing to note was that no one expected that there was going to be a drug that would add $10.3 billion in costs in its first year on the market. What does that mean? In 2014 not a single plan in Massachusetts, for example, was profitable – thanks to *Sovaldi* [sofosbuvir, **Gilead Sciences Inc.**]. Suddenly, all plans were aware that a single new drug could play havoc with their finances.

I don't think the pharmaceutical industry has begun to understand the implications. First, plans are paying a lot more attention to drug pipelines. They're watching them. Preparing for them. So that they're ready with management strategies that will allow them to attack both volume and price, nearly as soon as the drugs are launched.

Those management strategies boil down to restrictiveness. First, they're limiting the use of these high-cost drugs – the volume half of the spending equation. *Sovaldi* was a huge innovation – a much more effective, faster, better tolerated cure for HCV [Hepatitis C Virus]. When it first came out, physicians wanted to use it with virtually anyone who had HCV. Why wouldn't they? But the bills skyrocketed – no one had foreseen the number of people who would be getting this drug. But plans did catch up and, today, most plans restrict the use of HCV drugs to more severely ill patients – not simply to people infected with HCV.

As for the pricing half – that comes through smarter purchasing. Plans have become much more restrictive in their formularies – that is they are limiting the number of competing drugs physicians and patients can choose. They're limiting that choice to the drug on which they get the best deal. As soon as *Harvoni* [the hepatitis C drug from Gilead containing both ledipasvir and sofosbuvir] had a competitor – Viekira Pak from **AbbVie** – Express Scripts, the large PBM, signed an exclusive deal with AbbVie in return for a major discount. In an almost immediate response, Gilead did the same thing with Express Scripts' biggest competitor, CVS. And suddenly *everyone* was signing exclusive deals with the result that the post-rebate prices of these drugs fell by close to 50%. In the pharmaceutical industry we have never seen – at least as far as I can remember – a new specialty drug class where the net price fell within the first year of marketing. And with this success, payors are now looking to do the same thing with new drugs in new categories – like the new lipid-lowering agents likely to be approved this summer, the PCSK9 inhibitors. If the drugs are pretty similar, payors will choose one – the one that delivers the most value, with economics being a big and explicit part of value's definition. The question then becomes: how do you evaluate the drugs fairly so you can make a rational choice among them? How do you as the payor, and the doctor, and the employer and the patient know that the choice you made for your formulary is based on an honest assessment of the full value of the drug, not just its price?

MTS: ***And is that where Real Endpoints and your RxScorecard technology come in?***

RL: Yes. We've got a web-based tool that provides a transparent, systematic, objective, quantitative, apples-to-apples comparison of the value of a drug or regimen relative to the other therapies for that indication. To do that, our clinical team scores each drug on, depending on the indication, between 15 and 40 different elements of efficacy, safety, ease-of-use, and economics so you can see exactly how the therapies compare – where they're better, where they're not. You see a drug whole – not just one or two aspects of it. And you see it as you should see it: relative to its competition. For our payor and health system customers, the idea is to give them a tool that helps them select the right drugs for their formularies – to maximize the value of what we and they increasingly think of as their pharmaceutical investment. And because we're scoring pipeline drugs as well, we're also helping them understand the likely impact of new drugs and drug categories. For our biopharma customers, we're showing them a payor's view of their drugs – often very different from what their R&D and commercial executives think is the value – and the specific levers they can pull to increase the value to payors.

MTS: ***For those who are unfamiliar with the Memorial Sloane Kettering initiative around cancer pricing, DrugAbacus, can you give us a brief summary of what it is and the conclusions it came to?***

RL: The head of MSKCC's health policy group, Peter Bach, is a good friend. He'd seen our RxScorecard technology and realized he could use the technology behind it to start a debate around pricing: how do you make it a rational process? I'd argue that it is a rational process already – drug companies charge what the market will bear. But he argues that it's very difficult to tie price to value – drugs that deliver a few months of additional life are priced not too differently than drugs

that provide a more dramatic outcome benefit. Peter's notion: could we score drugs based on their relative benefits in survival and toxicity – and show how the price adjusts based on different assumptions of what constitutes value. For example, if you think that an additional year of life is worth $300,000 and I think it's worth $100,000, the price would be higher under your assumption than under mine. Likewise, if I valued the novelty of a drug—perhaps because I thought we should incentivize innovation even if the drug doesn't work any better—a first-in-class drug would get a higher price than a follow-on. In short, Peter's not saying he's got the answer to what a drug's price should be—he's saying, through this tool, let's make explicit what value assumptions we're using—and price accordingly.

MTS: ***Does the controversy around drug prices apply only to new drugs or also to drugs already on the market? Have generics helped bring down the cost of therapy?***

RL: It absolutely applies to older drugs. For most plans, the drug most payors would like to manage is *Humira*, the antibody from AbbVie approved way back in 2002 and used to treat a number of auto-immune disorders. This year it will probably do $14 billion in sales. It dominates its markets. Its cost has been increasing by double-digits annually. And plans, for a variety of reasons, can't do a thing about it.

You ask about generics. Certainly they've helped – dramatically. Probably 80% of prescriptions filled in the US are filled with generics. But for the most part, we've gotten those savings as the biggest drugs – *Zocor*, *Lipitor*, *Plavix* – all lost patent protection. We will not see as many generics in the drug categories that are today most concerning to payors, the specialty drugs, like *Humira*, because most of them are biologics, which, unlike most small molecules, can't be genericized. Because these biologics are made in living production systems, from living cells, they're in fact complex mixtures that no one can really prove can be reproduced exactly. They're not pure chemicals like small molecules, which you can copy from a recipe.

What every payor is waiting for, however, are biosimilars – an FDA-approved similar-to-*Humira* with the same mechanism of action, route of administration, dosage form, and strength as *Humira*. The FDA says that these drugs work the same as the innovators' and while they aren't interchangeable – as are generics – they may be able to be substituted. If biosimilars come out at a 30% discount to the brand, if physicians have some economic incentive to lower cost, and if physicians can be convinced that the biosimilars will work as well for their patients currently stabilized on brands as the brands themselves – yes, that's a lot of ifs – we will see a dramatic change in the cost curve.

MTS: ***We hear a lot about how the US market subsidizes lower prices in other countries. Are similar debates and concerns going on overseas?***

RL: The US does subsidize other markets. Drug companies price their drugs higher here because they can't elsewhere. In less developed countries governments simply won't, or can't, pay for expensive drugs. So companies often charge significantly less in those countries (sometimes leading to odd medical tourism phenomena – like US patients flying to Egypt to get *Harvoni*). More developed economics, like Europe and Canada are by and large single-payor systems – and those payors can bargain directly with manufacturers. They say what they'll pay. In the US, CMS – our largest payor – isn't allowed to bargain on price. This isn't to say that the developed markets aren't concerned about drug pricing but they can actually do something about it. And for whatever reason, those governments are willing to take the heat from their citizens when they say "no" to a manufacturer. The cancer drug *Abraxane* [developed by **Celgene Corp.**], for example, isn't paid for in many European countries. And there hasn't been a revolution about it. My sense is that US citizens would be far more vocal in similar situations.

MTS: ***What's the argument drug companies put forth in defense of their pricing strategies?***

RL: That it costs them a ton of money to come up with new drugs – and it does. That they're taking enormous risks in developing new drugs – and they are – and should be rewarded for doing so. That they need to get enough from their existing drugs to pour money back into this risky and expensive research. And that because Europe and Canada won't pay them what they need to survive and continue to innovate, the US has to pay the price.

MTS: ***Is that just a political stance to justify a high price? It's hard to read some of the commentary in the Wall Street Journal article about DrugAbacus and a similar one in the New York Times and not come to the conclusion that drug companies are price gouging patients desperate for any possible cure for their disease. Fair or unfair?***

RL: No, I don't think it's fair. Certainly politics is part of the issue. So is the stock market. Without question the extraordinary valuations in the biotech industry are based on what I believe are inflated expectations on the prices payors will pay. But we're seeing some extraordinary medical advances in all sorts of areas that have been made possible, at least in part, by huge pharmaceutical investments enabled by high US pricing. New immuno-oncology drugs, like the PD-1s and PDL-1s, are showing pretty dramatic improvements in overall survival for deadly cancers like melanoma. The PCSK9 inhibitors are a major advance for people with very high and uncontrolled cholesterol – people who had almost nothing before. But the difference now is that buyers are going to be willing to play one PCSK9 inhibitor off against the other – and that will drive down prices.

MTS: ***Flipping that around, what about the criticism that payors and providers simply want to pay less today for therapies and thus tend to discount or deny their value. I know when I covered managed care two decades ago, that was a common complaint against the managed care industry: that they were less concerned about patient care and simply interested in not paying for treatment in an effort to protect their profits. Again, fair or unfair?***

RL: It's a fair question—but not an easy one to answer because plans have to follow certain formulary rules and are also caught between competing goals. For example, the Affordable Care Act, among other things, incentivizes plans to attract new members. The main shopping criterion is price—but the #2 criterion is availability on the formulary of the potential member's drug. So you want to have drugs on your formulary that people want—which is to say market leaders…but market leaders also have the greatest ability to resist price negotiations. And meanwhile – though no one likes to talk about it – plans are very concerned with adverse selection. They want healthy people – and healthy people are less likely to be on high-cost therapies.

But you can't just cleave off expensive therapies. ACA requires you to have a formulary with all necessary drugs. If a drug's the only one out there, you've pretty much got to make it available. Medicare is even more prescriptive: in general, plans have to offer two drugs of each class. And a plan's coverage policies for them can't be too restrictive – or Medicare will overrule them.

So I don't think plans can yet be accused – as they were in the 1980s, when HMOs were on the rise – of focusing on costs at the expense of medical necessity. What you can say, however, is that plans don't want to allow the kind of prescribing freedom that drives up costs without meaningfully improving care.

MTS: ***Do you think the radical reimbursement changes you see coming to pharmaceuticals will play out in medtech?***

RL: Yes and no. On the "no" side: there are few medical new technologies that can change a payor's economics the way *Sovaldi* did. And that means payors won't spend as much time and attention on restricting them.

But on the "yes" side: as providers take on risk, they'll be far more selective in the technology they adopt. The schizoid nature of hospital economics – stay within the DRG, reduce readmissions, but keep beds filled and procedure volumes high – cannot continue. Many health systems are either becoming insurance carriers directly, like Northshore LIJ Health System here in New York, in which case the balance in incentives is shifting towards reduced procedure volume and cost; or becoming insurance-company proxies as ACOs, where they're paid to improve quality at lower cost. As providers take on more of the risk for the cost of care, all costs become subject to greater scrutiny. Already many device companies are feeling the growing influence of what is commonly called the economic buyer. Devices are a relatively small part of our overall healthcare budget, but device companies can expect to see greater scrutiny of device costs, if only because devices are predominantly used in a hospital setting.