

The policies stemming from DC will be important in determining what pharma products and medical devices are accepted and successful and which do not meet the standard set by the policymakers. **Robert Schooling** reports

A close-up, slightly blurred photograph of a white computer keyboard, serving as the background for the page.

WORKING WITH WASHINGTON

The president of the United States fired the CEO of General Motors. Depending on your ideological leanings, you may cheer or groan at the news—but the facts are plain to see and the reality has been evolving for some time now: the federal government is going to be increasingly in the middle of business—especially businesses that are heavily regulated by the government.

Pharmaceutical and medical device companies are clearly affected by this new reality. While they are not asking for any bailouts, they are nonetheless dependent on policymakers, regulators and a small cadre of influential individuals (as a tribute to the last administration, let's call them “deciders”) to approve reimbursement, set clinical guidelines, determine risk-benefit tolerances, approve risk mitigation plans, set liability standards and design a health system that encourages appropriate utilization of their products or services. The decisions made in Washington, DC, will echo out across the private healthcare sector.

One familiar with the healthcare sector might ask, “So what’s new?” After all, these “deciders” have long held a prominent role in clinical approval and reimbursement. Is anything really that different?

Yes. It is different. We’ve reached a tipping point. For example, whatever guidelines are constructed in Washington about comparative effectiveness research will ultimately pit products and services against each other based on cost or value.

The selection and design of these comparative studies will often end up being more important to a product’s success than all of the marketing efforts behind the product. And under healthcare reform, government and other payers will be even more pressured to set limits on what they will and won’t reimburse. Decisions about reimbursement will become inherently more political and based on many factors beyond clinical effectiveness.

The questions for those in the private sector are: How are those decisions going to be made? Will there be meaningful public input? History would suggest that advocacy and communications play a critical role in the way policymakers ultimately evaluate particular products and therapeutic areas and whether there is supportive policy and regulation in place to further their development.

“We know that the policies emanating from Washington will be critically important in determining what products are accepted and successful and which are not”

For product communicators, this poses a new challenge – they will now have to work through the labyrinthine layers of bureaucracy and deal with murky and often hard-to-quantify success metrics, rather than devoting all of their time and energy to informing patients or physicians.

But product managers and marketing communicators cannot simply pass the buck to their government relations colleagues or ignore the new advocacy needs because it’s not part of their traditional marketing portfolio.

In fact, put simply, it is now incumbent on product communicators to take responsibility for building their communications plans around these deciders as much as around their more traditional target audiences.

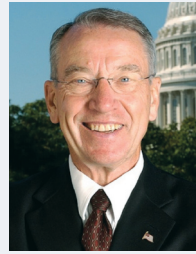
The reason is obvious: As we look to the next few years, we know that the policies emanating from Washington will be critically important in determining what products are accepted and successful and which are not, because they do not meet the standard set by the policymakers.

Product communicators must integrate public and regulatory affairs, marketing, communications and other disciplines to inform the system and to ensure that all considerations, beyond just the apparent cost of a product, are taken into account by payers, regulators and other deciders.

Here are some specific actions product communicators should consider taking:

Build communications around the value proposition for your product. In the long run (or increasingly the short run), payers will not pay for products when they don’t understand the value proposition. This isn’t simply a job for your payer group armed with clinical data and price charts – it’s your job to communicate

Healthcare reform, do or die



Sen. Charles Grassley

With the confirmation of former Kansas Gov. Kathleen Sebelius as secretary of Health and Human Services, President Obama now has his healthcare team in place—and it’s just in time.

Momentum to pass healthcare reform remains real. In addition, clarity regarding the key issues has also begun to emerge. The first issue on the table is whether Democrats and Republicans will compromise to pass reform or remain steadfast in their ideological positions. If a compromise is reached, reform may not be as broad as universal coverage, at least not in the short term. If they remain rigid in their ideological positions, one of two things will happen. Either reform will fail, or if Democrats include reconciliation in the budget resolution, they will use it to push through their own very partisan plan (the significance of reconciliation in this case is that any bill considered under its rules only requires 51 votes in the Senate instead of the usual 60). This could be a short-term success for President Obama, but it could risk being a long-term defeat, as it has the potential to end his efforts to change how Washington works, which could stall the rest of his agenda.

After the fight over whether reconciliation should be used to pass health reform, the next question is whether there should be a public option as part of the effort to provide coverage for the uninsured. Democrats are strongly supportive of such an effort. At her confirmation hearing, Sebelius said: “I think that at a time when approximately 30 percent of every healthcare dollar spent through a private insurance company ends up in administration, profiteering, advertising ... that so long as we remain dependent on private insurance companies, we’re never going to have quality, cost-effective healthcare for all Americans.”

Sen. Charles Grassley (R-IA), voicing an opinion held by nearly all Republicans, said: “There’s a lot of us that feel...that the government is an unfair competitor and that we’re going to get an awful lot of crowd-out.” The battle lines are drawn. While a compromise has not been discussed, the 2003 Medicare debate compromise could serve as a model. Fearing that some regions of the country would not have a choice of Part D drug plans, a government “fallback” option was included in the law, stipulating that if there were two or fewer plan options in a region, the government would offer a plan (this ultimately never materialized).

Each side will certainly have to compromise on another looming question in the healthcare debate: how to pay for covering the uninsured. Republicans (or least a small subset) will have to agree that some sort of tax increase will be necessary, and Democrats will have agree that it be broad-based (e.g., not a tax just on business or the wealthy) and it will probably be less than they want.

However, the biggest question on the table is how to reform the US healthcare delivery and reimbursement system. At the heart of the problem is the fact that the system is too expensive and costs keep rising. We can’t just cover the uninsured without doing something about the cost; we risk dooming universal coverage because we will be unable to afford it. According to Dr. Elliot Fisher of Dartmouth, “the payment system treats each physician and each physician’s service as a separate service that requires a separate bill. So the payment system does two things. It rewards unnecessary care... and it reinforces the fragmentation that causes so much difficulty for patients and physicians.” The good news is that there is a fair amount of bipartisan agreement that this issue must be addressed, and it may be what the two sides are able to build a consensus around.

William Pierce is a SVP at APCO Worldwide and served as spokesman for former HHS Secretary Tommy Thompson

The vital (but absent) role of physicians in health policy



Doctors have a critical role to play in health policy debates

The federal government is not only going to increasingly be in the middle of business—it's also increasingly in the middle of the practice of medicine. And while we are on the brink of a major transformation in the delivery

and financing of healthcare in the US, the voices of physicians are virtually absent from the public debate on health reform.

Physicians have a critical role to play in health policy debates: not only do they offer their experiences from being on the front lines of healthcare delivery, but the changes being contemplated in Washington, DC, will profoundly impact their ability to practice medicine and make a living. Yet most physicians are ill-equipped and ill-prepared to effectively engage in national policy debates.

Physicians have extensive training in operating within the constraints of hospital walls, but they have no formal training in influencing the decisions made in Washington—decisions that will profoundly affect the daily routine of how a hospital runs.

And like everyone else across the country, they are busy doing their jobs and living their lives, leaving little time to engage in the political process.

It's not for lack of interest that physicians stay away from policy debates. Most physicians are interested in health reform and understand that the decisions currently on the table could affect their daily practice of medicine, treatment options, reimbursement and even the innovation rate at which new therapies are evolving. They just don't know how to engage on these issues.

Professional medical societies are doing their best to keep up with the health reform debate, but they have limited resources and competing priorities to activate their physician members on broad health policy issues. Physicians need an easy and accessible way to make their voices heard in policy circles.

This provides an opportunity for product communicators who may find themselves working with physicians in a non-traditional manner: policy engagement. Product communicators should consider physicians an advocacy force if effectively mobilized on issues of common interest. Specific opportunities to engage physicians include:

- Building communication around the value of health. The overarching goal of most health-related legislation in Congress is to reduce spending while increasing quality and coverage.

While many factors drive healthcare spending, policy-makers have increasingly focused

their attention on spending associated with new medical technologies. Physicians are best equipped to speak to the value proposition of many products and technologies as they relate to everyday patient care.

- Supporting physician advocacy efforts as part of your communications platforms. Physicians and industry—if walking a fine line—can work together through many partnerships and alliances when advocating for better healthcare.

Helping to support physician policy education on relevant health reform topics could help to foster better relationships with healthcare professionals and their professional member organizations.

- Supporting physicians in their support of patients. Demonstrating that industry values the role of physicians in patient care can further help develop your relationships with patients and patient organizations.

Sustained outreach efforts designed to activate physicians on the host of issues about which they have knowledge and experience, such as cost and quality, could hold great potential for injecting a measure of reasonableness and practicality to the looming health reform debates.

It's time for all of us to ask our physicians to be part of healthcare reform; our country's health depends on it.

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with payers, policymakers and patients about how your product is solving their problems. Doing this in a disciplined way builds brand strength.

2 Make product communications a multi-directional conversation. The rise of social media is the harbinger of a different kind of dialogue—one that is multi-directional rather than uni-directional. In practice, this means activating others to help you get your message out. Partnerships with payers, enlisting patients and physicians as advocates and leveraging the microphone of policymakers are to your advantage.

3 Embed genuine patient advocacy in your communications. Active patient support for your product is critical. Too often, building patient advocacy is an after-thought or is neglected until there is a problem. This is very different than traditional marketing partnerships that are more focused on delivering a defined set of metrics.

These “transactional” relationships have value, but increasingly the non-transactional relationships with patient organizations and patients themselves will prove most productive.

4 Think about the intersection of policy and your product. What's the value of better compliance? Of greater quality of life? Are there disease categories where expedited review or higher reimbursement will fit into the agenda of controlling healthcare

costs? In a world of limited resources, these are the types of questions that will be increasingly addressed by policymakers. On the positive side, there may be real opportunities to grow market share by effectively engaging with the system.

For example, perhaps a portion of the money spent on product promotion aimed at individual patients could be better spent creating policy-level demand for appropriate incentives for early diagnosis, adherence, counseling, etc. In some cases, it is easier to change a system (even as difficult as that may be) than it is to change the individual behaviors of millions of patients through a communications program.

Conclusion

While there will be winners and losers, there may be a bright side as well. The “deciders” addressed through this kind of program can have a profound effect on the success of the product and can help create an environment of acceptance and support for a product that would be much more costly to create through traditional means.

In the words of President Obama: “Change has come to America.” The time to get out in front of that change is right now. ■

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