The NEW Washington Office

The legislative push for healthcare reform came with a speed and scope that surprised many in the pharmaceutical industry, drawing new attention to the Washington, D.C., offices of many drug companies. With this new attention comes the potential for new roles and responsibilities for Washington-based pharmaceutical company staff and an opportunity to have a significant impact. Staff members who prepare their company successfully for looming changes in the healthcare arena will create a competitive advantage.

To be truly effective, the "new" Washington office should be interdisciplinary, reflecting the diversity of issues under discussion that will impact the pharmaceutical industry, and, ultimately, the patients who benefit from their products.

A properly staffed and experienced Washington office steeped in the corporate history, culture, and interests can better leverage the specific expertise of outside lobbying, public affairs, public relations, and legal firms.

CONTRIBUTED BY: Dennis R. Cryer, M.D., FAHA, Chief Medical Officer, and Donna R. Cryer, J.D., CEO, of CryerHealth. CryerHealth, located in Washington, D.C., is a health advocacy and alliance development consultancy in the United States and abroad. For more information, contact Donna Cryer at dcryer@cryerhealth.com.

THE OLD OFFICE

In the past, the Washington offices of most pharmaceutical companies were led by former Capitol Hill staffers who hired mid- and junior-level colleagues, virtually all of whom had experience on the hill. Few, if any, had ever worked at corporate headquarters and fewer still were directly involved with the brands that were the engine for their company's success.

Focused on monitoring legislative developments and ensuring that the CEO was escorted to meetings with members of Congress, PhRMA, or other trade associations once a year, twice if there was trouble, the denizens of the Washington office lived well outside the notice of the vast majority of their colleagues in the commercial business or in the field. They were also well outside their potential for true corporate impact and rightful recognition.

In fact, some foreign-owned pharmaceutical companies did not even recognize the need for a presence in the nation's capital, figuring that the offices of their U.S. competitors would tackle any major issues facing the industry.

Change has been coming for some time. This past year's dramatic effort at reform simply brought new urgency to issues faced by legislators and policymakers. Earlier in the last decade, companies were alerted to the need for a stronger presence in Washington by the Medicare Modernization Act of 2003, which among its many provisions, created a drug benefit for Medicare beneficiaries. Companies scrambled to understand their new, largest customer and added CMS regulatory expertise to their managed markets teams. However, these individuals were usually located at headquarters rather than in Washington. Then, via the Food and Drug Administration Amendments Act of 2007, Congress greatly expanded the agency's powers and enacted significant new reporting requirements aimed at creating transparency in the pharmaceutical industry. Again, the individuals tasked with addressing these changes were headquarters based.

Now, President Obama envisions sweeping healthcare reform as a cornerstone of his accomplishments while in office. He underscored his commitment by creating a White House Office of Health Reform within months of taking office and sought smart, capable individuals to lead this office and HHS — leaders who can build coalitions in the halls of Congress, productively influence formal and informal policymakers, and drive change in Washington.

Far-reaching change to the healthcare landscape is clearly coming. How can pharmaceutical companies be effectively equipped to address the dialogue and debate that will precede policy and legislative action? More specifically, what skill sets are needed in their Washington offices?

THE NEW OFFICE

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ing the diversity of issues under discussion that will impact the pharmaceutical industry, and ultimately the patients who benefit from their products. The staff should include members who have cross-functional responsibilities, experience with state, regulatory, reimbursement, science/medical, and alliance development, as well as federal legislative operations.

The greater Washington, D.C., area is home not only to Congress, but an executive branch very active in health issues, including White House health and domestic policy staff; HHS, including FDA, NIH, and CMS; as well as a host of patient associations and medical societies. Each of these groups responds best to a somewhat different skill set, for example from the analytical approach to clinical trial data needed in successful FDA discussions to the economic and outcomes research insights needed for CMS evaluation. There is inherent value just in the proximity and ease of access for meetings, receptions, briefings, and emergent opportunities that foster the shift from one-off interactions to relationships. With ongoing relationships comes the ability to discern promptly shifting attitudes and new approaches to complex healthcare issues.

To maximize the effectiveness of the Washington office, closer relationships must also be forged between brand teams and District-based staff. Many brand managers could not tell you what the D.C. office does, and more importantly they do not have an appreciation for how an anticipatory policy framework and their D.C. office colleagues could benefit them. Long before a crisis emerges or a patent expiration looms imminent, Washington-based staff should proactively reach out to their colleagues at headquarters to fully understand the concerns and challenges of each brand and its lifecycle plan. Is reimbursement sufficient? Is the condition recognized as important by physician groups? Are there unforeseen hurdles or other barriers to patients and physicians accessing your drug?

The Washington office can also leverage the marketing team's research and knowledge from the field force, both sales and medical, about frontline issues faced in various therapeutic areas. This information can then be used to better inform members of Congress and their staffs who may be developing legislation, or regulatory agencies who are writing rules, to create ones that better enable safe and effective utilization of the product and appropriate access to it.

The New Washington Office

1. Staff with interdisciplinary/cross-functional team
2. Connect to needs of brand teams as well as larger corporate and industry issues
3. Fully integrate scientific/medical personnel to add credibility
4. Build alliances for corporate interests and initiatives that cut across brands
5. Be strategic in selection and use of lobbyists and consultants

In addition to the brand teams, the new Washington office has a lot to offer corporate communications. Staff often have on-the-ground insights into broad industry issues that can affect the company's reputation and competitive positioning. How quickly did the pharmaceutical industry shift from "We are healthcare" to "Medications are only 10% to 11% of the overall cost of healthcare" as the reform efforts began in earnest? A well-attuned D.C. office can help a company expeditiously shift focus and help corporate communicators react swiftly with appropriate messaging.

Because the new Washington office has a holistic view of the company, it can be an excellent lead for alliance development that benefits multiple brands and/or larger corporate interests such as health disparities or medication adherence. Participation in strategic coalitions also can position the company positively and create momentum on issues that a company could not affect as a solo player.

For example, D.C. staff participation in The Alliance for a Stronger FDA (the Alliance), an organization that has proven very successful in advocating for more non-user fee appropriations for the FDA, benefits marketing managers for existing and emerging brands, clinical trial teams, regulatory affairs staff, and companies.

According to Alliance President Wayne Pines, president of Regulatory Services at Apco Worldwide, "the strength of the Alliance is that it aligns companies with patient organizations and consumer groups."

A stronger and well-financed FDA is better able to evaluate drugs thoroughly and in a timely manner, flag and communicate issues earlier, and move appropriate drugs to approval more rapidly. This results in faster patient access to critically needed therapies and more profitable time on the market for companies.

Medical or external scientific affairs staff based in Washington may be the most ignored or underutilized asset in a pharmaceutical company's arsenal. Legislators and regulators love data. In the Congress, although there are many brilliant staffers, the vast majority do not have strong scientific backgrounds. Thus companies that have scientific or medical representatives on staff have a significant advantage in discussions. Transforming the interaction with agency and Congressional staff from a marketing or legal conversation to a scientific one can make a tremendous difference in the quality and outcome of the discussion and better inform the development of policy.

Additionally, coordinating regulatory affairs with Washington-based external medical affairs can provide a company with a richer understanding of the environment into which a product may emerge and new hurdles it might face during the evaluation process. Emerging priorities in health reform, anticipating concerns from advocacy organizations, and interests of agencies other than the FDA are examples that may influence clinical trial design or labeling negotiations.

Lastly, a properly staffed and experienced Washington office steeped in the corporate history, culture, and interests, can better leverage the specific expertise of outside lobbying, public affairs, public relations, and legal firms. This new office will ensure that relationships are developed inure to the pharmaceutical company and that billable time is focused for maximum impact on clearly defined goals that are in line with broader corporate strategy. New rules limiting lobbyist contact with policymakers make it more important than ever to have company personnel trained and able to carry the message directly.

Passage of health reform legislation will not be the last word. Pharmaceutical companies and other corporations with healthcare interests would do well to evaluate the capacity of their Washington outpost to anticipate and leverage current and future opportunities. ✦

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