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Prescription Pharmaceutical Companies with Embedded Consumer Health-care Businesses: Identifying and Managing Risks

Pharmaceutical companies are increasingly leveraging their consumer healthcare businesses to diversify their businesses beyond prescription-only drugs, including pursuing efforts to switch prescription-only drugs to over-the-counter (OTC). Compliance professionals should recognize that a consumer healthcare business has a very different business model than a pharmaceutical company and therefore faces, in many respects, different compliance risks. This can lead to a compliance culture at a consumer healthcare company that is not as robust as that at a pharmaceutical company. Given the more prominent role that consumer healthcare businesses are playing in the pharmaceutical industry, it is worth examining a few of the significant differences between the two types of businesses, and to highlight some of the key areas of risks that can arise in this context and the potential approaches to managing those risks.

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Notwithstanding similarities in certain regulatory obligations (such as those concerning manufacturing processes and safety reporting), because of the nature of their products and business practices, consumer healthcare businesses generally face a very different risk environment than their pharmaceutical kin. The FDA considers OTC drugs to be safe and effective for direct consumer use and therefore requires a broader margin of safety for OTC drugs than for prescription-only drugs. But because OTC drugs do not require prescriptions and consumer healthcare businesses have relatively limited interactions with healthcare professionals (HCPs), concerns about improperly influencing HCPs are not nearly as pronounced for consumer healthcare businesses as they are for pharmaceutical companies. For example, whereas pharmaceutical companies typically employ large sales forces to educate HCPs about their prescription-only products, any such "detailing" of HCPs by a consumer healthcare business is likely to be much more limited. In the consumer healthcare

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industry, a "sales force" usually does not refer to those who interact with HCPs but instead to representatives who sell inventories of OTC products to retail pharmacies for re-sale to consumers.

Moreover, certain laws that may be implicated by interactions with HCPs in the pharmaceutical context do not apply, or are unlikely to be applied, to consumer healthcare businesses. The Prescription Drug Marketing Act, which regulates the storing and distribution of prescription drug samples, does not apply to non-prescription products. The federal Anti-Kickback Statute and False Claims Act, two key laws the government has relied on to pursue pharmaceutical companies for violations regarding kickbacks to HCPs and off-label marketing, are triggered upon the federal government's reimbursement for a product under a federal healthcare program. Although the government may, in some circumstances, reimburse for OTC drugs, the volume of reimbursement is likely to be relatively low. Thus, from a practical standpoint, the risk of prosecution of consumer healthcare businesses under these laws is low.

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Indeed, unlike pharmaceutical companies, consumer healthcare businesses generally have not undergone intense government scrutiny of their marketing practices. In response to large fines and corporate integrity agreements with the government, pharmaceutical companies in recent years have reinforced to their employees the importance of compliance and implemented new controls, particularly regarding interactions with HCPs. Consumer healthcare businesses, however, have not felt the same pressure, which may result in a culture of compliance that is sometimes lacking. This is likely more true for the marketing and sales groups within a consumer unit than for the regulatory and manufacturing groups, where familiarity with laws and regulations, and being in compliance, are part of the job description. Marketing and sales employees may hold a mistaken perception that, because OTC drugs are considered safe for direct consumer use, their promotional and sales activities pose no greater compliance risk than the sale of any other consumer good.

In reality, however, for a consumer healthcare business embedded within a larger pharmaceutical company, even activities with minimal compliance risks for the consumer unit itself can still lead to serious cross-over risks for the larger pharmaceutical company. While marketing and sales employees may perceive their activities as relating solely to the OTC products they manage, the government is unlikely to take such a narrow view, instead attributing the conduct of the consumer healthcare business to the larger pharmaceutical company.

Compliance professionals should be especially cognizant of the risks created by a consumer healthcare business's interactions with HCPs. In certain instances, such interactions can create direct legal exposure for the pharmaceutical company. Key activities to consider include:

Prescription-to-OTC switch activities – Consumer healthcare businesses may increase their interactions with HCPs due to switch activities. The government could attribute communications about the switch candidate to the underlying approved prescription product. Such communications should be reviewed by the appropriate multi-functional committees to assess compliance risks to the pharmaceutical company.

Sampling to HCPs – Consumer healthcare businesses frequently distribute consumer product samples to HCPs. Those same HCPs likely prescribe products manufactured by the larger pharmaceutical company. Sending inordinately large amounts of samples, which could be considered items of value, could create at least a perception that the pharmaceutical company is attempting to improperly influence an HCP's decision to prescribe a product. In addition, certain state laws may restrict the distribution of items of value to HCPs or require the monitoring of promotional activity expenditures.

Joint marketing and promotional activities — Consumer and pharmaceutical colleagues may work together on campaigns to jointly promote consumer products and prescription-only products. Promotional materials that are created for such campaigns should be reviewed by the appropriate multi-functional committees to assess compliance risks to the pharmaceutical company.

Global marketing and promotional activities — Consumer healthcare businesses may have international affiliates that promote to HCPs outside the U.S. These activities can raise Foreign Corrupt Practices Act (FCPA) compliance risks, given that an HCP may be considered a government official depending on the country. In light of the increased scrutiny by the government in recent years of potential FCPA violations by pharmaceutical companies, it is especially important to properly manage these risks.

Even when consumer healthcare business activities do not present a legal risk per se, they may still damage the reputation of the pharmaceutical company. For example, a lavish industry golf event attended by consumer unit executives and retail executives might not violate any law, but it could attract negative attention to the pharmaceutical company as a whole.

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So how should compliance professionals go about managing the cross-over legal and reputational risks arising from a consumer healthcare business? One option is to adopt, wholesale, the controls that are imposed on the pharmaceutical unit. Theoretically, for instance, a consumer unit could implement in full the PhRMA Code, which reflects the pharmaceutical industry's standards for interactions with HCPs. The benefit in adopting a bright-line standard is that it avoids any confusion about what activities

are or are not permitted. The downside is that applying pharmaceutical standards across the board may not sufficiently take account of the consumer-specific business model, and may unnecessarily impede everyday business activities vital to a consumer healthcare business's success.

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A better option is to take a more nuanced approach that depends on the specific activity and attendant risk level. A consumer unit could implement controls based heavily on the PhRMA Code but create certain exceptions based on consumer-specific business practices. For example, while in the pharmaceutical context charitable contributions present the risk that contributions are viewed as kickbacks to HCPs, such a risk might be minimal or non-existent in the consumer context if contributions go exclusively to organizations affiliated with retailers rather than HCPs. In this scenario, then, pharmaceutical-based controls may be ill-fitting. For other activities, however, such as sampling to HCPs, implementing pharmaceutical-based controls wholesale (or close to wholesale) may be more sensible given that the activity necessarily involves interactions with HCPs.

In order to properly manage risks, compliance professionals should have a firm understanding of the business model and risks facing both the consumer healthcare business and pharmaceutical business. Regular communication between relevant members of the two business units is also essential, especially as pharmaceutical companies start expanding into prescription-to-OTC switch efforts that necessarily require close coordination between the two.

In sum, a consumer healthcare business's activities should not be viewed in a silo, given that what happens at a consumer unit can ultimately affect the larger pharmaceutical company.