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MANAGING PRODUCT LIABILITY IN THE PHARMA & HEALTHCARE SECTOR

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EXPERT FORUM

MANAGING PRODUCT LIABILITY IN THE PHARMA & HEALTHCARE SECTOR



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CD: What are some of the key trends in product liability that have affected the pharmaceutical and healthcare sector over the last 12-18 months?

Bell: Recent activity in the industry seems to be focused in two key areas. On the one hand, there is continued interest in concerns that therapies are being marketed or promoted for use beyond approved indications, whether the therapy is a pharmaceutical agent or medical device. On the other hand, there is also interest in whether the labels are accurate and defensible. Both of these product liability issues address the appropriate use and promotion of products, and both have stimulated class action litigation.

Wilkinson: Two interesting trends have emerged recently. First, courts are increasingly limiting the jurisdictions in which manufacturers can be sued following the US Supreme Court decision in *Daimler AG v. Bauman*. Second, the regulation of pharmaceutical and healthcare companies' use of social media is rapidly evolving. As to the first, Oklahoma and Illinois state courts, faced with personal jurisdiction challenges from defendants, recently held that they did not have jurisdiction over corporations based solely on the fact that they were alleged to have extensive pharmaceutical or medical device sales in the subject state. *Daimler*

articulates a standard that when a claim does not arise from a defendant's contacts with the forum state, jurisdiction may be asserted only in forums where it is incorporated, maintains its principle place of business, or is otherwise 'at home'. These recent decisions appear to restrict plaintiffs to properly bringing suit in forums in the corporation's home state or in the state where the plaintiff ingested the medication at issue. This developing body of law provides another means by which companies within the sector may have more control over where they face substantial litigation. As to the second, FDA recently released draft guidance concerning the use of social media as it relates to the marketing and promotion of life sciences products. Given the seemingly never-ending increase of society's use of the internet and social media, this is a key marketplace issue for companies in the sector.

Zayid: Three major trends are worth noting. Firstly, there have been more recalls related to manufacturing issues rather than the inherent properties of the products. Secondly, we continue to see more class action litigation in relation to medical devices. And thirdly, there is currently a greater focus on litigation questioning the risk and benefit profile for drugs prescribed for lifestyle and chronic conditions. In all these areas, the changing level of consumer access to information impacts how these issues play out in real time.

Parini: Things are always evolving, especially in different jurisdictions around the world. That said, there are a couple of trends that come to mind. The first is a relatively new theory of liability fabricated by plaintiffs' attorneys known as 'innovator liability'. After recent Supreme Court cases effectively shut down personal injury cases against generic drug manufacturers, plaintiffs have now sought to hold brand-name drug makers liable for injuries allegedly caused by the ingestion of generic versions of their products. Most courts have rejected the notion of holding a company liable for a product they did not make or sell. Still, some courts have not, and more decisions in this direction could threaten innovation more generally. Another trend is the filing of antitrust lawsuits following patent settlements in the US and other common law jurisdictions. Many of these suits are baseless, involving the enforcement of government-issued property rights.

CD: Have there been any recent legal or regulatory developments in this area? If so, what are the implications for companies?

Wilkinson: As to personal jurisdiction, the court in *In re Plavix Related Cases* relied on *Daimler* and found that Bristol-Myers Squibb and Sanofi – headquartered in New York and New Jersey, respectively – were not subject to personal jurisdiction in Illinois. The court rejected the plaintiffs'

argument that substantial sales revenue in Illinois subjected these corporations to general jurisdiction. Moreover, the Court found that because many of the plaintiffs had ingested the subject medication in states other than Illinois, their claims did not 'arise out of' the defendants' contacts with Illinois as is required to establish specific jurisdiction. The court thereafter dismissed the claims of all non-Illinois plaintiffs – which amounted to 97 percent of those who had filed suits – 486 of the 502 plaintiffs were dismissed. Conversely, a California appellate court recently reached a different conclusion, finding that it had specific jurisdiction over Bristol-Myers Squibb to hear claims by non-California residents. However, the California Supreme Court has granted a petition to review that opinion so the outcome is not yet final. If other states follow the lead of Illinois, and a similar decision in Oklahoma, plaintiffs' forum choices may be distinctly curtailed.

Parini: On innovator liability, I think the FDA's proposed rule to permit generic companies to change their labels would shift the way courts view this issue. Having generic companies more responsible for the safety of their products makes sense on several levels, not least of which is patient safety. On patent-related antitrust actions, the issue is getting more focus in the EU and in Australia and Canada.

Zayid: Increasing globalisation has led to greater cross-border regulatory cooperation. This means that what used to be an isolated issue in one market has a ripple effect. The involvement of one regulator triggers consequences all around the world. In addition, as regulators grapple with an increasingly complex supply chain, we are seeing stricter regulation of raw materials and other inputs that go into the product. In addition, traceability protocols for materials and final products have become commonplace globally, requiring companies to keep track of every element used in the manufacturing process as well as the end product itself.

Bell: There have been several recent developments. For product liability claims, the full extent of the implications of the Caronia case in the US – in which free speech affected off-label promotion allegations – continues to be unclear, with follow-up cases poised to provide more insight in this area. For labelling claims, developments in the medical device and food product industries continue to provide examples of claims that warrant attention. As courts apply increasing scrutiny to the rigorous evaluation of class certification requirements – particularly including the ability to calculate damages on a class-wide basis, companies facing class action product liability claims are in a better position to

force an earlier, more comprehensive review of issues that may limit the size of the potential classes or eliminate them altogether.

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McCarthy Tétrault LLP*

CD: How important is it for pharmaceutical and healthcare companies to plan in advance for the possibility of a product recall? What aspects should such a plan entail?

Parini: Product recall is obviously something we take very seriously as patient safety and product integrity are critical to our mission as a global healthcare company. It is extremely important that we are not just prepared for a possible recall situation, but proactive about monitoring and managing the quality of our product supply.

Zayid: It is very important for pharmaceutical and healthcare companies to plan in advance for the possibility of a product recall. Preparation for a product recall should begin long before a recall actually becomes necessary. Every company should have a product recall plan in place for the day when they find that a product recall has to happen. This will allow a fast and efficient response. Regulatory authorities in affected jurisdictions must be notified. Any product recall must be planned in conjunction with the regulator who is likely to impose requirements with respect to the extent and communication of the recall. Regulators have broad powers in this area and it is essential to ensure all legal requirements have been met. When a product recall becomes necessary, the company needs to clearly identify the product involved and the scope of the required recall. Does it involve all of a given product or only products manufactured, shipped or stored in certain locations? Can the affected product be identified by lot number or date? The company also needs to identify where the product is located and how much: in a warehouse, at retailers, in customers' hands, or elsewhere?

Wilkinson: It is critical for pharmaceutical and healthcare companies to have a thoughtful, meaningful, effective and workable plan to handle

a product recall. Effective planning is extremely important so as to minimise harm to consumers, stem any loss of consumer and patient confidence, and manage any potential exposure to regulatory issues. An effective recall plan should clearly identify the specific people who will implement the

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recall and their respective roles and authority, and it should obviously be structured so as to comply with FDA regulations as well as the regulations of other countries where the product is marketed. Companies should also consider the need to identify and engage outside experts as necessary for the particular situation. Key elements of a recall plan should detail coordination with FDA and any other regulatory agency, specify how to communicate recall notifications, and set forth the procedures to maintain meticulous records about recall notifications and product tracking. The framework

should be flexible and scalable in order to respond to a specific event – some recalls can impact numerous units while others impact a relatively small number. Finally, it is particularly important to conduct ‘recall drills’ to test the effectiveness of the plan prior to being faced with the need to implement it.

CD: If a product recall is deemed necessary, how should companies go about managing the crisis to avoid some of the common pitfalls?

Zayid: First, make sure your regulator is on-board and comfortable with your plan. Making clear that the company is fully cooperative with the regulator is essential. Early and clear communication to customers, retailers, distributors and suppliers is critical. Communication with suppliers, distributors and retailers can ensure a speedy and effective isolation and return of the product. Where the product is also in the hands of patients and customers, it is important to reach out with accurate and positive communication to customers and the public about the product recall. The communication should convey the company’s commitment to product safety and that all reasonable steps are being taken to address the problem and protect customers. Social media has proven to be an excellent tool in this regard. Paradoxically, taking immediate and effective steps to carry out a recall and communicate with the public can actually be a

good demonstration of a company’s commitment to product quality and safety. On the other hand, a company that appears to resist acknowledging a problem or fails to deal with it effectively can suffer a negative impact on its brand, long after the specifics of the recall are forgotten. Lost sales will result while the product is removed from the market and the recall process itself can be expensive. There may be a significant business interruption. These costs can be mitigated by planning your recall process in advance and ensuring that suppliers are in a position to work with you to make required changes quickly. Companies can also put in place systems to document costs associated with a recall which may facilitate recovering the costs from a supplier or insurer later. Of course, product recalls may give rise to significant legal exposure. All actions and communications should be considered in light of the company’s legal strategy.

Bell: Firstly, the company needs to get in front of any issues surrounding the recall and make sure that its message is effectively communicated to key stakeholders. Secondly, the company needs to be prepared to respond to queries from all stakeholders in a timely and efficient manner; a failure to do so is likely to mean that the company’s message will become distorted in the marketplace. Finally, the company should develop a recall strategy that can be effectively deployed through trade relations, and reach beyond the first sale of the product into

the distribution channel. Best practice implies the development of a crisis response strategy that is updated on a regular basis and is ready to be deployed in a timely fashion.

Wilkinson: Open and prompt communication is essential. Any perception – even if incorrect – of silence or slow communication can be criticised and construed as the company being indifferent to safety concerns. Companies should develop a crisis communications plan that will facilitate a quick, clear and accurate response to a recall. It should identify the appropriate actions and point persons, and could also include designing a recall website to be launched quickly if needed. A crisis communications plan should likewise include a protocol to alert your employees – particularly those in the field – with clear instructions on how to respond and handle the situation; and should also focus on staying in contact with consumers through emails or other communications that extend beyond any notice required by regulators.

CD: What additional challenges apply if a product recall is necessary across borders, in multiple jurisdictions?

Bell: Multiple jurisdictions will add to the complexity of effectively implementing a recall strategy. Staying on message across a broader group of stakeholders and adapting the message

as appropriate for different jurisdictions is likely to be a particularly significant challenge. As such, the internal challenge of managing the recall and the response may be as daunting as the external challenges. Accordingly, best practice implies that all relevant parts of the company be aware of the crisis response strategy and be prepared to implement it effectively. From a class identification and damages perspective, the largest additional challenge from multinational operations tends to be the potential proliferation of secondary distribution channels. Products and therapies that are repurchased for later resale, potentially in different jurisdictions or countries, generate sources of potential leakage in a recall plan. These distribution practices could expand class definition and the associated sales could inflate damages, if it cannot be shown that the sales were appropriately recalled.

Wilkinson: Recalls are becoming increasingly international in scope. It has been reported that in the second quarter of 2014, more than 25 percent of pharmaceutical recalls affected the US and at least one other country. The number is even greater for medical device recalls – 57 percent in the third quarter of 2014. Many of these recalls occurred in regions that are remote or impacted by political unrest, where manufacturers often lack a presence in the field. This makes a company's ability to marshal resources and manage a recall even more challenging. Companies who

regularly operate across borders should consider prophylactically identifying qualified foreign counsel and other in-country advisers who the company could immediately engage in order to handle a recall or comply with country-specific regulatory requirements in an emergent situation.

Zayid: Monitoring and meeting standards across multiple jurisdictions provides a particularly big challenge. Apart from maintaining knowledge of applicable regulations and administrative bodies for each jurisdiction, it is essential that companies remain nimble enough to immediately react in each affected jurisdiction, and that counsel in each jurisdiction are able to coordinate and share information and strategies seamlessly. Full coordination is the name of the game. Where similar regulatory actions are being instituted across jurisdictions, plaintiffs' counsel often cooperate and share information and work product. The defence must be aware of this and stay a step ahead. Aside from the legal aspect, companies will

have to learn to react quickly to manage reputational issues which may arise. With the rise of social media and networks, news of isolated issues in one jurisdiction can often spread quickly, affecting the company's image across multiple jurisdictions.

CD: Are potential class actions arising from product liability a major risk for pharmaceutical and healthcare companies? What steps can companies take to mitigate this risk?

Wilkinson: While any report of adverse events, unfavourable media articles or regulatory measures taken against a pharmaceutical or healthcare company could potentially give rise to the filing of a putative class action, it has become increasingly difficult for plaintiffs to certify class actions in the US where the claims include relief for personal-injury related damages. This is due to the inherently individualised issues that dominate the resolution of any such claim. It has instead become more common for pharmaceutical and healthcare companies to face such claims on an aggregated basis in the form of federal multi-district litigation or other similar aggregation procedures under individual state laws. While it can be challenging to manage and mitigate this risk, particularly given the zeal with which the plaintiffs' bar pursue such claims on an aggregated basis, there are steps companies can take in this regard. Obviously, accurate reporting to FDA and compliance with regulations will minimise such risk. Prompt and thorough investigation of reported adverse events is also essential. Companies can also consider steps to proactively identify products that may give rise to class actions by monitoring internet and social media postings.

Parini: Like other industries, healthcare companies face potential class actions in numerous jurisdictions around the world, including the US, Canada and Australia. The EU is currently expanding

class action law in some areas. One of the risks with class actions – and one I hope the EU figures out how to solve for before implementing its laws – is that oftentimes these cases are not about the alleged victims, but rather the plaintiffs' attorneys bringing the cases. It would be unfortunate if jurisdictions outside the US imported these perverted incentives to their countries.

Zayid: Class actions arising from product liability for pharmaceutical and healthcare companies have been, and remain, a very real risk. Unlike in the US, in Canada courts will frequently certify a class action involving personal injuries. Whenever a significant recall of a product occurs, the company should be prepared for a class action. This is particularly the case if any adverse regulatory finding occurs. There are several steps which companies can take in order to mitigate this risk. These include: maintaining a detailed knowledge of their supply chain; keeping up to date consumer safety regulations in each jurisdiction in which their product is available; maintaining a tried and tested recall action plan, and crisis management plan, which can be implemented immediately; and investing in product liability insurance. Companies need to be aware that they may also face shareholder class actions or class actions brought on behalf of insurance payers and purchasers following adverse events with the product. As a result, the stakes can be very, very high.

Bell: Class actions arising from product liability could be a major risk for life sciences companies. From our perspective, companies that are actively engaged early in the process are likely to be the most effective at addressing or potentially eliminating class action exposures. In the US, at least, it is often the case that class actions piggy-back on efforts by state or federal regulatory agencies. This means that companies are already involved, collecting and reviewing information for those enquiries. Thus, the material tends to be at hand for a significant and comprehensive response to early class action efforts. In economic terms, the companies have already borne much of the cost in addressing regulatory enquiries, while class action counsel often has neither invested in discovery nor prepared legal filings based on anything other than general, publicly-available information. Using the information gathered from the regulatory inquiries provides companies with an opportunity to focus subsequent class action litigation early in the process, potentially narrowing, if not eliminating, the scope and duration of class action claims to the appropriate level.

CD: How can product liability insurance help? What should a company consider when choosing the right policy to meet its needs?

Zayid: Insurance can be used to reduce or transfer the financial risks associated with a product recall. As with any insurance coverage, in determining what a company needs it is essential to look at the scope of coverage, any exclusions and the required premiums. Specific product recall

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Pfizer Inc*

insurance is available. Losses that may be covered under such policies include costs of the recall itself, loss of profits, costs to re-establish the product in the market, crisis response expenses, and expenses which a company may have to reimburse to customers. In some cases, a company’s commercial general liability or property insurance may respond to reduce the financial exposure arising from a recall. Companies need to look at the extent and terms of coverage they have for third party claims, property damage, contaminated products or business interruption. Depending on the details and

any exclusions, such policies may provide coverage. Another option is to consider requiring suppliers to put in place insurance coverage and have the company as an insured under the supplier's policy. Depending on the nature of the supplier and the relationship, this may be a practical alternative.

Parini: The use of insurance to protect against certain risks is a case-by-case assessment, with many companies electing to self-insure given the high cost of premiums for certain policies. It really depends on the needs and risk appetite of the company.

Wilkinson: Product liability insurance can be an effective tool for companies to manage risk. Product liability insurance generally covers losses from allegations of harm concerning a company's goods or operations. Companies should endeavour to obtain best-in-class CGL coverage that includes coverage for personal injury related claims. If applicable, companies should also ensure that their policy includes worldwide coverage as some policies sold to US companies will cover only products sold domestically unless worldwide coverage is specified. Companies should also take care to confirm that the liability limits of their policies are appropriate, and to also confirm that associated fees and costs will not be applied to any limits. Additionally, insureds should retain

the right to select the counsel who will represent them in any action covered by the policy. Recall insurance is typically separate from CGL coverage and insures against the economic losses associated with the costs of a recall, including costs associated with media issues. So, a separate recall policy is

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needed if insureds wish to have such coverage. If recall coverage is purchased, it is important to know the coverage-triggering events and to determine whether approval from the insurer is needed before issuing a recall.

CD: What final advice can you offer to pharmaceutical and healthcare companies on managing product liability?

Parini: I would separate product *liability* from product liability litigation. They are very different

in my view. As to the former, the best advice I ever received as an in-house attorney was to continuously evaluate every decision we make by the guiding question, “What would a caring company do?” For me, that answers most every decision involving product safety and quality. As for product liability litigation, you need to have the stomach to stand up and fight. Don’t be overly afraid of potential negative media or attention – most of the time most of the people understand if you give them both sides of the story. Sometimes I think we are too quick to settle cases because we don’t give juries and the public enough credit that they will get it right.

Wilkinson: The age-old adage that “an ounce of prevention is worth a pound of cure” remains as true today as it did more than 250 years ago, when Benjamin Franklin first uttered those words.

Zayid: The most essential factor in product liability management is preparedness. Up-to-date knowledge of consumer safety and protection laws, good relationships with the regulator in each of the

jurisdictions in which a product is sold or made, along with a plan to react quickly when concerns surface, go a long way to manage any product liability issues which may arise. In addition, while many companies may have legal and operational teams in place for quick reaction, it is also essential for a company to be prepared to maintain, and in some cases defend, its brand and reputation for patient safety. While legal issues are not as easily isolated by jurisdiction as they once were, reputational issues are even quicker to transcend borders.

Bell: Communication and responsiveness can be key factors in managing product liability concerns. Clear articulation of a management strategy provides an opportunity to offer assurances to stakeholders that product liability concerns will be addressed directly and effectively. Responsiveness to enquiries regarding the management activities provides further confidence, while also providing an opportunity to demonstrate focus on commercial issues. 