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DRUG AND MEDICAL DEVICE LITIGATION

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MINI-ROUNDTABLE

DRUG AND MEDICAL DEVICE LITIGATION

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Jennifer Hill focuses her practice on the defence of pharmaceutical and medical device manufacturers engaged in product liability litigation. She plays an instrumental role in analysing complex legal issues at various stages of litigation – from initial claim evaluation through dispositive motion practice. She also advises clients on issues governed by the Food and Drug Administration, including product labelling, recalls, regulatory compliance and risk evaluation and management.

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Chris Gramling represents clients in primarily pharmaceutical, medical device and other complex litigation matters in federal and state courts. His extensive experience extends from pre-lawsuit resolution efforts through the appellate process in large-scale product liability and commercial litigation. He is known for providing thoughtful, creative and steady counsel to help clients with effective risk mitigation and crisis management strategies.

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Stephanie McGraw represents clients in product liability, cannabis and business litigation in state and federal courts. She is an experienced litigator with first chair trial experience. She also has considerable alternative dispute resolution experience, including mediation and arbitration. The depth and breadth of her experience enables her to develop and implement efficient and effective litigation plans that advance client interests.

CD: Could you provide an overview of the key trends impacting drug and medical device manufacturers and sellers? How routinely do these companies find themselves a target for litigation?

Gramling: Pharmaceutical and medical device companies are regularly targets for litigation and enforcement actions. In addition to constant product liability litigation, such companies often face antitrust, shareholder and class action litigation. Congress, plaintiffs' lawyers and state attorneys general have also closely scrutinised pricing practices, most notably in the pharmaceutical industry. Other key trends include concerted efforts to expand and distort the public nuisance doctrine, ongoing generation of multi-district litigations (MDLs) and mass torts by plaintiffs' lawyers, including in the non-prescription consumer goods space, and the filing of no injury class action litigation. In the MDL and mass tort settings, there is an increased recognition of the need for early assessment of cases as years of experience has revealed that very high percentages of cases filed in such litigations suffer from significant defects, such as no evidence of product use or exposure, as well as no injury.

Hill: As with many industries, there has been an increasing focus on environmental, social and governance (ESG) policies and initiatives. From curbing carbon emissions to improving access to medical treatments, drug and medical device companies are finding new ways to meet the evolving expectations of the public. Because drug and device companies are often targets of high-profile litigation, ESG initiatives carry added significance, but can also draw scrutiny. In an industry where public perception is critical and can have a meaningful impact on a company's litigation risk and exposure, ESG messaging and policies will likely be an important consideration in both the boardroom and in future litigation.

McGraw: Product manufacturers are always at risk of litigation, and that is especially true for drug and device manufacturers. The coronavirus (COVID-19) pandemic-related pause on non-essential medical procedures may have created a slight dip in 'one-off' product liability litigation for the sector, but that is temporary, and larger litigations are busier than ever. Medical device and drug litigation is an attractive option for plaintiffs' counsel because they can amass an inventory of cases to pressure settlements in mass actions. The increase in popularity of third-party funding will continue to drive larger drug and device litigations.

CD: To what extent has there been an uptick in litigation in this sector in the wake of the coronavirus (COVID-19)

pandemic? What legal and commercial risks has the pandemic sparked?

Walther: The medical device industry has been hit particularly hard by the pandemic. In an effort to ensure that hospitals have the bandwidth to handle higher patient loads during COVID-19 surges, many states across the country have repeatedly limited or banned elective surgeries. The devices used during those surgeries generally account for a significant portion of the medical device industry's annual sales. Unfortunately, the industry has not experienced a commensurate drop in litigation. The pharmaceutical and medical device industries have experienced an upward trend in case filings over the past decade, and all indications suggest that those filings will continue to rise over the next several years.

McGraw: We have seen a lot more plaintiffs pointing to 'bad drug' or 'bad device' advertisements as the driving force for filing a lawsuit during the pandemic. Pandemic-related downtime at home in front of the television may have increased the audience viewing these commercials, but this is based on anecdotal evidence. Although we have seen a lower rate of 'one-off' product cases involving device claims, potentially because of the suspension of non-emergency procedures during the height of the pandemic, mass tort filings seem to be up.

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>
> *Stephanie McGraw, Shook, Hardy & Bacon LLP*

Hill: The COVID-19 pandemic has created an unprecedented backlog of cases, particularly in mass torts. In many jurisdictions, civil jury trials were halted for much of 2020 and into 2021, as the public health crisis made assembling jury panels and witnesses impractical. Courts and litigants have had to make adjustments – by conducting hearings and depositions by videoconference, utilising bench trials and compressing the length of jury trials. As courts begin to resume normal operations, there is a growing pressure to move cases toward resolution as quickly as possible. Companies facing litigation may need to be adaptable to creative approaches to resolving cases.

Gramling: To date, we have not seen a significant uptick in product liability litigation related to COVID-19 in this sector, likely due in large part to the deterrent effect of the Public Readiness and Emergency Preparedness Act and additional legislation passed at the state level. To the extent drug and medical device companies have entered into government contracts aimed at combating the virus, they can expect close scrutiny by Congress, the Department of Justice (DOJ) and others of how the money from the government has been spent. Such scrutiny could be in the form of congressional inquiries, DOJ investigations, False Claims Act and other litigation. Due to supply chain issues triggered by the pandemic, such companies may also find themselves involved in an increased number of contract disputes.

CD: Have any recent litigation cases involving drugs or medical devices caught your attention? What insights might be drawn from their outcome?

McGraw: The case law parsing out general and specific jurisdiction in the last five years is very exciting for the pharmaceutical and medical device industry. Although *Ford Motor Co. v. Montana* narrowed the promise of *Bristol-Meyers* by holding that products need not be designed, manufactured or sold within the forum state in order for a state court to exercise jurisdiction, cases like *Brandon v. Wright Medical Technologies* are already distinguishing specific facts from *Ford*. For example, in *Brandon*, the plaintiff underwent hip replacement in California and resided in California for five years after the surgery. After moving to Nevada, she returned to California for additional medical care related to her hip, including an explant surgery. She then brought suit in Nevada. The District Court of Nevada distinguished these facts from *Ford*, holding that *Ford*'s plaintiffs had a stronger connection to their forum states than *Brandon*. Unlike *Brandon*, *Ford*'s plaintiffs used the product in the forum state and suffered injuries in the forum state. *Brandon* will provide an important roadmap for product

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> *Jennifer Hill, Shook, Hardy & Bacon LLP*

defendants to make sense of *Ford* and *Bristol-Meyers*.

Hill: Plaintiffs' lawyers have sometimes used non-conventional theories to prosecute mass torts where individualised proof of traditional product liability elements is difficult or impossible. One recent example is public nuisance claims against opioid manufacturers. Rather than arguing that individual plaintiffs were injured by a defective product manufactured or sold by a specific defendant, plaintiffs' lawyers have instead pursued the theory that opioid manufacturers and sellers created a public nuisance by interfering with a common right to public health or safety. What constitutes a public nuisance, however, is not well defined, and opponents have argued that these claims could lead to unintended expansions of tort law. Recent decisions from the Oklahoma Supreme Court and a California trial court rejecting the public nuisance theory in opioid cases cast doubt on the theory's future viability in drug injury litigation.

Gramling: Recent rulings in the Zofran MDL, Incretin MDL, Zantac MDL and Viagra/Cialis MDL have demonstrated the continuing importance and availability in product liability litigation of both preemption and the exclusion of expert witnesses under Rule 702. In several of those matters, the presiding judge agreed to bifurcate the litigation to focus only on general causation and preemption. The recent rulings from the Oklahoma Supreme Court and a trial court in California holding that the defendant companies did not create a public nuisance could have significant impact on that and other ongoing litigations, as well as on efforts to expand the doctrine well beyond its original scope and application. The Taxotere litigation also is worthy of attention as it represents a departure from past unwillingness to pursue product liability claims involving oncology products. Recent defence trial wins in both prescription products and non-prescription consumer products cases could mark turning points in those litigations and demonstrate the resolve needed in the face of massive litigation and early trial losses. Finally, the ongoing litigation related to the 340B drug pricing programme could have significant implications for pharmaceutical companies by defining the scope of required discounts.

Walther: The Pennsylvania Supreme Court recently accepted a certified question from the Third Circuit concerning how the state applies comment k to medical device lawsuits. Pennsylvania, like many states, applies comment k as a categorical bar to strict-liability claims against pharmaceutical manufacturers. But over the last five to 10 years, some state and federal courts, applying Pennsylvania law, have declined to extend comment k's blanket approach to medical device cases, holding instead that comment k protection only applies on a case-

by-case basis in the medical device context. This distinction between drug and device cases creates an unnecessary uncertainty that is not supported by the text or policy of section 402A of the Restatement (Second) of Torts. It will be interesting to watch how the Pennsylvania Supreme Court resolves the question and if any other states follow suit.

CD: In the event of litigation, what preparatory steps do drug and medical device companies need to take? Are there any preemptive actions they should consider?

Walther: Due diligence is key. Before the pandemic, an increasing number of companies had started looking outside for innovation. COVID-19 only exacerbated that trend. Now more than ever, companies are shrinking their research and development budgets, and as a result, pharmaceutical and medical device companies have focused their growth efforts on acquiring new technologies from outside firms. While the industry still sees some blockbuster mergers, the majority are smaller-scale acquisitions that focus on adding specific products to the companies' already-existing lineups. These narrower acquisitions frequently carry a higher risk of leading to products-liability litigation in the future. When conducting an acquisition, companies need to carefully consider the litigation risks associated with the new product.

Are there any pending cases about the product? How many products have already been sold? Were the original company's manufacturing specifications in line with the acquiring company's expectations? Which employees is the acquiring company bringing in-house, and are those individuals bringing any baggage with them? In short, companies need to remember that they are not just buying a product; they are buying that product's history. It is critical to know that history so that the company can take measures to protect itself before finalising the acquisition.

Gramling: Drug and medical device companies need not wait for the actual initiation of litigation to prepare for litigation. In-house litigation counsel, working closely with outside counsel and legal colleagues counselling the business, are well-positioned to assess and mitigate litigation risk by monitoring trends and informing corporate practices to anticipate such trends. Active communication between litigation counsel and colleagues in both legal and business roles constitute an effective and essential best practice. While such coordination may not entirely avoid litigation, it almost certainly improves a company's position should litigation be initiated. Additional preparatory actions include regular assessment of document preservation practices and regular discussions about good documentation practices – recent high-profile attention to this issue in the opioid litigation serves

as a strong reminder of the importance of such practices. A thorough assessment by counsel of potential product risk and a clear record of regulatory interactions can also significantly improve a company's preparation for litigation.

Hill: Drug and device companies can put themselves in a better position by conducting early, pre-litigation risk assessments. This type of preemptive analysis can help to identify areas of potential exposure and guide the company in strategies to mitigate the risk of future litigation. If litigation does ensue following a risk assessment, the company is armed with a better understanding of the documents that will be necessary in discovery and the key witnesses who may be important for the defence. The company can also use the pre-litigation risk assessment to develop an early plan for approaching litigation before it is faced with court-imposed deadlines. Careful planning with a systematic risk assessment can be an effective tool not only to reduce the potential for future litigation, but also to improve the defence strategies.

McGraw: Having your discovery house in order before a complaint is served can save money and prevent headaches during litigation. First, we recommend in-house electronically stored information (ESI) and discovery counsel. It is always surprising when well-known, international companies have not made this investment. Relying on outside counsel for this type of work will drive up litigation costs and create additional business costs because company employees spend more time collecting documents for the attorneys. Additionally, in the event of ESI depositions, if you have in-house ESI counsel, the deponent is an experienced attorney with only ESI knowledge and not an employee with subject matter expertise. Second, it is important that employees are smart with how they create documents. Try to avoid co-mingling various products' complaint rate data or creating documents relating to more than one product. Similarly, try to ensure that communication with the US Food and Drug Administration (FDA) does not relate to more than one product. This is particularly important if you are providing recall updates to the FDA on several products – each email communication and any recall updates should focus on only one product. We have seen a trend in recent case law where courts are less inclined to allow defendants to make intra-document redactions for non-responsive materials. As frustrating as that is, it can be a bigger problem if an otherwise responsive, relevant document contains sensitive information about a non-responsive or non-relevant product. Third, be strategic about getting out in front of 'other similar incident' or 'substantially similar incident' information. Early discussions with in-house post-market surveillance subject matter experts can be an effective way to understand the universe of information that may be discoverable

and is instrumental in framing a broader litigation strategy for this type of information. Finally, in larger litigations do not be afraid to push for a Lone Pine orders in addition to standard MDL procedures like plaintiff fact sheets.

CD: How important is it to assess potential damages and settlement options in the early stages – and throughout – the dispute process? How should parties approach this aspect?

Gramling: Assessment of ultimate exit strategy – whether through dispositive motion, trial, and appeal if necessary, or other means of resolution – should be done early and often throughout the litigation process. Such assessment can be done in conjunction with an aggressive litigation posture and a clear indication of readiness to go to trial. An evidence-based understanding of various potential damages, gained through a survey of actual verdicts and other factors, both legal and business, is critical to such an assessment. Experience from many MDLs and mass tort litigations in the pharmaceutical and medical device industry demonstrates that a high percentage of filed cases qualify as no injury or low injury cases and this experience should be factored into the ultimate exit strategy. Some companies have used litigation counsel to drive this assessment while others have employed 'resolution counsel' to handle this component of the process.

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Hill: Assessing potential damages and settlement options is an important part of developing litigation strategy. Even at early stages when settlement may not be a serious consideration, defendants should carefully consider and assess their opponent's motivations and likely end goals. This analysis includes consideration of outcomes in comparable cases, the costs that each side is likely to incur in litigation, and the strengths and weaknesses of the claims and defences. Defendants in litigation should assess potential damages and evaluate resolution options at an early stage, and they should revisit their assessment periodically as the case progresses and at major case milestones. Many factors can impact the value of a case, and it is important to

be well informed when making strategic litigation decisions.

McGraw: It is wise to assess potential settlement options and to continue to reevaluate early resolution as litigation continues. However, that analysis cannot be made in a vacuum. Companies need to consider what preliminary internal discovery reveals and take into consideration the long-term market goals for a particular product or device. It is also important to weigh the potential scope of the litigation. For example, is this a product that has been in the market for a long time? What are the allegations? Who represents the plaintiff? These are all things that need to be scrutinised before you can properly calculate the 'value' of a settlement. In larger MDLs or consolidated actions, settlement or 'resolution' counsel obviously plays an important role. However, sometimes companies can go too far in compartmentalising settlement teams and litigation teams. There needs to be communication and coordinated strategic case handling so that decisions are made with a view toward the long-term goals of the company and the litigation.

Walther: The unfortunate reality is that lawsuits are expensive. They cost money to defend, bring negative media attention and distract employees from their day-to-day responsibilities. Companies, therefore, should always assess whether there is a cost-effective way to resolve a lawsuit in its infancy. When companies are not able to do so, it is imperative to avoid becoming intractable. While companies can estimate a plaintiff's potential damages at the outset of a case fairly easily, it is much more difficult to analyse potential liability at the early stages of a lawsuit. Drug and device products are, by their nature, complicated, and the individuals involved in early settlement negotiations will rarely have in-depth knowledge about the product at that time. Stay flexible and let your approach to settlement evolve as your knowledge about the product and the litigation evolves.

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CD: How important is it to engage expert witnesses to assist with examining

and presenting a case during litigation? In what ways has the role of the expert evolved?

Hill: Expert witnesses can play a powerful role in any complex litigation, and litigation involving drug and medical device companies is no different. Understandably, juries often attach significant weight to the opinions of expert witnesses. As a result, it is critical for courts to exercise their role as a gatekeeper in assessing the admissibility of expert testimony. In federal court, the advisory committee for the rules of evidence has proposed changes to Rule 702, seeking to clarify the standards for the admissibility of expert testimony. Those changes and the accompanying proposed committee notes re-emphasise the requirement for the proponent of expert evidence to demonstrate its reliability as a condition for admissibility. If accepted, these changes should encourage courts to better protect the courtroom from unreliable scientific evidence.

McGraw: Expert considerations need to be part of early strategy discussions, especially in larger, complex litigations. We have seen, time and again, that experts can make or break a case when you get to trial. Finding great experts who can explain technical and complicated theories to juries is critical. And it can take a lot of time. For that reason, it is important to start parsing out the answers to questions like: what type of subject matter experts do we need in this case? Who could serve as that expert? Are there consulting experts we need to retain? Are there corporate in-house subject matter experts we need to engage with early? Additionally, input from experts will also shape strategy for further case handling, including but not limited to product inspections and depositions of treating physicians or other experts.

Walther: Expert witnesses have long been critical to success in pharmaceutical and medical device cases, but recent societal changes have made it important to pay special attention to experts' backgrounds. Many potential jurors have developed a distrust of traditional appeals to authority. The days of experts duelling over credentials are over – a jury will no longer blindly trust the expert who graduated or works at the more prestigious university or hospital. Companies should consider retaining more experts who have little – if any – litigation experience. While it will require more work to get the experts ready to serve their reports and sit for their depositions, the jurors will tend to see them as more neutral and independent. The trust jurors give those experts will far outweigh the additional work it took to prepare them to testify.

Gramling: Expert witness engagement remains a critical factor in pharmaceutical and medical device litigation as nearly all MDLs and mass torts involve and hinge on expert witness issues related

to general and specific causation. Junk science continues to plague product liability litigation in particular – expert witnesses must, therefore, be prepared to demonstrate why the opponent's expert has not followed sound science, has misrepresented or otherwise misstated the state of science and has employed a suspect methodology in reaching their conclusions. The best expert witnesses can help not only litigation counsel but also judges and jurors to understand what can often be complicated scientific issues. Such experts can also help judges fulfil their role as gatekeeper in excluding unreliable expert testimony. To that end, companies may want to support efforts, led by the Lawyers for Civil Justice organisation, to clarify the court's role and duties under Rule 702.

CD: What advice would you offer to drug and medical device companies on setting out and executing a litigation strategy to maximise their chances of a favourable judgement?

McGraw: Spend the time to understand the scope of the alleged issue. Learning early on and evaluating what is in your company documents is key so that you can develop an appropriate strategy. Second, implement that strategy and try to drive the litigation as opposed to just reacting to plaintiffs' counsel. Third, make sure that all members of your litigation, and resolution teams, if you have one, are regularly communicating and are on the same page with respect to your strategy. Encouraging relationship partners to communicate that strategy to the entire litigation team, from partners to associates, is important to ensure that the strategy is consistently implemented. Next, start thinking about what types of experts and specific individuals you may want to retain early on.

Gramling: Drug and medical device companies should engage and involve trial counsel in the litigation as early as possible. Such early involvement can assure that all actions in the course of the litigation are taken with trial in mind. That 'trial-in-mind' approach can helpfully inform discovery strategy, expert witness strategy, company witness strategy and dispositive motion strategy. Such an approach can also lead to a sober assessment of relevant risks and can avoid the dangerous discounting of real risks. Working early with expert witnesses is likely considered conventional wisdom – not-so-conventional wisdom may be giving consideration, in appropriate circumstances, to opposing consolidation of lawyer-generated litigation into an MDL or mass tort litigation. Should an MDL or mass tort be established, companies should push for early assessment of filed cases – many of which will be no injury or low injury – as well as bifurcation of the litigation to focus initially on threshold issues such as general causation and preemption. Recent litigation successes support such approaches.

Walther: Do not forget the human side of your company. Too many defendants assume they will be more prepared than the plaintiffs to challenge the scientific issues raised at the Daubert stage but accept the notion that the plaintiffs will have a more 'human' story to tell if they can get to the jury. Do not give in to that fallacy. Drug and medical device companies are made up of good people who care deeply about developing and manufacturing products that improve and extend people's lives across the globe. When considering which employees to present as corporate representatives, choose employees who can tell that story.

Hill: Litigation strategy is not 'one size fits all'. What works for one company may not work for another. Because each drug and medical device company has unique needs and motivations, it is important to fully assess these individual factors when developing an effective litigation strategy. Companies should identify their own long- and short-term goals, guided by their individual business perspective, and allow their goals to define the litigation strategy. Litigation can take many different paths, ending with early resolution, voluntary dismissal, dispositive motions, trial, or otherwise. Having clearly defined goals at the outset will help the company identify favourable outcomes and milestones and navigate to success at earlier opportunities.

CD: What are your expectations for drug and medical device litigation in the months ahead? What factors do you believe will shape this space?

Walther: As the country continues to advance closer to the 'new normal', courts will start fast-tracking cases to get their dockets back under control. It will probably be several more months before trials completely resume in earnest, but when they do, there will be an enormous amount of activity in this sector. Hopefully we will see courts less willing to entertain endless, and costly, discovery battles, and instead start pushing the parties to advance their cases to reach the merits of the dispute. If they do, it will present an opportunity for pharmaceutical and medical device companies looking to defend their products rather than accepting a cost-saving settlement forced upon them by growing discovery costs.

Hill: Plaintiffs' lawyers have used social media, online advertising and lead generators to assemble massive inventories of product liability cases against drug and device companies. Additionally, the growing influence of third-party litigation funding by outside investors has increased the stakes of mass torts. The majority of the largest current MDLs in the US are cases brought against drug and medical device companies. Mass torts involving thousands or tens of thousands of plaintiffs are increasingly common,

and these trends show no signs of slowing. When cases are filed at such a rate, proper screening becomes difficult, requiring litigants to develop new and creative approaches to taking discovery and assessing the merits of individual cases.

Gramling: Anticipated decisions, whether at the trial court or appellate court level, in the opioid litigation and other major litigations in the pharmaceutical and medical device sector will likely have significant reverberations and implications for those matters and other litigations. Current efforts to amend Rule 702 and to secure early assessment of mass-filed cases could shape the course of MDLs in particular. Beyond the product liability context, the new administration and recent changes at the DOJ and Federal Trade Commission (FTC) are likely to impact antitrust risks these companies face. Scrutiny of pricing by congress and others will remain a challenge faced by the pharmaceutical industry, and trial court level cases related to the 340B drug pricing programme may reach the courts of appeals in the coming months.

McGraw: It is nearly impossible to talk about the future of any industry without addressing the impact of the COVID-19 pandemic. For manufacturers, ensuring quality and security of supply chains is important. We are concerned, especially for smaller, newer start-up type companies, that we will see product litigation that results from sourcing component materials from different or new suppliers. Additionally, it will be interesting to see what impact, if any, emergency use authorisation status has on product litigation. There are some interesting, implied preemption arguments that can be made in cases relating to products that received emergency use authorisations. And speaking of potential defences, companies and counsel need to pay close attention to statute of limitation defences. Allegations and facts relating to when a plaintiff discovered the alleged cause of an injury need to be thoroughly investigated. Furthermore, although many jurisdictions, like New York State for example, tolled the statute of limitations during the worst of the pandemic in the summer of 2020, some did not. CD