International Comparative Legal Guides

Drug & Medical Device Litigation 2020

A practical cross-border insight into drug & medical device litigation

First Edition

Featuring contributions from:

Addleshaw Goddard LLP
AllBright Law Offices
Allen & Gledhill LLP
Beccar Varela
Bull & Co Advokatfirma AS
Clayton Utz
COBALT
DRI – The Voice of the Defense Bar
Harris Kyriakides LLC
Kellerhals Carrard
Kennedy Van der Laan
Khurana & Khurana, Advocates and IP Attorneys
Kim & Chang
Michalopoulou & Associates Lawgroup
Preu Bohlig & Partner Rechtsanwälte mbB
Rodrigo, Elías & Medrano Abogados
Sidley Austin LLP
Sorainen
Studio Legale Russo Valentini
Veirano Advogados
Winston & Strawn LLP

dri™ ICLG.com

USA


Alycia A. Degen


Heidi Levine


Kara L. McCall


Andrew B. Talai

Sidley Austin LLP

1 Regulatory Framework

1.1 Please list and describe the principal legislative and regulatory bodies that apply to and/or regulate pharmaceuticals, medical devices, supplements, over-the-counter products, and cosmetics.

The U.S. Food and Drug Administration ("FDA") is the primary federal agency that regulates such products pursuant, generally, to the Federal Food, Drug, and Cosmetic Act ("FDCA"). *See generally* 21 U.S.C. § 301, *et seq.* The FDA has a variety of mechanisms (including warning letters) to address violations of the laws it administers, and works with the U.S. Department of Justice ("DOJ") and U.S. Attorneys to bring enforcement actions.

The Drug Enforcement Agency ("DEA") regulates certain drugs that have a potential for abuse under the Controlled Substances Act. *See generally* 21 U.S.C. § 801, *et seq.*

The Federal Trade Commission ("FTC") regulates advertising (other than labelling) for food, over-the-counter ("OTC") drugs, cosmetics, and non-restricted medical devices under the FTC Act, which prohibits a variety of "unfair or deceptive acts or practices", including the dissemination of false advertisements for food, drugs, non-restricted devices, and cosmetics aimed at consumers. *See generally* 15 U.S.C. §§ 45, 52, 55; 21 U.S.C. § 352(r). The FDA maintains authority over labelling for food, drugs, medical devices, and cosmetics, and over advertising for prescription drugs and restricted medical devices.

In addition, state agencies administer certain licensing and labelling requirements.

1.2 How do regulations/legislation impact liability for injuries suffered as a result of product use, or other liability arising out of the marketing and sale of the product? Does approval of a product by the regulators provide any protection from liability?

Generally speaking, private parties cannot sue to enforce the FDCA, since "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States". 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In addition, state-law actions may be expressly or impliedly preempted or otherwise barred by the doctrine of primary jurisdiction.

For prescription drugs that have been approved by the FDA, state-law claims that a manufacturer failed to warn of a particular adverse event are preempted if there is "clear evidence" that the FDA would not have approved the warning that plaintiffs have proposed. *Wyeth v. Levine*, 555 U.S. 555 (2009). For OTC drugs, the FDCA preempts any state or local government requirement "that is different from or in addition to, or that is otherwise not identical with, a requirement under" the FDCA, the Poison Prevention Packaging Act of 1970, 15 U.S.C. § 1471, *et seq.*, or the Fair Packaging and Labeling Act, 15 U.S.C. § 1451, *et seq.* For medical devices, where the FDA has established a federal requirement – such as in the case of a pre-market approved ("PMA") medical device – state law generally is prohibited from imposing a requirement that is "different from, or in addition to" the federal requirement. *Riegel v. Medtronic*, 552 U.S. 312 (2008). And in the food and dietary supplements context, the FDCA likewise expressly preempts certain claims. *See* 21 U.S.C. § 343-1.

1.3 What other general impact does the regulation of life sciences products have on litigation involving such products?

Products regulated by the FDA are frequently the subject of tort and consumer fraud litigation. Arguments may range from second-guessing the FDA's determinations about whether a product should be marketed, to disputing whether the regulated entity submitted correct data to the agency or should have made labelling changes in light of developing data. Such claims must navigate the preemption and primary jurisdiction framework noted above. These requirements are case-specific and depend in large part on governing case law and the particular FDA regulatory histories for a given life sciences product. In addition, compliance with federal regulatory requirements may provide a defence under state tort law or otherwise mitigate the entity's exposure to liability, including to punitive damages.

1.4 Are there any self-regulatory bodies that govern drugs, medical devices, supplements, OTC products, or cosmetics in the jurisdiction? How do their codes of conduct or other guidelines affect litigation and liability?

A number of voluntary organisations have developed best practices and other guidelines that can assist regulated entities in demonstrating that they complied with industry standards, or in otherwise mitigating potential liability. For prescription drugs, the Pharmaceutical Researchers and Manufacturers of America ("PhRMA") Code of Conduct addresses pharmaceutical companies' interactions with prescribing healthcare professionals. The Code of Conduct provides guidelines on various topics, including provision of meals and educational items, consulting or speaking programme arrangements with physicians, and the use of prescriber data. For medical devices, the Advanced Medical Technology Association ("AdvaMed") has developed a Code

of Ethics to ensure that relationships between medical device companies and physicians meet ethical standards. The Code of Ethics provides guidelines on a number of interactions with healthcare professionals, including continuing medical education ("CME"), educational and patient benefit items, and communications regarding the safe and effective use of medical technology.

For OTC drugs and dietary supplements, the Consumer Healthcare Products Association ("CHPA"), a member-based association representing manufacturers and distributors of OTC drugs and dietary supplements, has adopted guidelines on advertising practices for OTC drugs. CHPA's voluntary code sets forth various principles, including that advertising should urge consumers to read and follow label directions and that advertising should omit inducements, like prizes, that might encourage unnecessary use of the product. In addition, the Council for Responsible Nutrition ("CRN") and the National Advertising Division of the Better Business Bureau ("NAD") work together to increase monitoring of dietary supplement advertising. *See* CRN, *CRN/NAD Initiative: Stand Up for Truth in Advertising*, https://www.crnusa.org/self-regulation/crn-nad-initiative-stand-truth-advertising. CRN has developed a Code of Ethics for its members, as well as guidelines for specific types of supplements and cross-cutting issues, such as dosage recommendations. *See* CRN, Code of Ethics (*available at* https://www.crnusa.org/about-crn/code-ethics); CRN, *Voluntary Guidelines/Best Practices*, https://www.crnusa.org/self-regulation/voluntary-guidelines-best-practices.

Consumer product marketing is subject to industry self-regulation through the NAD, which evaluates all national advertising for truthfulness and accuracy. Specific challenges to a company's advertising can also be made either by a competitor company or by a consumer. Generally, NAD seeks voluntary compliance with its determinations regarding the truth and accuracy of challenged advertising. In cases where an advertiser declines to participate or to abide by the terms of an NAD decision, the issue is referred to FTC. In some cases, NAD will also reach out to the FDA on an issue.

1.5 Are life sciences companies required to provide warnings of the risks of their products directly to the consumer, or to the prescribing physician (i.e., learned intermediary), and how do such requirements affect litigation concerning the product?

Drug and medical device labelling must bear adequate directions for use, and must not be false or misleading in any particular, including by material omissions. 21 U.S.C. § 352(a)(1), (f)(1); *see id.* § 321(n). The FDA approves the labelling for prescription drugs and devices, and requires that manufacturers communicate adequate directions for use and warning information to prescribers through prescriber-facing labelling. *See* 21 C.F.R. Part 201, Subpart C (prescription drug-specific labelling requirements); *id.* §§ 801.109-110 (prescription device-specific labelling requirements). FDA regulations also impose requirements on patient/consumer-facing prescription drug labelling and advertising. *See* 21 C.F.R. § 202.1. These requirements include a "true statement of information in brief summary relating to the side effects, contraindications, and effectiveness", which must present a "fair balance" between safety and effectiveness information. *Id.* § 202.1(e), (e)(5)(ii).

For OTC drugs and devices, warnings must be conveyed to consumers on product labels and labelling. *See* 21 C.F.R. Part 201, Subparts A and C (general and OTC-specific drug labelling requirements); *id.* Part 801, Subparts A and C (general device labelling requirements).

Whether a state-law challenge to the FDA-approved labelling may proceed is subject to the pre-emption analysis described above. In addition, many states recognise that where drugs and devices are prescribed by healthcare professionals who must determine the appropriateness of the therapy for the patient (*i.e.*, the "learned intermediary"), the adequacy of the warning is determined *vis-à-vis* the healthcare professional, not the patient.

2 Manufacturing

2.1 What are the local licensing requirements for life sciences manufacturers?

The FDA has registration requirements for drugs, medical devices, foods, and dietary supplement facilities. *See generally* 21 U.S.C. §§ 350d (foods and dietary supplements), 360 (drugs and medical devices); *see also* 21 C.F.R. Part 1, Subpart H (foods and dietary supplements), Parts 207 (drugs), and 807 (medical devices). Most of these facilities would also be subject to detailed current Good Manufacturing Practices ("cGMPs") or, for medical devices, the Quality System Regulation ("QSR"), specific to the activities that take place at that facility. *See generally* 21 U.S.C. §§ 342 (definition of adulterated foods, including dietary supplements); 351(a)(1) (statutory cGMP provision for drugs and medical devices; *see also* 21 C.F.R. Parts 110 (conventional foods), 111 (dietary supplements), 210-212 (drugs, finished pharmaceuticals, and positron emission tomography drugs), 225-226 (medicated feeds and type A medicated articles), and 820 (QSR for medical devices). The FDA has the authority to inspect such facilities for violations of the GMP requirements, to make public its findings, and to bring enforcement actions if compliance is not achieved. 21 U.S.C. §§ 372, 374, 384c.

2.2 What agreements do local regulators have with foreign regulators (e.g., with the U.S. Food and Drug Administration or the European Medicines Agency) that relate to the inspection and approval of manufacturing facilities?

There has been an increasing trend towards collaboration and harmonisation between the FDA and its regulatory counterparts in other countries. For example, the FDA coordinates with foreign authorities regarding inspections. *See* 21 U.S.C. § 384e (authorising arrangements and agreements to recognise foreign government inspections). In the drug context, the FDA has entered into a Mutual Recognition Agreement ("MRA") with the EU, under which it collaborates with healthcare product regulatory agencies in the various EU member countries on routine establishment inspections. And in the medical device context, the FDA participates in the Medical Device Single Audit Program, under which a regulatory audit by one member agency satisfies regulatory requirements for all member governmental authorities.

The FDA has engaged in Cooperative Arrangements with several countries' food and healthcare product regulatory authorities. A Cooperative Arrangement is a written understanding that the FDA can establish with one or more foreign governments or international partners, and which describes the willingness and good-faith intentions of the FDA and its counterpart(s) to engage in cooperative activities. These arrangements vary by country and cover different types of products, product inspections, mutual recognition of different countries' regulatory requirements and frameworks, and durations. The FDA has also engaged with several EU Member States and other nations to share information from law enforcement or regulatory activities under confidentiality commitments. The specific types of product inspections and extent of confidentiality commitments vary by country.

2.3 What is the impact of manufacturing requirements or violations thereof on liability and litigation?

The FDA has authority to take a number of enforcement actions against violations of manufacturing requirements, including injunctions, civil and criminal penalties, product seizures, administrative detention of foods, and withdrawal of approval of abbreviated new drug applications ("ANDAs") for generic drugs. *See generally* 21 U.S.C. §§ 332, 333, 334, 335b, 335c. The FDA also has authority to seize or refuse admission of imports of regulated products that appear not to comply with manufacturing requirements, or for which manufacturers deny an FDA inspection. *See generally id.* §§ 381, 384b, 384c. In addition, tort and consumer fraud litigation may point to such regulatory violations in seeking to impose state-law liability, subject to the pre-emption analysis discussed above.

3 Transactions

3.1 Please identify and describe any approvals required from local regulators for life sciences mergers/acquisitions.

Under the Hart-Scott-Rodino Act ("HSR"), parties to certain transactions valued in excess of $90 million must first notify the Federal Trade Commission and the Antitrust Division of the Department of Justice and observe a statutory waiting period (typically, 30 days) prior to consummating the transaction. The HSR clearance is not limited to life sciences mergers/acquisitions, although in certain circumstances, an exemption may nullify a reporting obligation, or the HSR regulations may render a life sciences transaction non-reportable (*e.g.*, an acquisition of a target that has yet to commercialise a product may be not meet the HSR "size-of-person" threshold).

More particularly, for life sciences mergers/acquistions, there may need to be a notification to the FDA. Depending on the marketing authorisation type (*e.g.*, New Drug Application, Abbreviated New Drug Application, Pre-Market Application, Pre-Market Notification, Biologics License Application), and whether there are changes to the conditions in manufacturing and distribution, a company also may need to submit supplements for FDA approval. Changes to labelling, registration, and listing may need to occur. Depending on the product type, there may also be Drug Enforcement Administration implications. Additionally, there are various state licensing requirements to consider.

Life sciences mergers/acquisitions may require the approval of the Committee on Foreign Investment in the United States ("CFIUS"), a U.S. inter-agency committee that reviews the national security implications of foreign investments in U.S. businesses. Under interim regulations, CFIUS requires notification of mergers/acquisitions involving U.S. businesses that produce, design, test, manufacture, fabricate, or develop certain technologies, defined as critical technologies, in connection with at least one of 27 enumerated industries, including Research and Development in Biotechnology. These interim regulations, however, are subject to change in the final regulations expected on or before February 13, 2020.

Additionally, although not mandatory, any merger/acquisition not covered under the interim regulations noted above that could result in control of a U.S. business (including life sciences companies) by a foreign person, may make notification to CFIUS advisable. Even where notification is not required, CFIUS has jurisdiction to review any such transaction. Therefore, CFIUS may require parties to submit information for its review and approval prior to or post-closing, which could result in significant risk for the acquiring parties as CFIUS has the authority to unwind transactions, force divestiture, or place other limitations on the transaction.

3.2 What, if any, restrictions does the jurisdiction place on foreign ownership of life sciences companies or manufacturing facilities? How do such restrictions affect liability for injuries caused by use of a life sciences product?

The HSR Act does not limit foreign ownership of life sciences companies or manufacturing facilities. Foreign companies subject to FDA regulations, however, are required to have U.S. agents for registration purposes. Finally, the International Traffic in Arms Regulations ("ITAR") prohibit investors from certain jurisdictions, including China, from owning or controlling a registered entity.

4 Advertising, Promotion and Sales

4.1 Please identify and describe the principal legislation and regulations, and any regulatory bodies, that govern the advertising, promotion and sale of drugs and medical devices, and other life sciences products.

Under the FDCA, the FDA has the authority to regulate the advertising and promotion of prescription drugs in the United States. *See* 21 U.S.C. § 352(n). The FDA regulates prescription drug advertising and promotion pursuant to the FDCA and regulations found in 21 C.F.R. § 202.1. The FDA also issues guidance documents that provide its current approach to regulatory subjects, including advertising and promotion. In the case of any prescription drug distributed for sale, the advertising must include a true statement of the established drug name, printed prominently and in the correct size print, each ingredient of the drug, and any other information relating to side effects, contraindications, and effectiveness. 21 C.F.R. § 202.1(e)(5)–(7).

For OTC drugs, the FDA generally regulates the labelling for prescription and OTC drugs and promotional claims about prescription drugs, while FTC regulates advertising of OTC drugs. *See generally* FTC-FDA Liaison Agreement – Advertising of Over-the-Counter Drugs, 36 Fed. Reg. 18,539 (Sept. 16, 1971).

For medical devices, under the 1971 Memorandum of Understanding ("MOU"), the FDA regulates the labelling for medical devices, while FTC regulates "all advertising (other than labeling)" for most medical devices. *Id.* The exception to this rule is that the FDA has authority over the *advertising* for restricted medical devices. *See* 21 U.S.C. § 352(q), (r). Indeed, the FDCA explicitly states that restricted devices are not subject to FTC's broad authority over advertising. *Id.* § 352(r) ("no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 52 through 55 of title 15").

4.2 What restrictions are there on the promotion of drugs and medical devices for indications or uses that have not been approved by the governing regulatory authority ("off label promotion")?

Generally, the advertisement and promotion must adhere to the approved labelling of a product, as the FDCA prohibits the promotion of a misbranded drug. 21 U.S.C. § 331(a), (b). If an advertisement promotes uses or indications that have not been approved by the FDA, it would be deemed misbranded and subjected to potential penalties. *See id.* at § 331. However, the contours of the FDA's enforcement activities surrounding truthful off-label statements have evolved in recent years through court decisions rooted in the First Amendment. *See U.S. v. Caronia*, 703 F.3d

149 (2d Cir. 2012) (FDA regulations must be interpreted "as not prohibiting and criminalising the truthful off-label promotion of FDA-approved prescription drugs" where the off-label use itself is lawful); *see also Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196, 224 (S.D.N.Y. 2015) (truthful, off-label communications are protected by the First Amendment).

In 2018, the FDA issued new, non-binding, final guidance regarding off-label promotion, clarifying that manufacturers may have more room to communicate truthful and non-misleading information that is not in the product's FDA-approved labelling as long as it is "consistent with labeling". Communications must be consistent with the label regarding indication, patient population, limitations and directions of use, and dosing or use administration. Representations about the use of the product cannot increase the potential for harm relative to the information in the label. Finally, the directions for use in the label must enable the product to be safely used under the conditions represented in the communication. Accordingly, whether a specific off-label communication may be permissible requires a highly case-specific analysis.

4.3 What is the impact of the regulation of the advertising, promotion and sale of drugs and medical devices on litigation concerning life sciences products?

Personal injury or class action plaintiffs may point to advertising statements as the bases for misrepresentation, warranty, and consumer fraud claims. In those claims, plaintiffs generally aim to prove that company statements were false and misleading, and they may attempt to use the FDA's communications to support these claims. When the FDA sends a warning or "untitled" letter to a prescription drug manufacturer based on review of promotional materials, the FDA's letter generally contains language deeming the advertisement "false or misleading". Although such letters are neither formal findings by the FDA nor final agency actions, they can be admitted in litigation and used against manufacturers defending these suits.

As described above, plaintiffs must base their claims regarding drug or medical device advertising or promotion on federal law other than the FDCA (*e.g.*, Lanham Act), if permitted by those federal laws, or on state law, if permitted by statutes, regulations, and case law on pre-emption. For example, plaintiffs alleging that a manufacturer promoted its drug or medical device for an off-label use may not sue under the FDCA; rather, they must allege that this promotion violated another federal law, or a state law in a manner not pre-empted by the FDCA.

5 Data Privacy

5.1 How do life sciences companies which distribute their products globally comply with GDPR standards?

Companies worldwide have undertaken significant efforts to comply with the EU General Data Protection Regulation ("GDPR"), which became effective in May 2018. The law applies not only to companies established in the European Economic Area ("EEA") but also to companies located outside of the EEA (*e.g.*, in the United States) that offer goods and services to, or that monitor the behaviour of, individuals in the EEA. To the extent the GDPR applies, the law impacts a company's ability to collect, analyse, and transfer personal data (*i.e.*, information relating to an identified or identifiable individual – which includes key-coded data) throughout the product lifecycle, including, for life sciences companies, in the context of clinical trials, vigilance, medical research, and marketing. The GDPR not only places obligations on companies (*e.g.*, concerning provision of notice, retention, breach notification, international transfers), it also grants individuals various qualified data privacy rights (*e.g.*, to access or erase their personal data).

Companies that operate globally have had to consider not only the application of various jurisdictions' data protection laws to their operations but also differences that remain regarding the GDPR within different EU Member States. Notwithstanding EU-level guidance on the GDPR from the European Data Protection Board ("EDPB"), differences between jurisdictions remain. This has become a concern, in particular, for the life sciences industry, where key GDPR concepts such as whether or not to obtain consent to process personal data in the context of a clinical trial, who is a "controller" or "processor", the scope of the definition of the term "personal data", and requirements related to data anonymisation, remain unsettled.

5.2 What rules govern the confidentiality of documents produced in litigation? What, if any, restrictions are there on a company's ability to maintain the confidentiality of documents and information produced in litigation?

Assuming that the documents at issue are not privileged, there are generally no statutes or regulations that govern the confidentiality of documents produced by private parties in litigation, and the default rule is that all documents produced in litigation are considered public. It is commonplace, however, to enter into confidentiality agreements subject to court enforcement, which protect public disclosure of documents produced in litigation. These agreements typically protect from public disclosure documents that contain proprietary business strategies or know-how, as well as personal information (including medical and health information). The parties typically stamp documents with the words "Confidential" in order to reflect protection under the confidentiality agreement. Parties may also agree to stricter limits on certain highly confidential documents, including "attorneys' eyes only" provisions.

Litigants should also keep in mind, however, that the fact that the parties have agreed to confidentiality does not necessarily mean that confidential documents – to the extent they are filed on the court docket in support of motions or briefing – will remain under seal. Sealing will be subject to separate local rules of the court.

5.3 What are the key regulatory considerations and developments in Digital Health and their impact, if any, on litigation?

Following the 21st Century Cures Act ("Cures Act"), the FDA has taken steps to further clarify the framework for its regulation of digital health and which software functions are not subject to FDA regulation. 21 U.S.C. § 360j(o)(1). Among other things, the agency has issued updated guidance addressing clinical decision support software ("CDS") and wellness-related software functions.

More generally, the FDA continues to work to provide clarity on practical approaches to a number of emerging digital health issues, including wireless medical devices, device software functions, health information technology, telemedicine, medical device data systems, and interoperability.

When digital health involves the processing of personal data, data privacy and cybersecurity regulatory requirements can also be highly relevant. In the EU, the GDPR (discussed in question 5.1 above) can have significant impacts on digital health,

particularly in light of the potential for significant administrative fines (in 2019, regulators imposed fines of over $225 million and $120 million on two companies in particular) and the right the GDPR gives individuals who have suffered "material or non-material damage" to bring private actions. In the United States, the California Consumer Privacy Act ("CCPA") became effective on January 1, 2020. This law, which has much in common with the GDPR and provides a private right of action for data breaches in particular, is also expected to give rise to increased data security-related litigation in the years ahead. Although the CCPA contains an exception for certain health and clinical trial data, life sciences companies may still collect and maintain health-related data that is within the Act's scope.

6 Clinical Trials and Compassionate Use Programmes

6.1 Please identify and describe the regulatory standards, guidelines, or rules that govern how clinical testing is conducted in the jurisdiction, and their impact on litigation involving injuries associated with the use of the product.

The FDA regulates clinical trial and compassionate use programmes in the United States for various products ranging from medical devices to pharmaceutical products. *See, e.g.,* 21 C.F.R. § 50. In addition, the FDA issues guidance documents to ensure that companies maintain good clinical practice ("GCP") to ensure the integrity of clinical data and to help protect the safety of human subjects. *See* FDA, *Regulations: Good Clinical Practice and Clinical Trials* (Aug. 28, 2019), available at https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/regulations-good-clinical-practice-and-clinical-trials. GCPs include rules about clinical testing regarding informed consent, institutions that review clinical investigations, trial registration, financial disclosure by clinical investigators, and new drug applications, among other rules to implement the law. *Id.*

Although the FDA regulates clinical trials and compassionate use programmes, any litigation involving injuries allegedly associated with the use of products will be litigated in U.S. state or federal court, depending on the nature of the dispute, subject to the pre-emption analysis discussed above.

6.2 Does the jurisdiction recognise liability for failure to test in certain patient populations (e.g., can a company be found negligent for failure to test in a particular patient population)?

Plaintiffs in U.S. courts may argue that a manufacturer was negligent in failing to test an FDA-regulated product in a particular population. This theory may come into tension with the FDA's contrary conclusion that there has been adequate testing to market the product. Accordingly, such claims may be subject to a preemption analysis.

In addition, the FDA recently issued guidance encouraging greater inclusion of certain populations, such as underrepresented minorities, in clinical studies to enhance the diversity of clinical trial populations. *See* FDA, *Draft Guidance for Industry, Enhancing the Diversity of Clinical Trial Populations* (June 2019), available at https://www.fda.gov/media/127712/download. Among other considerations are broadening eligibility criteria and making participation less burdensome. *Id.* at 7, 9.

6.3 Does the jurisdiction permit the compassionate use of unapproved drugs or medical devices, and what requirements or regulations govern compassionate use programmes?

In certain circumstances, FDA regulations permit expanded access programmes, also referred to as compassionate use programmes, to provide access to investigational drugs outside traditional clinical trials for individual patients (including emergency use) and for more widespread use, under a Treatment Investigational New Drug application ("IND"). For all three types of expanded access programmes, the FDA must determine that the patient(s) has or have a life-threatening or serious condition, there is no comparable alternative therapy, the potential benefits to the patient(s) outweigh the potential risks, and providing the device or drug will not interfere with clinical trials. 21 C.F.R. § 312.305(a). The FDA also must determine that additional criteria for each of the three types of clinical trials are met. *See id.* §§ 312.310, 312.315, 312.320; *see also generally* FDA, *Expanded Access* (May 6, 2019), available at https://www.fda.gov/news-events/public-health-focus/expanded-access.

6.4 Are waivers of liability typically utilised with physicians and/or patients and enforced?

In some circumstances, physicians have used waivers of liability with their patients in addition to informed consent. Whether patient liability waivers are typically enforced varies by jurisdiction within the U.S. For example, New York is generally reluctant to enforce liability waivers in the healthcare context. *See* Anna B. Laakmann, *When Should Physicians Be Liable for Innovation*, 36 Cardozo L. Rev. 913, 932–33 (2015). In litigation, parties can challenge liability waivers explaining public policy concerns about patient vulnerability, diminished capacity, and uneven bargaining power, as well as other contractual concerns. In response, depending on the state, if a patient signs a waiver, the defendant physician may point to the contractual agreement as a defence to negligence. *See* Nadia N. Sawicki, *Choosing Medical Malpractice*, 93 Wash. L. Rev. 891 (2018), 913. If this contractual agreement is deemed enforceable such that the patient did waive all physician liability, the negligence claim may be dismissed. *Id.*

6.5 Is there any regulatory or other guidance companies can follow to insulate or protect themselves from liability when proceeding with such programmes?

With respect to compassionate use programmes, the FDA regulates compassionate use programmes in the U.S. A new federal law also gives people who have a life-threatening disease or condition the right to work with a licensed physician to request an experimental treatment from a drug manufacturer outside of the clinical trial context. *See* Tricket Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina, Right to Try Act of 2017, Pub. L. No. 115-176 (May 30, 2018), *codified at* 21 U.S.C. § 360bbb-0a. Unlike a compassionate use programme, this requires less oversight from the FDA and is not available until the patient has tried all FDA-approved treatment options. 21 U.S.C. § 360bbb-0a(a)(1), (b). Further, the patient must be certified by a licensed physician to be unable to participate in a clinical trial involving the eligible drug. *Id.* § 360bbb-0a(a)(1)(B).

With respect to clinical trials more generally, companies can reduce risk of liability by ensuring that their trials are HIPAA-compliant and that they receive informed consent from each

patient. Informed consent is required for most clinical trials before entering into a clinical trial to ensure the patient understands the risks and benefits of the programme. *See generally* 21 C.F.R. Part 50; *Informed Consent for Clinical Trials* (Jan. 4, 2018), available at https://www.fda.gov/patients/clinical-trials-what-patients-need-know/informed-consent-clinical-trials. HIPAA allows companies to collect and share patient information with the clinical trial sponsors who seek that data. *See* 45 C.F.R. § 160.

7 Product Recalls

7.1 Please identify and describe the regulatory framework for product recalls, the standards for recall, and the involvement of any regulatory body.

The Consumer Product Safety Act ("CPSA"), as enforced by the Consumer Product Safety Commission ("CPSC"), governs recalls for certain consumer products in the United States. The CPSA establishes reporting requirements for manufacturers, importers, distributors, and retailers, who must give notice to CPSC if information reasonably supports the conclusion that the product fails to comply with a rule, contains a defect that could create a substantial product hazard, or creates an unreasonable risk of serious injury or death. CPSC staff will then determine if corrective action is necessary. Of course, a company may choose – for business reasons – to undertake a recall even if CPSC decides that such action is not necessary under its standards.

The FDA governs recalls of foods, drugs, and medical devices. The FDCA prohibits the manufacture, introduction, or delivery in interstate commerce of misbranded or adulterated food, drugs, or devices, and such products are subject to injunctions and seizures. 21 U.S.C. §§ 331(a)–(c), (g), 332, 334. The FDCA specifically provides the FDA with recall authority in a number of provisions, including with respect to: infant formula; information obtained through the reportable food registry which indicates reasonable probability that use or exposure to a misbranded or adulterated product will cause serious adverse health consequences to humans or animals; medical devices for which there is a reasonable probability of serious, adverse health consequences, or death; and certain controlled substances. *Id.* §§ 350a(e)–(f), 350(l), 360h(e), 360bbb-8d. General FDA regulations governing recalls can be found in 21 C.F.R. Part 7 Subpart C, while regulations specific to recalls for infant formula and medical devices may be found in 21 C.F.R. Parts 107, Subpart E, and 810 respectively.

7.2 What, if any, differences are there between drugs and medical devices or other life sciences products in the regulatory scheme for product recalls?

While the CPSA generally governs product recalls, more specific product categories are often governed by other federal agencies. Under 21 C.F.R. Part 7, Subpart C, the FDA has guidelines applicable to recalls of food (including dietary supplements), drugs, and medical devices. Generally, most recalls in the U.S. are voluntary, although the FDA may request that a firm recall certain products in urgent situations. *Id.* § 7.40(b). However, the FDA may seize products or impose civil or criminal penalties if the relevant party does not voluntarily recall the product following a request from the agency. *Id.* § 7.40(c). For voluntary recalls, the FDA would expect that a company follow its regulations and guidance, and coordinate the recall through the FDA District Office. *Id.* § 7.46(a). The FDA requests that firms recalling products submit periodic status reports specified by the FDA at an interval determined by the relative urgency of the recall. *See id.* § 7.53. A recall is terminated when the FDA determines, either on its own or at the firm's request, that all reasonable efforts have been made to remove or correct the product in accordance with a firm's recall strategy, and it is reasonable to assume that the product subject to the recall has been removed and proper disposition or correction has been made, commensurate with the degree of hazard posed by the recalled product. *Id.* § 7.42; *see id.* § 7.51.

As noted above, separate regulations apply to recalls of infant formula and medical devices. Medical device manufacturers and importers must report to the FDA any correction or removal of a medical device if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health, within 10 working days of initiating that correction or removal. *Id.* § 806.10(a)–(b). Further detailed regulations then apply. Under 21 C.F.R. § 810.18, the FDA must provide public notice of mandatory recalls. FDA regulations require status reports during the mandatory recall, and the recall may be terminated when the FDA determines, either on its own or at the firm's request, that the person has taken all reasonable efforts to ensure and to verify that all health professionals, device user facilities, consignees, and, where appropriate, individuals, have been notified of the "cease distribution and notification" order, and to verify that they have been instructed to cease use of the device and to take other appropriate action; or has removed the device from the market or has corrected the device so that use of the device would not cause serious, adverse health consequences or death. *See id.* § 810.17.

Infant formula manufacturers must immediately take all necessary actions to recall formula if the FDA determines that an adulterated or misbranded infant formula presents a risk to human health. *Id.* § 107.200. In addition, manufacturers must promptly notify the FDA of voluntary recalls of infant formula that otherwise violate laws or regulations administered by the FDA. *Id.* § 107.210(a). In either of these two cases, the recalling firm must notify the FDA by telephone within 24 hours of the determination that infant formula must be recalled, provide a written report within 14 days of the beginning of the recall, and provide status reports to the FDA at least every 14 days until the recall is terminated. *Id.* § 107.240. The FDA will terminate the recall unless the Agency has information from the FDA's own audits or from other sources demonstrating that the recall has not been effective. *Id.* § 107.250.

7.3 How do product recalls affect litigation and government action concerning the product?

Manufacturers often voluntarily recall products in order to obviate administrative procedures – such as seizure or injunction – provided by statute. Where a manufacturer fails to comply with a recall, agencies have both administrative and civil penalties at their disposal. For example, the FDCA prohibits the manufacture, introduction, or delivery in interstate commerce of misbranded or adulterated food, drugs, or devices. 21 U.S.C. §§ 331(a)–(c), (g). Products that are or should be subject to a recall are subject to injunctions and seizures, and manufacturers may be subject to civil or criminal penalties. *Id.* §§ 332, 33, 334, 335b.

Typically, the initiation of a recall is not a *per se* admission that a product is defective for purposes of civil tort litigation. Indeed, the CPSA recognises that the use and definition of "defect" are "not intended to apply to any other area of the law". 16 C.F.R. 1115.4. However, manufacturers may still rightly be concerned about juror assumptions in the face of recall evidence.

7.4 To what extent do recalls in the United States or Europe have an impact on recall decisions and/or litigation in the jurisdiction?

Recalls, wherever they occur, can provide evidence for plaintiffs' lawyers in U.S. litigation, but they can also help defendants fight against certain lawsuits. Some states prohibit the use of evidence of a recall to establish a product liability claim, on the ground that it is prejudicial. Even in jurisdictions that do allow evidence of a recall, however, the plaintiff still must show that the *individual* product the plaintiff used specifically caused the plaintiff's injuries.

While a manufacturer cannot defeat a product liability claim simply by issuing a recall, it is a defence for the manufacturer to show that the plaintiff received notice of the recall, that the recall adequately warned the plaintiff of the dangers of the product, and that the plaintiff still proceeded to use the product.

7.5 What protections does the jurisdiction have for internal investigations or risk assessments?

Internal investigations generally are not protected from disclosure. Product risk assessments or investigations conducted by counsel, however, arguably could fall under the attorney-client privilege. The reasoning is that these risk assessments result in legal advice to assist the company in deciding how a product fits within its business strategy.

Governmental agencies typically do not permit a company to protect its internal investigation from disclosure, particularly if the investigation uncovered product safety problems that are required to be reported to the authorities.

Some U.S. states have created the "self-critical analysis privilege", which protects documents created in internal investigations. The reasoning is based on the encouragement of companies to aggressively investigate accidents or possible regulatory violations without concern that they may create an incriminating record that could be used as evidence of liability against them in civil litigation. Where the privilege is recognised, it typically requires that:

1. the information in question results from critical self-analysis undertaken by the party seeking protection;
2. the public has a strong interest in preserving the free flow of the type of information sought;
3. the information is of the type whose flow would be curtailed if discovery was not allowed; and
4. the information was produced with the expectation that it would remain confidential.

7.6 Are there steps companies should take when conducting a product recall to protect themselves from litigation and liability?

Manufacturers should ask counsel to review and advise on all communications regarding the recall. Failure to provide enough information can lead to liability for negligent recall or negligent failure to warn in some jurisdictions. On the other hand, a company does not want to overreact on limited or incomplete information – use of the term "recall" may provide fodder for plaintiffs' lawyers even when the company is not itself positive that a defect exists.

Under most circumstances, manufacturers should be proactive. Waiting too long to issue a recall can, in some jurisdictions, give rise to unfair trade practice liability. By contrast, a robust recall, when appropriate, may help prevent lawsuits and sometimes defeat class certification in economic injury cases. For example, at least some courts have found that a class action is not appropriate where the company has already undertaken a robust recall that provides all of the relief to which a plaintiff may be entitled.

8 Litigation and Dispute Resolution

8.1 Please describe any forms of aggregate litigation that are permitted (i.e., mass tort, class actions) and the standards for such aggregate litigation.

In U.S. federal courts, three forms of aggregate litigation are permitted: (1) class actions; (2) aggregate litigation; and (3) multidistrict litigation ("MDL").

Class actions are lawsuits in which class representative(s) sue on behalf of a defined group of people or entities, which is called the "class". In federal court, class actions are governed by Federal Rule of Civil Procedure ("FRCP") 23, which imposes a number of requirements in order for a putative class to be "certified" to proceed as a class action. For class actions seeking damages, plaintiffs must establish the requirements of: (1) numerosity; (2) commonality; (3) typicality; and (4) adequacy pursuant to FRCP 23(a), and must also establish one of the requirements under FRCP 23(b), such as that common questions of law or fact predominate. In state courts, class actions are governed by state rules of procedure, which differ depending on the state although many are patterned on FRCP 23.

Plaintiffs may also file lawsuits with other persons, but not on behalf of an unnamed class, in "aggregate" litigation. For instance, a group of 300 people can file their lawsuit together assuming the facts and issues in dispute for each plaintiff are similar. Defendants can move to sever the claims if they believe the claims are too unrelated to be tried together. The primary difference between aggregate litigation and class actions is how the plaintiffs are treated. In aggregate litigation, each plaintiff is treated as an individual, which means that each plaintiff must participate in the litigation and must prove certain facts, including how the defendant injured that plaintiff. Each plaintiff's claim is then ultimately tried individually. In class actions where a class has been certified, it is presumed that the facts concerning the class representative's claim will prove the claims on behalf of the entire class, who need not appear in the case or participate in any way. The class representative's claim is therefore tried, and the result of the trial applies to the entire class.

MDL refers to a federal legal procedure that allows the pre-trial coordination in a single federal court of hundreds or thousands of federal court cases where the plaintiffs share common issues. The decision to create an MDL is made by the Judicial Panel on Multidistrict Litigation ("JPML") and MDLs are governed by 28 U.S.C. § 1407.

States may have their own class action or multi-county litigation rules.

8.2 Are personal injury/product liability claims brought as individual plaintiff lawsuits, as class actions or otherwise?

Personal injury and product liability claims involving physical injury or property damage typically are brought as individual claims, or in some cases, aggregate claims. Class actions are uncommon because these types of injuries are generally too individualised to permit class certification. Personal injury/product liability actions are often coordinated in federal courts under the JPML rules. State courts also have methods for coordination. *See* question 8.1.

8.3 What are the standards for claims seeking to recover for injuries as a result of use of a life sciences product? (a) Does the jurisdiction permit product liability claims? (b) Are strict liability claims recognised?

The standards are as follows:

(a) The United States permits product liability claims, and state law provides the elements of those claims. Plaintiffs can bring several different types of product liability claims, the most common of which is negligence, which requires proof that the defendant's breach of a duty proximately caused the plaintiff's injuries. The negligence may be related to, generally, the design of the product, the manufacturing process, or failure to warn.

(b) State law governs strict liability claims and therefore the availability of such a claim will depend on the jurisdiction in which the plaintiff sues. However, most states recognise strict liability claims in product liability cases. A strict liability claim does not require a plaintiff show that defendant breached a duty, but will still have to show a product defect that proximately caused the plaintiff's injuries. In certain cases involving products that cannot be made completely safe, the failure to warn may be considered the "defect", even if the product itself is not defective.

8.4 Are there any restrictions on lawyer solicitation of plaintiffs for litigation?

The American Bar Association's ("ABA") Model Rule of Professional Conduct 7.3 provides that lawyers may not "solicit professional employment from a prospective client" in person, by telephone, or by real-time electronic contact unless the person being solicited is a lawyer or has a "family, close personal, or prior professional relationship with the lawyer". A lawyer may, however, direct an advertisement for services to the general public, such as through a billboard, an internet banner advertisement, a website, or a television commercial; a lawyer may also respond to a request for information. States generally follow or adopt ABA Rule 7.3, although some may impose additional or different requirements.

8.5 What forms of litigation funding are permitted/utilised? What, if any, regulation of litigation funding exists?

Litigation funding, which is also known as legal financing or third-party litigation funding ("TPLF"), "refers to the funding of litigation activities by entities other than the parties themselves, their counsel, or other entities with a preexisting contractual relationship with one of the parties, such as an indemnitor or a liability insurer". ABA 20/20, p. 1. In the United States, such funding is generally permitted. However, some states, such as New York and Delaware, have found litigation funding arrangements to be a violation of champerty doctrines that aim to preclude frivolous litigation.

TPLF is generally not regulated, but certain jurisdictions have begun to establish requirements for disclosure of TPLF arrangements. For example, the United States District Court for the Northern District of California adopted a rule requiring the automatic disclosure of third-party funding agreements in proposed class action lawsuits. In addition, Wisconsin has adopted a rule requiring mandatory disclosure of third-party litigation financing agreements.

8.6 What is the preclusive effect on subsequent cases of a finding of liability in one case? If a company is found liable in one case, is that finding considered *res judicata* in subsequent cases?

The doctrine of *res judicata* prevents a party from litigating a legal claim that was or could have been the subject of a previously issued final judgment, where: (1) a final judgment on the merits in an earlier action has been entered; (2) the parties in the two actions are identical; and (3) the causes of action (ether in name or substance) in the two actions are identical. However, even if these three elements are satisfied, *res judicata* does not apply where the party opposing it did not have a full and fair opportunity to litigate the claim in the prior action.

Relatedly, "collateral estoppel" refers to the effect of a judgment in foreclosing litigation in a subsequent action of an issue of law or fact that has been actually litigated and decided. To establish collateral estoppel, a party must show: (1) that the issue at stake is identical to the one involved in the prior litigation; (2) that the issue has been actually litigated in the prior litigation; and (3) that the determination of the issue in the prior litigation has been a critical and necessary part of the judgment in that earlier action.

8.7 What are the evidentiary requirements for admissibility of steps a company takes to improve their product or correct product deficiency (subsequent remedial measures)? How is evidence of such measures utilised in litigation?

Federal Rule of Evidence 407 governs the admissibility of subsequent remedial measures and provides that "[w]hen measures are taken that would have made an earlier injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove" negligence, culpable conduct, a defect in a product or its design, or a need for a warning or instruction. Evidence of subsequent remedial measures, however, is admissible and may be used: (1) to demonstrate ownership, control, or feasibility of precautionary measures; (2) to impeach a witness; and (3) if the measure was required by a government authority.

State law on admissibility of subsequent remedial measures varies by state, although many have adopted language akin to Rule 407.

8.8 What are the evidentiary requirements for admissibility of adverse events allegedly experienced by product users other than the plaintiff? Are such events discoverable in civil litigation?

Adverse event reports ("AERs") are generally discoverable in civil litigation. AERs may not be admissible, however, to the extent they are "hearsay" evidence or are determined to be more prejudicial than probative (*e.g.*, if a large number of AERs implies a defect in the product when the reports offer no proof that a defect exists). In addition, some states recognise a "self-critical analysis privilege" (discussed above) which prevents the admission of AERs at trial. Some courts will still admit AERs to (1) establish that the defendant knew its product was associated with a particular risk but failed to provide consumers with a warning of that risk, (2) assist a jury in assessing punitive damages, or (3) explain the basis for an expert's opinion presented at the trial.

8.9 Depositions: What are the rules for conducting depositions of company witnesses located in the jurisdiction for use in litigation pending outside the jurisdiction? For example, are there "blocking" statutes that would prevent the deposition from being conducted in or out of the jurisdiction? Can the company produce witnesses for deposition voluntarily, and what are the strategic considerations for asking an employee to appear for deposition? Are parties required to go through the Hague Convention to obtain testimony?

Under FRCP 30(b)(6), a party may name as a deponent a company or other organisation and describe with reasonable particularity the matters for examination. The named organisation must then designate one or more persons who consent to testify on its behalf on the matters for examination, and who must be educated to provide testimony on the identified topics. If the named organisation is a party to the litigation, no subpoena is required.

By contrast, a party must subpoena company employees if their testimony is sought in their individual capacity (unless the parties agree to waive subpoena requirements). FRCP 45 governs such subpoenas. FRCP 45 provides that all subpoenas must be issued out of the court where the case is pending and that a subpoena may only command a person to attend a trial hearing or deposition:

- within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
- within the state where the person resides, is employed, or regularly transacts business in person, if the person: (i) is a party of a party's officer; or (ii) is commanded to attend a trial and would not incur substantial expense.

Depositions of foreign witnesses are governed by FRCP 28, which permits litigants in federal court to take depositions in a foreign country under an applicable treaty or convention, under a letter of request, on notice, or before a person commissioned by the court to administer any necessary oath and take testimony. For example, if litigants in the United States wish to depose a European witness, the litigant must comply with the Hague Convention.

The United States does not have blocking statutes that would prevent a deposition in U.S. litigation from being conducted in or out of the country.

8.10 How does the jurisdiction recognise and apply the attorney-client privilege in the context of litigation, and with respect to in-house counsel?

In general, the attorney-client privilege protects communications between a lawyer and client (or the client's agent) made in confidence and for the purpose of obtaining or providing legal assistance to the client. The privilege applies to communications with in-house counsel as well as outside counsel, as long as the counsel is requesting or providing legal assistance (as opposed to business advice). State court privilege law is generally similar, although there may be some differences. For example, some states recognise a privilege only when communications are between counsel and the client's "control group" of employees, rather than all employees.

8.11 Are there steps companies can take to best protect the confidentiality of communications with counsel in the jurisdiction and communications with counsel outside the jurisdiction for purposes of litigation?

The best practice for protecting communications with counsel is to ensure that the communications remain confidential and limited to only those who have a need to communicate with counsel. The more non-lawyers involved in a communication, the less likely the communication is to be considered privileged. For communications with counsel outside the United States, the best practice would be to understand the privilege law of the two different jurisdictions and comply with the practice of the less protective jurisdiction.

8.12 What limitations does the jurisdiction recognise on suits against foreign defendants?

The requirement of personal jurisdiction is the primary limitation on suits against foreign defendants. Personal jurisdiction refers to the power that a court has over a party being sued in a case. Before a court can exercise power over a party, the United States Constitution requires that the party have certain minimum contacts with the forum in which the court sits. Accordingly, foreign defendants may seek dismissal of U.S. lawsuits in which they are named on grounds that the court does not have personal jurisdiction over them. Generally, a court will only have personal jurisdiction over a foreign entity if that entity is doing substantial business in the state such that it is essentially "at home" in the U.S. state ("general jurisdiction") or undertook some specific action in the U.S. state that is directly related to the allegations of the Complaint ("specific jurisdiction").

8.13 What is the impact of U.S. litigation on "follow-on" litigation in your jurisdiction?

This is not applicable.

8.14 What is the likelihood of litigation evolving in your jurisdiction as a result of U.S. litigation?

This is not applicable.

Note

The views expressed in this article are exclusively those of the authors and do not necessarily reflect those of Sidley Austin LLP and its partners. This article has been prepared for informational purposes only and does not constitute legal advice. This information is not intended to create, and receipt of it does not constitute, a lawyer-client relationship. Readers should not act upon this without seeking advice from professional advisers.

Acknowledgments

The authors would like to thank the following additional Sidley lawyers for their contributions to this article: Kate Heinzelman (Washington, D.C.); Rebecca K. Wood (Washington, D.C.); Diane C. McEnroe (New York); Carlo Felizardo (Washington, D.C.); Lauren Keane (Chicago); Rachel L. Hampton (Chicago); Bridget L. Murphy (Chicago); Matt Binder (Chicago); Bojan Manojlovic (Chicago); Jamie M. Sadler (Washington, D.C.); Deeona R. Gaskin (Washington, D.C.); Justin R. Becker (Washington, D.C.); Julie Becker (Chicago); Alan E. Rothman (New York); and Tatiana K. Fields (Los Angeles).

Alycia A. Degen focuses on the defence of class actions, product liability and mass tort litigation and complex civil and appellate litigation. She has experience in the areas of pharmaceuticals, medical devices, over-the-counter drugs and dietary supplements and other consumer products and services, as well as defending these companies against consumer fraud and unfair competition class actions. Alycia was recommended in *The Legal 500 US* in 2015 and 2016 for Litigation, Product Liability and Mass Tort Defense.

Sidley Austin LLP
55 West Fifth Street
Los Angeles, CA, 90013
USA

Tel: +1 213 896 6682
Email: adegen@sidley.com
URL: www.sidley.com

Heidi Levine is global co-leader of Sidley's Product Liability and Mass Torts practice. She defends companies in a range of product liability and mass tort litigation involving pharmaceutical drugs, medical devices, toxic torts and other products. Heidi most often acts as lead national litigation counsel in the mass tort context, representing clients in multidistrict litigation proceedings and related litigation. Heidi has earned notable recognition by *Chambers USA*, *The Legal 500* and *The American Lawyer*, among many others.

Sidley Austin LLP
787 Seventh Avenue
New York, NY, 10019
USA

Tel: +1 212 839 7366
Email: hlevine@sidley.com
URL: www.sidley.com

Kara L. McCall focuses her practice on the defence of companies in class action litigation, product liability and mass torts, and commercial litigation and disputes. Kara regularly represents life sciences companies and has successfully participated in the defence of pharmaceutical companies in class actions and multi-district proceedings. Kara has earned recognition from *Law360*, *The National Law Journal*, *The Legal 500* and *BTI Consulting* and was awarded for products liability in *Who's Who Legal: Life Sciences*.

Sidley Austin LLP
One South Dearborn
Chicago, IL, 60603
USA

Tel: +1 312 853 2666
Email: kmccall@sidley.com
URL: www.sidley.com

Andrew B. Talai is a member of Sidley's Supreme Court and Appellate and Commercial Litigation and Disputes practices. Andrew represents individual and corporate clients at all stages of litigation, with particular emphasis on appeals and critical motions. He has experience handling major cases that present challenging legal questions, including issues of constitutional law, statutory interpretation and administrative law.

Sidley Austin LLP
555 West Fifth Street
Los Angeles, CA, 90013
USA

Tel: +1 213 896 6148
Email: atalai@sidley.com
URL: www.sidley.com

Sidley comprises a diverse group of legal professionals who are dedicated to teamwork, collaboration and superior client service. Forging enduring relationships with the business community, while remaining attuned to the dynamic legal landscape, we understand and work to fulfil the needs of our global clients. We are proud to serve this high-calibre group of market leaders. The firm has built a reputation for successfully representing clients on complex transactional, regulatory and litigation matters spanning a range of legal areas. From our offices in the commercial, financial and regulatory centres of the world, we harness our knowledge to provide thoughtful advice for the myriad legal and business challenges that our clients face. We believe in creating opportunities for people of all backgrounds by retaining and promoting outstanding lawyers who reflect the global marketplace and communities we serve. Our dedication to achieving greater diversity and inclusivity extends beyond our firm to the legal profession as a whole.

www.sidley.com

SIDLEY

ICLG.com

Other titles in the ICLG series

Alternative Investment Funds
Anti-Money Laundering
Aviation Finance & Leasing
Aviation Law
Business Crime
Cartels & Leniency
Class & Group Actions
Competition Litigation
Construction & Engineering Law
Consumer Protection
Copyright
Corporate Governance
Corporate Immigration
Corporate Investigations
Corporate Recovery & Insolvency
Corporate Tax
Cybersecurity
Data Protection
Derivatives
Designs
Digital Business
Digital Health
Employment & Labour Law
Enforcement of Foreign Judgments
Environment & Climate Change Law
Family Law
Financial Services Disputes
Fintech
Foreign Direct Investment Regimes
Franchise
Gambling
Insurance & Reinsurance
International Arbitration
Investor-State Arbitration
Lending & Secured Finance
Litigation & Dispute Resolution
Merger Control
Mergers & Acquisitions
Mining Law
Oil & Gas Regulation
Outsourcing
Patents
Pharmaceutical Advertising
Private Client
Private Equity
Product Liability
Project Finance
Public Investment Funds
Public Procurement
Real Estate
Sanctions
Securitisation
Shipping Law
Telecoms, Media & Internet
Trade Marks
Vertical Agreements and Dominant Firms
Workplace Pensions

@ICLG_GLG

The International Comparative Legal Guides are published by:

global legal group