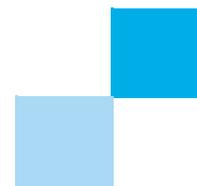


Medical technology multinationals and the US - navigating the regulatory framework



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Multinational pharmaceutical, biotechnology, and medical device manufacturing companies are generally accustomed to navigating the varying frameworks for doing business in multiple European countries. Additional layers of complexity, however, arise for these companies when doing business in the US, where they face a host of different regulatory and litigation challenges imposed by Congress, federal agencies, state legislatures, state agencies and courts.

Understanding and protecting against the risks raised by this complex legal environment requires substantial education in, and ongoing monitoring of, applicable requirements and prohibitions, the purposes behind them, the relevant regulatory and enforcement bodies, and the administrative and judicial mechanisms of enforcement.

At the federal level, companies must contend with the Food and Drug Administration, the Federal Trade Commission, the Center for Medicare and Medicaid Securities, the Office of the Inspector General in the Department of Health and Human Services, the Department of Justice (including the Attorney General, the US Attorney's Offices, the Federal Bureau of Investigation and the Drug Enforcement Administration), and also with the federal court system.

In addition, companies face an assortment of players at the state level, including state Attorneys General, state regulatory bodies with similar missions to those of the relevant federal agencies, and state courts. And because private individuals and groups enjoy open access to both the federal and state court systems, their actions as litigants can lead to new legal principles as well as liabilities.

Beyond the authorities that may impose legal sanctions, there are risks posed by exposure to adverse publicity associated with the regulatory requirements and prohibitions. If the public perceives a medical products company as having violated laws to protect health and safety, the damage to the company's reputation can well outweigh any actual legal sanctions imposed for a violation.

Against this background, this chapter provides an overview of the relevant US requirements at both the federal and state levels, highlighting the key enforcement bodies and mechanisms, and the circumstances in which legal liability may arise.

KEY FEDERAL PROGRAMMES AND LAWS

The Food and Drug Administration

The Food and Drug Administration (FDA), an agency within the US Department of Health and Human Services (HHS), is the gatekeeper to the US medical provider marketplace. The FDA must approve or

clear for marketing all new drugs and medical devices intended for sale in the US. However, its regulatory control does not end once a drug or device receives marketing approval. The FDA continues to exert its regulatory control post-approval and primarily does so in three areas: product quality, product promotion, and product safety assurance.

If a company, based in the US or elsewhere, violates the FDA's post-approval requirements, it can be subject to civil and criminal legal liability. The FDA may initially encourage the company to correct the problem voluntarily, for example, by recalling non-compliant products from the market. However, if companies do not voluntarily comply with FDA regulations, the FDA may resort to enforcement via legal sanctions. Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the FDA has the authority to seek (or in some cases to impose directly) a variety of civil sanctions and to initiate criminal prosecutions, which can target both companies and responsible individuals. Possible civil sanctions available to the FDA include warning letters, product seizure, injunctive actions, and civil monetary penalties.

Product quality (GMPs/QS). The FDA's philosophy is that product testing alone cannot ensure quality. The manufacturing process itself must be adequately controlled to ensure that a facility is manufacturing products that are both safe and effective. The FDA's requirements for product quality are known as Good Manufacturing Practices (GMPs) and are set out in the Drug GMP or Device Quality System (QS) regulations. These requirements apply to non-US manufacturing facilities if the manufactured drugs and devices are intended for sale in US markets, irrespective of whether the facility is owned by a US or non-US entity. In such cases, the FDA reserves the right to block the import of goods from non-compliant facilities.

GMPs provide standards in the following areas:

- Quality management and organisation.
- Buildings.
- Equipment.
- Production and process controls.
- Packaging and labelling controls.
- Product evaluation.
- Product distribution.

- Complaint handling.
- Servicing.
- Records.

Each manufacturer must determine the most effective methods for achieving compliance, as GMPs do not specify how manufacturers must obtain quality objectives.

The FDA inspects manufacturing facilities located outside the US according to the same standards (but with less frequency) as those within the US. If a foreign supplier site is non-compliant, the FDA may simply refuse to admit the goods into the US.

Recently, the FDA has obtained court orders to compel companies to forfeit allegedly ill-gotten profits from inadequate product quality operations. Schering-Plough gave up US\$500 million (about EUR390 million) in one such case.

Product promotion. The FDA also regulates the advertising and promotion of products within its jurisdiction in conjunction with the Federal Trade Commission (FTC) (*see below, Federal Trade Commission*). The FDA directly regulates the promotion of prescription drugs and prescription-type devices (known as restricted devices), while the FTC regulates the promotion of products such as over-the-counter drugs and non-restricted devices.

The FDA regulates product promotion materials, including the actual label on the product, as well as documents accompanying the product, such as brochures, booklets, calendars, and price lists, regardless of whether the material is physically attached to or distributed with the product. It also regulates product advertising, defined as "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through the media such as radio, television, and telephone communication systems."

Prescription drug advertisements must contain, among other things, "information in brief summary relating to side effects, contraindications, and effectiveness". Advertisements for restricted devices must include information about the "intended uses of the device and relevant warnings, precautions, side effects, and contraindications". All promotional materials must fairly balance benefit and risk information. Most drug and device promotion and advertising is not pre-approved. Instead, the FDA monitors drug and device advertisements for compliance and brings enforcement actions when violations are found.

A practice known as "off-label promotion" presents a particular pitfall for drug and device manufacturers. If a manufacturer promotes its product for a use that is not FDA-approved, such promotion qualifies as "off-label," and may lead to liability for introducing an unapproved or misbranded drug or device into commerce. For example, when Warner-Lambert promoted Neurontin, an epilepsy drug, for conditions such as migraine headaches and bipolar disorder, the company was at risk of FDA sanctions, as well as parallel action by the Office of Inspector General of HHS (OIG) for violations of the False Claims Act. Ultimately, Warner-Lambert concluded a settlement with the government for US\$430 million (about EUR335 million), which included a US\$240 million (about EUR187 million) criminal fine.

Adverse event reporting. The FDA requires that reports of adverse drug experiences and adverse medical devices reports be filed within certain time frames following the manufacturer's discovery of the events, depending on the severity of the event and labelling on the product; and they must be reported regardless of whether they occur in or outside the US. As one example of enforcement in this area, Hoechst AG, a non-US company, received FDA approval to market Merital (nomifensine maleate) for the treatment of clinical depression in 1984. Merital hit US markets in July 1985, but was withdrawn in January 1986 because of fatal hemolytic anemia associated with the drug.

Subsequently, the FDA learned that Hoechst AG knew of, but did not report - or cause Hoechst Roussel (its US subsidiary) to report - fatalities occurring before Merital's US approval. In December 1990, the US government criminally prosecuted Hoechst AG (but not Hoechst Roussel) and the Director of Hoechst AG's Clinical Research Division.

Department of Health and Human Services, Office of the Inspector General

Fraud, abuse and kickbacks. The federal anti-kickback statute is the US government's primary weapon in fighting fraud against Medicare, Medicaid, and other federal health care programmes. Its purpose is to prevent inappropriate financial incentives from influencing the medical care received by federal health care programme beneficiaries. The law is extremely broad and applies to many financial activities and relationships. It prohibits anyone from knowingly and wilfully offering, paying, soliciting, or receiving anything of value to induce or reward the purchasing, prescribing, or recommending of any item or service reimbursable by a federal healthcare programme.

Under the statute, both parties to a prohibited "kickback" are at equal risk. Giving anything of value to a customer (or potential customer) is illegal if done with "improper" intent to induce, reward, or generate business or potential business. Such "improper" intent need not be the sole, or even the primary, purpose for the gift - even if it is just one of several purposes it may render the gift illegal.

The anti-kickback statute imposes criminal, civil, and administrative penalties. Criminal violations, prosecuted by the US Department of Justice, are punishable by fines of up to US\$25,000 (about EUR19,000) and/or imprisonment for up to five years. The HHS OIG may also seek civil monetary penalties. Further, a provider may be excluded from Medicare, Medicaid, or other federal health care programmes, so that the government will not pay for any of the company's products.

Both Congress and the OIG have established several safe harbours for certain practices, including payments to bona fide employees and properly reported discounts. In addition, the OIG has provided guidance on navigating the statute, by issuing Special Fraud Alerts, Compliance Program Guidances, and Advisory Opinions. Several trade associations and professional organisations have also published guidance, including the Pharmaceutical Research and Manufacturers of America, AdvaMed, and the American Medical Association.

The anti-kickback statute has resulted in major fines or settlements not only for many hospitals and physicians, but also for several major pharmaceutical and medical device companies, including Schering-Plough, AstraZeneca and TAP.

Corporate integrity agreements. Corporate integrity agreements (CIAs) are agreements between the HHS OIG and health care providers that settle civil and criminal allegations of health care fraud and abuse. Providers enter into CIAs in exchange for the OIG's agreement not to use its authority to exclude them from participating in federal health care programmes. The duration of most CIAs is generally three to five years, but it can be longer depending on the severity of the fraud, and it can also be extended for subsequent violations.

Although the terms of each CIA differ, the OIG generally imposes a requirement that the company establish a comprehensive compliance programme modelled on the OIG's Compliance Program Guidance for the provider's industry. Such programmes generally require that the company:

- Appoint compliance officers.
- Develop a formal written compliance programme.
- Routinely audit and monitor the company's practices, policies, and procedures.
- Train employees on compliance.
- Review all claims submitted to federal health care programmes.

And, perhaps most importantly, the CIA usually requires companies to self-report violations (or suspected violations) to the OIG.

The OIG monitors hundreds of health care providers, practitioners, suppliers, payors, and other entities operating under CIAs. Among the companies that currently are subject to CIAs are Abbott Laboratories, Bayer, Endovascular Technologies, GlaxoSmithKline, Guidant Corporation, Medtronic, Pfizer, Schering-Plough and TAP Pharmaceutical Products.

US Attorneys' offices and private actions

The False Claims Act (FCA) is frequently used to combat fraud and abuse against the government. The FCA prohibits any person or entity from knowingly submitting a false or fraudulent claim for payment to Medicare, Medicaid, or any other federal health care programme. The Act imposes civil penalties of between US\$5,500 (about EUR4,287) and US\$11,000 (about EUR8,574) per false claim, plus three times the amount of damages sustained by the government.

The FCA encourages private whistleblowers (*qui tam* relators) to file a lawsuit on behalf of the government. At its discretion, the Department of Justice can intervene and assume responsibility for the lawsuit. If the suit succeeds, the whistleblower can receive 15% to 25% of the damages and penalties recovered, depending on his contribution to the case. Some whistleblower recoveries have exceeded US\$50 million (about EUR39 million).

The FCA requires the government or *qui tam* relator to prove that the defendant "knowingly" submitted false claims. "Knowledge" includes actual knowledge, a reckless disregard for the truth, or deliberate ignorance - a much more lenient standard than under the anti-kickback statute. It is not necessary to prove a specific intent to defraud; it is enough to prove that the defendant knew or should have known that its actions were improper. The burden of proof is "a preponderance of the evidence," which is also more lenient than most criminal statutes.

There has been a large increase in *qui tam* cases in the past several years. The pharmaceutical industry has been hit with significant fines and settlements for "causing" false claims to be submitted, even though companies did not directly submit payment claims to the government. Recent enforcement actions have involved Bayer, GlaxoSmithKline, Pfizer and Schering-Plough.

Congress has encouraged states to pass similar laws by promising to provide an extra 10% of recovery in successful state Medicaid fraud suits. Eleven states and the District of Columbia maintain such FCAs, and several other states are considering them.

Securities Exchange Commission and private securities litigation

The Securities Exchange Commission (SEC) has broad authority over all aspects of the securities industry, including regulation of all non-US issuers of securities registered in the US. Under the Securities Exchange Act, issuers must provide investors with financial and other information concerning securities being offered for public sale. They are liable for any misrepresentations or other fraud in the sale of securities. The Act provides the SEC with disciplinary powers over regulated entities and persons associated with them, and also requires companies with publicly traded securities to file periodic reports.

These rules are relevant to SEC-regulated medical products manufacturers, who frequently advise the public about progress in research and development, regulatory status, or projected sales of key products. Such statements have become the basis for litigation, on the argument that they failed to disclose material information or were simply false.

The SEC Division of Enforcement investigates possible violations and recommends SEC action when appropriate, either in a federal court or before an administrative law judge. Although the SEC has civil enforcement authority only, it works closely with various criminal law enforcement agencies throughout the country to develop and bring criminal cases when the misconduct warrants more severe action.

In addition to the SEC, plaintiffs in private securities litigations and prosecutors may bring civil and criminal actions for securities laws violations, including actions against foreign medical technology companies. Such actions may be brought on a number of different bases, including for:

- False and misleading statements over the safety and efficacy of a drug.
- Misrepresentations regarding drug trials and manufacturing.

- Misrepresentations over FDA approval status.
- Improper financial accounting.

The penalties for violating the securities laws can be substantial. In private litigation, plaintiffs can obtain monetary damages. In SEC civil enforcement actions, the SEC can, among other things, obtain injunctions, civil monetary penalties, and/or disgorgement of illegal profits. A court can also order a defendant to undergo audits and submit to special supervisory arrangements, and can also bar or suspend an individual from serving as a corporate officer or director. In SEC administrative proceedings, a company can be subject to:

- Cease and desist orders.
- Suspension or revocation of broker-dealer and investment adviser registrations.
- Censures.
- Bars from association with the securities industry.
- Payment of civil monetary penalties.
- Return of illegal profits.

The SEC also has the power under the securities laws to suspend trading in any stock for up to ten trading days.

Federal Trade Commission

FTC jurisdiction. The mission of the FTC is to ensure competitive US markets and to protect consumers from unfair trade practices, including false advertising. The FTC derives its authority to regulate drug or device advertising from the Federal Trade Commission Act (FTC Act), which prohibits false or deceptive advertising and the dissemination of any false or misleading advertisement. An advertisement is "misleading" in this context not only if it makes deceptive claims, but also if it fails to provide material information, is unfair, or makes a claim for which the advertiser does not have a reasonable basis.

For more than 30 years, the FTC has worked with the FDA under a Memorandum of Understanding (MOU) with respect to shared regulatory and enforcement jurisdiction over the advertising of drug products. The MOU grants the FDA primary regulatory responsibility over prescription drug advertising, and grants the FTC primary regulatory responsibility for over-the-counter drug advertising. However, even though the FDA's jurisdiction over prescription drugs advertising is primary does not mean that its jurisdiction is exclusive. If the FDA fails to act, the FTC can exercise its authority under the FTC Act.

The Lanham Act. The Lanham Act permits a company to sue a competitor that uses a promotional claim likely to mislead physicians or patients by misrepresenting the nature, characteristics, or qualities of its own or the competitor's products. The Act prohibits advertising messages that are false, literally true but have a tendency to deceive, or unsubstantiated. A successful Lanham Act plaintiff can obtain an injunction (stopping the campaign or requiring corrective advertising), as well as monetary damages (including return of profits, attorneys fees, and treble damages).

Advertising subject to the Lanham Act is not limited to "traditional" advertising (for example, magazine and television advertisements), but also includes verbal claims by sales representatives, website postings, e-mails, patient brochures, and patient testimonials. A single misleading promotional presentation to an individual purchaser may be enough to trigger liability under the Act.

Pharmaceutical companies have been caught under the Lanham Act for many types of claims, including downplaying the risk of side effects, overstating product efficacy, and making comparative claims in the absence of head-to-head data. For example, Johnson & Johnson violated the Lanham Act because its slogan "Nighttime Strength" for its antacid product implied that the product was specifically formulated for nighttime heartburn, but the company did not have advance substantiation for that claim.

Liability under the Lanham Act can trigger further litigation. For example, after a New York federal court issued an injunction prohibiting Pfizer from advertising the mouthwash Listerine as being "as effective as dental floss" in reducing the risk of gingivitis, consumer class actions were filed in almost a dozen jurisdictions around the country targeting the same advertising.

Department of Justice

Foreign Corrupt Practices Act. The Foreign Corrupt Practices Act (FCPA) is a far-reaching statute designed to prevent US involvement in "corrupt" activities with respect to commercial business outside the US. Under the FCPA, US companies (as well as their foreign subsidiaries and other foreign persons or entities in certain circumstances) and companies whose securities are registered on a US national securities exchange (issuers) are prohibited from corruptly making or offering to make payments to foreign officials for the purpose of gaining influence to obtain or retain business. The statute also prohibits the giving of false, misleading, or incomplete statements to auditors and has strict bookkeeping requirements.

The statute applies not just to foreign company issuers, but also to any foreign national who takes any action within US territory in furtherance of bribery of a foreign official. The action taken within US territory may be minimal and yet still be "in furtherance" of bribery elsewhere, creating a substantial risk of FCPA violations for any non-US company that has operations or connections in the US.

Courts have broadly interpreted the FCPA's reference to corrupt payments made for purposes of "obtaining or retaining business". For example, payments to obtain special governmental approvals or favourable tax results would violate the FCPA. However, the statute takes into account that not all payments to foreign governments are made "corruptly", and it therefore permits certain routine "facilitating payments" (commonly referred to as "grease payments"), such as those made for the purposes of obtaining permits or licences to qualify a company to conduct business or for processing visas. Certain other payments properly made, such as contributions to foreign political parties or candidates, are also not deemed "corrupt".

The FCPA provides two specific affirmative defences to charges of an illegal payment:

- That the payment was lawful under the written laws of the subject foreign country.
- That the payment was for a reasonable and bona fide expense (such as travel and lodging) directly related to the promotion, demonstration or explanation of products or services, or the execution or performance of a contract with a foreign government.

The penalties for violating the FCPA's anti-bribery provisions, administered by the Department of Justice, are severe. An issuer or domestic company that is not a natural person is subject to criminal fines of up to US\$2 million (about EUR1.6 million) per violation and civil penalties of up to US\$10,000 (about EUR7,800). With respect to employees or agents acting on behalf of issuers or domestic companies (including both US and non-US nationals), such individuals who wilfully violate the FCPA can be liable for up to US\$10,000 in civil penalties and up to US\$100,000 (about EUR78,000) in criminal fines, and can be imprisoned for up to five years. Any fines incurred by individuals cannot be paid, either directly or indirectly, by the issuer or domestic companies represented in connection with the violation.

In addition, a person or firm found guilty of, or in some cases, simply indicted for, violating the FCPA can be ruled ineligible to receive export licences, and can be barred from doing business with agencies of the federal government, including the SEC, the Commodity Futures Trading Commission, and the Overseas Private Investment Corporation. Further, such violations can give rise to a private cause of action for treble damages under the Racketeer Influenced and Corrupt Organizations Act (RICO), or to actions under other federal or state laws.

Health information privacy rules

As part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress adopted "Administrative Simplification" provisions designed to improve the efficiency and effectiveness of the health care system. Under these provisions, HHS has issued a series of regulations, including a complex regulation governing the privacy of personal health information (Privacy Rule).

The Privacy Rule prohibits certain types of health care entities (covered entities) from using or disclosing a patient's individually identifiable health information (protected health information, or PHI) without a written authorisation from the patient, unless the use or disclosure falls within a specific exception set out in the Privacy Rule. These covered entities (all limited to entities within the US) are health plans, healthcare clearinghouses, and healthcare providers that transmit health information in electronic form for certain specified purposes.

Because pharmaceutical companies generally are not any of these types of covered entities (at least in the clinical research context), they themselves are rarely directly subject to the Privacy Rule. However, the Privacy Rule still has an impact on pharmaceutical companies with respect to obtaining PHI from covered entities, such as principal investigators and trial sites. The Privacy Rule provides

some flexibility in this context, including by exempting certain research-related disclosures of PHI from the general requirement for a prior individual authorisation. Such disclosures are permissible for any of the following:

- Reviews preparatory to research.
- Research on decedents.
- Pursuant to an Institutional Review Board or "Privacy Board" waiver of the authorisation requirement.
- As needed to protect public health and safety, including by adverse event reporting.

Other than the four research-related exemptions from the individual authorisation requirement, the Privacy Rule also permits researchers or research sponsors to obtain certain PHI without individual authorisation by entering into a "data use agreement", that will allow them to obtain PHI from a covered entity in the form of a "limited data set." To qualify for inclusion in a limited data set, PHI must be stripped of all "direct identifiers" of the individual involved, as well as of any relatives, employers, or household members of that individual. The data use agreement between the covered entity and the recipient of the limited data set strictly limits the recipient's use and further disclosure of the information contained in the limited data set.

The Privacy Rule also limits pharmaceutical companies' ability to obtain or use PHI for marketing purposes. Marketing means making a communication about a product that encourages the purchase of the product, but does not include communications that recommend alternative "treatments" to an individual. Under the Privacy Rule, the only uses or disclosures of PHI for marketing that can be made without an authorisation are those attendant to either:

- A face-to-face communication (such as when a physician provides a patient with a free drug sample).
- The provision of a promotional gift of nominal value (such as a pen or similar item).

HHS is responsible for civil enforcement of the Privacy Rule and can impose fines of up to US\$100 (about EUR78) per violation and up to US\$25,000 (about EUR19,000) per person for violations of a single standard during a calendar year. As a practical matter, HHS takes a responsive rather than proactive approach to enforcing the Privacy Rule, relying on complaints from aggrieved persons to identify possible violations. Where possible, the agency seeks to resolve complaints through a process of conciliation, rather than imposing punitive measures.

The Department of Justice has enforcement authority with respect to criminal violations of the Privacy Rule, which occur when a person "knowingly and in violation of [the Privacy Rule] (1) uses or causes to be used a unique health identifier, (2) obtains individually identifiable health information relating to an individual, or (3) discloses individually identifiable health information to another person." A person found criminally liable can be fined as much as US\$250,000 (about EUR195,000), imprisoned for up to ten years, or both. To date, the Justice Department has pursued relatively few criminal enforcement proceedings under the Privacy Rule.

In addition to the federal Privacy Rule, all of the states impose restrictions on the use and disclosure of individually identifiable health information. Although most such restrictions currently do not specifically apply to drug or device manufacturers, California and several other states have recently enacted laws that do directly restrict those manufacturers' actions, such as in the context of clinical trials and marketing. HIPAA does not preempt any such state laws that are more protective of individual privacy.

STATE PROGRAMMES AND LAWS

State laws on marketing, promotion and related practices

State laws restricting the marketing or promotional activities of prescription drug or medical device manufacturers create a complicated framework within which manufacturers must operate. The regulatory schemes between states differ, and manufacturers must tailor their marketing and promotional initiatives to individual state requirements.

California, the District of Columbia, Iowa, Maine, Minnesota, Rhode Island, Vermont, and West Virginia currently have laws relating to the marketing and promotion of prescription drugs, most of which require manufacturers to provide the state with reports on gifts or marketing expenses. Others prohibit gifts or restrict direct-to-consumer advertising. A number of the laws authorise the state to bring an action and impose a civil penalty (up to US\$10,000 (about EUR7,800) in Vermont) for failure to comply with the reporting requirements. Several other states have legislation pending to address various aspects of drug and device marketing.

Disclosure of clinical trials

Maine is currently the only state that has enacted a law requiring prescription drug manufacturers to register clinical trials on a public website and to disclose the results of the trial. The required information includes the name of the entity conducting the trial, a summary of the trial's purpose, the dates of the trial, and information concerning the trial's results. The Maine law quickly captured the attention of lawmakers in other states, and many other state legislators have proposed similar legislation. Most such legislation makes no reference to specific types of clinical trials, but a few bills limit the reporting requirement to trials conducted in a public facility or trials requiring IRB approval.

Under federal law, a clinical trial must only be registered if it is for "serious or life-threatening diseases and conditions" and is conducted under the FDA's investigational new drug regulations. However, Congress is currently considering two clinical trial registry bills, both of which would require a clinical trial registry and results database, and one of which would explicitly preempt any state law relating to a clinical trial registry or database. Given recent publicity and pressure surrounding new drug approvals, the passage of such federal legislation seems quite likely in the relatively near future.

Product liability

Medical technology companies may be subject to state product liability laws through state "long arm" statutes, which permit states to exercise jurisdiction over an out-of-state (or foreign) defendant

who has sufficient contacts with the forum state. Jurisdiction on this basis is the basic prerequisite to a court action on a state law product liability claim.

A manufacturer that is subject to a court's jurisdiction with respect to product liability claims could be liable for any of the following three primary types of claims based on negligence, strict liability, or breach of warranty theories:

- Inadequate warnings, relating to improper instructions or failures to warn of dangers of the product.
- A design defect, meaning the product is inherently dangerous and unfit for its intended use even though it may actually work well.
- A manufacturing defect, occurring during the production process and usually limited to individual items in production.

The most frequent type of claims are for inadequate warnings. Manufacturers have a general duty to adequately warn users of their products' dangers. Although a manufacturer typically will be deemed liable only for known risks of harm, it has a duty to keep informed of the current scientific, technical, and medical information that is reasonably available. Courts have frequently found that, once a manufacturer becomes aware of a product's danger, it has a post-sale duty to warn the product's users.

Manufacturers must provide warnings not only for dangers arising from the intended use of the product as offered by the manufacturer, but also for dangers arising from possibly foreseeable misuse. In many jurisdictions, a manufacturer may discharge its duty to warn by providing the necessary warning to a learned intermediary, such as a prescribing physician, or a sophisticated user in cases where the product is intended for knowledgeable users or professionals.

Medical technology companies must take into account such product liability risks, which are potentially among the most costly of liability risks. Merely satisfying the requirements of federal regulators, such as the FDA, is generally not sufficient to assure that a manufacturer will be free from liability to consumers. To help minimise the risks of such liability, companies should develop systems and procedures to remain informed of developments in various product liability laws, and continually educate themselves on the types of claims that generate the most risk.

LESSONS LEARNED

The multiple and overlapping regulatory, liability, and enforcement schemes in the US are a serious challenge for medical technology companies marketing to US consumers or otherwise engaging in commerce in the US. Compliance programmes built for only one or two regulatory systems may not provide adequate protection. A comprehensive compliance programme is a critical first step to adequately protecting against the liability risks that both federal and state law in the US present.

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When the deal is complex, the choice is simple

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