PRACTICAL LAW COMPANY®

EU and US regulation of health information technology, software and mobile apps

www.practicallaw.com/3-518-3154

Lincoln Tsang, Vernessa Pollard and Daniel Kracov
Arnold & Porter LLP

The emergence of integrated health information systems, mobile apps and software-based medical devices presents significant opportunities in managing healthcare costs and achieving better outcomes. However, such innovation inevitably gives rise to new legal, regulatory and commercial challenges. This article analyses the developing EU and US approaches to health information technology (health IT) and mobile medical applications (MMAs), and the emerging rules and compliance issues for companies developing and marketing these products. In particular, it examines:

- Technological developments in health information and delivery systems.
- The EU approach to regulation.
- The US approach to regulation.
- Significant US FDA regulatory developments.

TECHNOLOGICAL DEVELOPMENTS IN HEALTH INFORMATION AND DELIVERY SYSTEMS

Consumers and healthcare providers are demanding more flexibility, interactivity and portability in health delivery systems, records management and treatment. Insurers and government entities that manage healthcare costs and payments are demanding greater efficiency and cost-savings and greater focus on preventive care. Many different companies are responding to these demands by developing integrated, software-based applications to optimise traditional medical devices. Medical device manufacturers, for example, are developing wireless-enabled medical devices and mobile apps that allow healthcare providers to access and evaluate patient vital signs and other information through remote monitoring or cloud-based data-sharing systems. The telecommunications industry, software developers and Internet Service Providers (ISPs) are also providing wireless solutions, technical support and healthcare solutions to healthcare providers, consumers and health systems.

EU APPROACH TO REGULATION

Background to EU policy on e-health and m-health

It has now been recognised by the European legislature and decision-makers that EU health systems are under mounting pressure to respond to the challenges relating to ageing population, citizens' rising expectation, migration and mobility of patients and health professionals. New technologies have the potential to revolutionalise healthcare and health delivery systems and to contribute to their future sustainability.

Enabling technologies are important for the improvement, prevention of illness and timely delivery of treatment, particularly:

- E-health (that is, using information and communication technologies (ICT) for the provision of health-related services).
- M-health (that is, using mobile communication systems for the provision of health-related services).
- Genomics (that is, use of genetic blue print to identify patient response to treatment or patient susceptibility to a clinical condition or disease, and such information may be presented in an electronic format as 'gene chip').

These essentially shift the current paradigm of treatment of the underlying conditions or illness to prevention and primary care to achieve and maintain wellness. E-health and m-health can assist in providing better citizen-centred care, as well as lowering costs and supporting interoperability across national boundaries, facilitating patient mobility and safety. There is a general consensus among the policy makers and industry that new technologies must be evaluated properly, including for cost-effectiveness, and equity; and health professionals' training and capacity implications must be considered.

The impact of information technology (IT) on cross-border healthcare provisions has been recognised by the European Commission (Commission) in its policy paper published in 2007 where ICT and allied enabling technologies have been considered as particularly important in tackling these new healthcare challenges in the coming decades. Three key challenges are identified by the Commission:

- Demographic changes including an increase in the ageing population that will have an impact on disease patterns and put downward pressure on the sustainability of EU health systems (highlighted in a World Health Organisation's (WHO) independent assessment).
- Emerging health threats, including new communicable disease patterns resulting from climate change that may require proper co-ordination and timely response to, and preparation for such health threats, globally. Such an effort will enhance the capacities and capabilities of the EU and those countries outside the EU to ensure consistency in regulatory and policy decision-making.
- An evolution in healthcare systems partly as a result of the rapid development of new technologies that are revolutionising the way health is promoted and illnesses are predicted, prevented and treated.

Analysis

Similarly, the European Medicines Agency (EMA) in its Road Map to 2015 on contributions to science, medicines and health also recognises the impact of new technologies, including e-health, on existing healthcare systems.

The Council of Ministers also recognised (in its assessment on innovation in the medical device sector published in 2011) the need to consider the interoperability and safety issues related to the integration of medical devices in e-health systems, especially personal health systems, and m-health systems. However, the deployment of information telecommunication technology systems is entirely a matter of national competence. Certain industry interest groups or initiatives have been established that have advocated the need for clarity and certainty on the regulatory standard to ensure timely market access to the new emerging IT technologies related to e-health and m-health. Such parties include the industry group European Industry Association for Radiological, Electromedical and Healthcare-IT industry (COCIR), which represent many key industry players such as the European Health Telematics Association, European Institute for Health Records and Integrating the Healthcare Enterprise.

It is generally agreed that the e-commerce revolution will have an important enabling role on e-health and m-health to ensure high quality, safety and efficient cross-border healthcare provisions within the EU and beyond. In its communication relating to telemedicine (providing healthcare services at a distance), the Commission indicates that e-health can help improve the lives of EU citizens, both patients and health professionals. However, as the Commission has put it, integrating services such as teleradiology (that is, transmission of radiological patient images, such as x-rays, CTs, and MRIs, from one location to another) and teleconsultation (that is, consultations where the healthcare provider and the patient are not at the same location) healthcare systems is a challenging task. The main issues concern:

- Building confidence in and acceptance of telemedicine services.
- Bringing legal clarity particularly in relation to the relevant regulatory regime.
- Solving technical issues and facilitating market development.

Certain medical device manufacturers have applied for the European Conformity mark (CE-mark) to be affixed to their patient care network or mobile software, including the apps designed to facilitate transmission of patient records for diagnosis and determination of the choice of treatment modalities, as well as outcome measurements.

Regulation of medical devices

In the EU, medical devices, low voltage equipment, machinery and radio and telecommunications terminal equipment are regulated under the New Approach (NA) directives, which are defined as directives that provide for the affixing of a CE-mark.

NA directives are based on Resolution 85/C 136/01 1985 on a new approach to technical harmonisation, and standards, which sets out a new regulatory approach based on the following agreed guiding principles:

- Legislative harmonisation is limited to products placed on the EU market that meet the essential requirements and benefit from free movement within the EU.
- Technical specification for assessing conformity with the essential requirements is set out in harmonised standards.
- Application of harmonised or other standards remains voluntary and the manufacturer can apply other technical specifications to meet the requirements.
- Products manufactured in compliance with harmonised standards benefit from a presumption of conformity with the corresponding essential requirements.

The NA requires standards to offer a guaranteed level of protection for the essential requirements established by the directives, and the national authorities to carry out their responsibilities to protect safety or other interests covered by the directives. Under the NA directives, a safeguard clause procedure is necessary to allow for contesting a product's compliance, or failures or shortcomings of harmonised standards.

The procedure for conformity assessment is risk-based, taking account the classification of the medical device and the intended clinical mode of use, and the nature and characteristics of the device. In the EU, medical devices fall into the following four distinct classes according to the risk assessment and characterisation:

- Class I.
- Class IIa.
- Class IIb.
- Class III.

The test for establishing essential requirements seeks to ensure that the device is designed and manufactured in such a way that when used under the conditions and for the purposes intended, it does not compromise the clinical condition, safety or the users. Any risks associated with its intended use should be acceptable risks when weighed against the benefits to the patient. The benefit/risk assessment should be compatible with the overarching objective of achieving a high level of protection of health and safety.

Under the current rules, devices that incorporate software or that are medical software in themselves must be validated according to the state of the art, taking into account the principles of development lifecycle, risk management, validation and verification.

Under EU rules, stand-alone software can be considered an active medical device, that is, any device operation that depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and that acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.

As indicated in the amendment to Directive 93/42/EEC concerning medical devices (Medical Devices Directive) adopted in 2007, the European legislature has contemplated that a medical device may include software either as a stand-alone device or in combination with another device for a medical purpose. A medical device is now defined in the revised Medical Devices Directive to mean any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together

with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for a medical purpose, provided that the principal intended action is not mediated through a biological process. An assessment of a medical purpose is usually based on the declared claims made by the manufacturer on the label, instructions for use and the promotional material consistent with the overarching purpose of the Medical Devices Directive to ensure a high level of protection of patients and consumers.

The Commission's established position distinguishes between two types of software:

- Software influencing the proper functioning of a device.
- Software used in combination with non-medical equipment.

Software related to the functioning of a medical device can be regulated as a stand-alone medical device or as an accessory to the medical device under the Medical Devices Directive. Software used with non-medical equipment is not considered a medical device. The key test is whether the software provides for a proper diagnostic or therapeutic purpose.

If the definition for a medical device, which is sufficiently broad and all encompassing, were to be given its purposive meaning according to established European jurisprudence, equipment, appliances or apparatus involved in e-health or m-health could be regulated as a medical device. This classification in itself may be somewhat artificial, given that mobile software equipment and appliances similar to medical devices are regulated under the NA directives. The NA seeks to address all hazards or risks related to the public interest that the directive intends to protect, such as protection of the consumers, patients or users. According to the Commission, regulatory compliance with the essential requirements can often require simultaneous application of more than one NA directive, and possibly with other EU legal instruments.

In its public consultation document concerning the recast (that is, codification or consolidation) of the Medical Devices Directive, the Commission asked whether the current approach to assessing essential requirements is sufficiently robust to innovative technologies and practices, including those that are based on nanotechnology, genetic testing and advancements in IT, which may be involved in the development of e-health or m-health across the EU. The consultation document also asked whether appropriate adaptation or reinforcement of the established principles underpinning essential requirements is required in the recast of the Medical Devices Directive.

Standard for conformity assessment of medical software

Under the NA regulatory framework, a medical device is presumed to conform with the essential requirements if it meets the appropriate harmonised standard. It has been considered that, until the amendment of the Medical Devices Directive, safety regulations for medical device software at least formally were not sufficiently rigorous to the extent that medical software was not legislatively classified as falling within the scope of the Medical Devices Directive.

The international standard EN/IEC 62304 has now emerged as a global benchmark for evaluating software development. This standard can sit side-by-side with the following standards to evaluate the design, management and safety of medical software:

- EN/ISO 13485 (quality management systems).
- EN/ISO 14971 (application of risk management).
- IEC 60601-1 (medical electrical equipment safety).
- IEC 61010-1 (electrical equipment safety requirements).
- IEC 60601-2 (medical electrical equipment particular requirements).

EN/IEC 62304 standard expects a manufacturer to assign a safety class to the software system. The classification is based on the potential for a hazard that could result in an injury to the user, the patient or other people and includes:

- Class A (no injury or damage to health is possible).
- Class B (non-serious injury is possible).
- Class C (death or serious injury is possible).

Similar to the EU device vigilance guidance, serious injury means injury or illness that directly or indirectly is any of the following:

- Life threatening.
- Results in permanent impairment of a body function or permanent damage to a body structure.
- Necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.

Interplay with Electronic Commerce Directive and other EU legal instruments

It has been recognised that e-health or m-health in the field of telemedicine is both a health service and an information society service. Therefore, it falls under Directive 2000/31/EC on certain legal aspects of information society services, in particular electronic commerce in the Internal Market (Electronic Commerce Directive). This is also recognised in Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (Cross-Border Healthcare Directive), which addresses patients' cross-border mobility including their ability to access services across borders. The Cross-Border Healthcare Directive requires the Commission to take measures to ensure the interoperability of means for the provision of e-health services including telemedicine.

The EU Court of Justice (ECJ) has ruled in various decisions that neither the special nature of health services nor the way in which they are organised or financed removed them from the regulatory control of the fundamental EU law principle of free movement. This includes the freedom of recipients of healthcare services established in one member state to seek and receive medical treatment from another member state, regardless of how the service is delivered (for example, by telemedicine).

EU law establishes a procedure that imposes an obligation on member states to notify the Commission and each other of all draft technical regulations concerning products and Information Society Services (ISS) including telemedicine before they are adopted and put into operation in national law.

Analysis

THE *KER-OPTIKA* CASE

Sale and distribution

The *Ker-Optika* case (*Case C-108/09 Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézete*) concerns the sale and distribution of contact lenses, which are regulated as medical devices under the Medical Devices Directive, in Hungary. In this case, the ECJ firstly assessed whether the process of internet sales and especially the delivery of the contact lenses, which are regulated as medical devices, to the consumer's home falls within the scope of the Electronic Commerce Directive. The ECJ distinguished between the selling of goods online and the delivery of products. The process of selling goods online falls within the scope of the Electronic Commerce Directive. However, the delivery of products, in this case a medical device, does not fall within the scope of the Electronic Commerce Directive.

Public health impact

In assessing public health impact, the ECJ appears to have applied the test of an informed and responsible consumer. The ECJ noted that examinations and advice are matters of the consumer's choice, which "is primarily the responsibility of each contact lens user". Consumers could be advised, in the same way as part of the process of selling the lenses over the internet through the interactive features on the internet site concerned, the use of which by the consumer is mandatory before he proceeds to purchase the lens. The ECJ considered that the internet, as a channel of distribution, offered the same quality of information for consumers as offline sales did. In addition, the ECJ stated that distribution via the internet might offer an advantage over an offline sale as the consumer had more time to consider the product and purchase. This way of distribution would be beneficial to the consumer's informed consent.

The ECJ appeared to robustly counter the alleged drawbacks associated with the use of the internet for providing healthcare advice, mostly relating to a lack of personal contact between the provider of goods and services and the consumer. In the ECJ's considered view, the internet is not only used as a means for approaching the potential consumer but also as an appropriate medium in which the purchased service can be carried out.

Relevance to telemedicine

The relevance of the *Ker-Optika* case to telemedicine is that the internet as a channel of distribution is equally suitable to provide the consumer with sufficient information as physical clinical establishments. The ECJ highlighted the advantages of the internet as giving the consumer more time to think about the purchase and any surrounding questions relevant to the use of a particular medical product. This decision together with a prior ECJ decision on internet sale of medicinal product provides a modern approach to assessing the broader public health impact in the new era of e-commerce and the increasing use of online and mobile services by consumers.

The Electronic Commerce Directive defines rules for the provision of ISS both within and between member states. The Commission believes that the Electronic Commerce Directive applies also to telemedicine. For business-to-business telemedicine services, the country of origin principle applies, that is, the service offered by the business must comply with the related rules of establishment. In the case of business-to-consumer activities contractual obligations are exempted from the country of origin principle. While the definition of medical activities is a matter for the member states, as a general principle, the classification of specific telemedicine services should ensure that these meet the same level of requirements as equivalent non-telemedicine services. That is to say teleradiology should not be less rigorous than radiology. This principle ensures that adequately regulated health services are not replaced by less regulated telemedicine services, and it avoids discrimination between providers of the same service that would be incompatible with the Electronic Commerce Directive.

The interplay of the Medical Devices Directive and the Electronic Commerce Directive has recently been the subject of an ECJ decision (*Case C-108/09 Ker-Optika bt v ÀNTSZ Dél-dunántúli Regionális Intézete*) (*Ker-Optika*) (*see box, The Ker-Optika case*). It has been argued that this decision supports the proposition that appliances or equipment intended for e-health or m-health would be subject to regulatory supervision under the Medical Devices Directive. However, this decision gives some clarity on the demarcation between the Medical Devices Directive and the Electronic Commerce Directive, and the scope of the respective regulatory regime, particularly in the area of internet sale and supply of a medical device.

In addition, an assessment of the extent of impact of the regulation relating to the spectrum and radiofrequency use on devices intended for e-health and m-health is required. Currently, regulatory supervision generally falls within national competence.

US APPROACH TO REGULATION

Background to US policy on e-health and m-health

In the US, many of these technologies are regulated by the Food and Drug Administration (FDA) as medical devices, if they are intended for use in the treatment, diagnosis or prevention of disease. For example, the FDA has recently cleared:

- A mobile app that allows physicians to view patient MRIs on a smart phone.
- A commercial ultrasound system that allows users to acquire and view foetal images on a smartphone.
- Various products that allow patients and physicians to review blood glucose meter readings and other health information through software or cloud-based data management systems.

The FDA is responding to these emerging technologies by re-examining traditional regulatory approaches to medical devices and wireless communications. Although the FDA recognises that health IT offers tremendous health benefits for Americans, it has also stated that these technologies pose potential health risks and accordingly, should be regulated appropriately. The FDA has set out the following four-pronged approach for regulating health IT, which seeks to balance innovation with safety:

- **Risk-based approach to regulatory decisions.** The degree of regulation should depend on the nature of device and risks posed.

- **Expect and require operational quality.** Health IT solutions should be designed and built using existing quality management systems for medical devices (for example, device quality regulations focus on achieving and maintaining product quality throughout the product's life-cycle from design to post-market improvements or changes).
- **Develop clear standards for interoperability.** Components and systems must interface without compromising the functionality or safety of integrated or surrounding systems or technologies.
- **Establish a robust learning infrastructure.** Current medical device post-market surveillance and data monitoring systems should be integrated into a national system to monitor the performance and safety of integrated devices and solutions. Its ultimate goal is to develop an integrated national system that monitors the marketplace performance and safety of these devices.

It is important to note that, in the US, the Federal Communications Commission (FCC) has jurisdiction over various media and communication technologies. These include the allocation of frequencies and the specification of technical requirements to ensure the security and reliability of wirelines, broadband and wireless communication devices. Because of their shared jurisdiction over health IT, the FDA and the FCC have announced efforts to develop a co-ordinated regulatory approach for wireless-enabled medical devices, mobile apps and other health IT. The two agencies have signed a memorandum of understanding, in which they agree to, among other things, exchange information on device marketing authorisations and consult on the development of standards for mobile devices and health IT.

For companies developing medical apps or software-based medical technology that may be regulated by the FDA, it is important to:

- Understand the requirements for the development, marketing, safety and quality of medical devices.
- Identify practical regulatory issues that may impact business objectives.
- Develop a compliance infrastructure to identify and manage potential compliance risks in an increasingly competitive market.

US regulatory framework for medical devices

Medical devices are defined as, among other things, instruments or apparatus (including components), intended for use when diagnosing, treating or preventing diseases, or medical conditions, or intended to affect the body through non-chemical means (*Federal Food, Drug and Cosmetic Act (FDCA) (21 U.S.C. § 321 (h))*).

The FDCA definition encompasses accessories and components of a finished medical device. Generally, accessories must comply with requirements that apply to the medical device with which they are intended to be used. Most accessories are authorised by the FDA as part of the marketing application for the underlying device, but certain off-the-shelf accessories are separately regulated if they are intended for general purpose use with a variety of medical devices. Components, for example, built-in modems or hardware, are generally exempt from medical requirements. Instead, the FDA requires the manufacturer of the finished medical device for which the component is made or used to ensure that component meets the manufacturer's specifications and other quality requirements.

The medical device definition also encompasses the regulatory concept of "intended use", the concept the FDA uses to determine whether a product is a medical device. Because a product's regulatory status depends on the manufacturer's intended use, products that may not appear to be medical devices may be subject to the FDA's requirements if they are intended to perform functions that bring them within the medical device definition.

This framework has important implications for smartphones, monitors and other software-based parts that are used with or in medical devices. In determining the requirements and responsibilities associated with such products, it is important to consider the intended uses, as well as the specifications, system components, and parts that are required to use or run the program, as some or all of these items may be accessories or components of the finished device.

Depending on the regulatory controls necessary to ensure that the product can be safely and effectively used as intended, medical devices are classified into one of three classes:

- Class I (low risk).
- Class II (moderate risk).
- Class III (high risk).

Classification, and associated exemptions, generally determine the level of pre-market review and post-market controls that will be required (if there is any uncertainty about the device classification and applicable requirements, sponsors can contact the Office of Device Evaluation (ODE) within the FDA for clarification, by submitting a request for classification, known as a "513(g) request"). The FDA expects the persons responsible for manufacturing or marketing a device to determine the classification and the corresponding regulatory requirements before commercialising the product. Most medical devices are subject to regulations known as "general controls", which include owner/operator registration and device listing, device good manufacturing practice (GMP)/quality systems (QS) requirements and adverse event reporting.

SIGNIFICANT US FDA REGULATORY DEVELOPMENTS

Final rule on medical device data systems

The FDA has recently issued a new regulation on medical device data systems (MDDS) (*FDA Final Rule on Medical Devices; Medical Device Data Systems, 76 Fed. Reg. 8637 (15 February 2011), 21 C.F.R. § 880.6310*). The regulation defines an MDDS as a device that is intended to transfer, store or display, or electronically convert medical device data from one format to another format in accordance with a preset specification without controlling or altering the functions or parameters of any connected medical devices.

Medical device data includes clinical assessments, physiological conditions or other information regarding the operation or functions of a connected medical device that is either:

- Originally obtained or directly available from a connected medical device.
- Manually entered into a device and then subsequently transmitted by or through an MDDS.

Examples of MDDS data retrieval, transfer and storage activities include:

- Collecting historical information from a ventilator and transferring it to a central patient data repository.
- Storing historical blood pressure information for later review.
- Displaying a previously stored electrocardiogram for a specific patient.

Examples of MDDS data conversion activities include:

- Converting digital data into a printable format.
- Converting data to HTML, PDF or HL7 format.
- Transferring, storing or displaying medical data, including historical records of alarms or other output from a connected medical device, "without analysis or specific recognition of the intent or significance of that data".

A device or system is not an MDDS, if it interprets or adds value to the medical device data by, for example:

- Charting or graphing data.
- Providing alarms or other information necessary for "active" or "continuous" patient monitoring or data that a healthcare professional relies on to take immediate clinical action.

Such devices are generally regulated by the FDA under different classification regulations.

Not every IT system or software solution that transfers medical data is considered an MDDS. For example, the MDDS rule does not apply to devices that are solely intended for use as general IT equipment (and not intended for a device use), for example, off-the-shelf wireless or backup systems. Additionally, general purpose IT equipment used in a healthcare facility to display or transfer medical data is not an MDDS, provided that it is not altered or reconfigured beyond the general manufacturing specifications to function as an MDDS.

Even with these broad exclusions, determining the status of an MDDS product requires a fact-specific, case-by-case analysis, based largely on the characteristics and functions of the solution. Companies that develop and market communication systems and software for use in healthcare applications or settings should assess whether those products are FDA-regulated MDDS products.

Draft guidance on mobile medical apps

The FDA has also recently issued a draft guidance that discusses in detail the regulatory approach the FDA intends to take for mobile platform apps, such as smartphones and tablets, that perform medical or diagnostic functions (*FDA, Draft Guidance for Industry and Food and Drug Administration, Staff Mobile Medical Applications (2011)*). The FDA has identified the following four categories of mobile medical apps that it intends to regulate as medical devices:

- **Applications that display, store or transmit patient-specific medical device data in its original format.** These applications meet the regulatory definition of an MDDS.
- **Applications that control the intended use, function, modes or energy sources of a connected medical device.** These apps are used to operate, power or control other medical devices. They are considered accessories and are regulated under the same classification regulation and other requirements as the medical devices they support or control.
- **Applications that transform or make a mobile platform into a regulated medical device.** These apps use attachments, display screens, sensors or other components to allow a smart phone or other mobile platform to perform the functions of a medical device. For example, an app that uses sensors on a smart phone to act as an electronic stethoscope would be required to meet the requirements for electronic stethoscopes.
- **Applications that create alarms, recommendations or new information by analysing or interpreting medical device data.** These apps perform healthcare provider (HCP) "decision support" functions by analysing, interpreting or characterising physiological data, symptoms or other inputs needed for diagnosis or treatment.

The draft guidance also lists several examples of apps that are not considered MMAs, including:

- Mobile reference materials and textbooks.
- Systems used solely to log, record or make suggestions related to general health and wellness (for example, dietary tracking logs, exercise suggestions or appointment reminders).
- Automated general office operations and electronic health records.
- General personal aids (for example, applications that use the mobile platform as a magnifying glass or mirror for general use). The FDA recognises that some of these apps technically meet the statutory definition of a medical device. However, it does not intend to regulate them as such unless it determines that further regulation is necessary.

Although the draft guidance may change in response to public comments the FDA receives, its issuance means that a number of companies that may have marketed health-related apps must now assess whether these apps are regulated by the FDA.

RECOMMENDATIONS FOR COMPANIES

Often, companies in the health IT space find that they are ill-prepared to meet the developing regulatory challenges. It is recommended that companies venturing into the health IT area invest at the early stages in developing a strong understanding of the legal and regulatory issues, and associated investments and timelines, for proposed products before developing the technology or making improvements to existing technology. Such companies must plan to invest in the infrastructure and processes necessary to ensure that regulated health IT remains compliant. A coherent and integrated commercial strategy for the development of devices relevant to e-health and m-health should be considered on a cross-border basis.

CONTRIBUTOR DETAILS

LINCOLN TSANG

Arnold & Porter LLP
T +44 207 786 6104
F +44 207 786 6299
E *Lincoln.Tsang@aporter.com*
W *www.arnoldporter.com*

Qualified. England and Wales, 1995

Areas of practice. Life Sciences including regulatory and compliance for pharmaceuticals and medical devices, EU administrative law.

Recent transactions

- Advising companies on global regulatory compliance programme for manufacture, clinical trials and pharmacovigilance.
- Assisting companies developing internal corporate procedures for e-commerce particularly in relation to disease awareness campaign.
- Defending companies in regulatory investigation and enforcement actions.
- Representing companies in market exclusivity challenges.

DANIEL KRACOV

Arnold & Porter LLP
T +1 202 942 5120
F +1 202 942 5999
E *Daniel.Kracov@aporter.com*
W *www.arnoldporter.com*

Qualified. US: Virginia, 1988; District of Columbia, 1988

Areas of practice. Pharmaceutical and medical device regulatory; compliance and enforcement matters.

Recent transactions

- Representing companies before the US FDA on issues relating to product clearance, approval, post-market safety crises and exclusivity challenges.
- Advising on global clinical trial compliance issues.
- Defending pharmaceutical and medical device companies in investigations and enforcement matters relating to product safety and manufacturing issues.
- Conducting comprehensive reviews of company processes and standards for promotional compliance, and defending enforcement actions relating to alleged off-label marketing.

VERNESSA POLLARD

Arnold & Porter LLP
T +1 202 942 5811
F +1 202 942 5999
E *Vernessa.Pollard@aporter.com*
W *www.arnoldporter.com*

Qualified. US: New Jersey; District of Columbia

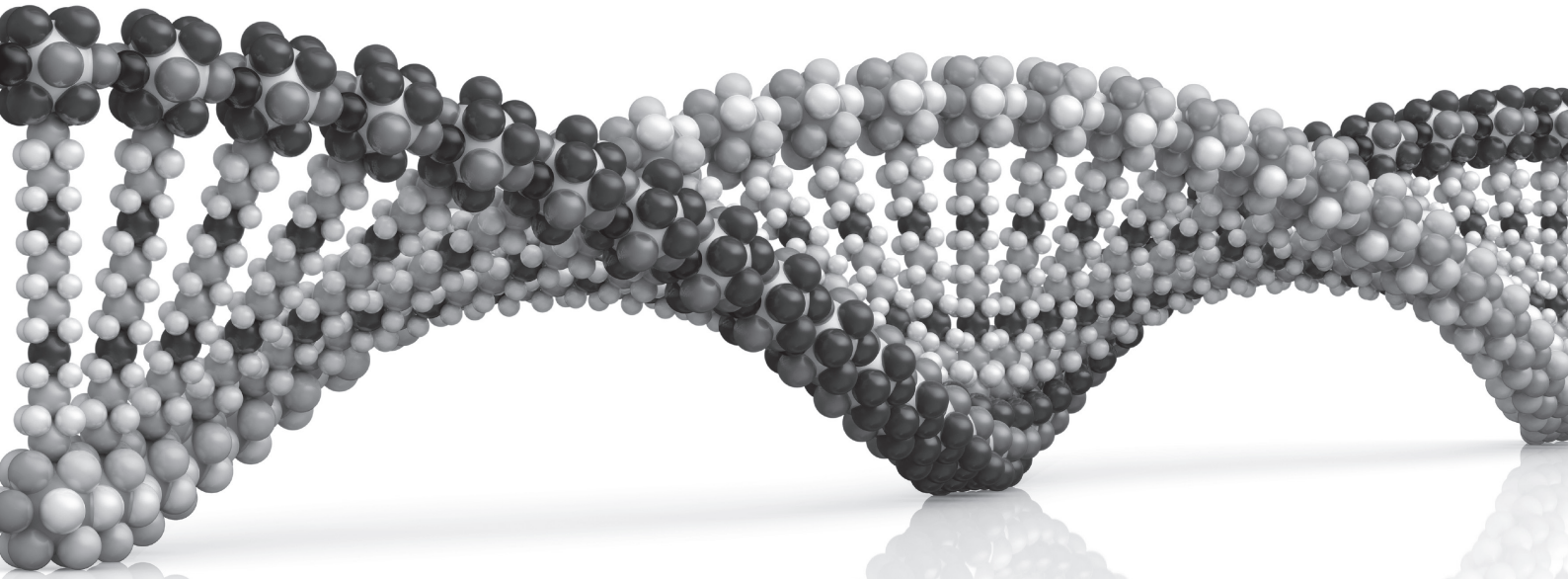
Areas of practice. Pharmaceutical and medical devices, principally focusing on regulatory matters involving the US Food and Drug Administration and US Department of Justice (DOJ).

Recent transactions

- Advising companies on regulatory, compliance, enforcement and legislative matters involving pharmaceuticals, medical devices, cosmetics, food, and medical technology and software.
- Advising companies on product approvals, Good Manufacturing Practice (GMP) and Quality System (QS) requirements, advertising and promotion, adverse event reporting, FDA Warning Letters, FDA inspections, recalls, import detentions and corporate compliance programmes.
- Representing technology, telecommunications and device manufacturers on integrated healthcare IT devices, wireless-enabled medical devices, medical mobile apps and disease management software.

ARNOLD & PORTER LLP

The Law Firm for Today's Pharmaceutical, Biotechnology and Medical Device Companies



Arnold & Porter LLP provides innovative, integrated solutions in the life sciences and healthcare arenas. And we do it with a global perspective. For the complex issues facing pharmaceutical, biotech, and medical device companies—including achieving approval, coverage and reimbursement, compliance and enforcement challenges, pricing and contracting, fraud and abuse and false claims matters, competitive concerns, lifecycle management, intellectual property and product liability litigation, transactions, and partnering—Arnold & Porter is the law firm.

arnoldporter.com

Brussels ■ Denver ■ London ■ Los Angeles ■ New York ■ Northern Virginia ■ San Francisco ■ Silicon Valley ■ Washington, DC