



INTRODUCTION TO GENOMICS & SMART MEDICAL DEVICES & PRODUCT LIABILITY

Karishma Paroha, Senior Associate

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Kennedys

Speaker - Karishma Paroha - Kennedys Biography



Karishma Paroha
Senior Associate

Tel: 020 7667 9163

email: karishma.paroha@kennedyslaw.com

25 Fenchurch Avenue, London, EC3M 5AD

Karishma Paroha, a Senior Associate at Kennedys, is a uniquely dually qualified Senior Solicitor and Barrister in Kennedys' Product Liability Team, who has accumulated wide-ranging experience in handling product liability matters, particularly consumer products claims and products claims emanating from the pharmaceutical industry over the past 15 years. During this time she has also developed extensive experience in the setting up and day-to-day handling of group actions (both Claimant and Defendant) and advises on strategy in relation to the conduct of and defending complex multi-party litigation, cross-border liabilities and multi-jurisdictional issues at national and international levels. She is particularly recognised for her knowledge on UK/EU regulatory and risk assessment to leading manufacturers and pharmaceutical companies and is an active member of Kennedys Life Sciences Regulatory Task Group. Her special expertise include complex product liability, product recalls, medical devices and clinical trials claims and contractual claims and disputes.

Karishma is an active member of Kennedys Autonomous Vehicles Committee, Emerging Risks Group and Life Sciences Regulatory Group. She has also been actively seeking to raise the awareness of Indian pharmaceutical companies and manufacturers and their Insurers to international liability exposure for many years. She collaborated with the Bombay Chambers of Commerce and Industry (BCCI) to organise the first International Pharmaceutical Claims Seminar, which took place in Mumbai in 2010. Since then she has helped to pioneer what has now become an annual BCCI Workshop on Managing Risks and Liabilities in the Pharmaceutical and Manufacturing (FMCG and F & B) sectors.

Karishma is a prolific writer publishing many articles and several book chapters (over 90 publications), most notably a Product Liability Chapter for a Claims Handling Practitioner's Guide and "*Strategies for Handling Cross Border Products Claims and Class Actions*" featured in the 9th edition of the most highly ranked International Comparative Legal Guide to Product Liability. She is also regularly invited to provide lectures on a wide range of topics including international law, product liability and group actions to leading international manufacturers and insurers in England, Denmark, the USA, India and elsewhere.

Legal 500 2018, recently quoted her as being "part of a team handling numerous claims against the insured of a number of large insurance clients" and recognised her as a "Next generation lawyer" in Defendant Product Liability.



GENOMICS

Genomics Week Of Action 4th - 9th March 2019

- The Health Education England's Genomics Education Programme:
 - NHS initiative
 - ensure its workforce has the knowledge, skills and experience necessary to remain a world leader in genomic medicine
- Goal for week:
 - spark a conversation among all health professionals; &
 - increase familiarity with the word 'genomics'
 - feel more comfortable discussing genomic testing with patients

Genomics Week Of Action 4th - 9th March 2019

I'm joining the #GenomicsConversation. Are you?



What is a Genome?

- A genome - an organism's complete set of DNA, including all of its genes.
- Each genome contains all of the information needed to build and maintain that organism.
- Around 25,000 genes in the human genome containing over 3 billion DNA base pairs
- Each gene provides the instructions for making proteins, hormones, immunoglobulins & enzymes which control essential communications & functions that keep our complex systems synchronised
- A complete set of genetic instructions, which provides the blueprint for everything that happens in our bodies

What is Genomics?

- Genomics identifies & analyses variations in the DNA called single nucleotide polymorphisms (SNPs)
 - A SNP may have no effect at all, or it can modify the proteins created by a gene, making them more or less effective
 - 4 to 5 million SNPs in a person's genome
 - May be unique or occur in many individuals
 - More than 100 million SNPs in populations around the world
 - Over 150 SNPs have so far been identified as having a direct impact on health
- When a cell replicates itself e.g. when a new protein needs to be produced or to replace dying cells in a tissue or organ, parts of the chromosome open to expose the required genetic information
- During this process, malfunctions can lead to errors or variations in newly created proteins

What is Genomics?

- Usually DNA errors are corrected before translated into a protein, but sometimes they become a permanent part of DNA, leading to alterations in a person's biochemistry & metabolism
- This can result in chronic diseases such as cancer
- Genomics provides clinicians with more information than ever before to enable personalised interventions bespoke to a patient's unique biochemical needs

The 100,000 Genomes Project

- Launched 2012
- NHS patients with a rare disease, their families & patients with cancer
- Currently largest national sequencing project of its kind in the world
- Aim - create a new genomic medicine service for the NHS transforming way people are cared for
- How best to use genomics in healthcare & how best to interpret the data to help patients
- 5 December 2018 - reached goal of sequencing 100,000 genomes from circa 85,000 people
- Combining genomic sequence data with medical records
- Patients may be offered a diagnosis where there was not one before
- Results will be returned to the NHS throughout 2019

UK & NHS - World leader in Genomics

- UK recognised worldwide leader in genomics technologies
- Unique structure of NHS allows us to deliver for patient benefit
- NHS world-leading healthcare system to predict and diagnose inherited & acquired disease & to provide personalised treatments & interventions

National Genomic Medicine Service

- March 2017, NHS England Board set out its strategic approach to build a National Genomic Medicine Service, building on 100,000 Genomes Project. Comprises 5 key elements:
 - A national genomic laboratory service through network of Genomic Laboratory Hubs
 - A new national genomic test directory to underpin genomic laboratory network
 - A national whole genomic sequencing provision & supporting informatics infrastructure
 - A clinical genomics medicine service
 - A national co-ordinating and oversight function within NHS England

Advantages of Genomic Testing

- Genomic testing has the potential to transform lives by:
 - Illuminating a patient's genetic blueprint
 - Supporting the health of the patient's natural defense system
 - Improving the patient's health
 - Intervening with predispositions to certain diseases
 - Saving more cancer patients via more accurate and earlier diagnosis and more effective use of therapies
 - Enabling a quicker diagnosis for patients with a rare disease - avoid diagnostic odyssey
 - Assisting with informed prescriptions - matching a patient to the most effective medications
 - Reducing the likelihood of an adverse drug reaction

Pharmacogenomics

- Study of how genes affect a person's response to drugs
- Combines pharmacology (science of drugs) & genomics
- Aim - develop effective, safe medications & doses tailored to a person's genetic makeup
- Current drugs - “one size fits all”
- Identifies:
 - Genetic markers that increase risk of adverse drug reactions
 - Genetic markers that reduce a drug's effectiveness
- Future - development of tailored drugs to treat e.g. cancer

Ethical, Social & Legal Implications

- Requirement for ethical standards for work involving human research subjects or human tissues
- Consideration of social, cultural and religious perspectives on genetics and health
- Possible discrimination by employers or health insurers
- US bloggers predicting:
 - use of genomics to detect gene mutations to identify persons at greater risk of idiopathic mesothelioma
 - Potential game changer for asbestos litigation - if a verifiable alternative cause
- Anticipate cases where an expert cannot confirm, or rule out, a genetic or chromosomal abnormality as the cause of a plaintiff's condition Kennedy's

Pharmacogenomics & Product Liability Claims

- *Zeller v. Sec’y of HHS, 2008 WL 3845155*
- Claims based on peculiar genetic susceptibility to injury
- *The Vaccine Court rejected genetic predispositions as a superseding cause of vaccine-related injuries, but only “[s]o long as the [product] was a substantial factor”*
- Modern version of the “eggshell” claimant rule
- *“Take your victim as you find him”*

Pharmacogenetics and Product Liability Claims

- *Mills v. Bristol-Myers Squibb Co.*, 2011 WL 4708850 (D. Ariz. Oct. 7, 2011)
- Plaintiff made allegations about pharmacogenomically based risks
- Plaintiff claimed
 - variant gene (CYP) could not metabolise defendant's drug as well as most other people
 - drug defective, not because of anything inherent in drug itself, but because less effective due to the plaintiff's peculiar genetic makeup
- Genetic variation claims
 - currently not considered legitimate product liability claim, since plaintiff is not asserting drug caused any injury that would not have happened
 - Until FDA decides to assess drug approvals & contraindications on basis of genetic subgrouping, such a claim not likely to be recognised



SMART MEDICAL DEVICES

Media Mania

- March 2019 - The two-part crossover special between BBC1's sister medical dramas Casualty and Holby City marking the 20th anniversary of Holby City
- Critical medical machinery falsely reports that stable patients are crashing
- Cyber attack - computer virus spreads through Holby wiping out vital computer software
- Medical staff are thrown into chaos

Media Mania



Smart Machines & Predictions

- In May 2018, at a US Consumer Product Safety Commission public hearing it was announced that there are:
 - Currently 8.4 billion connected things;&
 - 5 billion consumer applications
 - Numbers allegedly on track to double by the year 2020
- According to Gartner analyst Tom Austin:
 - “Smart Machine Age”
 - By 2021, smart machine revenues will reach \$29 billion
 - 30% of large companies will use devices or pieces of software that use some form of cognitive computing, deep learning, or artificial intelligence

Smart Medical Devices & Predictions for 2019

Medical Device Innovation Safety and Security Consortium states:

- 50 billion devices-based patient exposures annually
- FDA receives several hundred thousand reports of suspected device associated deaths, serious injuries & malfunctions every year & major source of risk is from tampering
- **CyberMDX** - cybersecurity specialists & technology entrepreneurs predict:
 - There will be more successful cyber-attacks targeting healthcare in 2019 than ever before; &

“

It's not at all unrealistic to fear that cybercrime will see its first healthcare fatality in 2019...

”



Smart & Internet of Things (IoT) Medical Devices

- Deep brain neuro-stimulators, cochlear implants, food drop implants, gastric stimulators, defibrillators, pacemakers
- Wearable technology e.g. for asthma & AI-powered insulin pumps
- Vulnerability issues when the software is hacked, malfunctions, or fails to update
- Hazards allegedly associated with device malfunctions - fire, burn, shock, tripping or falling, laceration, contusion, chemical exposure, bodily injury, & even death
- Cyber-attacks on connected medical devices could result in “*severe consequences on patient safety*”
- 2007, US VP Dick Cheney had his pacemaker’s wireless capabilities disabled to prevent assassination attempts

Recalls & Lloyd's Bashe Report (Feb 2019)

- FDA issued recalls for smart medical devices in 2004, 2012 & 2016 due to software issues allegedly leading to patient overdoses, injuries & death
- August 2017 - Circa 500 million radio-controlled implantable pacemakers made by Abbot Labs recalled by FDA due to fears their lax cybersecurity could be hacked to run the batteries down or even alter the patient's heartbeat
- Weaknesses discovered by MedSec - cybersecurity firm specialising in researching vulnerabilities in the medical devices & healthcare industries
- Pacemakers not removed from 465,000 patients, (invasive & dangerous) medical procedure & manufacturer issued a firmware update applied by medical staff to patch the security holes

Recalled IoT Pacemaker



Product Liability

- Following *Boston Scientific* - where claim related to software vulnerability &/or cyber security risks, allegations are likely to be made that the product has a design defective
- Under CPA 1987 strict liability on producer of software &/or smart medical device if vulnerability results in property damage &/or personal injury & not as safe “*as persons are generally entitled to expect*”
 - When a consumer has/uses an IoT medical device does the consumer expect that hackers will be able to infiltrate the software?
 - Does the consumer expect the product will be designed in a manner in which software can malfunction if software is not updated in a timely manner, or if the software update is interrupted?
 - If answered in the negative, the manufacturer may be subject to liability
- Determining liability will be complex with supply chain for design, manufacture, assemblage, shipping & sale of products

Insurance & Concluding Remarks

- Insurance policies may not provide coverage for every consequence of a cyber attack
- All IoT medical devices stakeholders - manufacturers, importers, software designers, app developers, etc. must prior to an acute IoT product failure occurring:
 - Carry out rigorous safety/security testing & monitoring of products pre-market
 - Carry out close & continuous scrutiny for their risk/benefit profile
 - Evaluate their insurance coverage & exclusions
 - Anticipate related issues of new IoT technology

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