MEDTECH COLLABORATION SERIES

HALSTON GROUP X CHARLTON REGULATORY CONSULTING

HALSTON GROUP

CHARLTON REGULATORY CONSULTING

MedTech+HealthTech:

NAVIGATING THE REGULATORY LANDSCAPE OF MEDICAL TECHNOLOGY

H B2B

TECH ORIGIN

MERCURY

SUSTAINABILITY PARTNERSHIPS


WHAT TO
EXPECT

The medical technology field has always been intertwined with regulation and companies have often faced complexities when it comes to adhering to those regulations. But with the industry expanding more into the digital realm encompassing both MedTech and HealthTech solutions, regulation is becoming even harder to navigate for those innovating in the field.

Halston Group has collaborated with Dr Iain Charlton from Charlton Regulatory Consulting, an expert in medical device regulation, to investigate the current MedTech landscape, how MedTechs can prepare for regulation as part of their route to market, and also how regulation is adapting to emerging technology trends.

THE MEDTECH MARKET

HG The MedTech footprint is growing, and the industry is in a time of fast-paced innovation, with 1 in 12 of all UK patents filed at the European Patent Office from the medical technology industry.

CRC ***It's lively, thriving and changing.***

The market needs technology that makes healthcare pathways more efficient and effective - global healthcare provision is stretched with a massive nursing shortfall that is predicted to get worse.

More and more companies are developing innovative healthcare and medical device software to meet this demand. A clear trend is in AI, and this is having a big impact, offering much better performance in diagnostics and informing treatment of conditions. It is being used more and more by innovators, and the regulators are allowing more and more AI based devices onto the market.

Competition seems high in the healthcare app space, in particular apps and services being marketed directly to consumers and the healthcare providers. A lot of new services claim to improve the efficiency and efficacy of many different clinical pathways, diagnose diseases and conditions better, and provide healthcare providers with much better clinical tools.

INTRODUCING CHARLTON REGULATORY CONSULTING

HG Both the MedTech and HealthTech fields are moving at a rapid pace, with entrepreneurs delivering ground-breaking innovations to the healthcare sector. But as one of the most regulated sectors, these innovations need to abide by current and upcoming legislation.

Charlton Regulatory Consulting provides advice and support to companies who are producing healthcare technology and medical device software.

CRC *We help navigate regulations and industry standards when bringing new products to market, covering regulations on medical devices, privacy and security, and the standards needed to provide service and software to customers in the UK, EU and US.*

We're especially attuned to early-stage companies, spinning out of Universities or clinical research, with a new idea in healthcare, but an uncertain route to the market. We can also help these companies as well as more established companies with the work involved in gaining software medical device clearance in the UK, EU and US, and in complying with the standards required to work with the NHS.

HG **ACCORDING TO THE UK GOVERNMENT, THERE ARE 4,190 BUSINESSES OPERATING IN THE MEDTECH SPACE, CONTRIBUTING £27 BILLION IN ANNUAL TURNOVER TO THE ECONOMY.**

Most of the entrepreneurs leading this growth have come from a clinical background, with many still acting practitioners. Their experience in the healthcare sector has enabled them to develop unique solutions that are truly needed by the health system and the wider public. However, whilst these entrepreneurs are experts in their chosen medical field, they often don't have extensive knowledge of the regulatory landscape and tend to seek external support.

Charlton Regulatory Consulting enables MedTechs to remain compliant in the field.

CRC *We support companies by providing specialist knowledge and understanding of the regulations and standards around medical devices, privacy and security during the development and marketing of their software, to open up their route to the market and adoption by their customers. Specifically, we help companies understand their regulatory strategy and how their route to market is affected by:*

- *classification as a medical device in the UK, EU and US, and how to avoid classification when it is not needed;*
- *how to obtain clearance in these territories;*
- *the impact of privacy and security regulations on their operations and products; and*
- *additional UK standards they will need to comply with to engage with the NHS.*

We help across these subjects in a flexible, time efficient manner, understanding that

early stage companies cannot afford full-time regulatory support.

With a regulatory strategy in place, we can also support companies with the task work involved in gaining medical device clearance and complying with other regulations and standards, such as:

- *implementing a quality management system and gaining ISO 13485 quality management certification;*
- *implementing a security, business continuity and privacy management systems and gaining ISO 27001, ISO 27701, ISO 22301 certification;*
- *preparing UK and EU medical device submission technical documentation;*
- *preparing US medical device submissions (such as Pre-Market Submission, Pre-Market Approval and De Novo);*
- *preparing documentation for compliance with NHS standards such as DSPT, DCB0129 and DTAC;*
- *supporting compliance with US healthcare information and privacy regulations such as HIPAA and the CCPA; and*
- *supporting compliance with other security frameworks such as NIST and SOC2.*

Finally, there are some specific supporting regulatory roles that we can fulfil, such as acting as the required UK Responsible Person for an overseas manufacturer, or acting as Person Responsible for Regulatory Compliance to early stage companies to comply with EU medical device regulations.

COMMON REGULATORY HURDLES

HG As a MedTech company, there are many hurdles they will face when it comes to regulation, however Dr Iain Charlton explores common challenges faced by most.

1. **CRC** *In the UK and EU, the time to obtain clearance is definitely a factor, due to the increased burden on the Notified Bodies caused by the new EU MDR and the new UKCA mark. For software medical devices, the EU MDR moved many products from Class I to Class IIa, which means the quality system and technical file assessment burden on the Notified Bodies also went up. There are not enough Notified Bodies to handle the increased volume of clients and submissions, and the industry needs to create more capacity to help reduce the time taken to onboard new clients and complete assessments.*

2. *Another challenge is creating a regulatory strategy that matches a vision for growth. Reducing risk classification or avoiding classification altogether can often mean reducing how effective healthcare technology is. For instance, bringing software to market that can reliably diagnosis a disease, or radically improves the treatment of a condition will need to be cleared as a medical device, but watering down the intention to providing information that merely provides additional data to assist clinicians may be much less impactful on the treatment pathway.*

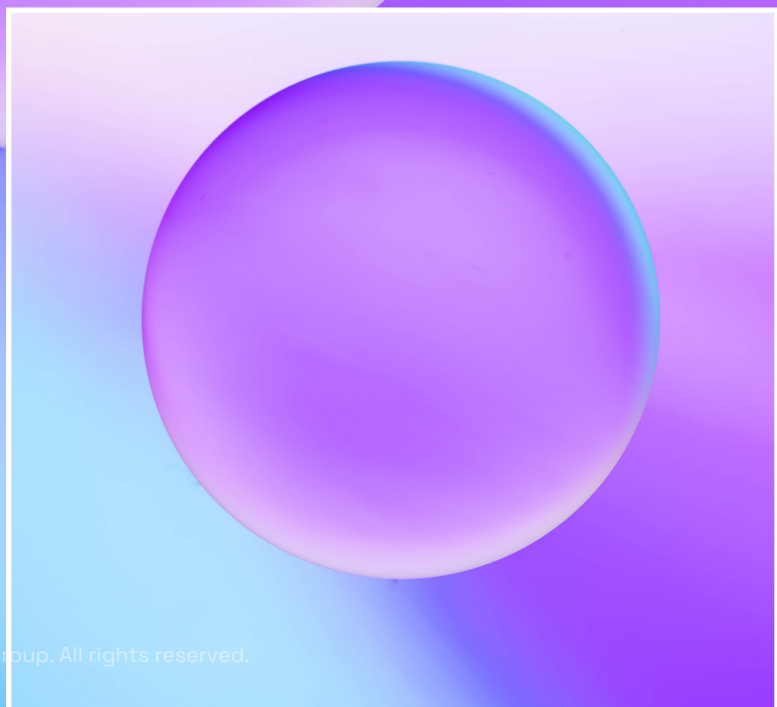
3. *With the need to clear medical devices, there is also a challenge in gaining experience through research and prototypes for early stage companies. It's often vital to get early experience and understand what will support clinicians and patients best, but beyond early research, this can be challenging to achieve without needing to complete the majority of clearance activities and gain approval from the MHRA.*

HG Beyond this, there are some 'hidden hurdles' that more often than not, MedTechs are unaware of.

CRC *Medical device classification is sometimes not anticipated or fully understood, and this can mean unexpected delays and costs in bringing healthcare and medical technology to market.*

Patent infringement and freedom to operate can also be a factor, and this can sometimes raise its head late in the process when a company gets big enough to be noticed, and a challenge is then raised that is a significant blocker to growth and profit.

There are also NHS standards that health tech companies have to meet before they can commission health tech software and products within NHS Trusts (for instance, DCB0129, DSPT and DTAC). No two Trusts are the same, and these hurdles are often not raised early in the engagement process, meaning they appear late, causing a slow down or halt to the adoption of new technology.



PHYSICAL DEVICE VS SOFTWARE
THE REGULATORY DIFFERENTIATORS

CRC *Software and physical devices are classified according to the same regulation but against slightly different criteria, although the principles of classifying according to the risk they pose to patients are very similar.. Under the UK and EU MDR, there are classification rules intended purely for software, designed to ensure that all low, medium and high risk software is classified appropriately.*

One major difference for software and services is the concept of "clinical decision support software" (CDSS), which can be brought to market without clearance when certain conditions are met. Establishing a clear position on this can sometimes be nuanced, and companies should take care to avoid unlawfully placing medical device software on the market.

There are further differences in the way a software or service firm needs to comply with the regulations and standards, and there are aspects that simply don't apply to software, making compliance a little simpler. Software has no physical manufacturing facility, and no sterilisation, packaging, distribution chain, transport and so on. This means there are a lot of clauses of standards and regulations that don't apply, and other regulations that don't apply at all (e.g. RoHS, machinery, PPE and EMC being the main ones).

When bringing a software medical device to the market, there are different standards to be followed to achieve compliance, however these are finer details, rather than major differences in the pathway to regulatory clearance. One particular requirement for software is managing cybersecurity risks, with specific standards to follow for this. Cybersecurity standards are currently under development in the EU and this is going to become more prominent with the emergence of AI regulation.

REGULATIONS' IMPACT ON NHS ADOPTION

CRC *First and most seriously, not having regulatory clearance makes placing a medical device on the market unlawful. If the MHRA acts to remove an unlawful device from the market, this would cause significant financial and reputational damage to a company.*

From this sense, regulatory clearance is no more or less important to the NHS, however the NHS have other standards in place to ensure that they adopt healthcare and medical technology safely. These are the Data Security and Protection Toolkit (DSPT), the DCB0129 clinical risk management standard, and the recently adopted Digital Technology Assessment Criteria (DTAC). A new policy from the Department of Health and NHS England is expected in Autumn 2023 on an assessment framework for healthcare and medical technology for adoption in the NHS, including the standards already mentioned, and further NICE evaluations.

INTERNATIONAL ADOPTION

HG Whilst the NHS will be a clear target for many UK MedTechs to embed their solution, the adoption timescales are significantly longer than private healthcare operators. This means companies will look externally to build a portfolio of clients whilst tackling the NHS procurement model. Dr Iain Charlton provides a few considerations that will help create a more seamless international adoption.

CRC *Formulate a territory strategy with a balanced regulatory, operational and legal plan for all territories. For medical devices, there are further considerations:*

- *There needs to be (by law) a "local representative" in most territories - a legal entity who acts on your behalf - and you'll need to onboard a company or stand up an operation prior to you placing a product on the market*
- *Privacy regulations also require local representation (eg the GDPR) and the same companies that provide medical device representation can often help*

Even with clearances in place, standing up an operation overseas is a significant undertaking that can be underestimated in cost and complexity.

EMERGING REGULATORY CHANGES

HG With such fast-paced innovation in the MedTech sector and wider economic changes, legislation needs to respond with appropriate guidance and regulations to ensure direction and support.

Dr Iain Charlton explores the developing trends and how the regulation sector is evolving in response to a growing MedTech field.

CRC *There are a number of changes happening currently.*

The change that continues to have the biggest impact on medical device companies is the transition to the new EU MDR. This means that manufacturers will eventually need to have all of their devices re-assessed by their Notified Bodies, and the backlog of devices to assess is very large, and has led to the transition period being extended.

The introduction of the UKCA marking process following Brexit is also ongoing, and offers similar challenges, as there are a lot of devices needing assessment. This process has likewise been extended to allow for the increased pressure on the Assessment Bodies.

In the EU, the AI Act is being introduced, and this has already gone through the process of hearing challenges and proposed amendments, proposed amendments, with the Act potentially coming into force within 2023. The new Act seeks to control the application of AI across numerous fields and areas, one being its use in medical devices. The regulatory pathway for medical devices will not change, and the same regulators are expected to assess the use of AI alongside the medical device assessment, but this will inevitably place further burden on the Notified Bodies. To date, very few Bodies have achieved the designated status of AI Notified Body. The UK government has a less burdensome approach to AI regulation, so how much and how quickly the government will act to introduce controls is not yet clear.

AI REGULATION

HG A lot of the emerging technologies in the MedTech field utilise some form of AI, but as this is new a technology area that's full capabilities have yet to be uncovered, it can often be hard for companies to define their solution and understand where it fits within current legislation. Dr Iain Charlton details how AI-based platforms are covered by current legislation and explores how regulations can become more robust to protect people's safety, rights, and freedoms.

CRC *It is very true that AI is getting popular!*

Software with AI in it is still subject to the same medical device, privacy and security regulations, so MedTechs should be aware of this and not expect that AI gets any sort of free pass. Where things are really emerging is in the control of areas in which the use of AI may be forbidden, and how companies should be obliged to consider safety, rights and freedoms when using AI in areas that are not currently regulated.

There are things to consider that directly impact medical device clearance and the interaction with privacy regulations now, and some things to consider for the future.

Things that MedTechs need to know now are:

- *whatever you do, the regulators need to know that an AI is safe and effective, so you need to prove this with clinical evidence and/or performance testing*
- *the FDA are now regulating some software where AI is used as medical devices, where it was previously classified only as "decision support software" and exempt from medical device regulation*
- *the regulators (particularly FDA) have always been concerned with bias and will want to know how this has been addressed*
- *there are some (very few) international standards on AI that regulators may expect you to apply*
- *in the UK, the "AI and Digital Regulations Service for health and social care" provides useful guidance for developers and adopters of AI and digital technology.*[1]

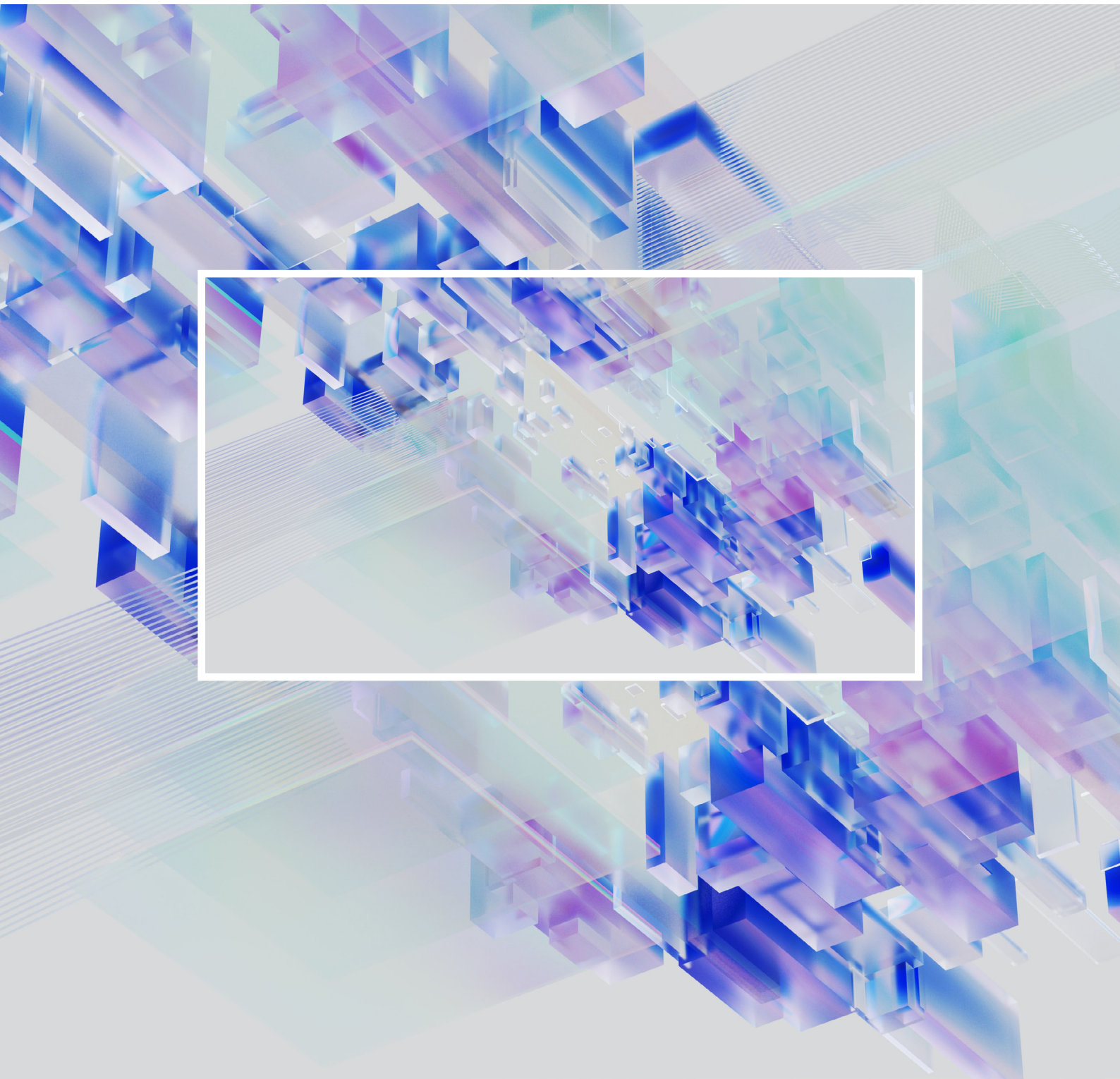
Important things to be aware of and follow are:

- *the EU AI Act, which is still intended to come into force in late 2023 and apply to anything new placed on the EU market after then*
- *the UK government approach is more pro-innovation, and as yet has not produced and concrete recommendations on UK regulations - it is likely to be much less onerous than the EU regulation*
- *The US FDA action plan for AI in medical devices, which will likely result in updates to FDA guidance*

I think that there are areas that really need to be addressed in order for us to have a regulatory landscape that protects people's safety, rights and freedoms, in a reasonable timeframe, and is workable for industry:

- *the capacity of the existing medical device regulators to assess AI*
- *how to control AI that is not regulated as a medical device where poor training and bias could lead to clinical harm*

- *the interaction with privacy regulation, and how to balance the public interest and the rights of the individual. A test case here would be personal data being used to train an AI, and a data deletion request subsequently being denied on the grounds that the data is used in maintaining the safety of a medical device*
- *having a good system of disclosure from AI providers on serious security, privacy or safety incidents*
- *how to achieve transparency from a technology that is often inherently not understandable or explainable*
- *clear standards and guidance to support good practice in training and validating AI performance*
- *harmonisation of standards to regulations, and a consensus across territories on a concise set*
- *labelling and communicating to the public where AI is being used*



STRAIGHT TO CONSUMER

HG Another trend that is developing in the MedTech sector is straight to consumer devices or applications, which encompass solutions designed purely for consumer use that do not go through the more traditional clinical pathway. But how does this model impact the regulatory standards MedTechs must abide by?

CRC *The regulations and standards are set up to deal with selling directly to consumers, with mechanisms for understanding and setting the standards for home use and over-the-counter products. This tends to mean that a higher level of risk and "usability" needs to be considered, accounting for all of the potential ways that a layperson could make mistakes, and this will attract greater scrutiny under review for regulated medical devices.*

When devices and services are sold directly to consumers, the manufacturer can have much less control and visibility of the way the products are used. The challenge is to find ways to effectively monitor whether products are used as intended, how often they are used, how effective they are and whether there are any new safety issues that were not anticipated.

There is also personal data privacy to be considered for software and services, as when patients interact directly, they are often sharing their personal data and healthcare data, often including "special category" data. This means that there is an overlap between medical device, privacy and security regulations. There are further ethical considerations and challenges to be considered, as companies must be careful to use data only for the purposes the consumers agreed, and avoid straying into new product development or generalisable research.

EXPERT ADVICE

HG Dr Iain Charlton delivers his final piece of advice to those looking to enter the MedTech space.

CRC

HAVE A HEALTHY RELATIONSHIP WITH REGULATIONS AND QUALITY STANDARDS:

Don't see regulations and standards as just barriers and blockers - the drive to produce the highest quality, safest, most effective product will naturally place yours ahead of your competitors as well as ensuring it complies with the relevant standards and regulations.

REMEMBER THE MORAL REASONS: WE WANT TO INNOVATE TO HELP PATIENTS

Keep a patient centred mission at the heart of your organisation and hold yourself to a high standard of integrity. With healthcare technology and medical devices, mistakes could result in serious harm or even death, even if it's indirectly - nothing should come before our duty to prevent this

My message to people on medical device quality and privacy have always been:

> "IF YOU CANNOT PUT YOUR HAND ON YOUR HEART AND SAY IT'S OK, THEN IT IS NOT OK - IT DOESN'T MATTER IF YOU CAN PROVE IT'S LEGAL, YOU SHOULD NOT DO IT."

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