



The 2013 Malcolm Carlisle Lecture

“Device Regulation and Liability – Taking Things Beyond Criticism”

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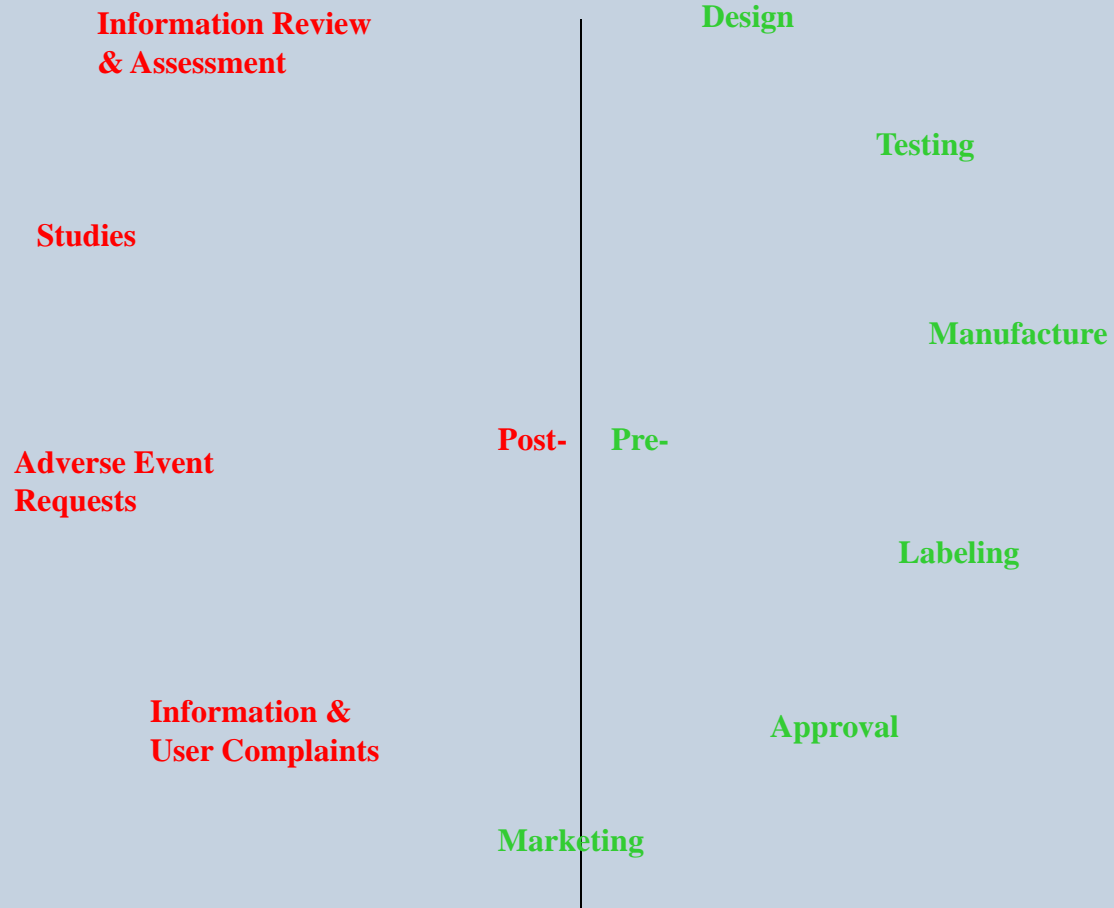
Erasmus Professor of the Fundamentals of Private Law, Erasmus University, Rotterdam

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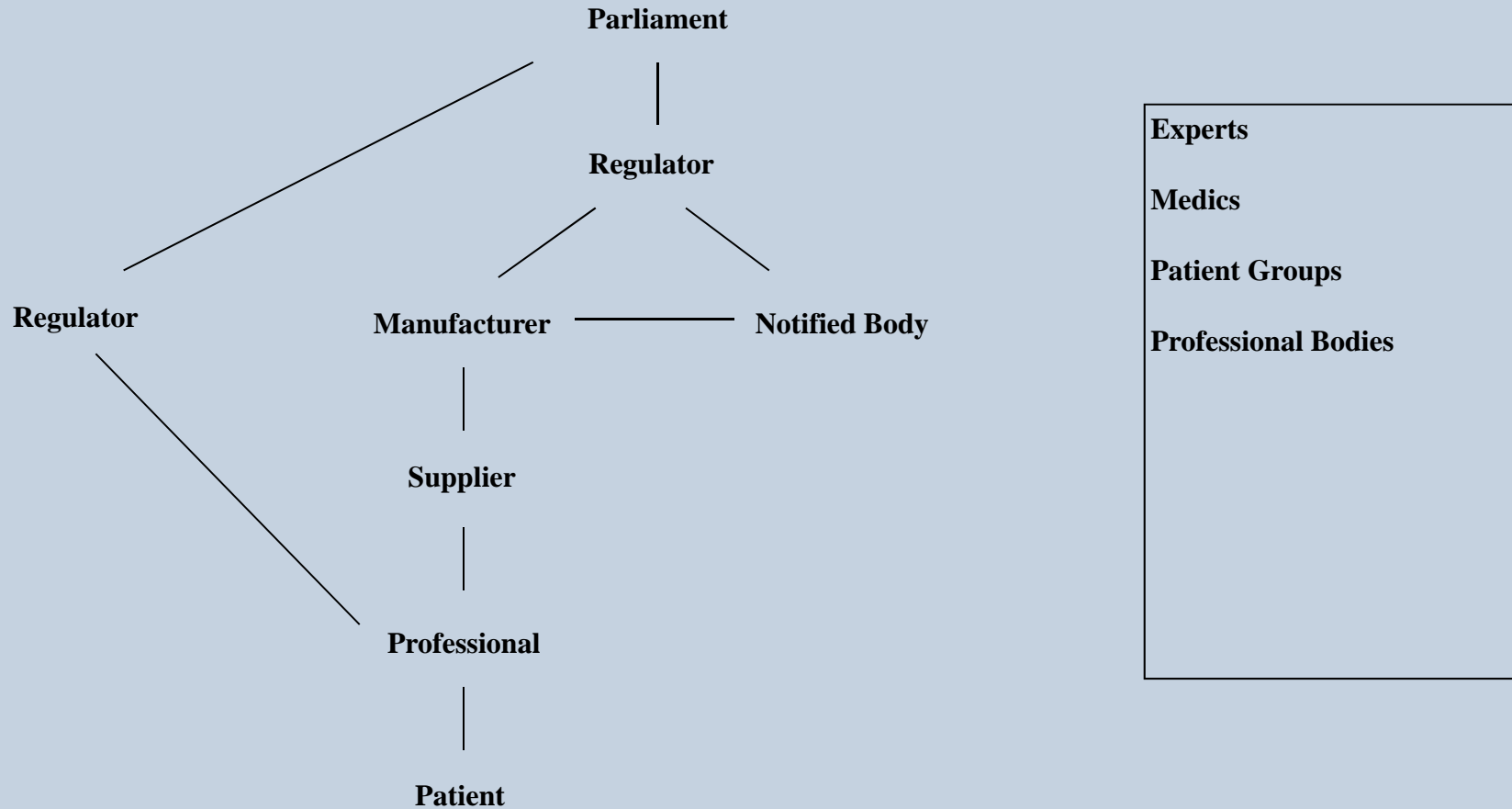
- A. Regulation
- B. Enforcement
- C. Liability and Compensation

A. The Regulatory System

- Pre-marketing
- Post-marketing PMS



Tiers: Meta-Regulation



Health warning over hip implants
Tens of thousands of patients who received hip replacements are at the centre of a major health alert over concerns they are poisoning their bodies.



EDITOR'S CHOICE
Serious risks from metal-on-metal hip implants
BMJ 2012; 344:doi:10.1136/bmj.e1539 (Published 1 March 2012)



7,000 MORE British women than previously thought have faulty breast implants, Government warns
By JENNY HOPE
PUBLISHED: 15:39, 15 March 2012 | UPDATED: 15:36, 16 March 2012

B. Enforcement of Regulatory Law

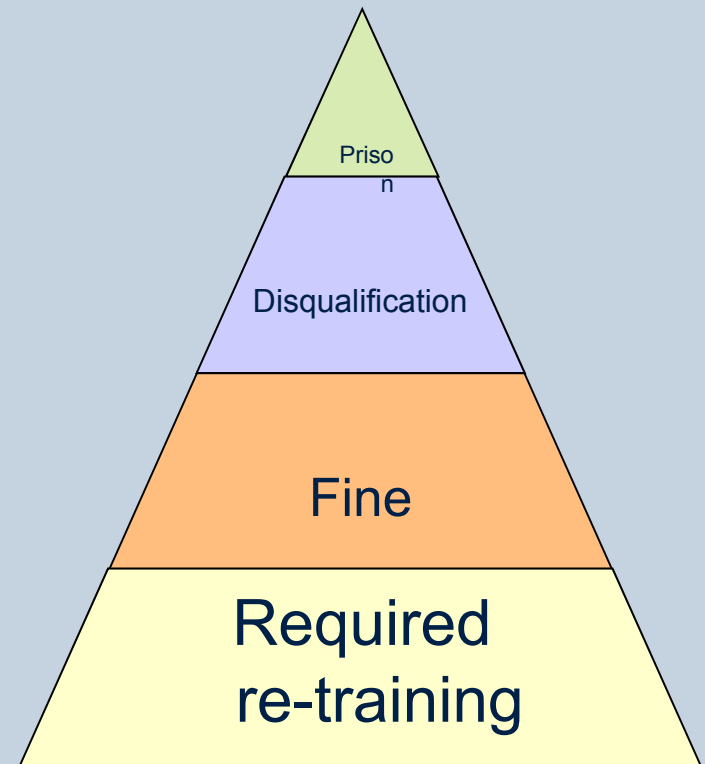
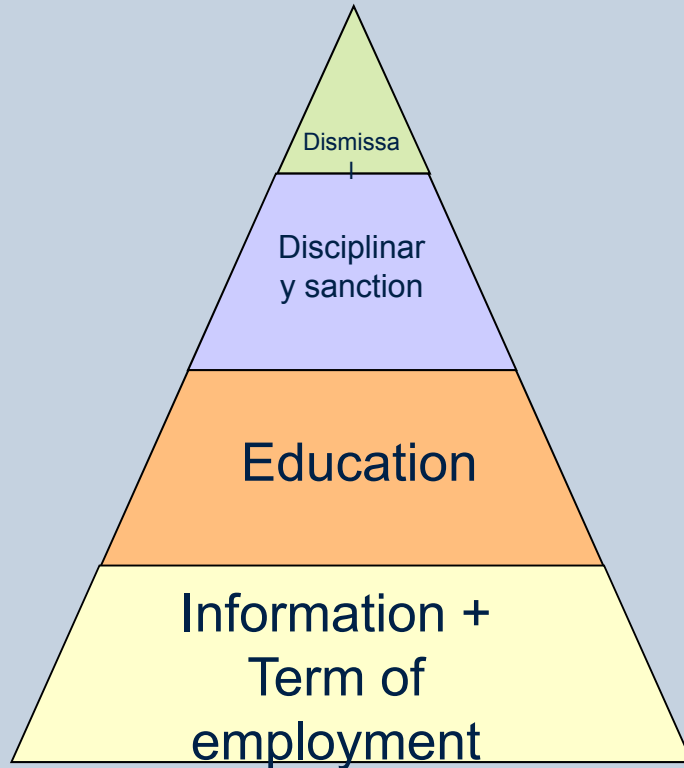
- Policy?
- Consistency?
- Effectiveness?
- Harmonisation?

B. Enforcement of Regulatory Law - Theories

- Deterrence
- Rational calculator
- Responsive Regulation

Two Braithwaite Pyramids

Internal Compliance + External Sanctions

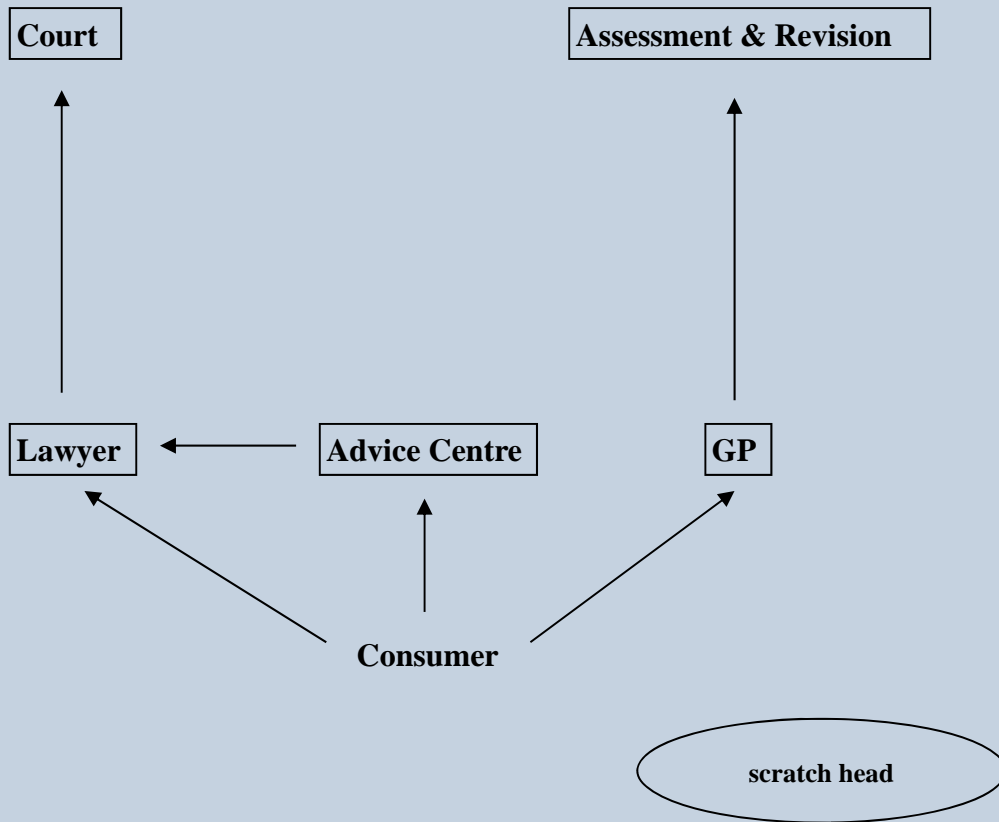


B. Enforcement - Psychology

People obey rules if

- The rule confirms to the individuals' own internal ethical values;
- The process of making and enforcing rules is fair;
- They are highly influenced by peers: compliance within regulated enterprises is repeatedly shown to be socially constructed

C. Liability and Compensation

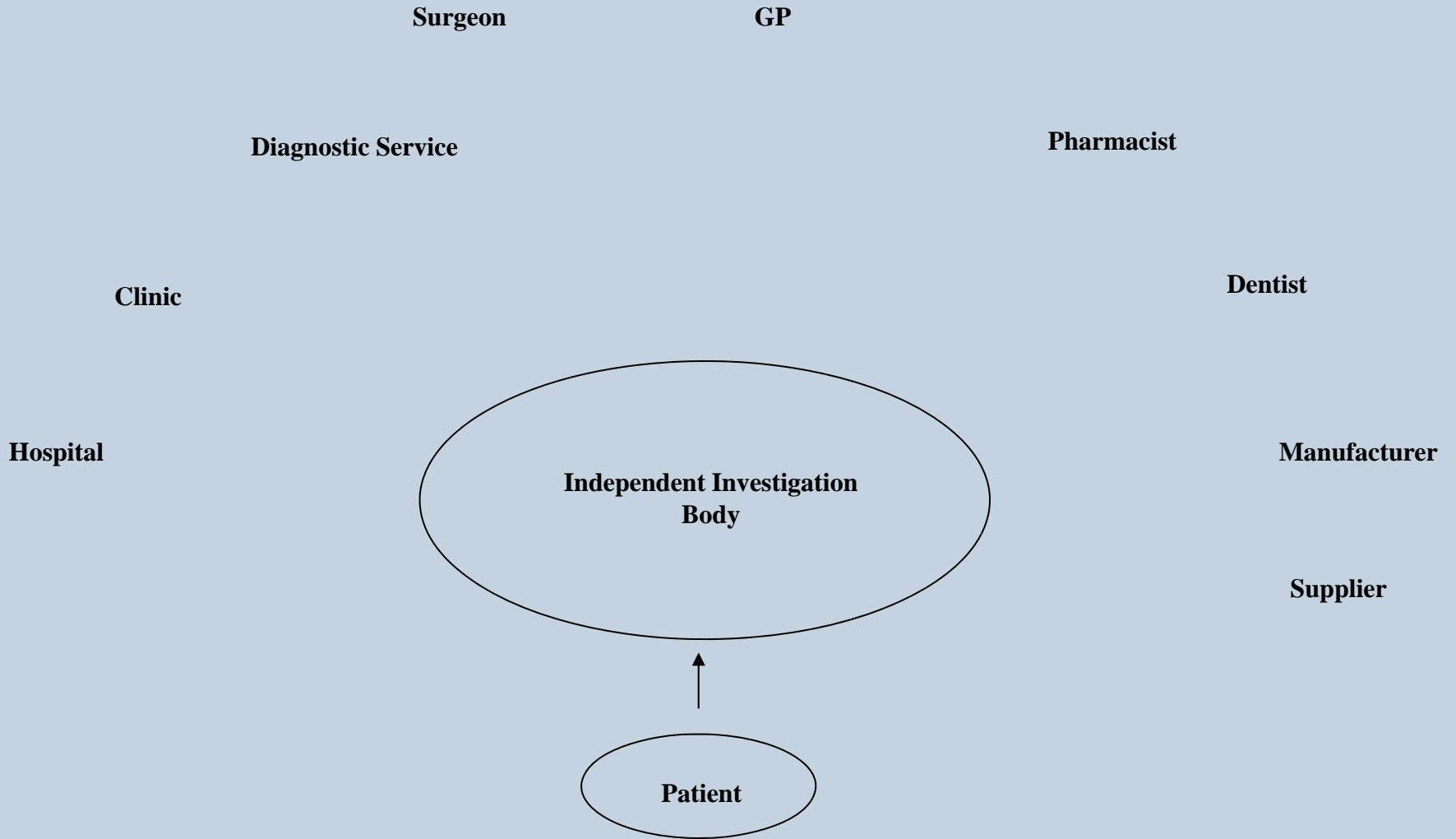


C. Liability and Compensation

The Consumer ADR movement – Ombudsmen

Personal Injury Solutions

- Nordics
- France ONIAM
- Ireland Injuries Board
- UK NHS (PHSO) → private healthcare ombudsman
- Medical devices and medicines?



D. Going Beyond Criticism

- Regulatory architecture – completing robustness
- Enforcement policy & practice – harmonisation
- Liability and Compensation – resign a more holistic, integrated system

D. Going Beyond Criticism -

- Building Trust
- Ethics as the basis of regulation, compliance, enforcement, care and compensation



JASON KWOK/CNN