

Protecting  
Advocating  
Serving

# Right-Touch Regulation

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11<sup>th</sup> Annual OIA Conference

Bad Nauheim, Germany

6 October, 2019



# Presentation Overview



- Introduction to FSMB
- Background on Right-touch Regulation
- Right-touch Regulation and Risk
- Current and Future Applications

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# Federation of State Medical Boards

- Represents all 70 state medical and osteopathic boards in the United States and its territories
- Co-owns the USMLE (United States Medical Licensing Examination)
- Secretariat, International Association of Medical Regulatory Authorities (IAMRA)
- Publishes the *Journal of Medical Regulation*, since 1915
- Board Chair: Dr. Scott Steingard (Arizona)
- Mission: Support medical regulation through education, assessment, research and advocacy while providing services and initiatives that promote patient safety, and quality health care and regulatory best practices.

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# Right-touch Regulation



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# Right-touch Regulation

## Formal Definition:

- ‘Right-touch regulation is based on a proper evaluation of risk, is proportionate and outcome focused; it creates a framework in which professionalism can flourish and organisations can be excellent’

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- ‘Right-touch regulation is based on a proper evaluation of risk, is proportionate and outcome focused; it creates a framework in which professionalism can flourish and organisations can be excellent’

## Common Definition:

- ‘The minimum regulatory force required to achieve the desired result’

# Principles of Right-touch Regulation

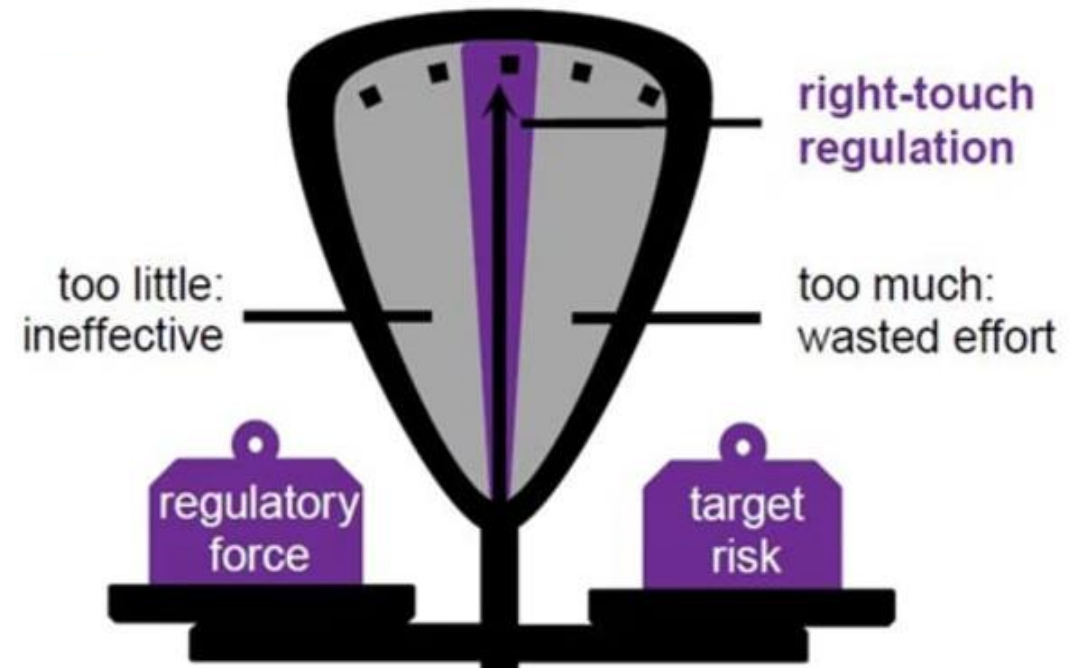
Regulation should aim to be:

- Proportionate: regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised
- Consistent: rules and standards must be joined up and implemented fairly
- Targeted: regulation should be focused on the problem, and minimise side effects
- Transparent: regulators should be open, and keep regulations simple and user friendly
- Accountable: regulators must be able to justify decisions, and be subject to public scrutiny
- Agile: regulation must look forward and be able to adapt to anticipate change



# 8 Elements of Right-touch Regulation

1. Identify the problem before the solution
2. Quantify and qualify the risks
3. Get as close to the problem as possible
4. Focus on the outcome
5. Use regulation only when necessary
6. Keep it simple
7. Check for unintended consequences
8. Review and respond to change



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# What do we mean by risk?

- Risk refers to the risk of **harm** to the public that the regulator is there to reduce

# Risk, Harm and Hazards

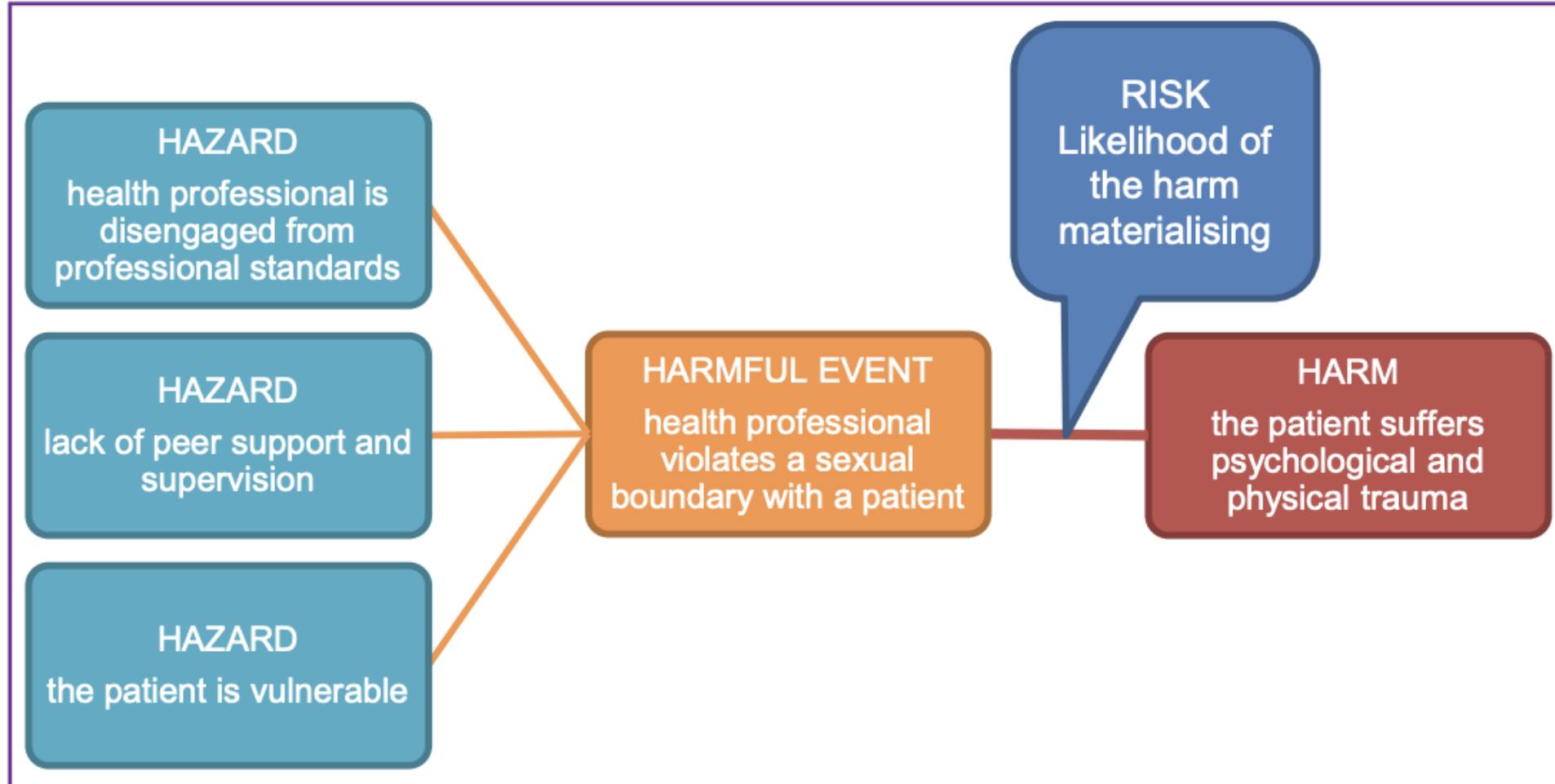


Figure 4. How hazards create the risk of harm – an example from healthcare.

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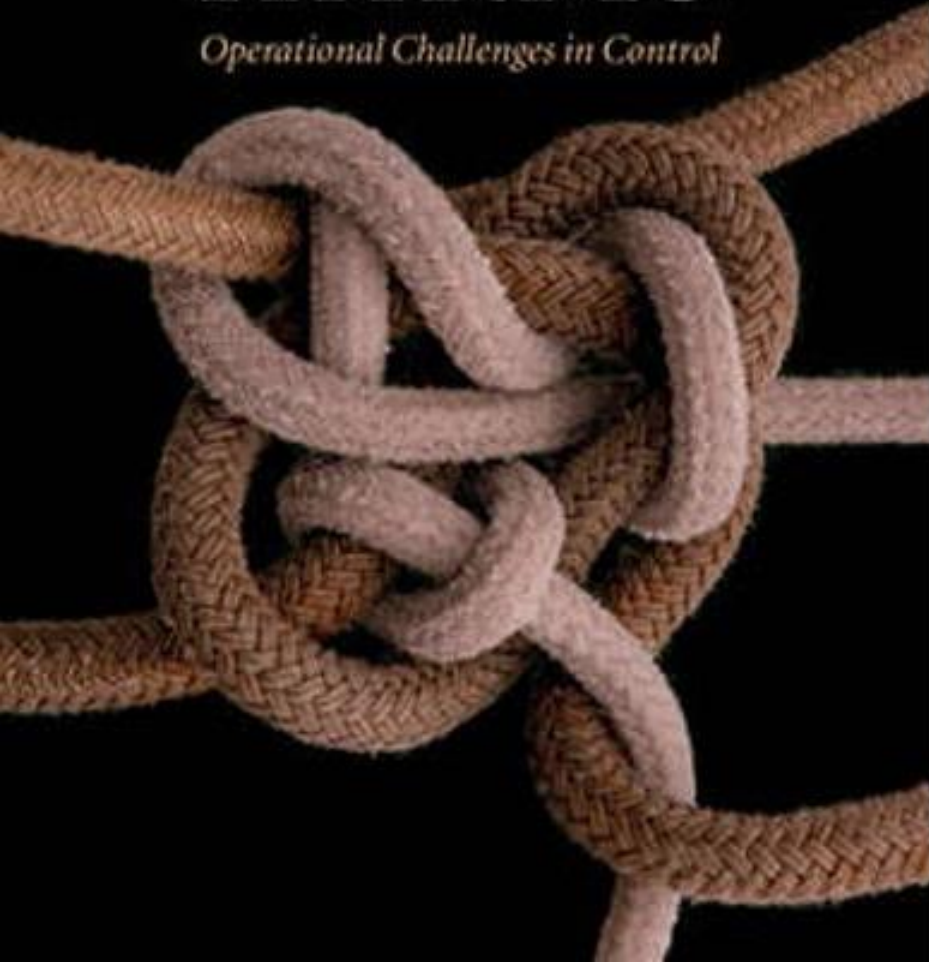
# What does that mean for regulation?

- Risk refers to the risk of **harm** to the public that the regulator is there to reduce
- Risk-based regulation focuses on identifying and addressing the **causes** of a risk of harm, rather than responding after the harm has occurred
- Once a risk has been evaluated, a decision needs to be made about its **tolerability**.

MALCOLM K. SPARROW

# THE CHARACTER *of* HARMS

*Operational Challenges in Control*



## Risk Reduction (Sparrow)

- Focus on “Expert” rather than “Legal” model of regulation
- Focus more on identifying and reducing “bads”, less on defining and promoting “goods”
- Practice “Regulatory Craftsmanship”
- Master new organizational methods (less program-centric, more problem-centric)
- Fit different regulatory structures to different classes of risk
- Use risk-mitigation as the foundation for partnerships
- Understand types of risk that pose special challenges



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# Risk Factors, defined...

- A risk factor negatively impacts any facet of performance
- A support factor helps to foster, develop or improve performance, fostering safe practice and promoting quality
- Risk and Support factors can exist at individual, organizational and system levels

Takahashi et al., 2017





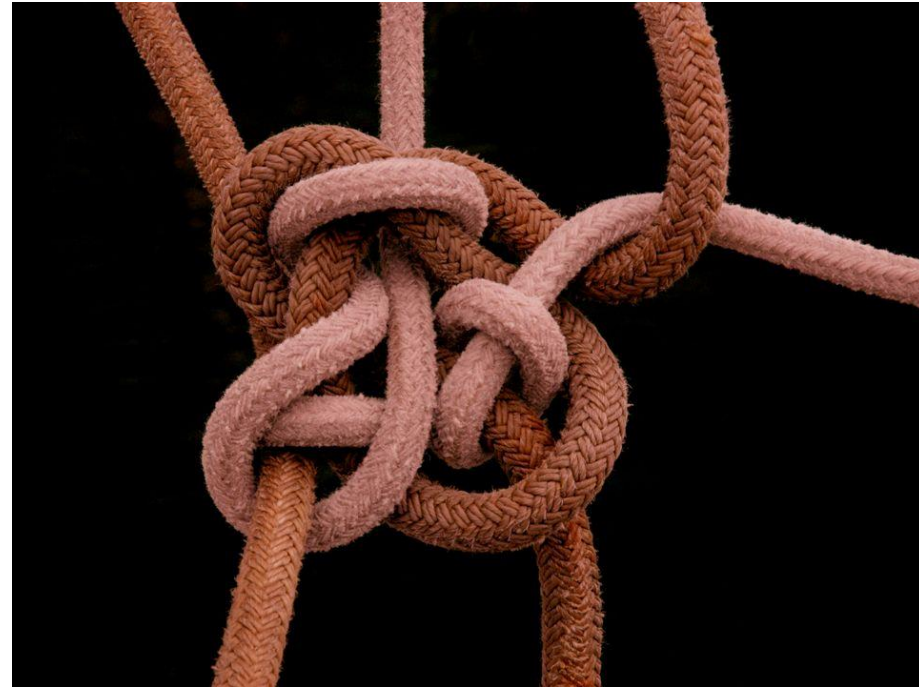
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# US Context

- What could risk-based and/or right-touch regulation mean for state medical boards and the FSMB?
  - Duty to Report
  - Opioid Crisis
  - Sexual Misconduct
  - Incompetence
  - Unprofessionalism



# FSMB Workgroup to Study Risk and Support Factors Affecting Physician Performance

- Collect and evaluate data and research on risk/support factors, including practice context, gender, time in practice, examination scores, and culture;
- Convene stakeholder organizations and experts to discuss patient safety issues and ethical and professional responsibilities related to performance;
- Identify principles, strategies, resources and best practices for assessing and mitigating potential impacts on performance;
- Provide information to state medical boards about risk and support factors, impact on patient care, and key principles for consideration of fair, equitable and transparent regulatory processes.



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# Right-touch Regulation and Technology

- Supply of raw data is greater than ever
  - Focus on Data Capabilities and Preparedness
  - Licensing Decisions: Achieve quicker analysis of critical static elements
  - Increase capabilities for prediction and early intervention
- Work towards digitization of key regulatory elements
- FSMB's *Healthcare and Digital Credentials* Report (available at [fsmb.org](https://www.fsmb.org))
  - AI + Blockchain = Regulatory efficiency and improved stakeholder experience



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# FSMB Taskforce on Artificial Intelligence

- Evaluate the intersection of care delivery models which utilize AI with existing FSMB policies,
- Create a public-facing platform to provide educational resources to state boards and the public,
- Identify opportunities to collaborate with interested domestic and international stakeholders to develop policies and standards
- Study the ability of AI to support state medical boards with their regulatory responsibilities and adjudicatory functions





PROMOTING THE HIGHEST STANDARDS FOR  
MEDICAL LICENSURE AND PRACTICE

Thank You!  
Danke Schön!



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