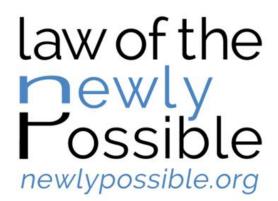# Developing Danger

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Dangerous innovation

- Existing dangers
  - Motor vehicles, personal medicine, homes….

- Emerging dangers
  - Drones….

- (As always, categorization depends on how we draw the boundaries of our system)
  - *Lawyers and Engineers Should Speak the Same Robotic Language,* newlypossible.org

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Danger

when a technological failure would imperil

(substantially, irreversibly, and noncompensably)

the physical safety of others

How safe is safe enough?

- What is reasonable safety?

- What is reasonable assurance thereof?

- Who makes this assurance?

- Who has the burden of proof?

- Who decides?

Delegating the safety case

- Developers make a public argument for the safety of their systems

- Regulators, with input from the public, evaluate the reasonableness of that argument

- Regulators exercise substantial discretion and receive substantial deference

Why?

- Flexibility for developers

- Flexibility for regulators

- Information for regulators and the public

Statutory/regulatory triggers

(ex ante approval; not ex post liability....)

- Obtain prior approval
- Avoid subsequent disapproval
- Clarify relevant legal provisions
- Obtain an exemption for legality
- Obtain an exemption for marketability

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Mechanics

1. **Scope:** A developer identifies an activity (product, process, service….) for which it wants or needs a specific regulatory action

2. **Documentation:** The developer documents its planned conduct (design, testing, marketing, monitoring….) over the lifecycle of this activity

3. **Presentation:** The developer publicly presents this documentation in the form of a safety case

4. **Public comment:** The regulatory agency and interested parties comment on this safety case

5. **Public response:** The developer publicly addresses these comments

6. **Agency determination:** The agency determines whether the manufacturer has presented a reasonable safety case

7. **Agency action:** The agency conditions its primary regulatory action on compliance with this safety case

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Example: automated vehicles

1. **Scope:** Company X wants DMV to permit registration of its new vehicles

2. **Documentation:** Company X documents its design process (ISO 26262), the results of its testing and simulation, and its plans for monitoring and updating

3. **Presentation:** Company X releases this information publicly and argues why it demonstrate a reasonable approach to safety

4. **Public comment:** Academics, consumer watchdog groups, and Company X's competitors identify general and specific concerns

5. **Public response:** Company X substantiates or modifies its safety case in response to these concerns

6. **Agency determination**: The DMV determines whether Company X's safety case, including its response, is reasonable

7. **Agency action:** The agency agrees to register vehicles that the developer certifies to comply with its safety case

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Ex post liability

- Relationship between safety case approval and civil liability can vary across states
    - Analogy: Negligence per se

- Noncompliance as evidence (or proof) of negligence, defect, or misrepresentation

- Compliance as evidence (or proof) of reasonable conduct and reasonable design

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Analogies

- EU type approval (homologation)

- Environmental impact statements

- Notice and comment rulemaking

- Functional safety and risk management

- Community benefit agreements
  and good neighbor agreements
  - h/t Michael Baram's talk at this conference

Challenges

- Delay

- Caution

- Stasis

- Capture

- Compliance industry

- ….

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Progress….

Replacing an old set of problems with a new set of problems…

…and hoping that the new set, in aggregate, is smaller than the old set.

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