Developing Danger

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May 27, 2015
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
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
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
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 demonstrates 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
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
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
• ....
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.