

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

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

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 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
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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.