The Legal Aspects of Regulatory Compliance

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I. General Theories of Legal Liability

Administrative Law

- FCC
- OSHA
- FDA
- State Agencies
Civil Law

- tort – injuries to persons or property
- contract
- antitrust, unfair competition etc.

Criminal Law

- intentional misconduct
II. Who is at Risk?

- Manufacturers designers and distributors of products
  - direct and indirect
  - severally and jointly
Employees are protected by “master-servant” rule

Independent contractors are not
III. Administrative Liability

- Public interest standard
  - health safety and welfare of public is paramount
  - typical violation is putting a non-compliant product on the market or into service

- Technical vs. administrative non-compliance

- Sanctions for rule violations
  - generally broad spectrum of enforcement options
FCC Sanctions for EMC violations

- fines and forfeitures -- can be assessed per violation or per day for continuing violations to a maximum continuing violation of up to $97,500.

  • interference to licensed services $7K
  • marketing unauthorized equipment $7K
  • use of unauthorized equipment $4K
  • unauthorized emissions $4K
• upward adjustments in fines for:
  ➢ egregious conduct
  ➢ ability to pay
  ➢ intentional violations
  ➢ substantial harm
  ➢ prior violations
  ➢ substantial gain
  ➢ repeated violations
Recent examples of FCC fines:

2003 -- $100K fine to Itron for selling non-compliant wireless meter readers

2004 -- $125K fine to Pilot Travel Center for selling non-compliant CB radios at 11 pilot travel outlets

2004 -- $75K fine to ACR Electronics for advertising and trade show displays of pre-compliant personal locator beacon without the required disclaimer; each ad and display was a separate violation
• cease and desist orders

• equipment seizures -- can be done via “in rem” actions

• grant revocations – rare

• Public Notice of violations
Recent examples of FCC Notices:

2003 -- Vector Manufacturing; 6 models of battery chargers labeled as complaint; prior to enforcement action FCC warned retailers not to sell or risk sanctions

2004 -- All music retailers warned that electronic instruments and recording equipment were subject to FCC rules and selling of non-compliant equipment would risk sanctions
- Consent Decrees – “negotiated” settlements
  - customer notifications
  - fixes
  - recalls
  - implementations of QA program
IV. Civil Liability

Negligence

- “reasonableness” standard
- elements -- duty, breach, causation, injury
- compensatory and punitive damages
- applies to designers, manufacturers, vendors, test labs
Warranty and Contract

- express and implied warranties
- promises and representations made in contracts
- parties must be in privity
- damages generally limited to economic injury
Strict Product Liability

- no-fault
- must show defective product
- product must have been used in a foreseeable way
- compensatory and punitive damages
- everyone in chain of distribution can be liable
V. Why Multiple Theories of Liability

- Elements of proof are different
  - fault required for negligence
  - defective product required for SL
  - warranty only covers products not services
  - warranty and contract requires privity with plaintiff

- Recoveries are different
  - punitive damages available under negligence and SL
  - economic loss only under contract and warranty
VI. Trends in Law

- Evolving notions of what is a “defective” product
  - non-state-of-art EMC design

- Expanded concept of foreseeability of harm
  - foreseeable misuse

- Expanded class of protected plaintiffs
  - bystanders, “good Samaritans” covered
VII. Case Studies on Liability for Non-Compliance

Case Study #1:
ABC company makes a plasma TV that emits on a search and rescue frequency. A monitoring satellite picks up the TV signal and sends out a “rescue alert”. State and federal emergency response personnel show up at the home of the TV owner. Who is responsible for what?
• **Owner**

  ➢ **FCC administrative liability**

    » must cease operations
    » could be fined for unauthorized emissions
    » TV could be seized

  ➢ **Other administrative liability?**

    » could be assessed the cost of a responding to false alarm
• **TV Manufacturer**

  ➢ **FCC liability**

    » could be fined for marketing violations or unauthorized emissions
    » Public Notice could be issued warning retailers not to buy
    » could be compelled to sign consent decree on recalls/fixes

  ➢ **Civil Liability**

    » would be liable to purchasers and dealers under warranty or contract theory (economic damage only)
Case Study #2:
XYZ company makes an oxygen monitor but fails to test for EMC as required by FDA. Sells it to a hospital under a purchase order requiring it be “safe and effective for use in an OR”. Monitor malfunctions due to EMC susceptibility problem in the OR and a patient is injured. Who is responsible for what?
• Hospital

  ➢ Administrative liability?

    » FCC doesn’t regulate EMC susceptibility; FDA regulates medical device sales not use
Civil liability

» could be liable for negligent purchase and use of susceptible monitor

» could be liable under breach of patient services agreement

• **XYZ Company**

  ➢ Administrative liability

  » could be liable to FDA for misbranding or adulteration of medical device; failure to obtain marketing approval
Civil liability

» could be liable to patient for negligent design, manufacture and/or marketing of monitor

» could be strictly liable for placing a defectively designed device on the market that would foreseeably be used in a high EMI environment

» could be liable to hospital and dealers for breach of contract or warranty for sale of non-FDA-compliant device
What if monitor received FDA clearance based on improper susceptibility testing performed by independent EMC lab?

• EMC Lab

➢ Administrative liability?

» not the manufacturer or marketer of the device
➢ Civil liability

» could be liable to patient under negligence or contributory negligence theory

» could be liable to manufacturer under a breach of contract theory
Case Study #3:
Company X wants to sell stock to the public. A due diligence report indicates that a line of products are not in compliance with FCC rules. The public offering states that X “meets all governmental requirements” for its products. What could happen?
Company X could face civil liability for SEC rule violations if investors are not informed of FCC violations and violations are considered material.
Case Study #4:
Company Z makes electronic devices. It has a revolving line of credit for business operations. The loan documents require Z to be in compliance with “all applicable government rules and regulations.” Lender take a security interest in Z’s inventory. Subsequently, lender discovers from an FCC enforcement notice that Z was fined for shipping a quantity of non-compliant products. What could happen?
Lender

- could call in the loan and/or levy on Z’s inventory under a breach of contract theory.
VIII. Minimizing Exposure to Liability

Warnings for safe use; dangers of foreseeable use

- would warnings have worked with the susceptible oxygen monitor?

Disclaimers and hold harmless provisions in contracts

- would this work for the TV manufacturers in the S&R case?

- for the EMC lab in the monitor case?
QC and adherence to standards programs

Thorough documentation of product design

State of art design and testing
IX. When You Discover a Compliance Problem

- Assess the problem completely – technical and administrative
- Consult with counsel on extent of legal exposure
- Get the regulatory agency involved early to head off larger problems later on
  - Some agencies require that you report non-compliance
- Seek favorable rule interpretations, STAs, testing allowances, waivers to correct/minimized violations
Thank You