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The Legal Aspects of Regulatory Compliance

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14-Dec-04

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 for selling non-compliant wireless meter readers

2004 -- $125K fine for 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?

- <u>Owner</u>
  - 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

- <u>TV Manufacturer</u>

  - 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

- <u>XYZ Company</u>
  - 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?

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- 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?

- <u>Lender</u>
  - 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

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Thank You