ANATOMY OF A LAWSUIT

PRACTICAL REALITIES OF CLINICAL TRIALS LITIGATION

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Plot … and Subplot

Background of Research

AbioCor: totally implantable artificial heart

Feasibility study of 15 patients

Eligibility:

- within 30 days of death (70% likelihood)
- maximum medical management
- ineligible for heart transplantation

IPAC (Independent Patient Advocacy Council)

Patient's Course

- 11/5/01: patient receives implant
- 11/01, 12/01: doing well
- 12/31/01: minor stroke, still doing quite well
- Early 2/02: returned to hospital
- Early 3/02: back on ventilator
- Spring, summer '02: efforts to get pt home
- Early 7/02: extubated, somewhat better
- 8/25/02: stroke $\Rightarrow$ death
- 8/27/02: vent, heart turned off

Quinn v. ABIOMED et al.

Filed October 16, 2002
plaintiff-attorney: Alan Milstein

DEFENDANTS

- Drexel University (private medical school)
- Tenet HealthCare Corporation
- Hahnemann Hospital (owned by Tenet)
- ABIOMED, Inc.
- David Casarett, MD (patient advocate/PA)

Primary Allegations

- Breach of Informed Consent
  - Patient did not know device was experimental
  - Patients within 30 days of death are vulnerable to 'therapeutic misconception'
- Wrongful life
- Loss of consortium
- Product liability
- Fraud, negligent misrepresentation, negl/int'l infliction of emotional distress, etc

Primary Allegations, cont.

- Patient advocate malpractice:
- PA allegedly
  - Did nothing at the informed consent conference, other than to ask patient, family if they had questions
  - Failed to advise patient regarding whether it was in his best interest to participate
  - Failed to set up communication with the wives of the other subjects
  - (Etc.)

Procedural Summary

- October, 2001: complaint filed
- February 2002: Tenet, Hahnemann, Drexel settle
- Attorneys for ABIOMED, PA conduct informal conversations with Milstein
- Milstein approaches liability insurance company directly, offers to settle for small sum

Procedural Summary, cont.

- Liability insurance company orders defense attorneys to settle the case
  - No depositions, no document exchanges--no discovery undertaken
- By stipulation among attorneys, all claims against PA are dropped, with prejudice
- Total amount of settlement among 4 defendants (Tenet, Hahnemann, Drexel, ABIOMED): $125,000

Problems with Allegations

- "Wrongful life" vs. "Loss of consortium" vs. final settlement stated as "Wrongful death"
- Patient advocate "standard" requiring PA to tell prospective research subject whether it is in his best interest to enroll
- Bare fact that patient was eligible for trial (within 30 days of death) $\Rightarrow$ patient should not enter trial

Insights, Lessons

- A: Plaintiff-attorney controls the public face of the suit
- B: Defense attorneys work under significantly, unavoidably conflicted loyalties
- C: It is important to read insurance contracts
- D: Settling cases is a troubling, albeit complex option

A. Plaintiff-attorneys control the public face of the suit

- Plaintiff-attorneys:
  - write the complaints
  - speak to media
- Defendants:
  - constrained by confidentiality
  - public statements can be misconstrued by plaintiff-attorney, thus creating hazard
  - settlements usually require confidentiality, so defendants' side may never come out
  - even plaintiff-attorney may never know the facts

B. Defense attorneys work under significantly, unavoidably conflicted loyalties

- Insurer retains attorney, controls defense
  - Like managed care: preferred attorney roster, utilization management
- Many attorneys regard insurer as a 'client', alongside defendant
- Defendant's wishes, interests, can clash with insurer's

Conflicted Loyalties, cont.

- Defense attorneys may not be party to coverage disputes between insurer and defendant/insured
  - Mission to defend insured should not be deterred by disputes between insurer and insured
  - Attorney must not be caught between two ‘clients’
- Unlike HMO, attorney cannot plead insured’s disagreements with insurer’s constraints on defense
- Situation clashes with law’s usually strong proscription against conflicts of interest

C. It is important to read insurance contracts

- Procedural oddity:
  - Insurer must approve each attorney expenditure (akin to HMO arrangements, incl. 'preferred provider' list)
  - IPAC's insurance policy had sizeable deductible
  - Attorneys routinely asked insurer for permission to spend IPAC money
- Procedural oddity:
  - insurer required settlement without consent of insured
  - may not have been entitled to do so

From insurance contract …

- "We may, at our discretion, investigate any 'occurrence' and settle any claim or 'suit' that may result. But: (1) The amount we will pay for damages is limited as described in "Limits of Insurance" ... ; and (2) **Our right and duty to defend does not begin until the applicable limit of your self-insured retention has been used up** in the loss reserves and payment of judgments, settlements and defense expense." [emphasis added]

D. Settling cases is a troubling, albeit complex option

- Strong temptation to settle
  - Institutions: limit disclosure of sensitive details
  - NFP institutions: severe drop in donations 2° suit
  - Insurers: high costs of defending suits
  - Significant uncertainties in jury decisions
  - High cost of appealing undesirable jury verdict

D. Settling cases is a troubling, albeit complex option, cont.

- Problems with hasty settlements
  - Dishonor those who are wrongly maligned
  - Reward plaintiff-attorneys even for bogus cases, encourage more such suits
  - "In terrorem" effect on research community
  - Create pseudo-standards by default
  - Defer opportunity for courts to become clearer on the issues, provide better guidance on research-related injuries

THE ROAD AHEAD:

A TWISTED PATH …