ANATOMY OF A LAWSUIT

PRACTICAL REALITIES OF CLINICAL TRIALS LITIGATION

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Third National Medical Research Summit, 2003

Plot … and Subplot

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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)

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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 ⇒ death
• 8/27/02: vent, heart turned off

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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, neglig/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) ⇒ patient should not enter trial

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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 …