“We Were All Sold a Bill of Goods”
Litigating the Science of Breast Cancer

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Overview

- Tension between technology, science, cost control
  - HDC-ABMT as illustrative
  - Conflicting values
    - Availability of therapy
    - Evaluating therapeutic effectiveness
- Role of litigation
  - Strategies/tactics
  - Health policy
- Policy considerations
The ABMT Procedure

- Provide standard chemotherapy with FDA-approved drugs (responsiveness)
- Aspirate/rescue bone marrow stem cells
- Administer HDC (2x-10x standard dose)
- Reinfuse bone marrow stem cells
- Add growth factor
- Wait and watch
- Painful and toxic
Factors Driving Utilization

- Phase II studies (Antman, Peters)
- Judicial decisions—*Fox v. HealthNet*
- Entrepreneurial oncology
- State legislative mandates
- Federal agency decisions—OPM
- Physician/patient advocacy
- Media attention—horror stories
The HDC/ABMT Experience

Clinical utilization path (off protocol)
- Court cases: 1991-2002
- Federal and state mandates

Emergence of a treatment
- 1975
- 1987
- 1988
- 1992

Legitimation

Evaluation
- Comb therapy
- Hi-dose chemother
- Bone marrow tx
- Adjuvant therapy
- Growth factors
- Phase 2 studies
- Transplanters

Clinical evaluation path (on protocol)
- Patient advocacy
- The media tells the story
- Technology assessments: 1988-96
- Randomized clinical trials: 1990-2003
- ASCO: 1999; Audits: 2000

-23,000–40,000

-1,000
Legal Issues: Methods

Analyzed all reported HDC-ABMT cases

- Jury verdicts (4)
- Litigated cases from 1988-2002 (88)
- Focus on leading cases
  (i.e., Fox v. Health Net)

Fox as paradigmatic case
Legal Issues: Methods

• Interviewed leading plaintiffs’ and defense counsel (4 of each)
  ➢ Semi-structured interview protocol
  ➢ Litigation strategies
  ➢ Negotiating strategies
  ➢ Lessons learned

• Responses consistent within groups, but not monolithic
Litigation Trends

Outcomes maddeningly unpredictable

- No pre-Fox/post-Fox differences on who wins
  - ERISA vs. Non-ERISA cases
  - 1988-1993: insurers 17, patients 16
  - 1994-2002: insurers 26, patients 28
  - Litigation peaked in 1993-1994

Settlement negotiations dramatically favor patients post-Fox

Jury verdicts split
Primary Legal Issues

- Contract interpretation re: exclusion of HDC-ABMT
- Standard of care vs. experimental therapy
- Bad faith
- Informed consent
- Role of expert witnesses/scientific evidence/clinical trials
- Role of sympathy and emotion
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The Contract

- Defense—experimental/investigational exclusion

- Plaintiffs
  - Provisions ambiguous
  - Often bifurcated in contract
  - Paid for similar procedures for men
  - Extension of recognized treatments

- Marketing considerations

- More tightly drafted over time
Standard of Care

- Defense—experimental, not standard of care

- Plaintiffs
  - Relied on community oncologists to show widespread use of HDC-ABMT
  - HDC-ABMT as extension of recognized treatments, not a new innovation
Bad Faith

- Key to strategies—punitive damages

- Defense
  - Reasonable attempt to deal with controversial procedure - not bad faith
  - A legitimate dispute

- Plaintiffs
  - Inconsistencies re: other unproven procedures
  - “He who has the gold makes the rules.”
Informed Consent

**Defense**
- MDs informed patients that experimental (in context of RCT, not in clinical treatment)
- Patients cross-examined on contract and MD’s explanation

**Plaintiffs**
- Great concern

**Courts**
- Ignored
- Link rejected
- Negligible role hard to understand
Strategic Challenges: Expert Witnesses

- **Plaintiffs--widespread use**
  - Treating physician/community oncologists
  - No hope—“I did it to help the patient.”
  - Vulnerable on the science

- **Defense reliance on medical director**
  - Expert opponents unwilling to testify
  - Experimental tx
  - Vulnerable to inconsistent decisions and not seeing patient
Strategic Challenges: The Science

- Should have been defense strength
  - Courts not receptive to academic experts
  - Key to avoiding punitive damages
- Plaintiffs relied on Peters/Antman
  - Not equivalent to laetrile – not quacks
  - Extension of recognized treatments—”I’ve been doing this for 25 years.”
  - Prevailing clinical practice
Strategic Challenges: Sympathy and Emotion

- Fundamental to plaintiffs’ strategy
  - Defense downplayed it as a factor
- Negative image of insurers, MCO’s
- Medical director’s failure to examine patients
- “Once opening arguments begin, the defendant is in trouble.”
- Public mindset of no limits
Different Narratives: I

- Plaintiffs—“Her only hope” - easy to sell as sound bite
  - Improved patients’ quality of life
- Defense: more complex
  - “Why would women go through this?”
  - Cases were never winnable
    - Sympathetic patients
    - Arrogant/inconsistent administrators
Different Narratives: II

- Both sides correct: widespread diffusion, but experimental
- Overlap on bad faith
- Backdrop of antipathy to insurers/managed care
  - Media horror stories
Different Narratives: III

- Disputes over proper forum for resolving cases
  - Defense wanted clinical trials
  - Plaintiffs’ attorneys wanted judicial forum

- Science vs. law
  - Both failed
  - Hard to “sell” science in court
Ethical Issues

- **Conflicting physician roles**
  - Informed consent process
  - Entrepreneurial oncology

- **Experimental therapy and RCTs**
  - Need to protect scientific evaluation process
  - Role of insurers

- **Litigation represented different moral views of the world**
  - Last chance vs. unproven treatment
  - Treatment-related mortality
Policy Aspects: 1

- Values in conflict
  - Scientific effectiveness vs. legitimate patient demands
  - Lack of mediating institution

- Initial conditions matter
  - Once procedure diffuses, difficult for courts to intervene
  - Entrepreneurial oncology

- Technology Assessment
Policy Aspects: II

- **Role of the courts**
  - Limited once procedure diffuses
  - Limited influence on policy
  - Deferential to medical expertise
  - Reluctance to intervene

- **State/federal mandates**

- **Comparative institutional analysis**
Policy Aspects: III

- Trial tactics/strategies key to litigation outcomes
  - Strategic vulnerabilities in future litigation
  - *Abigail Alliance v. Eschenbach*
Conclusion

- Mechanism needed to determine effectiveness before diffusion
- Litigation is no way to make sound health policy
- “We were all sold a bill of goods”