"We Were All Sold a Bill of Goods"

Litigating the Science of Breast Cancer

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Overview

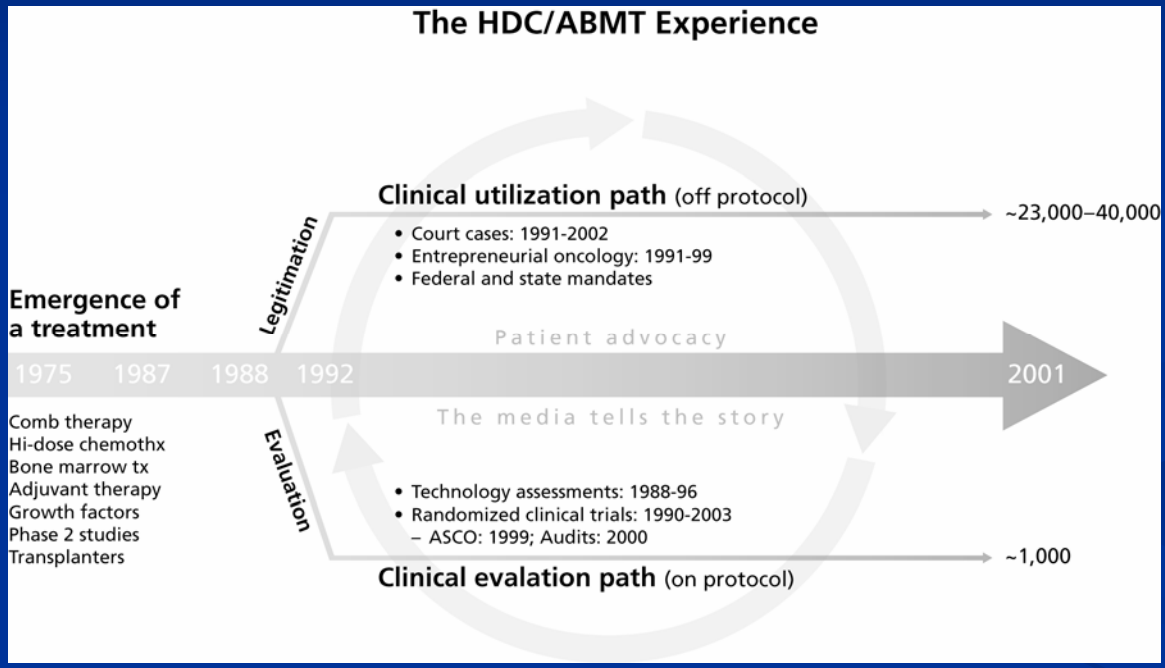
- Tension between technology, science, cost control
  - HDC-ABMT as illustrative
  - Conflicting values
    - Availability of therapy
    - Evaluating therapeutic effectiveness
- Role of litigation
  - Strategies/tactics
  - Health policy
- Policy considerations

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)
~23,000–40,000
• Court cases: 1991-2002
• Entrepreneurial oncology: 1991-99
• Federal and state mandates
Legitimation
Emergence of a treatment
Patient advocacy
1975
1987
1988
1992
2001
The media tells the story
Comb therapy
Hi-dose chemothx
Bone marrow tx
Adjuvant therapy
Growth factors
Phase 2 studies
Transplanters
Evaluation
• Technology assessments: 1988-96
• Randomized clinical trials: 1990-2003
– ASCO: 1999; Audits: 2000
~1,000
Clinical evalation path (on protocol)

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

Litigation Issues	Plaintiffs	Defense
Contracts	Ambiguous	Excluded
Standard of Care	Widespread diffusion	Experimental
Bad faith	Arbitrary/inconsistent	Legitimate dispute
Informed Consent	Not fully informed	Clearly told
Expert witnesses	Avid supporters	Medical director
The science	Not laetrile	Unproven
Sympathy/emotion	Fundamental	Equivocal

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: I

- 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”