Creating an Oligopoly in the Treatment of End Stage Renal Disease and the Subsequent Impact on Home Hemodialysis Therapies in the United States

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Agenda

- History
- Disease & Modalities
- Economics
- Consolidation & the Oligopoly
- Treatment Modality Trends

History

- Technology vs. Cost
- Cost was expected to be minimal:
  - Projected: $200,000,000 to Medicare in Year 1
  - Transplant technology would reduce expenditures
  - First Year cost to Medicare: 1 Billion
- Social Security Amendment of 1972
  - Anyone that had paid into Social Security is eligible for coverage after a 33 month waiting period
  - Outpatient (less expensive than in-patient) clinics would become an extension of the physician practice

History

- Expenditures continue to rise
- Approximately $20 billion (2012) to Medicare covering < 1% of the Medicare population but consuming 7% of the Medicare Budget
- 1980s – Consolidation begins with small for-profit chains emerging
- 1990s – Consolidation continues with additional corporate structures that allow the physician to be a joint venture partner
- 2000s – Medicare continues a cost cutting strategy by not raising reimbursement rates with the thinking that commercial insurance companies (20% of the patient population) paying for most of the service
- 2010s – Medicare introduces a bundled payment establishing a single payment amount for each treatment in an attempt to control costs
- Present patient trends within the United States project growth to escalate beyond the current 3% (with a mortality rate of 20%) as a result of diabetes, hypertension, and the aging population

Disease & Treatment Modalities

- Almost 90% of patients with renal failure have diabetes or hypertension
- Demographics – Incidence and prevalence in African Americans and Hispanics are significantly higher than whites
- For patients with renal failure, there are four possible treatment modalities each with an economic benefit or cost
  - In-Center Hemodialysis
  - Peritoneal Dialysis
  - Home Hemodialysis
  - Transplantation

In-Center Hemodialysis

- Patients are treated 3x per week in an outpatient setting for 3 to 4 hours each session
- Patients typically fall out of the workforce while being treated causing an economic drain
- Medicare pays a bundled rate and commercial insurance companies pay a negotiated rate typically more than three times the Medicare rate.
- Economics: Facilities cost between $1 & $2 million – Large fixed cost structure requiring volume for profitability
- Patient Outcomes – Mixed – there is considerable literature that argues that patients should be treated more frequently.

Peritoneal Dialysis

- Patients dialyze in the home using a catheter and dialysis solutions 7 days a week
- Economics: Low fixed costs, fewer drug needs, and higher variable costs
- Outcomes: Patients tend to say in the workforce and are healthier – Risk of Peritonitis & Peritoneal membrane failure after 1 year of treatment

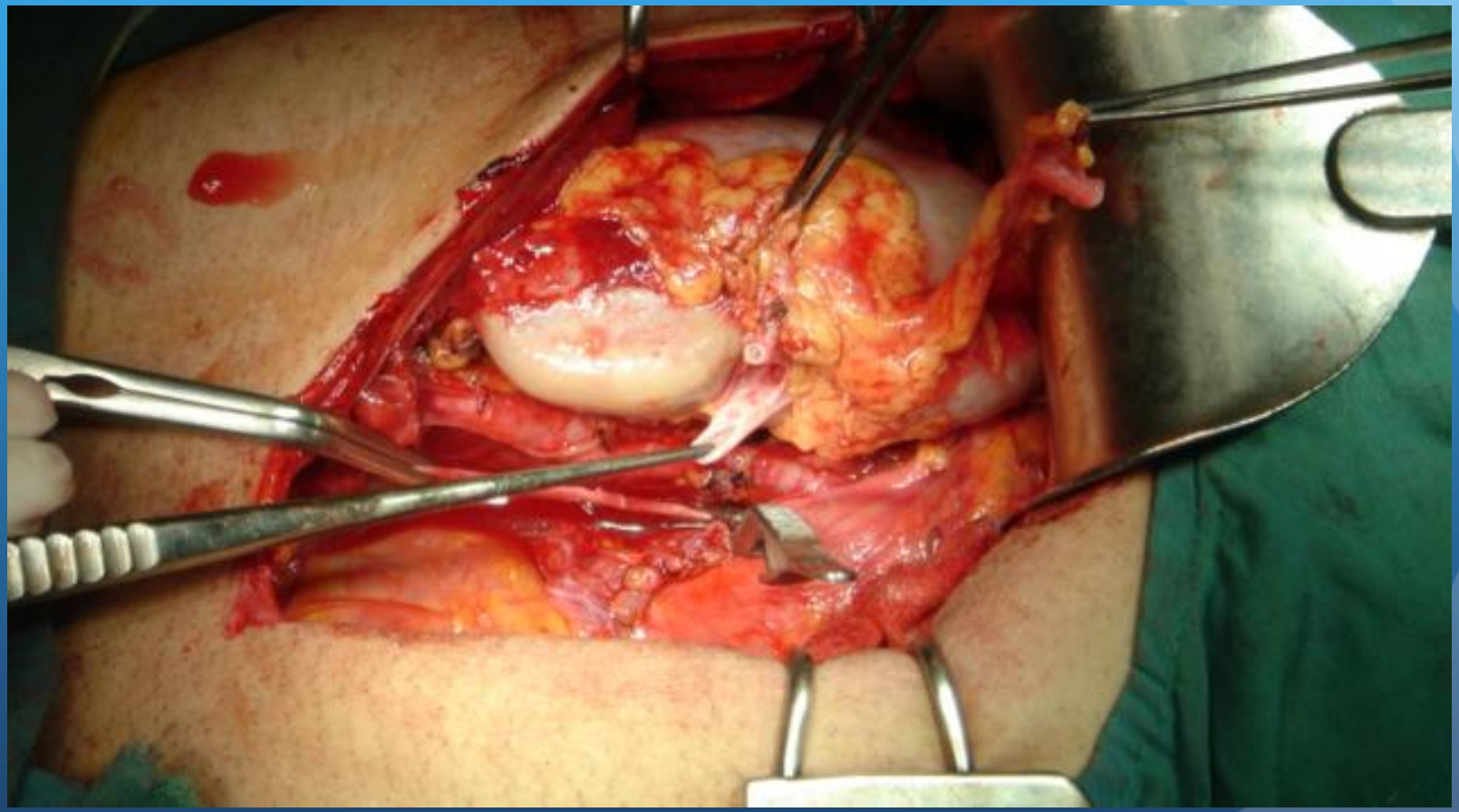
Home Hemodialysis

- Patients dialyze at home 6x per week for 1 to 1.5 hours
- Economics: Low Fixed Costs & Higher Variable Costs
- Outcomes: Patients tend to stay in the workforce with lower drug needs with higher mobility (machine is portable)

Transplant

- Best treatment for a patient
- Economics: High upfront cost of over $200,000, may continue working, but with high immunosuppressive drug expenditures ($15,000 per year)
- Outcomes: Likely the best for the patient with a higher probability of serious infection – Few transplants <15 thousand performed each year due to a lack of kidneys

Transplant



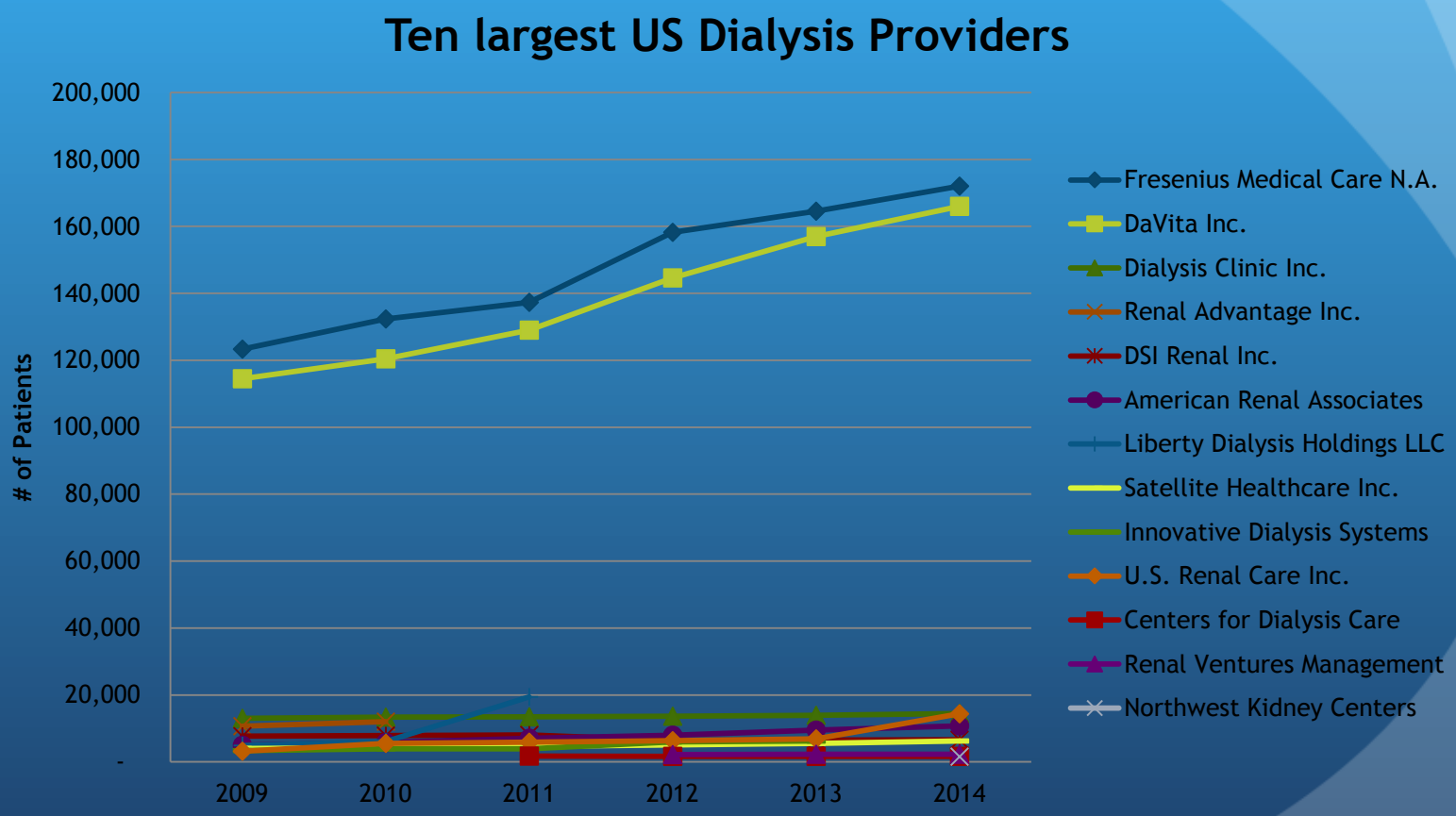
Consolidation & the Oligopoly

- Question: Has consolidation had an impact on the type of delivery for patients based on profit and expense considerations
- Hypothesis: The creation of an oligopoly has created an environment that drives patients towards in-center home hemodialysis
- Two largest providers control 70% of the service market
- Data was collected from three sources:
  - United States Renal Data System (University of Michigan)
  - Financial Filings by the Publicly Traded Companies
  - Nephrology News and Issues data collection for the ten largest dialysis providers in the United States

Consolidation

- Mergers & Acquisition Strategy
- Small to Medium Size Targets
  - Revenue Enhancement
    - Commercial leverage to renegotiate third-party payer contracts through market leverage
    - Ancillary revenue through subsidiaries, if available
  - Expense Reduction
    - Roll-up – Elimination of Administrative overhead
    - Leverage in purchasing drugs and supplies

Formation of the Oligopoly as measured by Patients



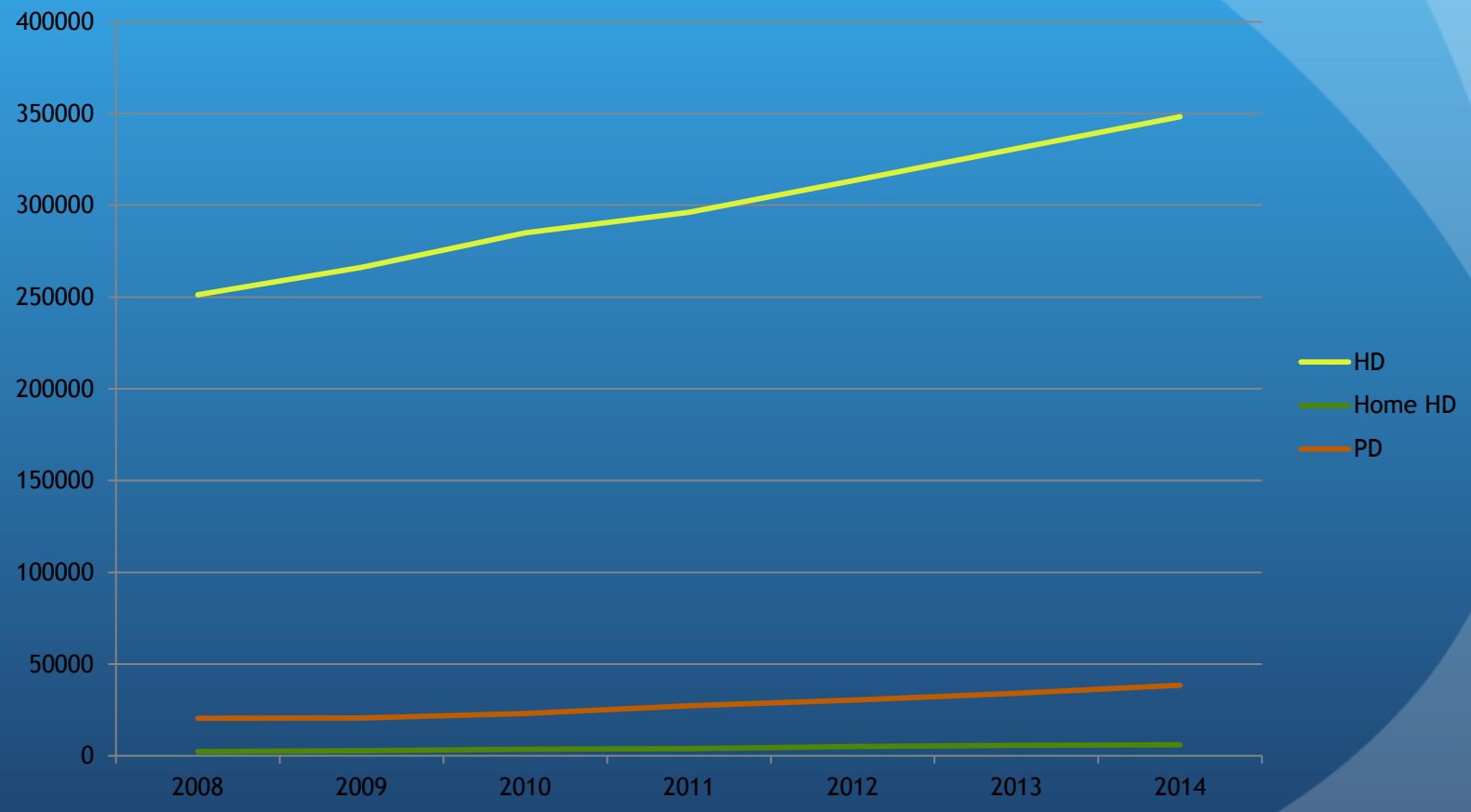
Fresenius Medical Care

- Based in Bad Hamburg, Germany
- Serves patients through outpatient clincs (acquired nmc in 1997)
- Manufactures dialysis medical equipment and supplies
- Owns Venofir (iron sucrose drug company)

DaVita

- 2nd Largest operator of dialysis clinics in the United States
- Owns DaVita Labs, the largest provider of dialysis lab analysis in the United States

Treatment Trends



Initial Conclusions

- With the exception of transplantation, treatment modalities such as peritoneal dialysis and home hemodialysis remain an insignificant treatment modality in so far as numbers of patients.
- Given profit incentives by large publicly traded companies such as Fresenius and DaVita, it can be inferred that this trend will continue
- Given the Federal Government's concern with Medicare expenditures, questions arise as to whether or not reductions or raises, previously taken by the pharma industry, will continue.
- How will ARA's public offering impact the industry – Does this make them a target and what is the private equity exit strategy?
- US Renal and DSI merger – how much will be divested?
- Does the Medical Director compensation model need to be changed to encourage other treatment modalities?

Further Study

- Grant Application to study the economic cost shift from Medicare to commercial insurance carriers
- Changes in FTC interpretations of Hart Scott Rodino testing
- How are joint venture financing structures used to circumnavigate antitrust law.
- Does joint venture structures with physicians contribute to incentives that lead to prescriptions for in-center hemodialysis
- What is the true economic cost of patients unable to work