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An Analyst's View of the Implications of Regulatory Compliance to Value

David Moskowitz, RPh.

November 13th 2003



2003
November



Legislative and Regulatory Environment

- Hatch-Waxman act 1984
- PDUFA 1992
- Canadian drug re-importation
- Medicare/Medicaid pricing- state and federal
- FDA compliance
- Sales and Marketing practices





Compliance Impact to Value -Case Study

- **Compliance with Good Manufacturing Practices – FDA**
- **Sales and Marketing practices –**
 - ✓ **State Attorneys General**
 - ✓ **Department of Justice**

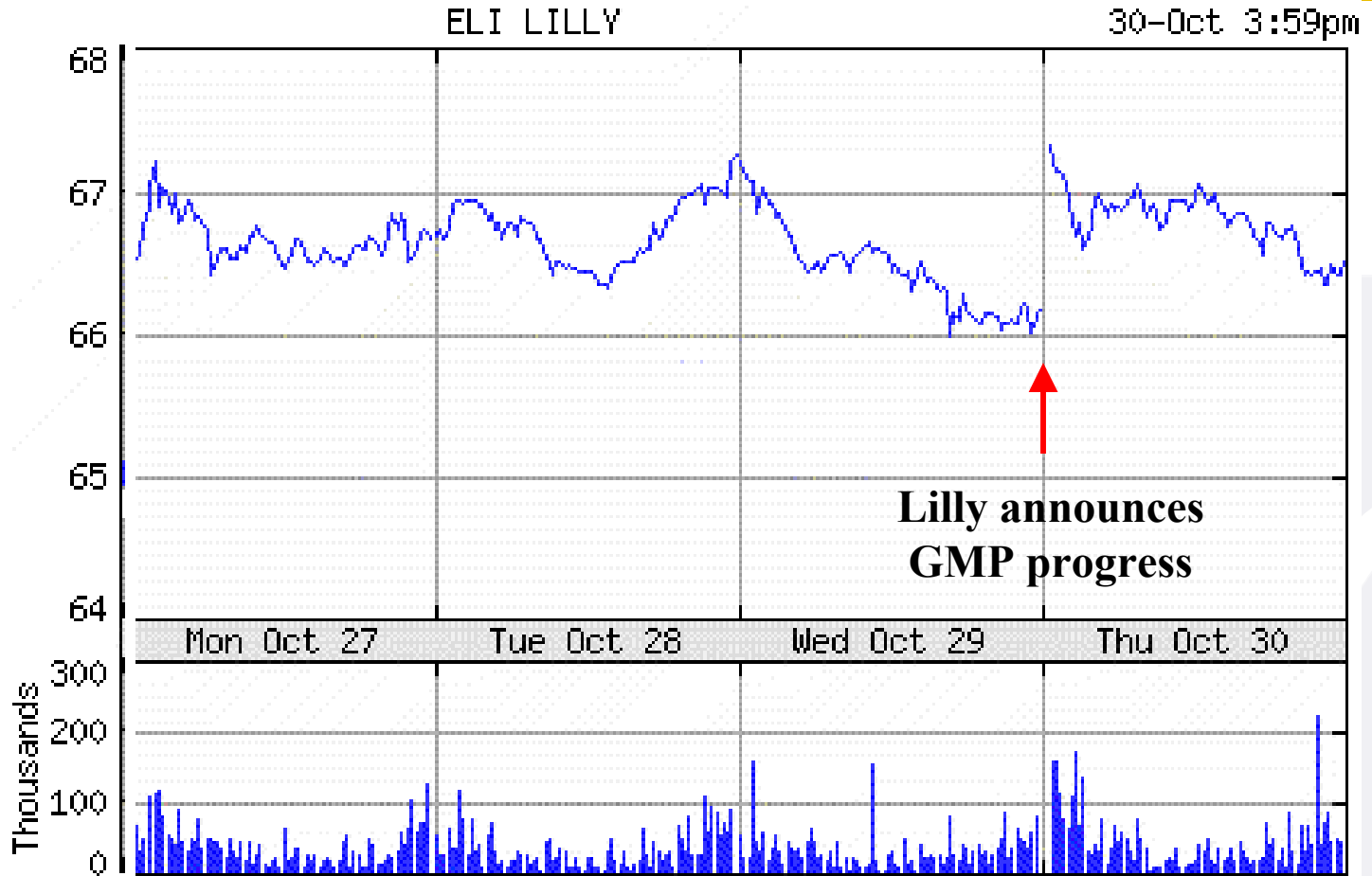


Companies with significant regulatory and compliance issues in recent years

- **Wyeth**
- **Eli Lilly**
- **Schering Plough**
- **Abbott Laboratories (non-covered)**



Lilly reports reaching a level of current Good Manufacturing Practices compliance.



Source: Yahoo Finance

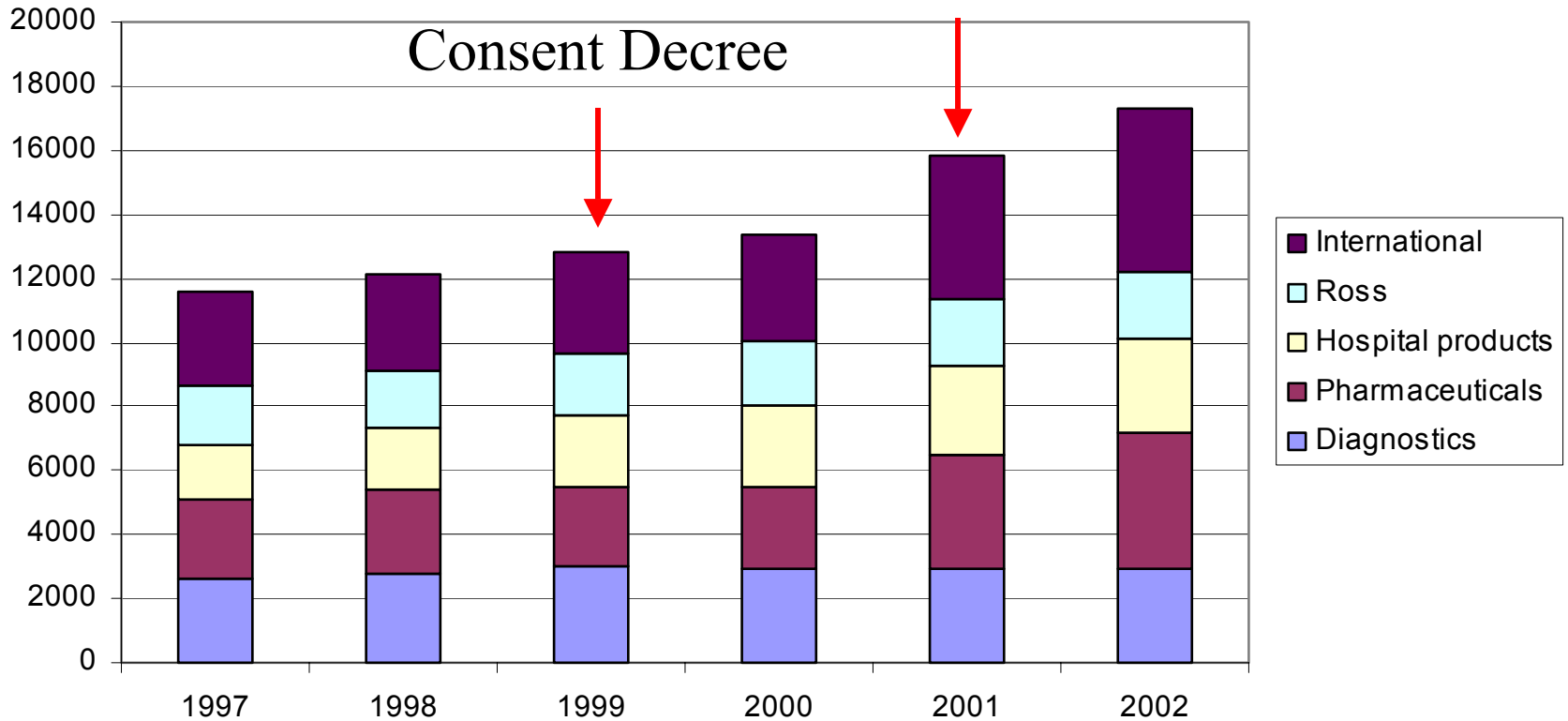


Economic Considerations

- Operating Earnings
- Balance sheet
- Market value
- Competitive position
- Opportunity costs (Alza bid, Future value, cost of capital)
- Goodwill – stakeholders – physicians, patients

ABT Revenues by Category 1997-2002

Knoll acquisition



Source: Company Reports

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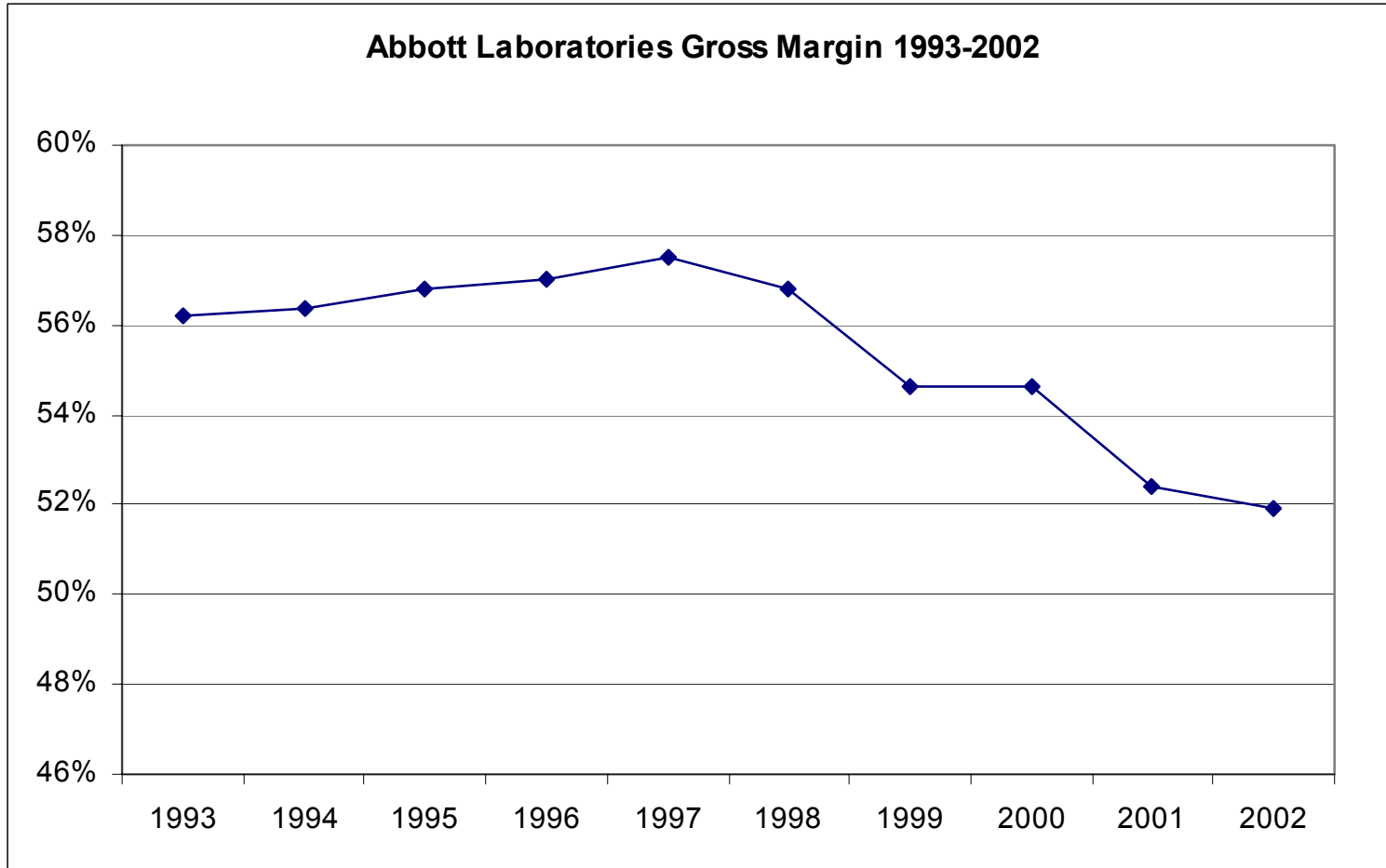
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Margins Impact



Source: Company Reports & FBR estimates

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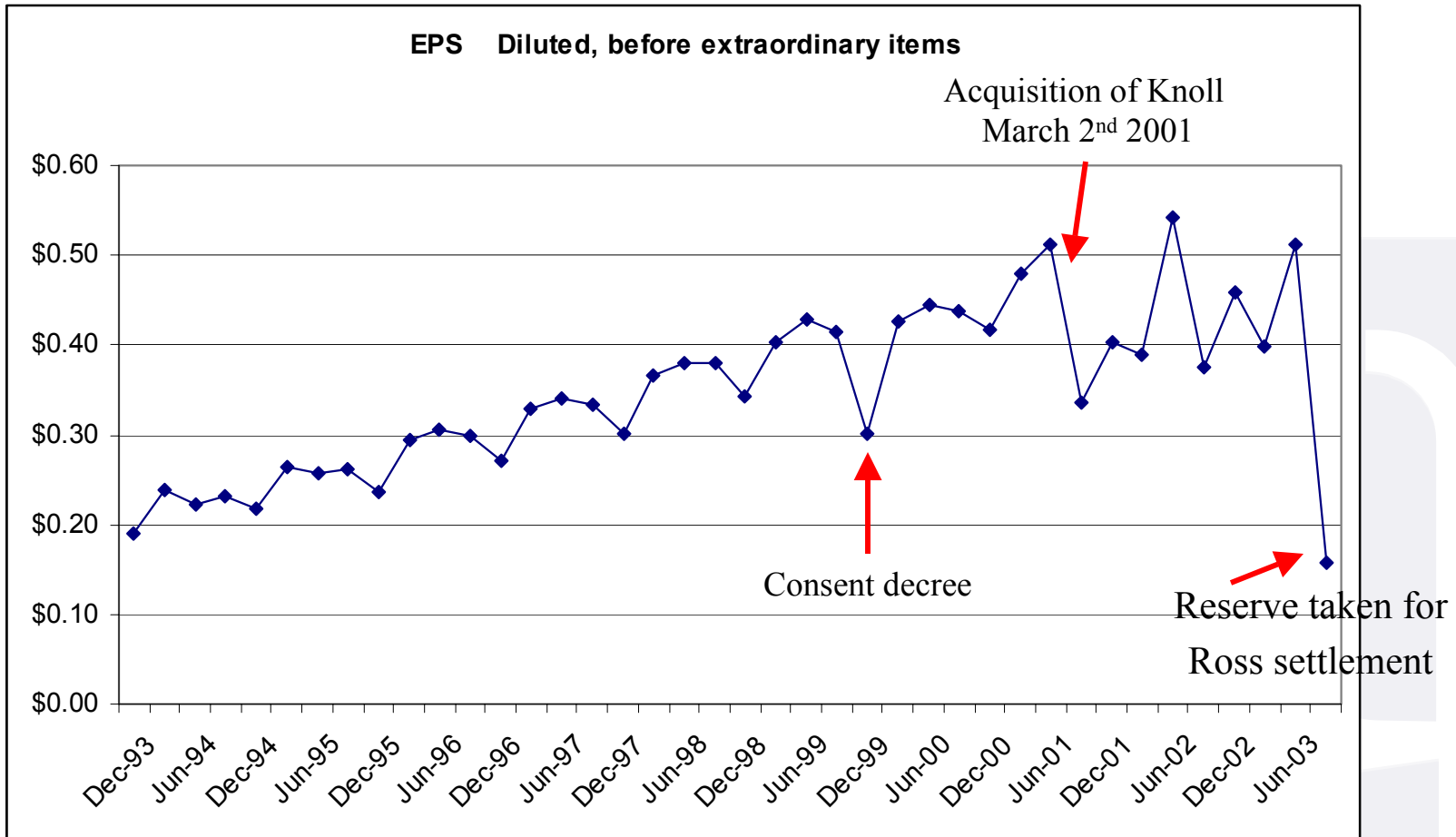
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ABT Earnings per Share 1999-2003



Source: FactSet, Company Reports and FBR estimates.

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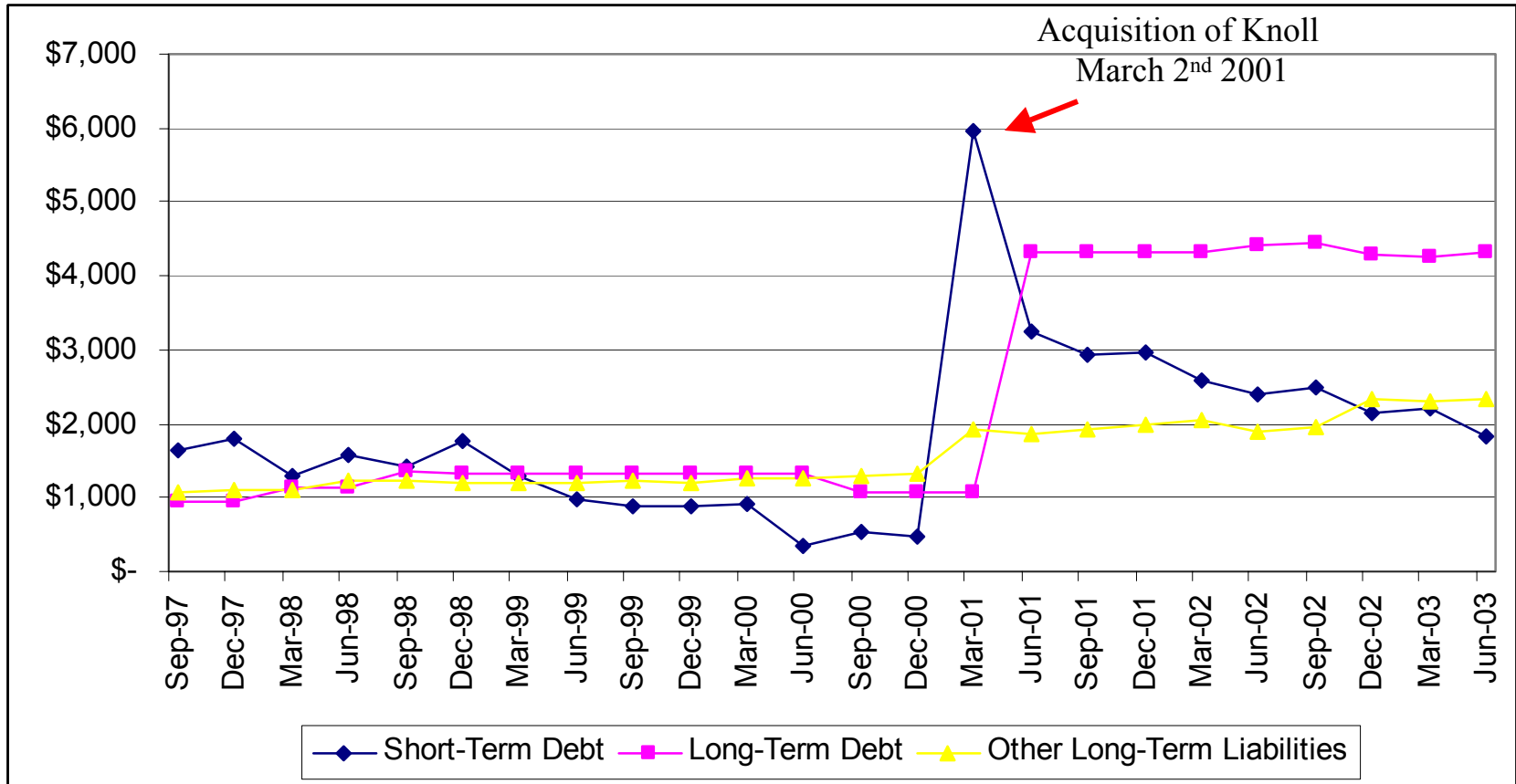


Balance Sheet Impact

- Fines
 - 1999 FDA \$100 million
 - 2001 50% of the \$875 million fine relating to illegal sales and marketing practices for Lupron (Takeda incurred the balance).
 - 2003 \$600 million in criminal and civil penalties related to its Ross Division's CG nutritional business.
- Changes in debt levels/debt ratings
- Shareholder's equity
- Cap Ex

Debt levels for ABT 1997-2003

Millions



Source: Company Reports & FBR estimates

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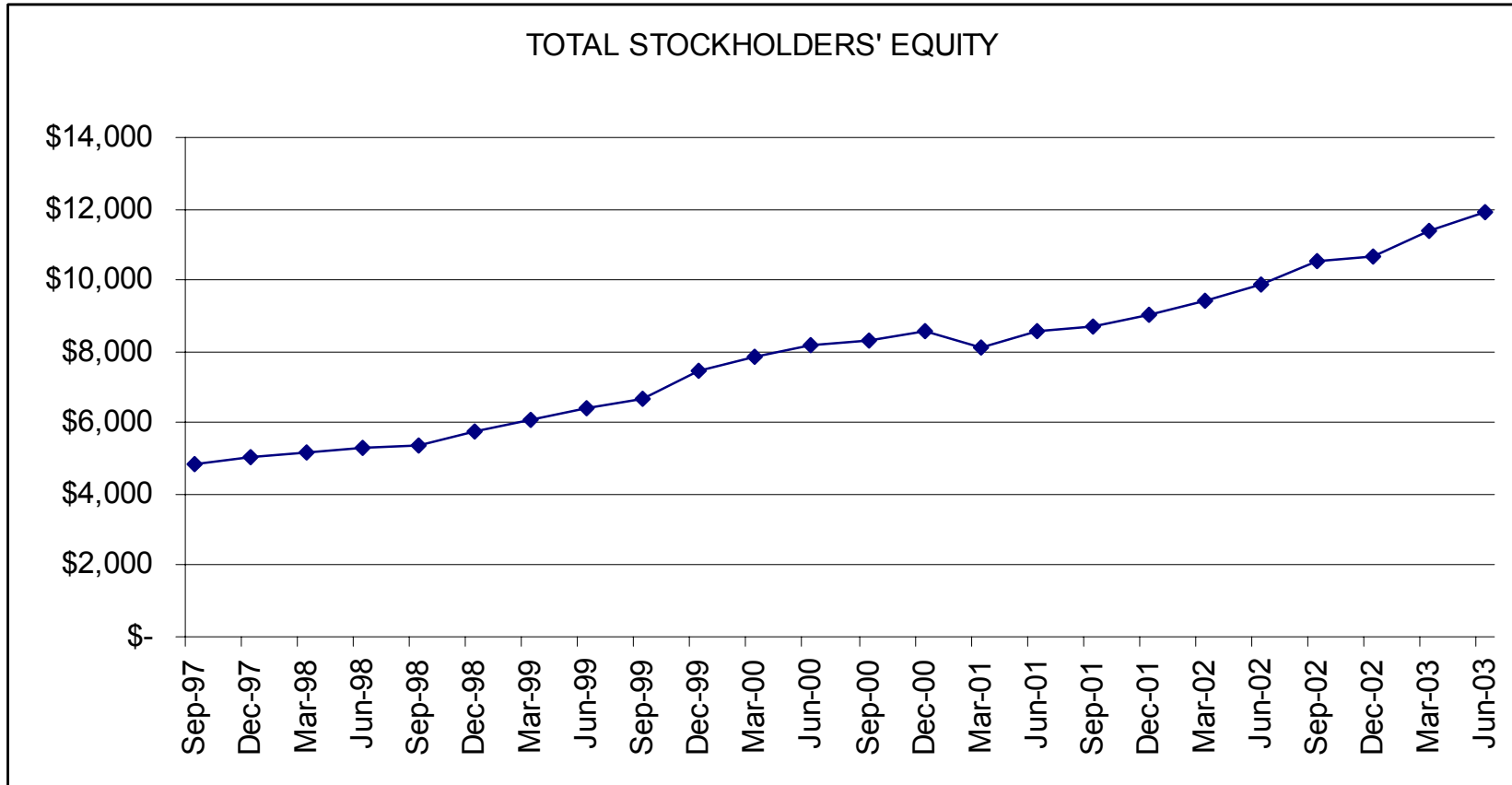
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ABT Shareholder Equity 1997-2003

Millions



Source: Company Reports & FBR estimates

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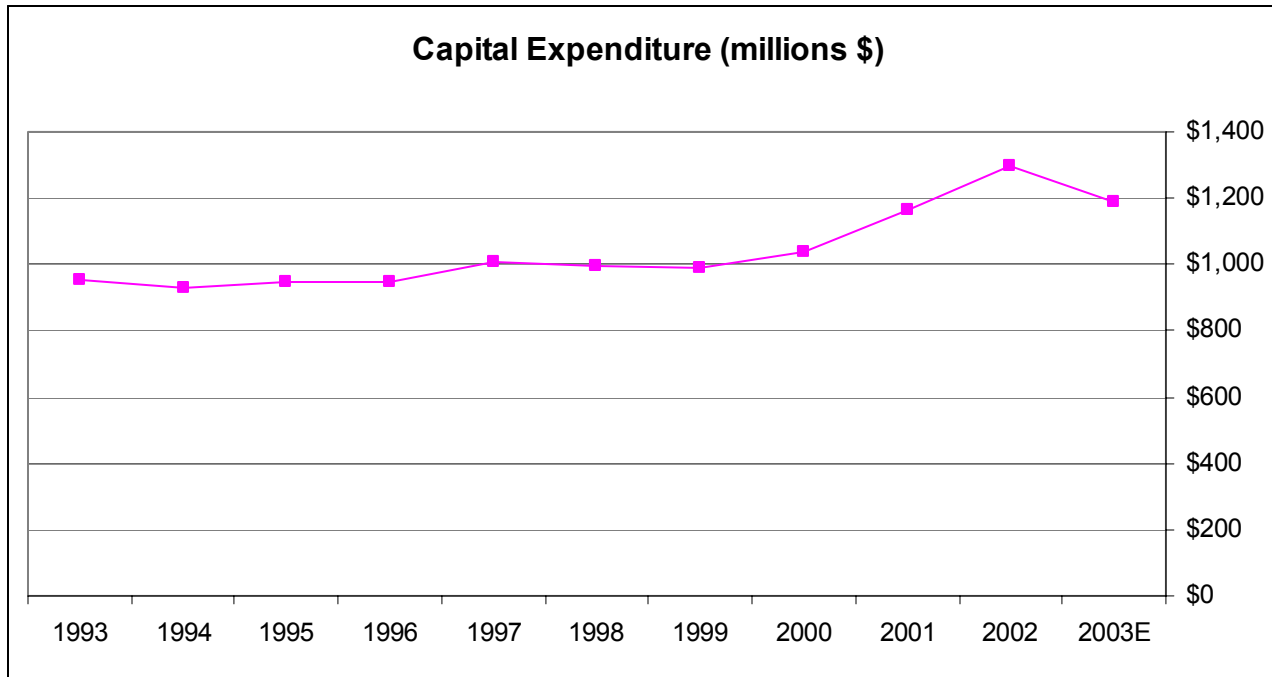
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ABT Cap Ex

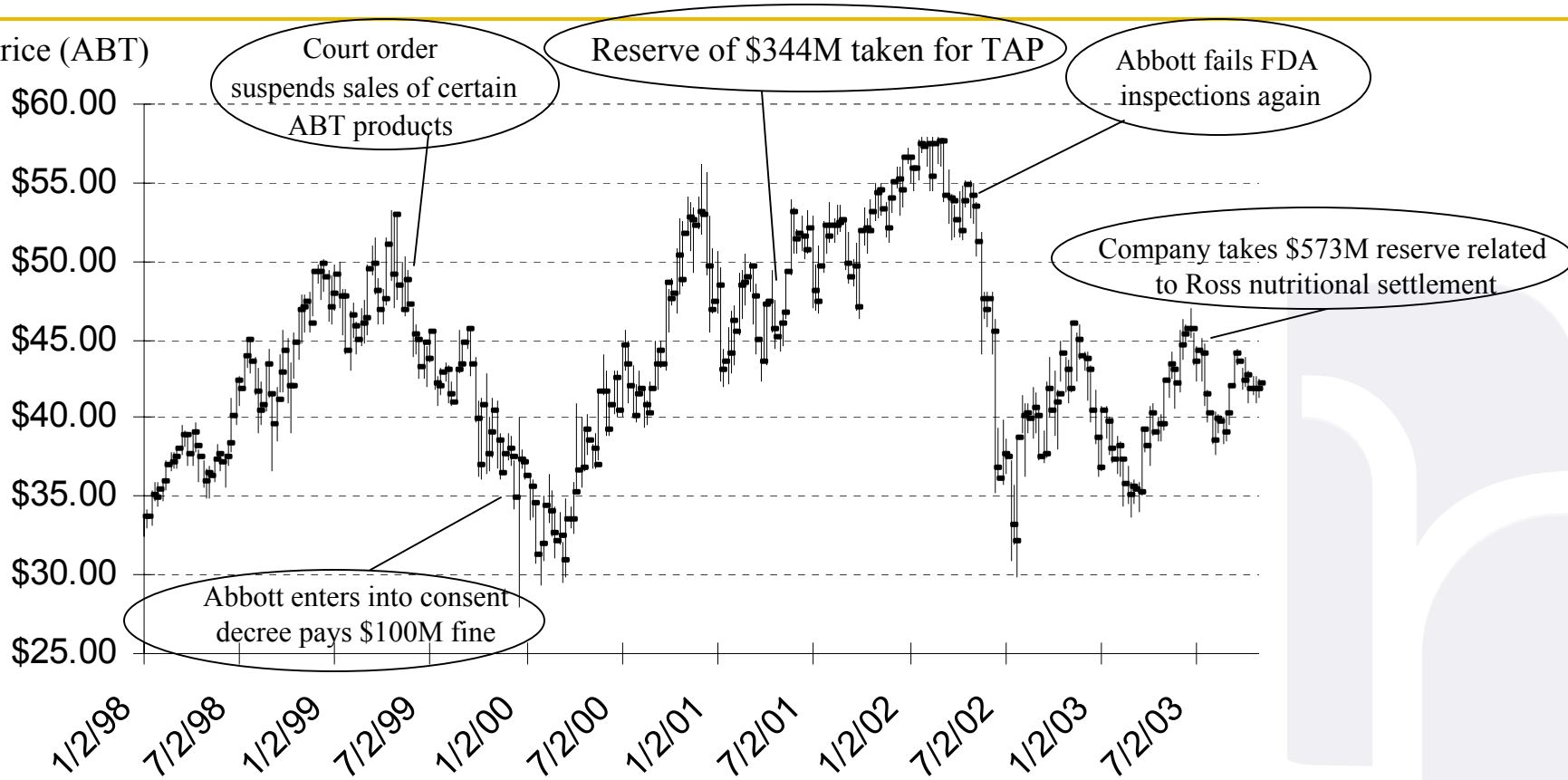


Source: Company Reports & FBR estimates



FDA injunction halts distribution of certain diagnostic products

Stock Price (ABT)



Source: Company Reports, FactSet & FBR estimates

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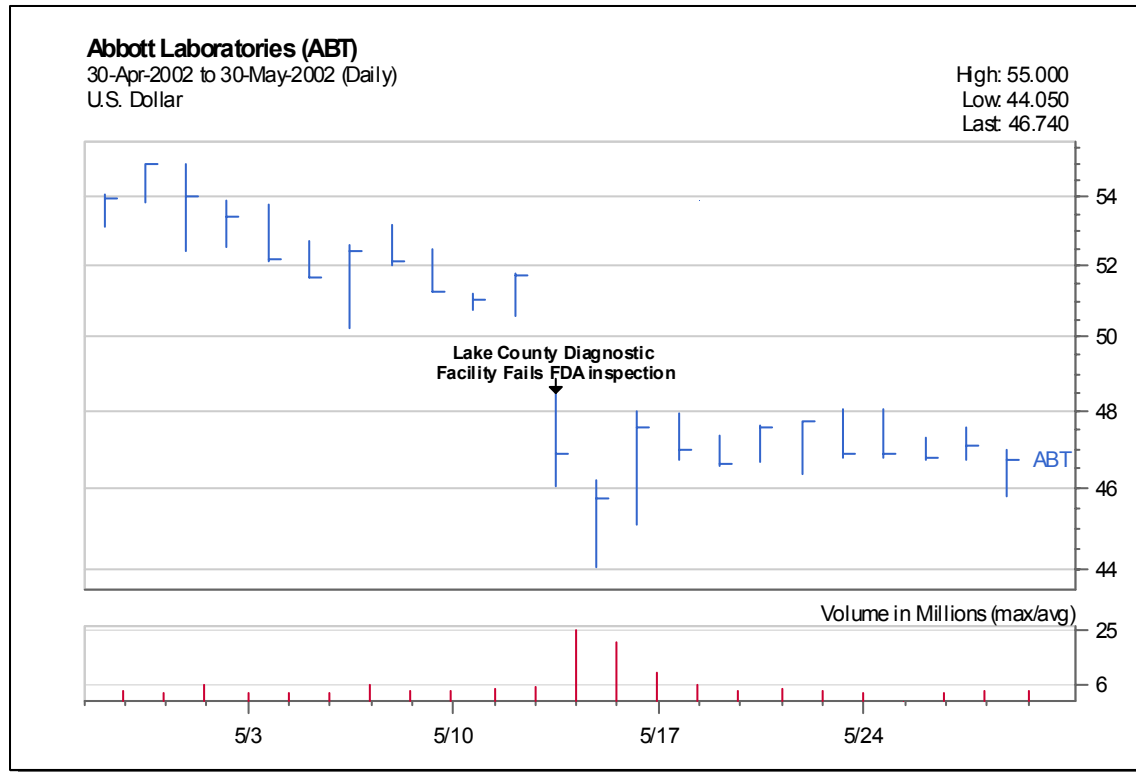
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Regulatory compliance and stock price

Abbott falls \$4.84, or 9.5%, closing at \$46.05 in one day, after the FDA decided its Lake County, Ill.,-based diagnostic manufacturing facilities still didn't meet quality standards.



Source: Company Reports, FactSet & FBR estimates

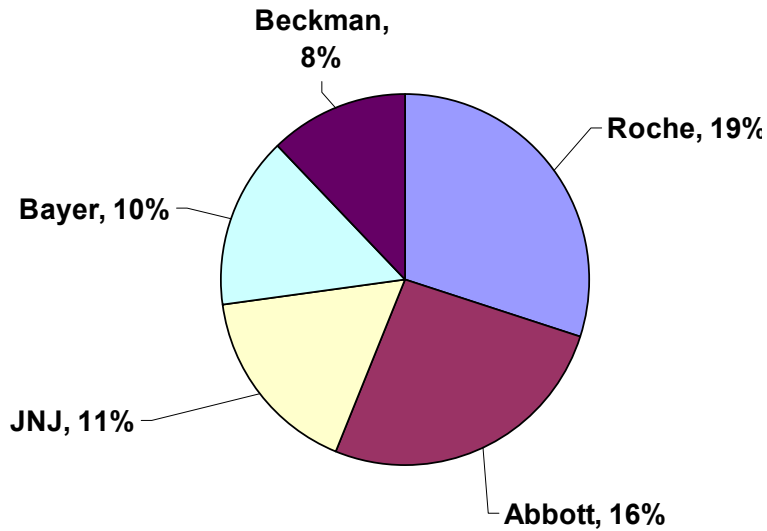


ABT Stock Price Action

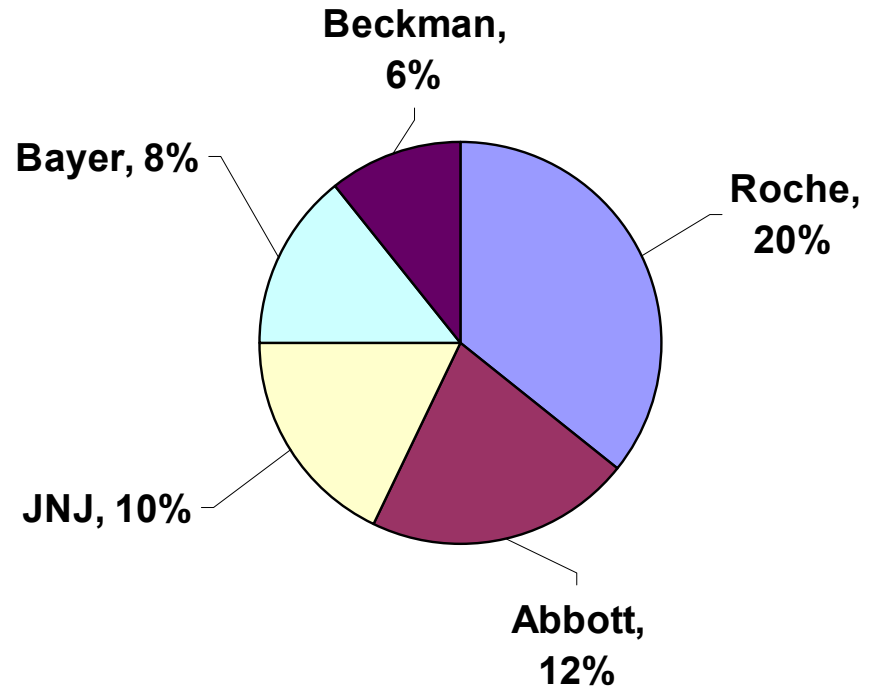
- Share price on 1/99 was \$49.00, it ended the year at \$35.50 (12/99), a 28% drop.
- The company lost \$21 billion (one third) in market cap between the beginning of 1999 and the end of 1999.

Dynamics of in-vitro diagnostics market 1999 and now.

1999



2003E



Source: Company Reports & FBR estimates

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Opportunity Costs

- Measurable
 - Alza deal falls through
 - Stock currency (Knoll acquisition cash deal)
 - Cost of debt
 - P/E multiple discount
- Goodwill
 - FDA relationship
 - Physician Letters
 - Patients
 - Employees





Summary

- Immediate loss of value; creates medium to long-term barriers.
- Credibility
- Management assessment critical to Wall St. (we start our analysis with management quality, ability to execute, track record).
- Distraction to management.
- Post Enron era exacerbates the issues (multiple issues makes the situation worse).
- Recoverability? Management change may be necessary if credibility is lost.



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