C A S E 1

The Cottages Senior Living

Instructor's Manual

CASE SYNOPSIS

Cottage Senior Living (CSL), a family-owned assisted living company headquartered in Huntsville, Alabama, developed or acquired nine continuing care retirement communities (CCRCs) in seven locations in Alabama and one each in Mississippi and Tennessee. Cliff White, president of CSL and the son of the founders, assembled the leadership team of CSL at a strategic planning retreat to move the business "to the next level." Three questions needed to be answered: 1) How to grow? 2) Where to grow? and 3) Do we have the organizational capacity to grow?

The first and second questions required the examination of vertical integration (offering services not presently offered) and horizontal integration (locations in new cities and new states). The third question had to be addressed to effectively answer the first two questions.

The long-term care industry provided health, social, and residential services to disabled and elderly patients requiring assistance with daily living. The assisted living industry provided senior care services through two branches – continuing care communities and homes for the elderly. Both were driven by the increasing population (77 million) and longer life expectancy of the baby boomer generation. CSL operated in a highly-regulated environment that stipulated staffing and facility (building) requirements. CSL's facilities ranged in size from units of 10 to 48, three memory care units with 32 units each, and one active-adult facility with 54 units. Three of CSL's facilities offered assisted-living and memory care units, one offered assisted living and active adult units and the remaining five offered assisted living facilities only.

LEARNING OBJECTIVES

After reading this case you should be able to:

1. Understand the structure of the assisted living industry.
2. Articulate strategic alternatives for growth that will meet CSL's objective.
3. Understand vertical and horizontal integration.
4. Evaluate the impact of introducing new regulatory parameters, e.g., certificate of need, on CSL's organizational capacity.
5. Recommend and justify a strategic choice for CSL.

SUGGESTIONS FOR EFFECTIVE TEACHING

Two teaching plans are offered, both designed for 120 minute classes. Teaching Plan 1 focuses on the Strategic Thinking Map discussed in Chapter 6 to guide analysis and discussion. Teaching Plan 2 utilizes Strategic Position and Action Evaluation (SPACE) analysis to guide discussion.

Teaching Plan 1

The following teaching plan is based on a 120-minute class.

Time (minutes)	Description
5	Instructor - Introduction to the case, the decision maker, focus of the case.
15	Instructor - Presentation and discussion of the Strategic Thinking Map – Hierarchy of Strategic Decisions and Alternatives (IM Exhibit 1).
10	Randomly selected students – The organization of the industry, the structure of CSL, and CSL's desired market characteristics.
30	Students individually or in teams – use IM Exhibit 2 to strike-out unselected strategies and develop rationales for their selections.
15	Students individually or in teams – prepare one PowerPoint slide showing their strategy map for CSL.
30	Randomly selected students or selected teams – present their map and rationales.
15	Instructor – compare and contrast the student or team created maps with the map shown in IM Exhibit 3.

IM Exhibit 2 is a truncated version of IM Exhibit 1(columns in IM Exhibit 1 for directional strategies and implementation strategies have been removed). Directional strategies have already been determined from information presented in the case; implementation strategies will be determined later based on student recommendations for appropriate adaptive, market entry, and competitive strategies.

IM EXHIBIT 1 – Strategic Thinking Map – Hierarchy of Strategic Decisions and Alternatives

Directional Strategies	**Adaptive Strategies**	**Market Entry/ Exit Strategies**	**Competitive Strategies**	**Implementation Strategies**
	Expansion of Scope	***Purchase***	***Strategic Posture***	***Service Delivery***
Mission	Diversification	Acquisition	Defender	Pre-service
Vision	Vertical Integration	Licensing	Prospector	Point-of-service
Values	Market Development	Venture Capital Investment	Analyzer	After-service
Goals	Product Development		Reactor	
	Penetration	***Cooperation***		***Support***
		Merger	***Positioning – Marketwide***	Culture
	Reduction of Scope	Alliance	Cost Leadership	Structure
	Divestiture	Joint Venture	Differentiation	Strategic Resources
	Liquidation			***Unit Action Plans***
	Harvesting	***Development***	***Positioning – Market Segment***	Objectives
	Retrenchment	Internal Development	Focus/Cost Leadership	Actions
		Internal Venture	Focus/Differentiation	Timelines
	Maintenance of Scope	Reconfigure the Value Chain		Responsibilities
	Enhancement			Resources
	Status Quo	***Market Exit***		Results Measures
		Fast/Slow		
		Partial/Complete		

Source: Peter M. Ginter, W. Jack Duncan, and Linda E. Swayne, *Strategic Management of Health Care Organizations*, 8th edition (Hoboken, NJ: Wiley & Sons, 2018).

IM EXHIBIT 2 – Strategic Thinking Map Adapted for the Cottage Senior Living Case

Adaptive Strategies	**Market Entry/ Exit Strategies**	**Competitive Strategies**
Expansion of Scope	***Purchase***	***Strategic Posture***
Diversification	Acquisition	Defender
Vertical Integration	Licensing	Prospector
Market Development	Venture Capital Investment	Analyzer
Product Development		Reactor
Penetration	***Cooperation***	***Positioning – Marketwide***
	Merger	Cost Leadership
	Alliance	

Reduction of Scope	Joint Venture	Differentiation
Divestiture		
Liquidation	***Development***	***Positioning –***
Harvesting	Internal	***Market Segment***
Retrenchment	Development	Focus/Cost
	Internal Venture	Leadership
Maintenance of	Reconfigure the	Focus/Differentiation
Scope	Value Chain	
Enhancement		
Status Quo	***Market Exit***	
	Fast/Slow	
	Partial/Complete	

IM EXHIBIT 3 – Marked-up Strategic Thinking Map for the Cottage Senior Living Case

Adaptive Strategies	Market Entry/ Exit Strategies	Competitive Strategies
Expansion of Scope]	***Purchase***	***Strategic Posture***
~~Diversification~~	~~Acquisition~~	~~Defender~~
~~Vertical Integration~~	~~Licensing~~	Prospector
~~Market~~	~~Venture Capital~~	Analyzer
Development	~~Investment~~	~~Reactor~~
~~Product~~		
~~Development~~	~~***Cooperation***~~	***Positioning –***
~~Penetration~~	~~Merger~~	***Marketwide***
	~~Alliance~~	~~Cost Leadership~~
~~***Reduction of Scope***~~	~~Joint Venture~~	~~Differentiation~~
~~Divestiture~~		
~~Liquidation~~	***Development***	***Positioning –***
~~Harvesting~~	Internal	***Market Segment***
~~Retrenchment~~	Development	~~Focus/Cost~~
	~~Internal Venture~~	~~Leadership~~
Maintenance of	~~Reconfigure the~~	~~Focus/Differentiation~~
Scope	~~Value Chain~~	
~~Enhancement~~		
~~Status Quo~~	~~***Market Exit***~~	
	~~Fast/Slow~~	
	~~Partial/Complete~~	

RATIONALE FOR IM EXHIBIT 3

The case narrative illustrated that Cliff White wanted to grow the organization – he was not interested in a reduction in scope in any form or in maintaining the status quo. Thus, all students should delete elements of the reduction of scope and the status quo element of maintenance of scope. As far as expansion of scope, Cliff and his leadership team appeared to be most interested in developing new markets (market development), and enhancing the quality of services offered by CSL (that could entail product/service enhancement). Although product development has been eliminated in IM Exhibit 3, it is possible for students to make a case for CSL's development of services not currently included in their portfolio, for example, home health services.

The elements of diversification, vertical integration, and penetration were struck from expansion of scope as not being suitable strategies to reach the Cottage's goal. What remained are the market development, product development (elements of expansion of scope) and enhancement (element of maintenance of scope). The choices in the column "market entry/exit strategies" were built on the choices in the adaptive strategies column. Reconfiguring the value chain was not something Cliff was interested in, but students might be able to come up with interesting ideas for that market entry/development strategy. The "market exit" elements were easiest to eliminate–because CSL demonstrated through its financials that it was under no pressure to exit any of its existing markets. Likewise, no inclination seemed to exist for Cliff to teach someone else how to be successful in CSL's niche in the CCRC industry – something that could occur by pursuing cooperative strategies. The entry strategies that were consistent with the path to success demonstrated by CSL were acquisition and internal development. Further, the market entry/exit strategies that remained in column two of IM Exhibit 3 answer the question "How to grow?" through acquisition and internal development.

In terms of competitive strategies, CSL was not a defender as demonstrated by Cliff and his leadership team focusing on growth rather than maintenance; nor did CSL aspire to be the cost leader because CSL targets private pay customers who are not seeking the lowest prices; nor would CSL aspire to utilize focus/cost leader for the same reason. CSL had demonstrated its ability to analyze opportunities and prospect for markets as evidenced by CSL's desired market characteristics: strong demographics – age and income qualified customers (market penetration in the 5 to 10 percent range) and population growth exceeding 2 percent year-over-year; towns and communities undergoing re-urbanization ("main street living") – communities with re-urbanization plans that were being executed; and

reasonably priced land near the main street area. Differentiation and focus remained as strategies. CSL might well be served by carefully examining its product-line offerings and focusing on congregate assisted living at the exclusion of further entries into memory care (narrowing the scope of operations). Or, take a bold plunge into product/service development and pursue the increasing growth market of Alzheimer care.

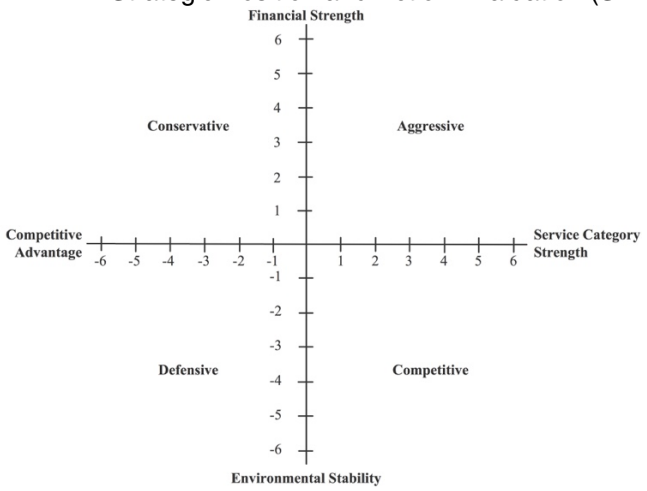
Teaching Plan 2

The following teaching plan is based on a 120-minute class.

Time (minutes)	Description
5	Instructor - Introduction to the case, the decision maker, focus of the case.
15	Instructor - Presentation and discussion of Strategic Position and Action Evaluation (SPACE) (IM Exhibit 4 and IM Exhibit 5).
10	Randomly selected students – The organization of the industry, the structure of CSL, and CSL's desired market characteristics.
30	Students individually or in teams – use IM Exhibit 5 to conduct SPACE analysis.
15	Students individually or in teams – prepare one PowerPoint slide showing their SPACE analysis using IM Exhibit 4.
30	Randomly selected students or selected teams – present their SPACE analysis and rationales.
15	Instructor – compare and contrast the student or team created maps with the map shown in IM Exhibit 6.

IM Exhibit 4 is the definition of the four quadrants of the Strategic Position and Action Evaluation (SPACE) matrix. IM Exhibit 5 is the set of evaluation factors for SPACE analysis. IM Exhibits 4 and 5 may be reproduced and distributed to students for their individual or group analysis as envisioned in Teaching Plan 2.

IM EXHIBIT 4 – Strategic Position and Action Evaluation (SPACE) Matrix



Aggressive Posture

This posture is typical in an attractive service category with little environmental turbulence. The organization enjoys definite competitive advantage, which it can protect with financial strength. The critical factor is the entry of new competitors. Organizations in this situation should take full advantage of opportunities, look for acquisition candidates in their own or related areas, increase market share, and concentrate resources on products having a definite competitive advantage.

Competitive Posture

This posture is typical in an attractive service category., The organization enjoys a competitive advantage in a relatively unstable environment. The critical factor is financial strength. Organizations in this situation should acquire financial resources to increase marketing thrust, add to the sales force, extend or improve the product line, invest in productivity, reduce costs, protective competitive advantage in a declining market, and attempt to merge with a cash-rich organization.

Conservative Posture

This posture is typical in a stable market with low growth. Here, the organization focuses on financial stability. The critical factor is product competitiveness. Organizations in this situation should prune the product line, reduce costs, focus on improving cash flow, protect competitive products, develop new products, and gain entry into more attractive markets.

Defensive Posture

This posture is typical of an unattractive service category in which the organization lacks competitive product and financial strength. The critical factor is competitiveness. Organizations in this situation should prepare to retreat from the market, discontinue marginally profitable products, aggressively reduce costs, cut capacity, and defer or minimize investments.

Source: Peter M. Ginter, W. Jack Duncan, and Linda E. Swayne, *Strategic Management of Health Care Organizations*, 7th edn (New York: Jossey-Bass imprint of John Wiley & Sons, 2013), pp. 273-277. Adapted from Alan J. Rowe, Richard O. Mason, Karl E. Dickel, Richard B. Mann, and Robert J. Mockler, *Strategic Management: A Methodological Approach* (Reading, Massachusetts: Addison-Wesley Publishing, 1994).

IM EXHIBIT 5 – Strategic Position and Action Evaluation Factors

Factors Determining Environmental Stability

Technological changes	Many	0	1	2	3	4	5	6	Few
Rate of inflation	High	0	1	2	3	4	5	6	Low
Demand variability	Large	0	1	2	3	4	5	6	Small
Price range of competing products/services	Wide	0	1	2	3	4	5	6	Narrow
Barriers to entry into market	Few	0	1	2	3	4	5	6	Many
Competitive pressure	High	0	1	2	3	4	5	6	Low
Price elacity of demand	Elastic	0	1	2	3	4	5	6	Inelastic
Other: _____	_____	0	1	2	3	4	5	6	_____

Average - 6 =

Critical factors

Comments

Factors Determining Service Category Strength

Growth potential	Low	0	1	2	3	4	5	6	High
Profit potential	Low	0	1	2	3	4	5	6	High
Financial stability	Low	0	1	2	3	4	5	6	High
Technological know-how	Simple	0	1	2	3	4	5	6	Complex
Resource utilization	Inefficient	0	1	2	3	4	5	6	Efficient
Capital intensity	High	0	1	2	3	4	5	6	Low
Ease of entry into market	Easy	0	1	2	3	4	5	6	Difficult
Productivity, capacity, utilization	Low	0	1	2	3	4	5	6	High
Other: _____	_____	0	1	2	3	4	5	6	_____

Average =

Critical factors

Comments

Factors Determining Competitive Advantage*

Market share	Small	0	1	2	3	4	5	6	Large
Product quality	Inferior	0	1	2	3	4	5	6	Superior
Product life cycle	Late	0	1	2	3	4	5	6	Early
Product replacement cycle	Variable	0	1	2	3	4	5	6	Fixed
Customer/patient loyalty	Low	0	1	2	3	4	5	6	High
Competiton's capacity utilization	Low	0	1	2	3	4	5	6	High
Technological know-how	Low	0	1	2	3	4	5	6	High
Vertical Integration	Low	0	1	2	3	4	5	6	High
Other: _____	_____	0	1	2	3	4	5	6	_____

Average - 6 =

Critical factors

Comments

* Represents important competitive advantages.

Factors Determining Financial Stability

Return on investment	Low	0	1	2	3	4	5	6	High
Leverage	Imbalanced	0	1	2	3	4	5	6	Balanced
Liquidity	Imbalanced	0	1	2	3	4	5	6	Balanced
Capital required/capital available	High	0	1	2	3	4	5	6	Low
Cash flow	Low	0	1	2	3	4	5	6	High
Ease of exit from market	Difficult	0	1	2	3	4	5	6	Easy
Risk involved in business	Much	0	1	2	3	4	5	6	Little
Other: _____	_____	0	1	2	3	4	5	6	_____

Average =

Critical factors

Comments

Source: Source: Peter M. Ginter, W. Jack Duncan, and Linda E. Swayne, *Strategic Management of Health Care Organizations*, 7th edn (New York: Jossey-Bass imprint of John Wiley & Sons, 2013), pp. 273-277. Adapted from Alan J. Rowe, Richard O. Mason, Karl E. Dickel,

Richard B. Mann, and Robert J. Mockler, *Strategic Management: A Methodological Approach* (Reading, Massachusetts: Addison-Wesley Publishing, 1994).

The instructor should expect students individually or in groups to produce a SPACE evaluation factor form that is somewhat similar to IM Exhibit 6 and a SPACE Profile similar to IM Exhibit 7. In IM Exhibit 6, the value of the "Average" is the median of the values circled in the factor description. The instructor may note that in the Rowe, Mason, et al., reference that the authors use the arithmetic mean as the value of "Average." The scale used in the SPACE Factors evaluation is an ordinal one rather than an interval one and thus an arithmetic mean may produce specious results.

IM EXHIBIT 6 – SPACE Factors Form Completed

Factors Determining Environmental Stability

Technological changes	Many	0	1	2	(3)	4	5	6	Few
Rate of inflation	High	0	1	(2)	3	4	5	6	Low
Demand variability	Large	0	1	2	3	4	(5)	6	Small
Price range of competing products/services	Wide	0	1	2	3	4	(5)	6	Narrow
Barriers to entry into market	Few	0	1	2	3	4	(5)	6	Many
Competitive pressure	High	0	1	2	(3)	4	5	6	Low
Price elacity of demand	Elastic	0	1	(2)	3	4	5	6	Inelastic
Other: _____	_____	0	1	2	3	4	5	6	_____

Average - 6 = 3

Critical factors

Demand variability
Price range of competing products/services
Barriers to entry into market

Comments

Demand variability is small because of the Baby Boom demographic.
The price of competing products is narrow since they appeal to the same high-end individual paper market.
The barriers to entry into the market, especially regulatory, capital intensity, and how-to knowledge.

Factors Determining Service Category Strength

Growth potential	Low	0	1	2	3	4	5	(6)	High
Profit potential	Low	0	1	2	3	4	(5)	6	High
Financial stability	Low	0	1	2	3	4	(5)	6	High
Technological know-how	Simple	0	1	2	(3)	4	5	6	Complex
Resource utilization	Inefficient	0	1	2	3	(4)	5	6	Efficient
Capital intensity	High	0	1	(2)	3	4	5	6	Low
Ease of entry into market	Easy	0	1	2	3	4	(5)	6	Difficult
Productivity, capacity, utilization	Low	0	1	2	3	(4)	5	6	High
Other: _____	_____	0	1	2	3	4	5	6	_____

Average = 4.5

Critical factors

Growth potential
Profit potential
Financial stability
Ease of entry into market

Comments

Demographics, especially the aging baby boomers, offer significant growth potential.
CSL offers both profit potential as the financial data suggests and the company has financial stability with its established development partners and relationships.
The market is difficult to enter due to regulatory requirements, capital intensity, and technical expertise.

Factors Determining Competitive Advantage*

Market share	Small	0	(1)	2	3	4	5	6	Large
Product quality	Inferior	0	1	2	3	4	(5)	6	Superior
Product life cycle	Late	0	1	2	(3)	4	5	6	Early
Product replacement cycle	Variable	0	1	2	3	4	(5)	6	Fixed
Customer/patient loyalty	Low	0	1	2	3	4	(5)	6	High
Competiton's capacity utilization	Low	0	1	2	3	(4)	5	6	High
Technological know-how	Low	0	1	2	3	4	(5)	6	High
Vertical Integration	Low	(0)	1	2	3	4	5	6	High
Other: _____	_____	0	1	2	3	4	5	6	_____

Average - 6 = -2.5

* Represents important competitive advantages.

Critical factors

Product quality
Product replacement cycle
Customer/patient loyalty
Technological know-how

Comments

CSL offers a high-quality product with significant customer or patient loyalty - families refer friends and other family members.
The product replacement cycle is fixed and is a function of the age of the facilities.
CSL possesses considerable technological know-how and uses it to control costs.

Factors Determining Financial Stability

Return on investment	Low	0	1	2	3	4	(5)	6	High
Leverage	Imbalanced	0	1	2	3	4	(5)	6	Balanced
Liquidity	Imbalanced	0	1	2	(3)	4	5	6	Balanced
Capital required/capital available	High	0	1	(2)	3	4	5	6	Low
Cash flow	Low	0	1	2	3	4	(5)	6	High
Ease of exit from market	Difficult	0	(1)	2	3	4	5	6	Easy
Risk involved in business	Much	0	1	2	(3)	4	5	6	Little
Other: _____	_____	0	1	2	3	4	5	6	_____

Average = 3

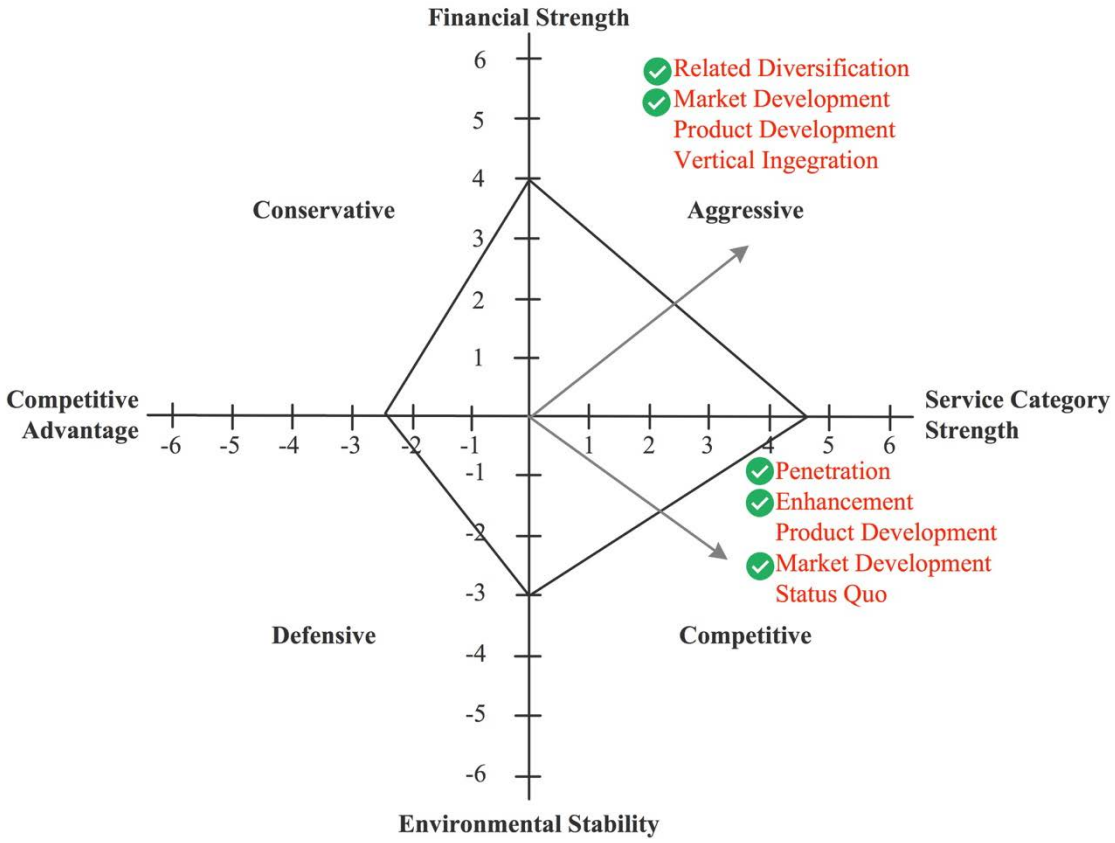
Critical factors

Return on investment
Leverage
Cash flow

Comments

CSL generates high returns on investment and significant cash flow with a balance of equity and debt financing.

IM EXHIBIT 7 – SPACE Profile for CSL



RATIONALE FOR IM EXHIBIT 7

In IM Exhibit 7, the largest area in the SPACE profile is in the right hemisphere with an almost equal area found in each of the right quadrants. The case narrative illustrated that Cliff White wanted to grow the organization – he was not interested in a reduction in scope in any form or in maintaining the status quo. The completed SPACE Factors form (IM Exhibit 6) shows that financial strength and service category strength direct CSL to an aggressive competitive posture to use its financial strength to penetrate markets, enhance service offerings, and develop markets. Although product development was not identified as selected or "checked" element in Exhibit 7, it is possible for students to make a case for CSL's development of services not currently included in their portfolio, for example, home health services.

CASE QUESTIONS FOR CLASS DISCUSSION

1. How to grow?
2. Where to grow?
3. Does CSL have the organizational capacity to grow?

QUESTIONS WITH ANSWERS FOR CLASS DISCUSSION

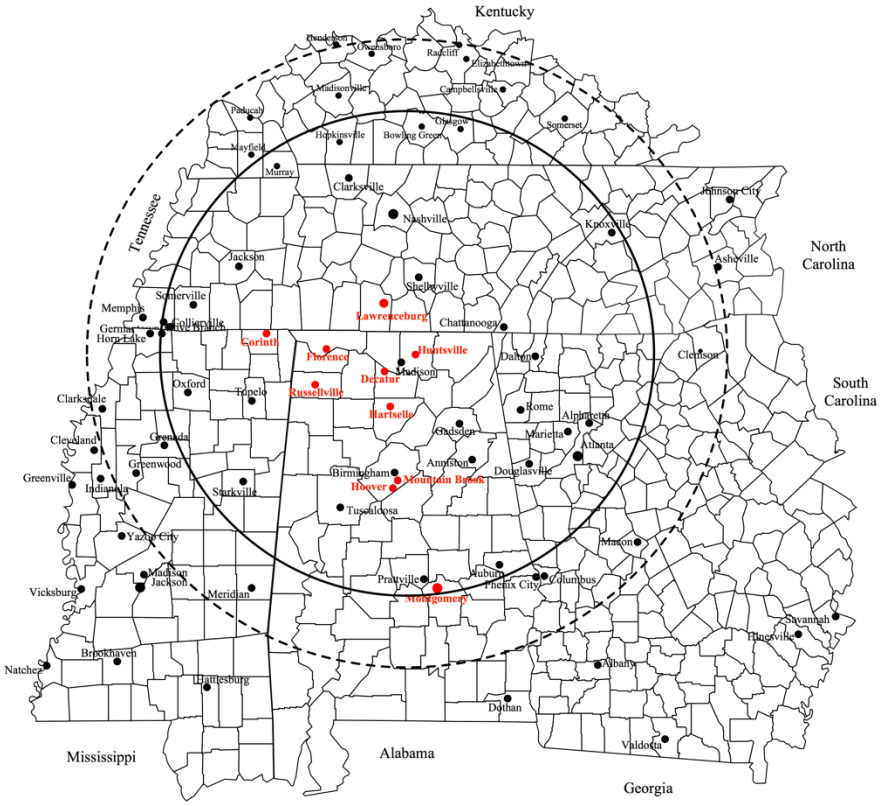
1. How to grow?

   Choices are: acquisition and internal development, product development, and enhancement.

2. Where to grow?

Market development - the case suggested expanding the market reach of CSL by adding 50 miles to the radius of its markets (see case Exhibit 9), reproduced here as IM Exhibit 8.

IM EXHIBIT 8 – Exhibit 9 from the Case



The large metropolitan areas of Atlanta, Memphis, and Nashville were not attractive locations as CSL's Regional Managing Director stated, "the metro areas … are challenging." Although Greg Dykes, the Regional Managing Director did not further explain his observation, the instructor could ask students to identify the challenges of operating within large metropolitan areas. Students may produce a list similar to this one:

- CSL has no experience in a city larger than Huntsville, Alabama (about 193,000[1]).
- Real estate in the affluent communities is expensive.
- Competitors are already present (it should be noted that this challenge may also be an opportunity in the form of acquisition opportunities such as the one CSL undertook for its Mountain Brook, Alabama facility – one of the wealthiest U.S. communities.[2]
- Operating costs are likely higher, especially wages.
- Many wealthy urban and suburban dwellers buy second homes outside metropolitan areas to use during retirement.[3,4]
- Traffic congestion may present transportation issues.

One of the participants suggested college towns as potential locations for growth. The principle difficulty presented by such locations is the likely absence of reasonably priced real estate. Students may be asked to evaluate

nearby towns and cities. For example, students could be directed to evaluate Opelika, Alabama, a city bordering the City of Auburn, that is undergoing a downtown revitalization.[5] An excellent resource for more information on downtown revitalizations is provided by the U.S. Department of Agriculture through its National Agricultural Library.[6] The USDA resource includes links to revitalization case studies, community planning resources, funding sources, journals, organizations, and more.For instructors desiring a written assignment associated with the case, students, individually or in teams, may be assigned one or more cities from the expanded map in IM Exhibit 4 and asked to prepare a formal suitability analysis on a location or locations. The suitability analysis should focus on 1) demographics, 2) downtown revitalization efforts, and 3) reasonably priced land near the downtown. For example, if Tupelo, Mississippi were to be assigned, it is reasonable to expect students to use a simple Google search and a Google Scholar search and produce references similar to the following.

Demographics: C. J.. Gates and A. M. Cooke. "Mississippi Census Snapshot: 2010." (2011), available at: http://escholarship.org/uc/item/7f2231j6

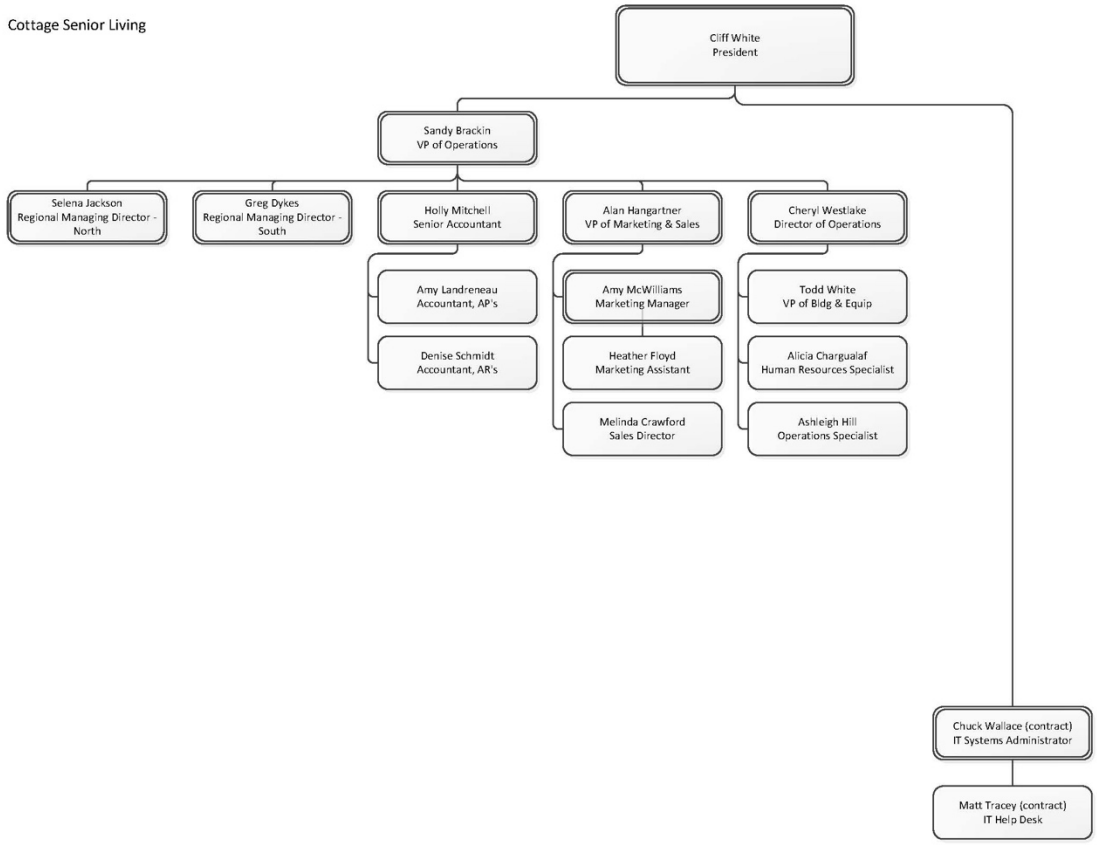
Downtown revitalization: Z. Orsborn, "What is next for downtown Tupelo?, *Northeast Mississippi Daily Journal* (September 4, 2016) available from: http://www.djournal.com/news/business/what-s-next-for-downtown-tupelo/article_6ce44568-3f56-5d13-a504-9cb3b5e23499.html

Commercial real estate prices: Loopnet.com is a valuable site for locating commercial property.[7] Loopnet search results for Tupelo, Mississippi may be found at this location: http://www.loopnet.com/Mississippi/Lee-County-Commercial-Real-Estate/

3. Does CSL have the organizational capacity to grow?

The question is not one of staffing individual locations – staffing requirements were outlined in the case in Exhibit 3. The answer focuses on the capacity of the existing management team to manage the development of a new location. Such an analysis may involve the organizational chart shown in IM Exhibit 9. From examination of the organizational chart (case IM Exhibit 9 is developed from Exhibit 8 in the case), one may conclude that CSL's span of management is narrow at the time of the case. As the number of locations increases the challenge may be in the area of the "Regional Managing Director" positions – it may be necessary to add and redefine the regional alignment.

IM EXHIBIT 9 – CSL Organizational Chart



EPILOGUE

In late summer 2017, CSL was working on a management contract for two communities within its existing footprint. These facilities were severely distressed and near bond default. In addition, CSL had made progress on the Trussville, Alabama project and should be ready to break ground in the fall 2017. CSL was acquiring land in Arab, Alabama for a new "ground up" development.

REFERENCES

[1] "Huntsville," Official Website of the City of Huntsville, Alabama, available at: https://www.huntsvilleal.gov/business/city-of-huntsville/facts-figures-about-huntsville/

[2] J. D. Crowe, "Mountain Brook one of the wealthiest communities in U.S.," *The Birmingham News* (December 30, 2008) retrieved from: http://blog.al.com/spotnews/2008/12/mountain_brook_one_of_us_wealt.html

[3] M. Norris and N. Winston, "Second-home Owners: Escaping, Investing or Retiring?" *Tourism Geographies* 12, no.4 (2010), pp. 546-567.

[4] W. Barrett, "The Best Places to Retire in 2015," *Forbes* (March 17, 2015) retrieved from: https://www.forbes.com/sites/williampbarrett/2015/03/17/the-best-places-to-retire-in-2015-2/#428e7a231472

[5] C. Nelson, "The Revitalization of Downtown Opelika," *The Opelika-Auburn News* (January 29, 2014) retrieved from: http://www.oanow.com/corner/features/the-revitalization-of-downtown-opelika/article_375b2f41-3807-58ae-a372-37fa3357e88e.html

[6] United States Department of Agriculture, "Downtown Revitalization," available at: https://www.nal.usda.gov/ric/downtown-revitalization

[7] A. Devine, "List Me." *Journal of Property Management* 66, no. 2 (2001), pp. 96.

C H A P T E R 1

The Nature of Strategic Management

SUGGESTIONS FOR EFFECTIVE TEACHING

Each chapter begins with a one-page overview of why this chapter is important for strategic managers/leaders. We conclude that organizations need a process to help them remain relevant and responsive to the changing environment.

Then we move to discussing how much change is taking place by asking the question: "In the age of rising costs and increasing quality demands, are health systems adequately addressing these problems?" Although the United States has the most advanced health care system in the world, it has many cost and quality problems and is undergoing rapid change. Efforts at remaking the health system must focus on system-wide cost and quality issues. Such an approach should encourage students to begin thinking about developing rational, well-thought-out strategic responses to a changing environment.

To stimulate student thinking and participation in class discussion, we try the following exercise. We ask the class to suggest external issues that will require responses from health care organizations. Sometimes it is helpful to cite what has happened beginning in the year 2015 through today and then ask students to speculate on the changes likely to take place from today to the year 2020. This exercise helps students understand the magnitude of change facing all health care organizations. The following format may be useful to generate discussion.

What changes have taken place? (2015 through Today)		Speculate on possible future changes. (Today through 2020)	
World	Health Care	World	Health Care

We usually conclude that there is more change taking place than ever before and the rate of change seems to be increasing. The only way to cope with such change is to strategically manage the organization. In addition, it seems certain that there will be more change in the health care industry in the next five years than in the past five years, so being able to successfully navigate rapid and transformative change and deliver positive results will become increasingly important in healthcare careers. Learning about strategic management and its application is therefore a worthy exercise for prospective healthcare leaders.

The first section in the chapter mentions changes that are currently taking place in health care. These changes are categorized into legislative/political, economic, social/demographic, technological, and competitive changes. We classified these changes to encourage students to begin to organize their thinking (using a systems approach) and ask them to discuss additional changes.

At some point, we usually say, "If there is no change expected, you really don't need strategic management – you need long-range planning." This is a good time to make sure students understand the difference. The difference is discussed under the heading "The Foundations of Strategic Management." Once the students understand that there is considerable external environmental change, we indicate that strategic management is how organizations cope with change and deal with dynamic environments.

As a way of introducing the model of strategic management, we begin by discussing the "map and compass" – our metaphor for planning and learning. In our view, strategic management involves creating models or maps for thinking about strategy concepts but with the understanding that users will also have to think – reinvent or use their compasses. When the maps seem to no longer work strategic thinkers understand rely on their compass to get back on track and are able to redesign their maps (current understanding of strategic management). This metaphor is useful in relating to our model of strategic management as it incorporates analytical approaches (strategic planning) as well as learning concepts (strategic thinking and managing strategic momentum). We explain that analytical or rational approaches to strategic management rely on the development of a logical sequence of steps or processes (linear thinking). Emergent models rely on intuitive thinking, leadership, and learning (lateral thinking) (see Henry Mintzberg, "The Design School: Reconsidering the Basic Premises of Strategic Management," *Strategic Management Journal* 11, no. 3 (1990), pp. 171–195). Analytical models are similar to a map whereas emergent models are similar to a compass.

We emphasize that a model is an organizing framework used to conceptualize a complex process. Without some type of organizing

framework, strategic management becomes an overwhelming task. A model shows relationships and the underlying logic of a phenomenon. Models are abstractions of reality (shortcuts to storing masses of data). Models draw upon "systems" thinking – they illustrate interrelationships. A model can clearly show the necessary steps in a process and become a means for communicating the steps.

It is also important to introduce strategic management as the organizational mechanism to cope with change. This requires introducing strategic thinking, strategic planning (as the process of developing a plan), and managing strategic momentum (carrying out the plan). We introduce Exhibit 1-1 as the vehicle to discuss and differentiate these concepts. It may be used as the model or map for the entire book and course. We discuss strategic thinking, strategic planning and managing strategic momentum in considerable detail and discuss who performs these activities within the organization.

A NOTE CONCERNING CHAPTER LEARNING OBJECTIVES AND THE CHAPTER STRATEGIC MANAGEMENT COMPETENCY

The chapter **learning objectives** concern specific, reasonably measureable chapter elements that students should know and be able to describe, explain, discuss, clarify, justify, and so on. The chapter **competency** describes the overall applied skill that the student should be able to perform after completing the chapter. Together, the ten chapter strategic management competencies specify the level of knowledge, skills, and abilities that will enable the student to develop a complete and meaningful strategy for a health care organization.

LECTURE NOTES

We usually spend a few minutes introducing the class discussing why this chapter is important as discussed above.

I. Managing in a Dynamic Industry.

A. Many environmental changes are taking place. The instructor may ask the class to suggest external issues that will require responses from health care organizations. Sometimes it is helpful to provide some historical perspective citing what happened in the 1980s through today (PPS, managed care, AIDS, Balanced Budget Act, HIPAA, PPACA, and others) and then ask students to speculate on the changes likely to take place from today to the year 2020. At this point, the "What has Changed?" exercise discussed above works well.

B. It should be noted that not only is there more change taking place than ever before, the rate of change seems to be increasing.

C. The economy is more global – many new markets and competitors.

D. Many industries overlap (hotels operating nursing homes, hospitals offering home health care, and so on).

E. Competition has increased (from within as well as outside the traditional health care industry).

F. It is the adoption of strategic management that has allowed organization to cope with industry change and shifts.

II. Coping with Change.

A. Strategic management is the way organizations systematically assess, monitor, and respond to external change.

B. Strategic management is a fundamental leadership function.

III. The Foundations of Strategic Management.

A. Strategic management has its origins within the military.

B. Business enterprises have successfully used strategic management for a number of years and must be credited with enhancing and promoting its concepts and methods.

C. There has been an evolution of the concept of strategic management. Initially it had a distinctly long-range planning flavor – extending today's operations and budgets into the future. However, over time strategic management became a system to identify and understand environmental changes that enabled the organization to be successful in its environment.

D. In the past thirty-five years, strategic management concepts have been employed extensively within health

care organizations.

E. We differentiate strategic management from health policy. Mike Morrisey does a nice job of explaining health policy in Essentials for a Strategic Thinker 1-3. This discussion should conclude that strategic management concerns one organization coping with a changing environment whereas health policy concerns many organizations and the "rules" for provider and consumer behavior.

F. In recent years the expansion of health care systems, fragmentation of markets, the growth of investor-owned hospital companies, and an emphasis on cost containment and quality have induced individual health care organizations to adopt strategic management.

III. The Dimensions of Strategic Management.

A. There are many ways to think about the strategic management process in organizations.

B. Analytical or rational approaches to strategic management rely on the development of a logical sequence of steps or processes (linear thinking). Emergent models rely on intuitive thinking, leadership, and learning (lateral thinking).

C. It is not a question of which model is right or better, but when and under what circumstances they are useful to understand what managers do or should do.

D. The methods are both complementary and contradictory – the analytical model is similar to a map whereas the emergent model is similar to a compass. Both may be used to plot a course to a defined destination but in some cases they may indicate different directions. Maps are better in known worlds, compasses are more helpful when there is less certainty and only a general sense of direction is indicated.

E. Why do we need a model of strategic management? A model is an organizing framework used to conceptualize a complex process. Without some type of organizing framework, strategic management becomes an overwhelming task. A model shows relationships and the underlying logic of a phenomenon. Models draw upon "systems" thinking – they illustrate interrelationships. A model can clearly show the necessary steps in a process and become a means for communicating the steps. As illustrated in Exhibit 1-1, strategic management has three

elements – strategic thinking, strategic planning, and managing strategic momentum. These activities are interdependent and activities in one element affect, and are affected by, the others. The model incorporates the analytical/planning approach and the emergent/learning views of strategic management.

Generally, strategic management is an externally oriented philosophy of leading and managing an organization using strategic thinking and periodic strategic planning. Strategic thinking is a way of thinking or mindset underlying the strategic management philosophy. Strategic planning is the periodic process of creating strategy or a plan using strategic thinking. Managing strategic momentum concerns the active implementation of the strategic plan using strategic thinking. Strategic thinking occurs at an individual level, strategic planning is usually a periodic group activity, and managing strategic momentum is a continuous organization-wide process of actively pursuing strategic goals. Strategic management is the term commonly used to describe all three activities.

F. We introduce the systems perspective to encourage students to think about classes, categories, and relationships – to order or make their thinking more systematic. To us, strategy making is a disciplined thought process – "strategic thinking." *Strategic thinking* is an intellectual activity underlying strategic management that is perceptive to emerging changes, considers strategic implications, and develops transformative responses. At its most fundamental level, strategic thinking includes the states of awareness, anticipation, analysis, interpretation, synthesis, and reflection. We emphasize that leaders must be strategic thinkers and may use systems concepts to better understand the relationship of the organization to its environment and the relationships within the organization. Successful leaders see these relationships and create a vision for new relationships in the future. Descriptions of the strategic thinking states are presented in Exhibit 1-2.

1. *Strategic thinking is central to leadership:*

   - acknowledges the reality of change,
   - questions current assumptions and activities,
   - builds on an understanding of systems,
   - envisions possible futures,
   - generates new ideas, and
   - considers the organizational fit with the external environment.

2. Strategic thinking is everyone's job. Everyone should be encouraged to think strategically and consider how to reinvent what they do in light of the changing environment.

G. Strategic Planning:

- provides a sequential, step-by-step process for creating a strategy,
- involves periodic group strategic thinking (brainstorming) sessions,
- requires data/information, but incorporates consensus and judgment,
- establishes organizational focus,
- facilitates consistent decision making,
- reaches consensus on what is required to fit the organization with the external environment, and
- results in a documented strategic plan.

1. Situational analysis.

i. External environmental analysis – What the organization should do.
ii Internal environmental analysis – What the organization can do.
iii Mission, vision, values, and objectives – What the organization wants to do.
iv Strategy formulation.
v Planning the implementation.

2. A group process of key players – strategic planning is a group process. Strategic planning requires that key strategic thinkers periodically come together to share ideas and develop a map for the organization.

.H. Strategic Momentum.

1. Managing the strategy: Day-to-day activities to manage the strategy to achieve strategic goals.

- is the actual work to accomplish specific objectives,
- concerns decision-making processes and their consequences,
- provides the style and culture,
- evaluates strategy performance,
- is a learning process, and

- relies on and initiates new strategic thinking and periodic strategic planning.

2. A particular outcome for an organization may be intended (deliberate strategies), unrealized, or emergent. Thus, sometimes strategies work out, sometimes they do not and other times they evolve into something new and initially unintended.

3. An organization-wide activity. As with strategic thinking, everyone must strategically manage.

I. The Benefits of Strategic Management.

1. Strategic management is a way of managing that provides an organizational self-concept and vision for the future – a philosophy of management.

2. Vertical and horizontal communication throughout the organization is enhanced.

3. Strategic management encourages innovation and change. Responding to change is the key to success.

4. It is probable that the strategically managed organization will experience increased revenues and reduced costs (greater profitability). Several studies are provided in the Notes listed at the end of the chapter.

J. What Strategic Management Is Not.

1. Strategic management provides no guarantees for success.

2. Strategic management is not merely a technique – it is a philosophy of management.

3. Strategic management is not a process of completing paperwork nor a series of documents, but an attitude.

4. Strategic management is not a process of simply extending into the future what the organization is doing today. An attempt is made to identify issues that will be important tomorrow in order to begin to deal with them today.

K. A Systems Perspective.

1. Strategic management is a study of relationships between cooperating and competing systems. The use of the systems approach requires managers to define the organization in broad terms and attempt to identify the important variables and interrelationships that will affect a decision.

2. Within organizations, we can visualize interacting technical subsystems, social subsystems, informational subsystems, structural subsystems, and so on. In addition, management itself can be viewed as being made up of various subsystems such as planning, staffing, organizing, directing, and controlling.
3. Managers must be systems thinkers. Managers may use systems concepts to better understand the relationship of the organization to its environment and the relationships within the organization. Successful mangers see these relationships and create a vision for new relationships in the future.

L. The Level and Orientation of the Strategy.

1. Corporate level – "What business(es) are we in?" It implies multiple markets/products/technologies. In addition, it questions, "What business(es) should we be in?"
2. Divisional level – "How (or on what basis) do we compete?" Competition in a single market (single product line, well-defined market, one technology); SBU or SSU. NOTE: In the health care field, SSU or strategic service unit is used most frequently (as we have throughout this text).
3. Organizational level – strategies typically concern one organization competing within a specific well-defined service area such as a hospital or long-term care facility.
4. Unit level – delineates strategies within departments such as finance, marketing, clinical, pharmacy administrative and so on.

IV. The Importance of Leadership

A. Leadership Roles throughout the Organization.

1. Although the CEO has the ultimate responsibility, strategic management has become a line job with each manager responsible for the strategic implications of his or her decisions.
2. Over the past decade, many large formal planning staffs have been dissolved as organizations learned that strategy development cannot take place in relative isolation.

V. Practical Lessons for Health Care Strategic Thinkers.

A. Strategic management is complex and difficult.
B. No single approach is likely to be adequate.

C. Some logical approach is needed as a starting point.
D. Models should not be applied blindly.
E. Strategic management is not always a structured, well-thought-out exercise. Sometimes we learn by doing.

NOTE: If you are using cases in the course, you may want to assign Resource 1: Analyzing Strategic Health Care Cases at this point and schedule a class meeting to discuss your philosophy of case analysis.

QUESTIONS FOR CLASS DISCUSSION

1. Explain why strategic management has become crucial in today's dynamic health care industry.

Strategic management has become crucial in today's dynamic health care industry because significant change comes from many sources. Health care leaders have to deal with complex and sometimes conflicting issues and trends. It is likely that there will be new opportunities and threats to organizations that have yet to be identified or fully assessed. And, it seems certain that there will be more change in the health care industry in the next five years than there has been in the past five.

2. What is the rationale for health care organizations' adoption of strategic management?

Health care leaders will have to cope with change and position their organizations to take advantage of emerging opportunities while avoiding external threats. Strategic management has become a major thrust guiding the management of all types of contemporary organizations. Business organizations embraced strategic management as a way to anticipate and cope with a variety of external forces beyond their control. The environmental uncertainties and competitive pressures that moved business organizations to adopt strategic management beset health care organizations as well. Strategic management provides a basic understanding of how and why an organization survives and grows.

3. Trace the evolution of strategic management. Have the objectives of strategic management changed dramatically over its development?

The concept of strategy is derived from the military. In the 1950s several authors began to relate strategic management to business. Strategic planning developed in the 1960s and 1970s as leading business organizations began practicing and publicizing its merits. Early on,

strategic management included planning and budgeting, with planning being the central theme.

In the past thirty years, strategic management concepts have been employed within health care organizations. Prior to 1980, individual organizations had few incentives to employ strategic management because most health care organizations were independent, freestanding, not-for-profit institutions, and health services reimbursement was on a cost-plus basis. In recent years the expansion of health care systems, the fragmentation of markets, the growth of investor-owned hospital companies, and the emphasis on cost containment and quality have induced individual health care organizations to investigate strategic management.

Throughout its history, strategic management has retained its basic emphasis on planning but has been expanded to encompass implementation and control (managing strategic momentum). More and more health care organizations have committed to the process as a means of managing increasingly large, complex, and diversified organizations in dynamic environments.

4. How is strategic management different from health policy?

There has been substantial health planning in the United States. However, strategic planning is organization specific. Strategic planning helps an individual organization respond to state and federal policy and planning efforts, as well as to a variety of other external forces. Therefore, strategic management concerns one organization coping with a changing environment whereas health policy concerns many organizations and the "rules" for provider and consumer behavior.

5. Compare and contrast the analytical view of strategic management with the emergent, learning approach. Which is most appropriate for health care managers?

Analytical or rational approaches to strategic management rely on the development of a logical sequence of steps or processes (linear thinking). Emergent models, on the other hand, rely on intuitive thinking, leadership, and learning. Both approaches are valid and useful in explaining the process of strategic management. Neither the analytical nor the emergent model, by itself, is enough. Both approaches are required. It is difficult to initiate and sustain organizational action without some logical plan. Yet in a dynamic environment, such as health care, we must expect to learn by doing and establish new directions as we progress.

6. Why are conceptual models of management processes useful for practicing managers?

Conceptual models are useful because they are abstractions of reality that attempt to identify, simplify, and explain processes, patterns, and relationships inherent to a phenomenon. By eliminating much superfluous data, models enable managers to better understand complex processes and their interdependent variables as well as the underlying logic. Models facilitate learning and help achieve consistency in application.

7. What is a strategic thinking map? How are strategic thinking maps useful? What are their limitations?

Through a theoretical model, managers can gain an appreciation of the required inputs to strategic management, the processes involved, and the outputs of the process. A strategic thinking map is a diagram of the theory. These maps depict strategy processes and are designed to start the process and to ignite strategic thinking. The strategic thinking maps will start us on the journey to develop a comprehensive strategy for the organization but the map cannot anticipate every contingency. Today's templates will not be adequate for solving all of tomorrow's problems. Therefore, we will have to think, analyze, use our intuition, and reinvent as we go. If strategy can be described in a disciplined way, then there will be an increased likelihood of its successful implementation. Strategy maps will help organizations view their strategies in a cohesive, integrated, and systematic way.

8. What are the major activities of strategic management? How are they linked together?

A model or map that accounts for the analytical and emergent views of strategic management that illustrates and organizes the major components is presented in text Exhibit 1-1. As illustrated in Exhibit 1-1, strategic management has three elements – strategic thinking, strategic planning, and strategic momentum. These activities are interdependent and activities in one element affect, and are affected by, the others. The model incorporates the analytical/planning approach and the emergent/learning views of strategic management. Strategic managers must become strategic thinkers able to evaluate the changing environment, analyze data, question assumptions, and develop new ideas. They must also be able to develop and document a plan of action through strategic planning. Strategic planning has three parts – situation analysis, strategy formulation, and planning the implementation. Strategic planning is a decision-making and documentation process and creates the strategic plan. Once a strategic plan is developed, strategic managers must manage strategic momentum. As strategic managers attempt to carry out the strategic plan they must evaluate its success, will learn more about what works, and must utilize new strategic thinking that may initiate new strategic planning. Strategic momentum may provide new insights for the implementation planning, strategy formulation, or the situation.

9. Differentiate among the terms strategic management, strategic thinking, strategic planning, and strategic momentum.

Generally, strategic management is an externally oriented philosophy of leading and managing an organization using strategic thinking and periodic strategic planning. Strategic thinking is a way of thinking or mindset underlying the strategic management philosophy. Strategic planning is the periodic process of creating strategy or a plan using strategic thinking. Strategic momentum concerns the active implementation of the strategic plan using strategic thinking. Strategic thinking occurs at an individual level, strategic planning is usually a periodic group activity, and managing strategic momentum is a continuous organization-wide process of actively pursuing strategic goals. Strategic management is the term commonly used to describe all three activities.

10. In an organization, who should be doing strategic thinking? Strategic planning? Managing strategic momentum?

Strategic Activity	Description	Scope
STRATEGIC THINKING	Fundamental strategic skill, a way of thinking, mindset underlying strategic management.	Individual
Strategic Planning	Periodic process of creating a plan (strategy) using strategic thinking.	Group
Strategic Momentum	The continuous philosophy of leading and managing an organization using strategic thinking and periodic strategic planning.	Organization

11. Is strategic thinking enough? Why do we engage in strategic planning? What are the elements of strategic planning?

The organizational processes that managers use include situational analysis, strategy formulation, and planning the strategy implementation. These aid the organization in understanding the system of competitive behavior and the impact of a strategy. That is, they aid in developing the understanding, ability, and willingness to act to best position the organization within the external environment and implement a strategy that will help assure success.

Situational Analysis – the interaction and results of external analysis, internal analysis, and statement of vision, mission, values, and goals. It forms the basis for the development of strategy and drives the strategy.

1. External analysis – analysis of opportunities and threats to determine what the organization should do.
2. Internal analysis – represents the capabilities of the organization or what the organization can do. This analysis reveals strengths and weaknesses of the organization.
3. Vision, mission, values and goals – codification or declaration of

the situation and determination of direction to state what the organization wants to do.

Strategy Formulation – answers the questions: "What business are we in?" "What business should we be in?" "How are we going to compete?" Strategy formulation consists of two interrelated activities:

1. Development of vision, mission, values and strategic goals (directional strategies) which set the broadest direction for the organization, and
2. Development of the adaptive, market entry/exit, and competitive strategies, and the writing of the strategic plan.

Planning the Implementation – development of specific activities to carry out value adding service delivery and support strategies. Service delivery strategies include pre-service, point of service, and after-service strategies. Support areas include culture, structure, and strategic resources. Action plans are developed for each organizational unit and are made up of objectives, activities to achieve the objectives, timelines, and budgets as well as controls to monitor and modify the objectives' based on accomplishments.

12. What is meant by realized strategies? How can strategies be realized if they were never intended?

Realized strategies can be either deliberate or emergent. Deliberate strategies are intentionally developed by management and subsequently realized by the organization. Emergent strategies were never intended or expected by management but did occur over time because of forces in the external or internal environment, because no strategy was developed at the outset, or because the strategies were displaced along the way. Thus, a strategy can be realized (it occurs) but it was never intended.

13. *What can cause well-thought-out strategies that were developed using all the steps in strategic planning to change?*

The possibilities include:

1. There is a reformulation of the strategy during implementation as the organization gains new information and feeds that information back to the formulation process, thus modifying intentions en route.
2. The external environment is in a period of flux and strategists are unable to accurately predict conditions; the organization may therefore find itself unable to respond appropriately to a powerful external momentum.
3. Organizations in the external environment implementing their own strategies may block a strategic initiative, forcing the

activation of a contingency strategy or a period of "groping."

14. *Explain and illustrate the possible benefits of strategic management. What types of health care institutions may benefit most from strategic management?*

Strategic management is a philosophy and benefits are not always quantifiable. One benefit that can be quantified is improvement in long-term financial performance (increased ROI or ROA, reduced days in accounts receivable, high occupancy, and so on). Strategic management helps tie the organization together with a shared value system and provides managers with specific goals and direction in decision-making. Another benefit is an increase in communication throughout the organization, as well as better overall coordination. Further, innovation and change are encouraged, thus lessening the resistance to change.

All types of health care institutions may benefit from strategic management, but those that are large in size, offer many diverse services through interrelated functions, have low profitability, face low market growth in a highly competitive environment, or encounter frequent technological and regulatory change will benefit most.

15. *At what organizational level(s) may a strategy be developed? If at more than one level, how are the levels linked by the planning process?*

Strategy may be developed at any level of the organization. However, the strategies will have a different scope as well as purpose at different organizational levels. Strategic management creates a hierarchy of strategies that are linked. The implementation of strategy at one level is linked to the formulation of strategy at another level. To illustrate, unit-level strategies should help to achieve organizational-level strategies, organizational strategies are the means to achieving divisional-level strategies, and divisional-level strategies are the means to achieving corporate-level strategies.

Corporate level – the broadest level of strategic management. It defines the general markets or "businesses" in which the organization operates.

Divisional level – semi-autonomous organizational units (SBUs or SSUs) that operate within the various markets. This level deals with how an organization should compete in a given market as well as allocation of resources to achieve a competitive advantage in that market.

Organizational level – strategies typically concern one organization competing within a specific well-defined service area such as a hospital or long-term care facility.

Unit level – strategies are developed within departments – marketing, finance, clinical, pharmacy, human resources, and administrative, or support areas – culture, organization structure, facilities and equipment to support higher level strategies.

CASE 1

The Pharmaceutical Industry: An Industry Note

The pharmaceutical industry consisted of all enterprises that were involved in the invention of drugs, production of the active substances in drugs, formulation of the drugs, and promotion of them to the public, as well as the specialists who prescribed them.

The Products

A drug was considered to be any article (other than food) that was intended to be used in diagnosis, treatment, prevention, mitigation, or cure for humans or other animals. Drugs were classified as prescription, generic, or over-the-counter (OTC). Prescription drugs were sold only in pharmacies and required an authorization to sell the drug to a patient written by a physician (a prescription). Generic (or generic equivalent) drugs contained the same active ingredient as a specific brand name prescription drug and required a prescription, but were only allowed to be produced after the brand name drug's patent had expired. OTC drugs were freely available to the public.

This case was written by Leonidas Kyriazis, MBA, and Linda E. Swayne, PhD, both from The University of North Carolina at Charlotte. It is intended as a basis for classroom discussion rather than to illustrate either effective or ineffective handing of an administrative situation.

Prescription versus OTC

The Food and Drug Administration (FDA) through its *OTC Drug Monographs* defined 80 therapeutic categories and 800 significant active ingredients that could be used by consumers in self-diagnosis and self-treatment without prescriptions. More than 100,000 products were manufactured (mainly by pharmaceutical companies) for the OTC market. The pharmaceutical companies had some, but not complete, freedom to decide whether a product would be sold as an OTC drug – when the preparation contained, as an active ingredient, one or more of those included in the list of 800. If a product contained an active ingredient that was not on the OTC list, it had to be registered with the FDA and usually became a prescription drug. Pharmaceutical companies were able to request that any prescription product be transferred to the OTC list, but FDA approval for the change depended on the nature of the product and its safety for public use.

In the US market, prescription drug sales (in dollars) predominated; however, OTC sales numbers were rather inaccurate as the data collection method was continuously changed (Exhibit 1/1).

Generic Drugs

New products that were the result of research and development (R&D) by pharmaceutical companies were usually covered by patents. Patented products enjoyed exclusivity in the market to sell the active ingredient for a specific indication, as long as the patent was valid (20 years, starting from the day of patent application). For the period that the drug was protected by a patent, monopoly pricing was in effect and the price was usually well above the price of the same product after the patent expired. Exhibit 1/2 compares the average price of patented, brand name, and generic drugs.

A drug could become generic after the expiration of the patent. Competitive firms could produce the drug and sell it at lower prices, effectively competing with

Exhibit 1/1: Sales of Prescription and Over-The-Counter Drugs

Year	**1999**	**2000**	**2001**	**2002**
Prescription sales (in billions)	$125.8	$145.6	$164.1	$182.7
Prescription as % of all drug sales	*87%*	*90%*	*91%*	*91%*
Increase in prescription sales		15.7%	12.7%	11.3%
OTC sales (in billions)	$18.9	$16.7[a]	$17.1[a]	$17.2[a]
OTC as % of all drug sales	*13%*	*10%*	*9%*	*9%*
Increase of OTC sales		−11.6%	2.4%	0.6%
Total (in billions)	**$144.7**	**$162.3**	**$181.2**	**$199.9**

[a]Does not include WalMart

Sources: National Association of Chain Drug Stores (www.nacds.org); Consumer HealthCare Products Association (www.chpa-info.org)

Exhibit 1/2: Average Retail Prescription Prices of Drugs

Year	Brand Name	Generic	Average
2002	$75.82	$27.16	$54.73
2003	$84.21	$30.56	$59.30

Source: National Association of Chain Drug Stores (www.nacds.org/wmspage.cfm?parm1=507)

the innovator. When a drug came "off patent" and became generic, it was usually referred to by the name designating the active chemical ingredient. Thus, when the patent for PRILOSEC (manufactured by AstraZeneca) expired, the generic appeared in the market as *omeprazole*. A patent could expire but a brand name, once registered and protected, belonged to the company that registered it.

Market Size and Major Players

Although the world pharmaceutical market represented about $0.5 trillion in sales, more than 80 percent of these sales were in 10 nations (Exhibit 1/3). The United States alone was responsible for approximately 45 percent of world spending. In the United States the spending was $793 per capita, representing 2.1 percent of GDP. The United States was the only leading market without general government price controls on drugs.

Similar to other industries in the 1990s and the early 2000s, the pharmaceutical industry responded to the challenges of globalization. Many smaller companies

Exhibit 1/3: Pharmaceuticals Sales, Top 10 Markets, June 2003 to June 2004

		Sales (in billions)	Population	Per capita spending	GDP (in billions)	% of GDP
1	US	$228.7	288,368,698	$793	10,857.2	2.1%
2	Japan	$55.4	127,619,000	$434	4,317.1	1.3%
3	Germany	$27.8	82,537,000	$337	2,403.1	1.2%
4	France	$26.4	58,518,748	$451	1,757.6	1.5%
5	UK	$18.4	58,789,194	$313	1,798.5	1.0%
6	Italy	$17.9	56,305,568	$318	1,465.8	1.2%
7	Spain	$12.8	42,717,064	$300	838.6	1.5%
8	Canada	$10.5	31,413,990	$334	853.8	1.2%
9	China	$6.6	1,284,530,000	$5	1,409.8	0.5%
10	Mexico	$6.3	97,483,412	$65	615.1	1.0%

Source: "Health Care in Focus," *Chemical and Engineering News* 82, no. 49 (2004), p.18

merged to form large conglomerates to create worldwide strength. The merger history for the major players over the past five years is summarized in Exhibit 1/4.

As the largest market in the world, the US pharmaceutical companies were actively involved in mergers. As a result, the largest players world wide were also generally the largest in the United States (see Exhibit 1/5).

Exhibit 1/4: Five-year Merger History of the World Top 10 Pharmaceutical Companies

	Corporation	Market Share based on sales 2003	1998	Agglomerate of
1	Pfizer	10.1%	9.0%	Pfizer, Pharmacia, Upjohn, Warner-Lambert, Searle
2	GlaxoSmithKline	6.6%	7.2%	Glaxo, Wellcome, SmithKline French, Beecham
3	Sanofi-Aventis	5.4%	5.8%	Sanofi, Syntelabo, Hoechst, Rohne-Poulenc, Fisons
4	Merck & Co	4.8%	4.2%	
5	Johnson & Johnson	4.8%	3.6%	
6	Novartis	4.3%	4.2%	Ciba-Geigy, Sandoz
7	AstraZeneca	4.1%	4.3%	Astra, Zeneca
8	Bristol-Myers Squibb	3.4%	4.2%	Bristol-Myers Squibb, DuPont Pharma
9	Hoffmann-La Roche	3.3%	3.1%	
10	Abbott	2.8%	3.3%	Abbott, BASF Pharma (Knoll)
	Total 10 Corporations	49.6%	48.9%	

Source: "Health Care in Focus," *Chemical and Engineering News* 82, no. 49 (2004), p.18

Exhibit 1/5: Leading 20 Corporations by US Sales, 2004

	Corporation	Total Sales[a] (in billions)	Growth	Market Share		Corporation	Total Sales[a] (in billions)	Growth	Market Share
1	Pfizer	$30.7	5%	13.1%	11	Lilly	$8.0	6%	3.4%
2	GlaxoSmithKline	$18.8	1%	8.0%	12	Abbott	$6.5	16%	2.8%
3	Johnson & Johnson	$16.2	7%	6.9%	13	Hoffmann-La Roche	$6.1	16%	2.6%
4	Merck & Co	$15.0	8%	6.4%	14	TAP Pharmaceutical	$4.7	−5%	2.0%
5	AstraZeneca	$11.3	12%	4.8%	15	Boehringer Ingelhein	$3.7	21%	1.6%
6	Novartis	$10.2	7%	4.3%	16	Forest Lab	$3.4	16%	1.4%
7	Sanofi-Aventis	$10.0	12.6%	4.3%	17	Teva	$3.4	17%	1.4%
8	Amgen	$9.5	23%	4.1%	18	Schering Plough	$2.9	−27%	1.2%
9	Bristol-Myers Squibb	$9.2	−4%	3.9%	19	Eisai	$2.5	11%	1.1%
10	Wyeth	$8.2	11%	3.5%	20	Watson	$2.4	18%	1.0%

[a]Represents prescription pharmaceutical purchases including insulin at wholesale prices by retail, food stores and chains, mass merchandisers, independent pharmacies, mail services, non-federal and federal hospitals, clinics, closed-wall HMOs, long-term care pharmacies, home health care, and prisons/universities. Excludes co-marketing agreements. Joint-ventures were assigned to the product owner. Data were run by custom redesign to include completed mergers and acquisitions.

Source: IMS Health, IMS National Sales Perspectives™, 2/2005 (see http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891374,00.html)

To be successful, pharmaceutical companies attempted to discover medications that improved the medical condition of human beings but at the same time had to be able to recover the huge R&D expenses. Thus, most major pharmaceutical companies targeted the largest therapeutic classes (Exhibit 1/6) with brand name (patented) products (Exhibit 1/7).

Exhibit 1/6: Leading 20 Therapeutic Classes by US Sales, 2004

	Indication or Class Description	Class	Sales[a] (in billions)	Growth	Market Share
1	Hypercholesterolemia (cholesterol-lowering drugs)	HMG – COA Reductase Inhibitors (Statins)	$15.50	12%	6.6%
2	Antiulcerants (Gastric Ulcers, GERD[b])	Proton Pump Inhibitors	$12.50	−3%	5.3%
3	Antidepressants (depression fighting drugs)	Selective Serotonin Reuptake Inhibitor, Selective Norepinephrine Reuptake Inhibitor (SSRI/SNRI)	$11.00	1%	4.7%
4	Antipsychotics (Schizophrenia, mental illness)	Antipsychotics, Other	$9.10	12%	3.8%
5	Antiepileptics (Epilepsy)	Seizure Disorders	$8.20	19%	3.5%
6	Anemia (blood disorder)	Erythropoietins	$8.00	8%	3.4%
7	Antiarthretics (relieve pain of arthritis)	COX-2 Inhibitors	$5.30	0%	2.3%
8	Hypertension (reduce high blood pressure)	Calcium Blockers	$4.40	1%	1.9%
9	Hypertension (reduce high blood pressure)	Angiotensin II Antag	$4.40	24%	1.9%
10	Hypertension (reduce high blood pressure)	Ace Inhibitors	$3.90	−5%	1.7%
11	Osteoporosis (bone disease)	Bisphosphonates	$3.60	15%	1.5%
12	Diabetes	Insulin Sensitizer	$3.40	12%	1.4%
13	Pain Relief	Codeine and combinations	$3.30	5%	1.4%
14	Blood-Thinner, Antistroke	Antiplatelets, Oral	$3.30	31%	1.4%
15	Antiallergic	Antihistamines, Caps/Tabs	$3.20	−9%	1.4%
16	HIV	HIV-Reverse Trans Inhibitors	$3.10	8%	1.3%
17	Asthma	Steroid, Inhaled	$2.90	26%	1.2%
18	Contraceptive	Oral Contraception	$2.80	−2%	1.2%
19	AIDS, Multiple Sclerosis	Immunologic Interferons	$2.80	5%	1.2%
20	Ulcerative Colitis, Crohn's Disease	Gastrointestinal Antiinflammatory	$2.70	15%	1.2%

[a]Represents prescription pharmaceutical purchases at wholesale prices by retail, food stores and chains, mass merchandisers, independent pharmacies, mail services, non-federal and federal hospitals, clinics, closed-wall HMOs, long-term care pharmacies, home health care, and prisons/universities.

[b]GastroEsophageal Reflux Disease

Source: IMS Health, IMS National Sales Perspectives™, 2/2005 (see http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69891394,00.html)

Exhibit 1/7: Leading 20 Products by US Sales, 2004

	Brand	Marketer	Action	Indication	Sales[a] (in billions)	Growth	Market Share
1	LIPITOR	Pfizer	Circulatory and blood	Hypercholesterolemia	$7.70	14%	3.3%
2	ZOCOR	Merck	Circulatory and blood	Hypercholesterolemia	$4.6	4%	1.9%
3	PREVACID	Takeda, Abbott	Stomach	Gastric ulcers, GERD[b]	$3.8	−5%	1.6%
4	NEXIUM	AstraZeneca	Stomach	Gastric ulcers, GERD[b]	$3.8	23%	1.6%
5	PROCRIT	Johnson & Johnson	Circulatory and blood	Anemia	$3.2	−3%	1.4%
6	ZOLOFT	Pfizer	Antipsychotic	Depression	$3.1	8%	1.3%
7	EPOGEN	Amgen		Anemia	$3.0	−4%	1.3%
8	PLAVIX	Sanofi-Aventis, Bristol-Myers Squibb	Circulatory and blood	Acute coronary syndrome, stroke, thrombosis, blood thinner	$3.0	33%	1.3%
9	ADVAIR DISKUS	GlaxoSmithKline	Breathing	Asthma	$2.9	26%	1.2%
10	ZYPREXA	Lilly	Antipsychotic	Schizophrenia	$2.8	−10%	1.2%
11	CELEBREX	Pfizer	Pain relief and anti-inflammatories	Arthritis	$2.7	7%	1.2%
12	EFFEXOR XR	Wyeth	Antidepressant	Anti-aging, anti-depressant	$2.6	22%	1.1%
13	NEURONTIN	Pfizer	Pain relief and anti-inflammatory	Postherpetic neuralgia (PHN).	$2.6	5%	1.1%
14	NORVASC	Pfizer	Blood pressure	Hypertension, angina	$2.4	10%	1.0%
15	PROTONIX	Wyeth	Stomach	Gastric ulcers, GERD[b]	$2.2	28%	1.0%
16	SINGULAIR	Merck	Breathing	Asthma	$2.1	25%	0.9%
17	RISPERDAL	Janssen	Antipsychotic	Schizophrenia	$2.0	2%	0.9%
18	PRAVACHOL	Sanofi-Aventis, Bristol-Myers Squibb	Circulatory and blood	Hypercholesterolemia	$2.0	−2%	0.8%
19	FOSAMAX	Merck	Osteoporosis	Osteoporosis	$2.0	9%	0.8%
20	SEROQUEL	AstraZeneca	Antipsychotic	Schizophrenia	$2.0	31%	0.8%

[a]Represents prescription pharmaceutical purchases at wholesale prices by retail, food stores and chains, mass merchandisers, independent pharmacies, mail services, non-federal and federal hospitals, clinics, closed-wall HMOs, long-term care pharmacies, home health care, and prisons/universities.

[b]GastroEsophageal Reflux Disease

Source: IMS Health, IMS National Sales Perspectives™, 2/2005 (see http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_49695983_69890133,00.html)

R&D

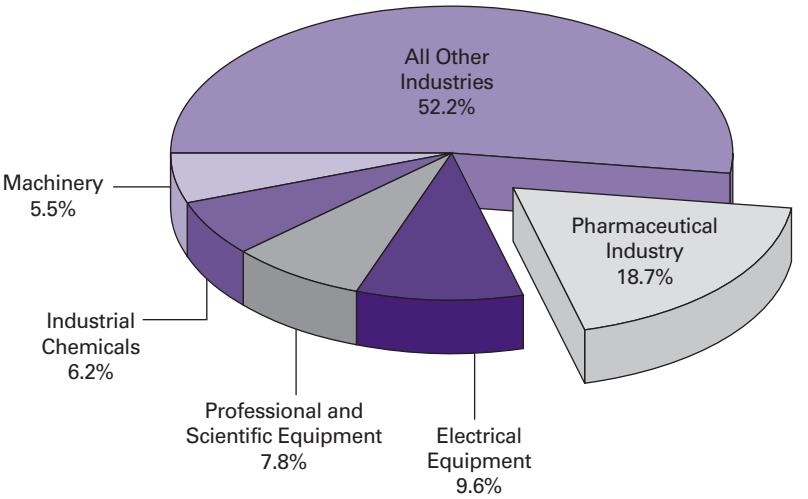
The pharmaceutical industry relied on new product development. In 2004, the pharmaceutical industry spent 18.7 percent of all self-performed R&D in the United States, more than any other single industry (Exhibit 1/8). R&D spending reached the record amount of $38.8 billion in 2004, an increase of 12.6 percent over 2003 (not including the $10.5 billion R&D spending by Biotech companies).[1]

Worldwide pharmaceutical industry R&D spending increased eight times between 1980 when it was $2 billion and 2004 when it was $38.8 billion (Exhibit 1/9).

R&D spending for the top 10 US leading corporations as a percentage of revenue was between about 11 and 25 percent (Exhibit 1/10).

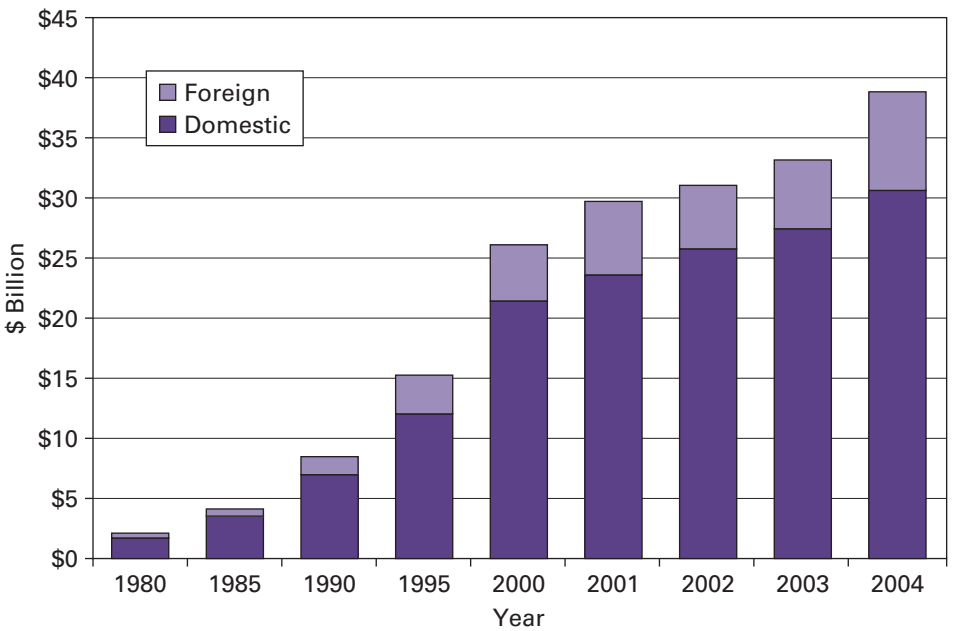
Although the money spent increased rapidly over time, the number of products in the late development stage in 2004 were fewer in number than there were in the mid-1990s, indicating that the R&D productivity had not increased.[2] R&D money was spent searching for new molecules, preparing for pre-clinical trials, and undergoing

Exhibit 1/8: 2004 Self-Performed Basic R&D Spending



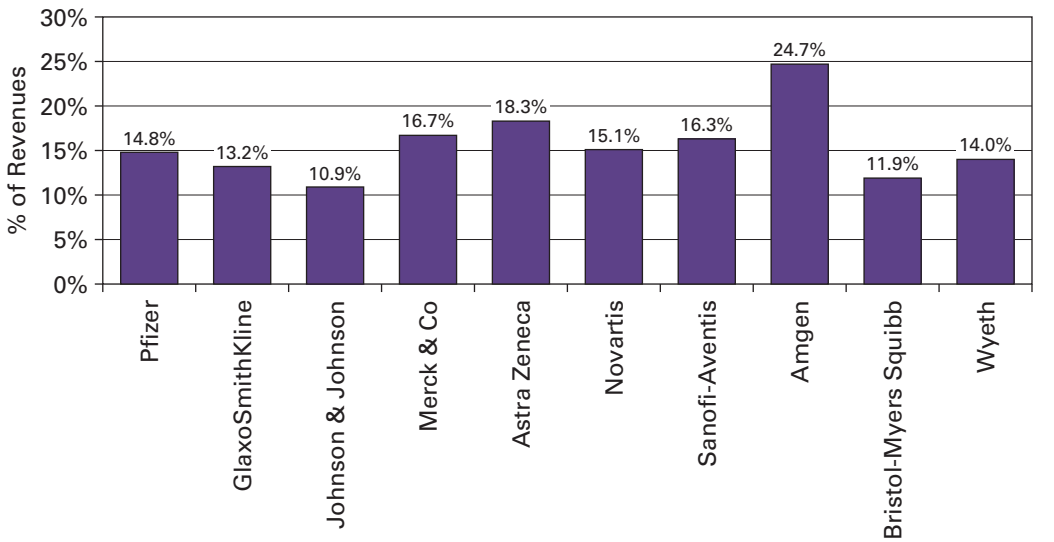
Source: Profile Pharmaceutical Industry 2004 (www.phrma.org)

Exhibit 1/9: R&D Spending by US Pharmaceutical Industry in US and Other Countries



Source: Profile Pharmaceutical Industry 2004 (www.phrma.org)

Exhibit 1/10: R&D Spending of the 10 Leading Pharmaceutical Corporations



Source: SEC filings (www.Morningstar.com)

clinical trials. Drug development was a highly speculative process and R&D expenses were spread between the successful and unsuccessful trials. Only one molecule out of 1,000 entering the R&D pipeline emerged as an approved drug.[3] Despite a drug passing the pre-clinical trials and reaching Phase I, it only had a probability of 10 percent to make it to the market. Even if it reached the market, it had only a 30 percent probability of becoming profitable.[4] Of the new drug applications approved by the FDA in 2002, only 22 percent were for new chemical entities; the majority were new formulations or line extensions of existing products.

The pharmaceutical industry operated under constant pressure to produce new products – especially those that could be patent protected and become profitable. And at the same time that productivity of R&D spending was not improving early in the 21st century, important and profitable products were coming "off patent" further pressuring pharmaceutical companies (see Exhibit 1/11).

As their blockbuster drugs came off patent, the pharmaceutical companies counted on R&D for new products that would take their place – or they tried to extend the successful patents they had. For example, AstraZeneca's PRILOSEC (*omeprazole*), with sales over $5 billion, came off patent in 2002 but AstraZeneca managed to replace it with a slightly modified product – NEXIUM (*esomeprazole*).

As the costs for R&D soared, research productivity did not improve and pressures for profitability did not change, many of the large companies turned to in-licensing.[5] In the past, small R&D companies had difficulty engaging large partners to in-license drugs, and even if they managed to reach an agreement, their products were not actively promoted because the large companies' in-house products had priority. With fewer breakthrough discoveries, licensing became

Exhibit 1/11: Drugs Lost (or Losing) US Patent Protection

	Product	Marketer	Action	Indication	When	Global Sales (in billions)
1	PRILOSEC (*omeprazole*)	AstraZeneca	Stomach	Gastric ulcers, GERD	Dec 2002	$5.70
2	PAXIL (*paroxetine*)	GlaxoSmithKline	Antipsychotic	Depression	Sep 2003	$3.3
3	CLARITIN (*loraladine*)	Schering-Plough	Allergy	Allergic rhinitis	Dec 2002	$3.2
4	NEURONTIN (*gapapentin*)	Pfizer	Pain relief, anti-inflammatory	Epilepsy, neuropathic pain	Oct 2004	$2.7
5	AUGMENTIN (*amoxilin, clavulanate*)	GlaxoSmithKline	Antibiotic	Bacterial infections	Jul 2002	$2.1
6	OXYCONTIN (*oxycodone*)	Purdue Pharma	Narcotic	Pain	Mar 2004	$2.1
7	CIPRO (*ciprofloxasin*)	Bayer	Antibiotic	Bacterial infections	Jun 2004	$1.6
8	DIFLUCAN (*fluconazole*)	Pfizer	Antifungal	Fungal infections	Jul 2004	$1.2
9	CELEXA (*citalopram*)	Forest	SSRI	Depression	Oct 2004	$1.1
10	ZOCOR (*simvastatin*)	Merck	Circulatory and blood	Hypercholesterolemia	2006	$5.0
11	NORVASC (*amlodipine*)	Pfizer	Blood pressure	Hypertension, angina	2006	$4.3
12	ZOLOFT (*sertraline*)	Pfizer	Antipsychotic	Depression	2006	$3.1
13	PRAVACHOL (*pravastatin*)	Sanofi-Aventis, Bristol-Myers Squibb	Circulatory and blood	Hypercholesterolemia	2006	$2.8
14	ZITHROMAX (*azithromycin*)	Pfizer	Antibiotic	Bacterial infections	2005	$2.0
15	AMBIEN (*zolpidem*)	Sanofi-Aventis, Bristol-Myers Squibb	Sleep aid	Insomnia	2006	$1.5
16	ZYRTEC (*cetirizine*)	Pfizer	Allergy	Allergic rhinitis	2007	$1.3
17	ZOFRAN (*ondansetron*)	GlaxoSmithKline	Antinausea	Chemotherapy induced nausea	2005	$1.2

Source: IMS Health, IMS National Sales Perspectives™, 2/2005 (see: http: //www. imshealth.com) and "Health Care in Focus," *Chemical and Engineering News* 82, no. 49 (2004), p. 18.

more important and the large companies became more willing to acquire or promote licensed products. In 2001, in-licensed products generated 16 to 20 percent of the revenue of the 20 largest pharmaceutical corporations; revenue generated by in-licensed product was expected to reach 40 percent by 2007. Many of the

agreements made during 2004 were with biotech companies that co-promoted the in-licensed products. In 2003, the large corporations were paying an average of $110 million as up-front payment rights for a product that had reached Phase III clinical trials.[6]

Some analysts believed that the pharmaceutical industry was effectively dividing into two sectors: companies that were becoming very specialized R&D organizations and others that were focusing on sales and marketing. However, the largest organizations attempted to continue doing both.

Regulation

FDA Approval Process

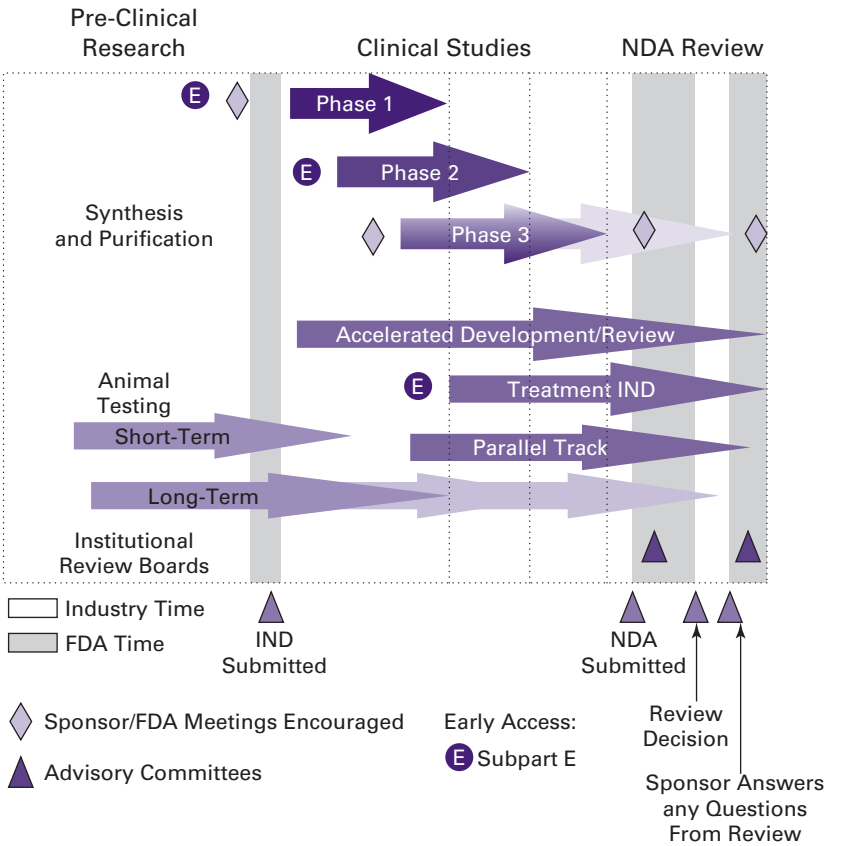
To introduce a new drug to the US market, FDA approval was required – a complicated, time-consuming, and expensive process (see Exhibit 1/12). The organization seeking approval (the "sponsor") went through two different evaluation stages:

1. The Investigational New Drug (IND) Review Process to determine whether the product was suitable for use in clinical trials, and
2. The New Drug Application (NDA) Review Process to determine the benefit/risk profile of a drug prior to its approval for marketing.

One of the most important parts of the drug approval process was the clinical studies that were designed to distinguish the drug's effect from other influences on humans – for example, a spontaneous change in disease progression or the effect of a placebo (an inactive ingredient that looked like the test drug). These studies were typically conducted in the United States under an approved investigational new drug application, in accord with FDA rules on human studies and informed consent of participants. There were three different phases of trials in the pre-approval stage and one in the post-marketing stage:

- **Phase I**: The first trials in humans to test a compound for safety tolerance and pharmacokinetics.[7] These trials usually employed normal, healthy volunteers.
- **Phase II**: Pilot studies to define efficacy and safety in selected populations of patients with the disease or condition to be treated, diagnosed, or prevented. Dose and dosing regimens were assigned for magnitude and duration of effect.
- **Phase III**: Expanded clinical trials intended to gather additional evidence of effectiveness for specific indications and to better understand safety and drug-related adverse effects.
- **Phase IV**: Post-marketing studies were conducted to determine the incidence of adverse reactions. These studies could result in serious consequences for the company if they proved that serious adverse effects existed that were not identified in Phases I–III.

Exhibit 1/12: New Drug FDA Approval Process



Source: Food and Drug Administration (www.fda.gov)

New drugs were usually protected by patents. Once a patented drug exceeded its protected time period, market exclusivity could be sought (the patent would expire, however competitors would still not be allowed to offer the product as long as the exclusivity period lasted). When the patent protection and market exclusivity were exhausted, other manufacturers could begin offering a generic version – provided that the generic product was evaluated (tested) to be certain that it was equally safe and offered the same efficacy[8] as the branded product. Typically, the manufacturers of generic drugs did not need to repeat all the studies originally done for a drug's approval. This kept the cost for the introduction of a generic drug down, encouraged competition, and kept drug costs lower for patients.

Exhibit 1/13 lists the control stages that both brand name and generic drugs were required to go through to be approved. A generic drug supplier was required to go through the abbreviated new drug application (ANDA) review process for the

Exhibit 1/13: NDA vs. ANDA Review Process

Brand Name Drug NDA Requirements	**Generic Drug** ANDA Requirements
Chemistry	Chemistry
Manufacturing	Manufacturing
Controls	Controls
Labeling	Labeling
Testing	Testing
Animal Studies Clinical Studies Bio-availability	Bio-equivalence

Source: Food and Drug Administration (www.fda.gov)

active ingredient(s). The possible generic was rigorously reviewed – its labeling, chemistry, manufacturing, and controls had to be identical (excluding the parts indicating the patent protection) and the testing procedure must be repeated similarly to the new drug application process. The difference for generics was that the animal studies, the clinical studies, and the bio-availability were replaced by bio-equivalence studies. Two products are considered bio-equivalent if, when they were given to the same individual patient, the patient absorbed the same amount of drug into the bloodstream and at the same rate.

The procedure used to verify the bio-equivalence was to measure the concentration of the drug in the blood of the patient at different times after administering it. If the measures were the same, the brand name and the generic drug were considered therapeutically equivalent. Only when the drug was not absorbed into the bloodstream – a rather rare case – would clinical studies have to be redone.

Market Exclusivity

Because the FDA approval process was lengthy (and totally out of the control of the organization submitting a drug for review and approval), US lawmakers decided to incorporate a provision into the Hatch–Waxman Act that allowed the innovator to apply for an extension of the patent coverage based on the length of the FDA approval process.[9] According to the statute, no ANDA filings (request to begin the generic drug approval process) could be submitted during a granted exclusivity period. A 5-year period of exclusivity (past the patent expiration) could be granted to new drug applications for products containing chemical entities either alone or in combination that had never previously been approved by the FDA.

A 3-year period of exclusivity could be granted for a drug that contained an active moiety[10] that had been previously approved, when the application contained reports of new clinical investigations conducted by the sponsor that were essential to approval of the application. For example, the changes in an approved

drug product that affected its active ingredient(s), strength, dosage form, route of administration or conditions of use might be granted exclusivity if clinical investigations were essential to the approval of the application containing those changes.

For drugs whose NDA was submitted before January 1, 2002, six additional months of exclusivity could be obtained under the Food and Drug Administration Modernization Act of 1997, if the sponsor submitted requested information relating to the use of the active moiety in the pediatric population.

Finally, a reason for a sponsor to be granted exclusivity beyond the patent protection period was if the drug was developed to cure diseases affecting less than 200,000 people. Such a drug could be designated an "orphan drug" by the FDA.[11] Sponsors of orphan drugs were granted 7 years of market exclusivity as well as tax incentives for clinical research.

Liability and Unforeseen Effects

On September 30, 2004, Merck voluntarily withdrew its second best-selling drug, VIOXX, as the pain medication for arthritis seemed to be responsible for increased risk of cardiovascular disease.[12] Pfizer admitted that one of its best-selling medicines, CELEBREX, could impose increased risk of heart problems. AstraZeneca reported that a trial of IRESSA, a lung cancer drug approved in 2003, showed that the drug did not prolong life. Eli Lilly warned doctors that STRATTERA, its drug to treat attention deficit disorder (ADD), had caused severe liver injury in at least two patients.[13]

These examples illustrated the uncertainty facing the pharmaceutical industry. Long-term use of some drugs proved to be harmful to some patients and the drug had to be removed from the market after huge investments in R&D and marketing. New drugs not only had to be tested thoroughly before their approval but also as they were being used after introduction. Enormous liabilities occurred if a product failed to be as safe as was predicted through the pre-approval studies (Phase I, II, and III trials).

Off-Label Promoting of Pharmaceuticals[14]

The FDA approved a medicine for a specific indication and the marketer was obligated to inform physicians and the public not only about the specific indication but also about the recommended dosage and duration. Promotion (advertising or personal selling) for a different indication was not permitted and could result in substantial penalties from the FDA if its rules were violated.

Although the marketer of a drug was restricted to a specific indication, physicians had the discretion to prescribe a drug for any indication and in combination with any other medication that they believed might help their patients. The term "off-label" was used to describe the prescribing of a medication for an indication that had not been FDA approved. Physicians might prescribe off-label products

on the basis of their own clinical experience or on published clinical studies by other physicians. Not all physicians were eager to do so, however, because their recommendations exposed them to malpractice lawsuits.

The pharmaceutical companies were often reluctant to seek approval for additional indications of a drug because the market might not be of sufficient size to justify the added expense. The Food and Drug Administration Modernization Act of 1997 provided a way for pharmaceutical companies to legally disseminate information on off-label use of their products. According to this Act, when asked by a physician, a firm could distribute peer-reviewed journal articles about off-label indications, provided that the company made commitments to the FDA to submit a supplemental new drug application (SNDA).

If the off-label usage for a drug was sufficiently different from its previously approved use, a patent might be granted that would provide exclusivity for that specific use. Such was the case with WELLBUTRIN and ZYBAN produced by GlaxoWellcome.[15] WELLBUTRIN was prescribed for depression, but it also was used off-label for smoking cessation. In this case, the $350 million spent for its SNDA approval provided Glaxo with a new patent that protected the company's interests and enabled it to sell ZYBAN to a wide customer base of smokers who wanted to quit.

The Drug Crisis or Who Pays the R&D Cost?

US prescription drug sales grew 8.3 percent to $235.4 billion in 2004. "*This is the first year since 1995 that the pharmaceutical industry has scored less than double-digit growth,*" explained Bruce Boggs, president of IMS Americas (a pharmaceutical market research firm). "*However, the industry delivered solid performance overall despite significant business pressures in areas such as drug safety, pricing, and generic competition.*"[16] See Exhibit 1/14 for sales between 1995 and 2004.

From 2000 to 2005, prescription drugs sales increased more than 47 percent using constant 2004 dollars, a figure that was more than five times the increase in the consumer price index during that same time period. The fact that the cost of the average prescription increased no more than 30 percent over these years suggested that the usage of drugs was increasing.

During the years 1999 to 2005, the top pharmaceutical companies started spending a higher percentage of their cost for operating expenses (R&D, sales, administration), thus the manufacturing cost of the drugs (cost of goods sold) became a smaller percentage of costs (see Exhibit 1/15). This increase in spending for operating expenses was attributed to direct to customer advertising, increased cost for research and development, and expenses related to mergers.

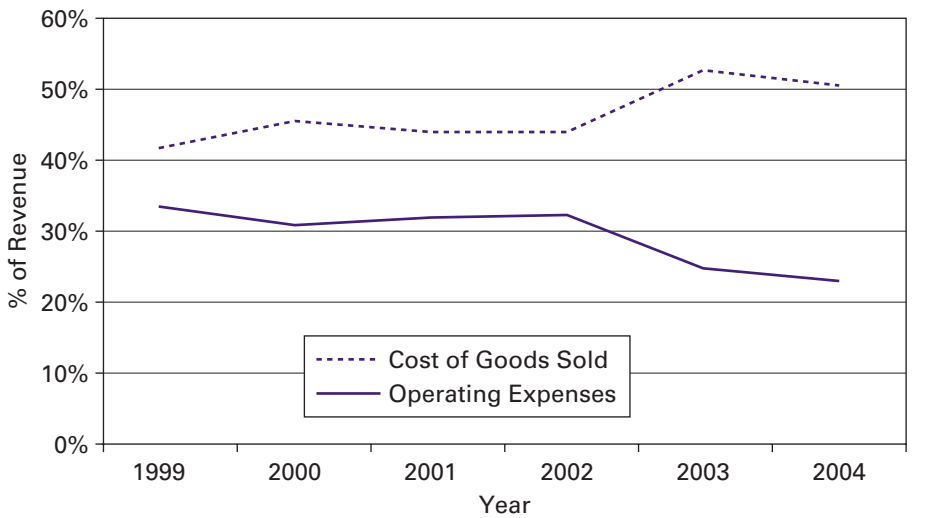
Brand name drugs operated in a protected environment and enjoyed premium prices, often two to three times more expensive than generics. After 2000, generic drug sales increased by an average of 26 percent per year. However, by 2004, this increase had slowed to only 10 percent.[17]

Exhibit 1/14: US Prescription Drug Sales 1995–2004

Year	1995	1999	2000	2001	2002	2003	2004
Consumer price index	152.4	166.6	172.2	177.1	179.9	184.0	188.9
Prescription drug sales (in millions)	$72,200	$125,800	$145,600	$164,100	$182,700	$203,100	$235,400
Adjusted sales (constant 2004 dollars) (in millions)	$89,492	$142,639	$159,720	$175,034	$191,840	$208,509	$235,400
Prescriptions (in millions)	2,125	2,707	2,865	3,009	3,138	3,215	3,318
Cost per prescription (constant 2004 dollars)	$42.1	$52.7	$55.7	$58.2	$61.1	$64.9	$70.9
Change		25.1%	5.8%	4.3%	5.1%	6.1%	9.4%
Inflation		9.3%	3.4%	2.8%	1.6%	2.3%	2.7%

Source: IMS Health, IMS National Sales Perspectives.™ 2/2005 (see: http://www.imshealth.com)

Exhibit 1/15: Ten Largest US Pharmaceutical Companies Expense Allocation



Source: SEC filings (www.Morningstar.com)

Medicare Part D

US spending on health care was expected to soar in 2006 when Medicare[18] was scheduled to start covering the cost of prescription drugs. Medicare Part D provided for the elderly who could not afford the prescriptions their doctors ordered. Estimates were that the expansion of Medicare's drug coverage would inflate

health care spending by more than $50 million per year for the next decade.[19] The forecast was that, for the decade 2006 to 2015, the cost of prescription drugs to the US government would be $724 billion (almost double the figure of $400 billion that Congress had in mind in December 2003 when it approved the Medicare Modernization Act).[20]

Formularies and Pharmacy Benefit Managers

To reduce the costs associated with pharmaceuticals, insurance companies and hospitals developed clinical formularies.[21] The lower cost was achieved by selecting lower cost drugs or those that generated "rebates" directly from the manufacturers of the drugs. Rebates occurred by having only one or two brands for the treatment of various conditions, thereby limiting competition – in some cases, severely. The physicians were required to choose drugs from the formulary or their patients were required to pay the full cost of the drug. Formularies were used primarily by hospitals and managed care insurance programs.

Because the prescribing physicians and the patients were not particularly happy with the restrictions forced by the formularies, companies such as MedCo emerged. These companies, called pharmacy benefit managers (PBMs), claimed that they could offer prescription drugs at lower costs by negotiating significant volume discounts with drugmakers. Many insurance carriers used PBMs.

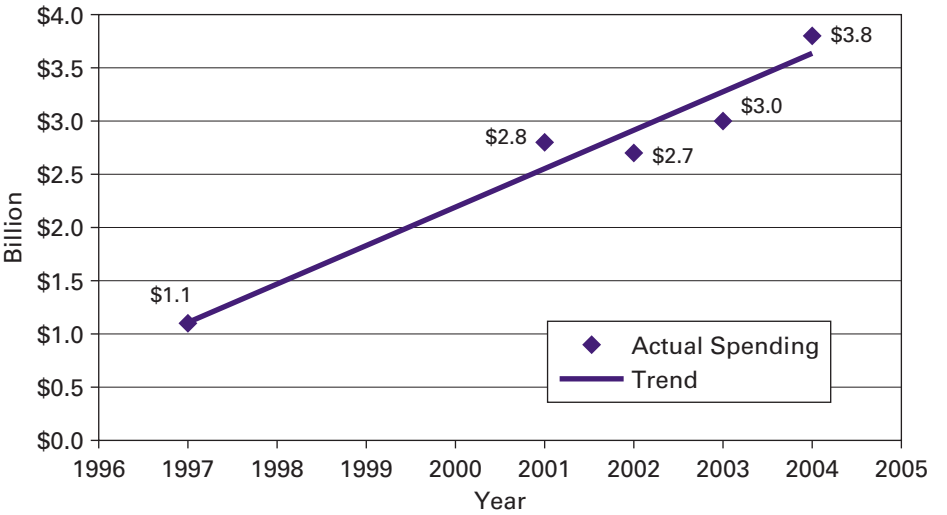
Industry Criticisms

Many critics claimed that the cost of brand name drugs was not justified by the benefits offered to the public and accused the pharmaceutical companies of having no interest in supplying the public with safe medicines at affordable prices. In addition, critics claimed that the new drugs did not necessarily have improved properties against existing drugs but only showed positive results against placebos.[22] Further, critics felt that pharmaceutical companies inflated their expenses by performing unnecessary R&D and promoted expensive drugs of dubious value.[23]

Other critics claimed that the pharmaceutical companies overcharged the public for their products because they charged by the pill and not by the active substance.[24] They claimed that the pharmaceutical companies were "bribing" physicians by subsidizing their lifestyles in the name of professional education.[25] Still other critics complained that pharmaceutical companies actively lobbied the US Congress to maintain high drug prices; however, those very same pharmaceutical companies sold the same products at much cheaper prices in other countries.

Many critics went beyond accusations and proposed a reorganization in the way drugs were priced. One recommendation was that the government would buy patent rights from the innovators and provide them for public usage at generic prices rather than the monopoly prices associated with patents.[26] Another recommendation was that drug companies should be regulated as "public utilities."[27]

Exhibit 1/16: Evolution of DTCA Spending in US (1997–2004)



Source: See references 28 and 29

Finally, there was a strong debate about direct to consumer advertising (DTCA) of drugs. DTCA reached $3.8 billion in 2004[28] from $1.1 billion in 1997[29] when the FDA lessened regulations for advertising prescription drugs in the media (see Exhibit 1/16).

On a global scale only the United States and New Zealand permitted DTCA, whereas the European Parliament overwhelmingly voted against it. The total sum spent in 2004 on DTCA was more than Coca-Cola, Pepsi Cola and Cadbury Schweppes together spent each year to promote their soft drink beverages.[30]

Among the leading 10 drugs in the US market, the promoters spent from 1.6 percent to 5.8 percent of the sales for DTCA in 2004 (see Exhibit 1/17).[31]

The critics claimed that DTCA, accounting for 14 percent of promotional activities (see Exhibit 1/18), was not only increasing the cost of drugs but also drug utilization, and was usually deceptive, misleading, and irresponsible.[32]

The pharmaceutical industry rejected these accusations claiming that innovative brand name medicines did not contribute more than 7 percent to US health care costs. The industry presented cases where the cost of the medication at $1,000 saved the patient $14,000 that otherwise would have been spent on surgery and hospital expenses.[33]

The Future

The pharmaceutical industry remained very profitable. The high investment in R&D and the resulting new products made the industry one of the most innovative in the United States as well as world wide. Cost/benefit analysis of the facts

Exhibit 1/17: Leading 10 Products by US Sales, 2004, and $ Spent on DTCA

	Product	Marketer	Sales (in Billions)	Media Expenditures (in millions)	%
1	Lipitor	Pfizer	$7.7	$119.4	1.6%
2	Zocor	Merck	$4.6	$95.4	2.1%
3	Prevacid	Takeda, Abbott	$3.8	$125.0	3.3%
4	Nexium	AstraZeneca	$3.8	$219.3	5.8%
5	Procrit	Johnson & Johnson	$3.2	$62.3	1.9%
6	Zoloft	Pfizer	$3.1	$80.9	2.6%
7	Epogen	Amgen	$3.0	N/A	N/A
8	Plavix	Sanofi-Aventis, Bristol-Myers Squibb	$3.0	$118.1	3.9%
9	Advair Diskus	GlaxoSmithKline	$2.9	$98.9	3.4%
10	Zyrpexa	Eli Lilly	$2.8	N/A	N/A

Source: Jim Edwards, "Sleep, Diet Awaken as Pharma Regroups," *Brandweek* 46, no. 21 (2005), p. 60.

Exhibit 1/18: Promotional Spending by Pharmaceutical Companies for Prescription Drugs, 2001

Promotional Activity	Spending
Free samples	55%
Detailing (rep activities directed towards physicians)	29%
Direct-to-consumer advertising	14%
Medical journal advertising	2%
Total	**100%**

Source: The H.J. Kaiser Family, News Release, June 11, 2003 (see http://www.kff.org/rxdrugs/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14379)

indicated that many drugs were good value for the money compared to other health services; however, criticisms increased along with the price of the drugs.

The industry looked to the future with cautious optimism but was skeptical as to its ability to maintain high growth rates and whether the investment in R&D would provide lucrative pay back. In addition, industry leaders were concerned that the high (and rising) costs for drugs resulting in increased total spending in the United States compared to the rest of the world, would result in government intervention to reduce margins.

Further, recent advances in science represented both threats and opportunities for the industry. Advances in biotechnology could make many traditional drugs obsolete, as could genome mapping whereby patient-specific drugs might completely transform the entire industry.

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3. "The Drug Crisis," *CA Magazine* 137 (2004), p. 10.
4. "Health Care in Focus", *Chemical & Engineering News* 82, no. 49 (2004), p.18.
5. Intellectual property rights acquired for a fee to use or commercialize drugs. (See www.cticseattle.com/abou_frame-glos.htm)
6. "Health Care in Focus," p. 18.
7. Pharmacokinetics: how the drugs moved through the body after they were swallowed or injected.
8. Efficacy: ability to control or cure an illness.
9. Frequently Asked Questions for New Drug Product Exclusivity. (See FDA: http://www.fda.gov/cder/about/smallbiz/exclusivity.htm)
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32. Mathews Meril Jr., "Direct To Consumer Ads," *USA Next* (April 21, 2005).
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Pharmaceutical Industry Note
Instructors Manual

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Case 1 Pharmaceutical Industry Note
Instructors Manual

Overview

This Industry Note presents information about the US pharmaceutical industry. Brand name, generic, and over-the-counter (OTC) drugs are defined. The position of the US market in the world pharmaceutical market, the major players, the merger history of the largest organizations as well as the leading therapeutic classes and the leading products in US market are discussed. Research and development spending for pharmaceutical companies in the US market is compared to spending worldwide. Finally, the Industry Note describes the regulatory issues such as the process for the approval of new drugs, awarding of patents, and market exclusivity. The Note closes with a discussion about the pricing crisis and other criticisms leveled at the pharmaceutical industry.

Intended Audience

This Industry Note was written to be used along with the Salix Pharmaceuticals, Inc. case, but can be used as a stand alone Industry Note or in conjunction with any other pharmaceutical company case. Graduate students in health administration strategic management or strategic marketing courses are the primary audience; it may be used for MBA students.

Key Issues

- Growing concentration in the pharmaceutical industry.
- FDA regulatory process for the introduction of new and generic drugs.
- Large pharmaceutical companies' focus on "blockbuster" drugs for the US market.
- Extending patent protection.
- Public criticisms and pharmaceutical industry responses.

Teaching Objectives

- To provide background information that levels the playing field for students in the analysis of cases related to the pharmaceutical industry.
- To identify and understand the critical factors for success in the pharmaceutical industry.
- To identify and analyze important current and emerging issues that can impact a pharmaceutical company.
- To speculate on the likely future issues that will have significant impact in the pharmaceutical industry.
- To foster strategic thinking.

SWOT Analysis (For the Industry Note only Opportunities and Threats or OT of the SWOT are useful as Strengths and Weaknesses or SW are internal to a specific organization)

Opportunities

- Massive markets are underserved with significant needs for pharmaceutical products.
- New drugs from Biotechnology.
- Reducing costs of the R&D services in the development of new therapeutic drugs.

- Aging population in the US and Europe could create additional needs for medicine.

Threats

- Increasing regulation for FDA approval.
- Increasing public concern about the cost of the drugs.
- Increasing public pressure for safer drugs.
- New generation of treatments from genome decoding could make drugs obsolete for many diseases.
- R&D costs will increase faster than the income from the new drugs.

Suggestions for Effective Teaching

Health administration students are generally familiar with the US health care system. This Industry Note will provide necessary information for the pharmaceutical industry, enabling a level playing field for the students to analyze any pharmaceutical company case and specifically the Salix Pharmaceuticals, Inc. case.

MBA students need the opportunity to better understand the context for health care in the United States. There are a number of "overviews" of the US health care system available (see for example, Case 1: The US Health Care System – Participants, Financing, and Trends: An Industry Note," by Stuart A. Capper in *Strategic Management for Health Care Organizations*, 5th edition, Oxford: Blackwell Publishers, 2006) that will introduce the context for the pharmaceutical industry. Then, this Industry Note provides students with the necessary data to understand the problems and issues facing the pharmaceutical industry in today's health care environment.

Questions and Answers

1. Do Americans spend too much for drugs?

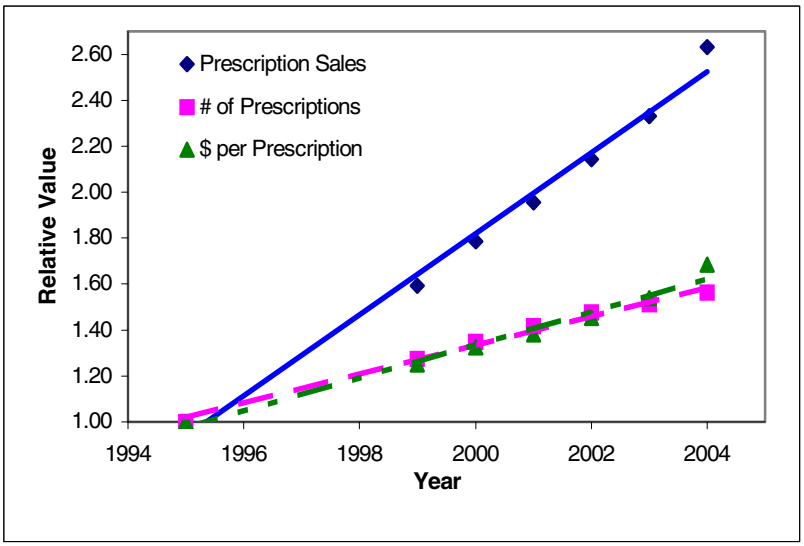
As presented in Case Exhibit 3 of the Industry Note, Americans spent almost double per capita for drugs compared to the second highest spending nation (Japan). In fact, US citizens accounted for almost half of world spending for drugs. Based on these data, the answer is that Americans appear to spend too much for drugs compared to the rest of the world.

The continuous and consistent increase in number of prescriptions per year and the increase in the costs for prescriptions are presented in Case Exhibit 14 in the Industry Note. If we normalize the data and plot them against time, a graph (as presented in IM Exhibit 1) reveals that the number of prescriptions per year increased from 1995 to 2004 at the same rate as the cost of each prescription. Comparing the slope of these two parameters with the slope of the prescription drug sales change, we come to the conclusion that the increased number of prescriptions accounts for almost all the increase in prescription drug sales.

The cost per prescription was increasing because of the higher spending for R&D for new drugs. As indicated in Case Exhibit 8 in the Industry Note, the pharmaceutical industry spent the most on R&D in the USA. Case Exhibit 9 in the Industry Note indicates that the R&D spending more than doubled for the years between 1995 and 2004. This expense was inevitably passed on in the cost of the drugs. The legal environment in the United States allowed the innovator patent

protection (and sometimes exclusivity) that generated a return on investment. Thus, the United States appears to be the R&D laboratory for the world.

IM Exhibit 1
Change in Prescription Drug Sales, Number of Prescriptions and Cost per Prescription from 1995 to 2004 (Constant Dollars)



The number of prescriptions written per year could be a result of the increased spending by pharmaceutical companies on the promotion of drugs. As illustrated in Case Exhibit 15 in the Industry Note, there was a clear trend of increased operating expenses compared to the cost of goods sold for the ten largest US pharmaceutical companies. Here we have to acknowledge a factor which seems to be rather unique for the United States compared to the rest of the world: the direct to consumer advertising (DTCA). DTCA was considerably increased (Case Exhibit 16 in the Industry Note) since 1997 when regulations changed allowing pharmaceutical companies to advertise directly to consumers, providing appropriate side-effects and warnings were included. The investment in DTCA per product is presented in Case Exhibit 17 in the Industry Note. The breakdown for promotional spending is presented in Case Exhibit 18 of the Industry Note.

2. Should the pharmaceutical industry become even more regulated? If the government buys the rights to patented drugs and then distributes the drugs to the public, will the costs for pharmaceuticals be reduced?

The expected result from the proposed regulation is to return to the public the "deadweight loss" or the great margin (created by monopolistic conditions from patent protection granted to the innovator). The supporters of the regulation expect to cure the "corruption" (excess profits) generated by the pharmaceutical companies lobbying for protection as well as the imbalance created by the fact that the payor is different from the buyer (payor: insurance companies and eventually the patient, compared to the buyer to whom the marketing is directed: the physicians, compared to the user: patients needing the drug). The supporters of the regulation recognize that the cost for research has to be paid; they propose that the US government buy the patent rights

and make them available to the public. Under this proposal, the pharmaceutical market becomes a perfectly competitive market and the deadweight loss disappears.

The opponents of the regulation argue:

- Innovation is sustainable only when sufficient funds flow into research. The funds will flow into research only if investors realize returns to justify the risk. This means that the government has to pay the same amount of money for the research as the total markup of that attributed to the brand name drugs to maintain the same level of innovation.
- If the government (public) pays for the research, some value has to be directed to the entire industry and distributed to each innovator. If market forces do not decide this value, then is very likely that the result will be more corruption and more lobbying than when the market decided the value.
- The generics component of the pharmaceutical industry has the characteristics of an oligopoly. Thus, we cannot reach perfect competition, fully eliminating the deadweight loss in the pharmaceutical market because the required safety standards raise the barriers to entry so that not anyone can freely enter or exit this market.

Whether the deadweight loss can be reduced or eliminated depends on the importance that society places on the innovative products from pharmaceutical research.

3. Is acquisition the most effective method to increase market share for pharmaceutical companies?

In recent years, many medium to large companies merged to form even larger conglomerates for worldwide strength. Some companies, such as Johnson & Johnson, Merck, and Roche, did not embrace the merger strategy but maintained their independence. Most of the companies that were involved in the merger frenzy failed to increase market share, whereas all the major companies that remained independent manage to increase share (see Case Exhibit 4 and 5). Overall the ten largest players increased their market share from 48.9 percent to 49.6 percent from 1998 to 2003, but it was the independent firms that had the greater growth.

4. When one of the major pharmaceutical companies planned the development of a new drug, what was the minimum revenue it would need to generate?

The largest corporations became focused on large development projects because they required large returns to impact their revenue and bottom line. For example, Pfizer generated $31 billion in US sales (see Case Exhibit 5). To maintain double-digit growth, Pfizer needed to generate $3 billion in new US revenue every year – in addition to covering the revenue that was lost because of patent expiration (see Case Exhibit 11). Because of the commitment of resources, the major companies generally were not interested in projects that were expected to generate less than $0.3 billion a year in new revenue. This focus on huge R&D projects with potentially huge returns by the largest firms enabled smaller firms to be successful meeting the needs of patients of less common diseases and ailments.

5. Does the competition by generic drugs against the brand name drugs impact the innovation of new drugs?

Some students may think that generics dampen new drug development. In actuality, they may encourage R&D activity. The innovators would like to maintain their monopoly power for as long as possible whereas the public would like to have the benefit of the innovation at the lowest cost. In 1984, the Hatch-Waxman Amendments imposed rules for generics (see Case Exhibits 12 and 13 in the Industry Note) to maintain drug safety. Generics began with the FFC&D Act (practically creating the generic drug industry in the USA) that attempted to provide some monopoly power to the innovator, but over time reducing the cost of the drugs to allow more people to receive the benefits of the innovation. In general, generics cost about 50 percent of the cost of brand name drugs (see Case Exhibit 2 in the Industry Note) while offering the same efficacy.

The expiration of exclusivity and impact of competition lowered the profitability for the innovator. Thus, to maintain profitability (typically desired by shareholders), pharmaceutical companies constantly have to innovate and develop successful new drugs.

6. What is the minimum value of new drugs that the pharmaceutical industry must introduce every year to avoid shrinking?

Calculated from the Industry Note Exhibit 11, IM Exhibit 2 illustrates that the drugs that leave patent protection represent an average of $7.3 billion per year.

IM Exhibit 2

Year	Sales (in $ billion)
2002	11.0
2003	3.3
2004	8.7
2005	3.2
2006	16.7
2007	1.3
Average	**7.3**

After patent expiration, these products generally face competition from the generics, causing the company's market share to erode and margins to shrink. Therefore, if the pharmaceutical industry wants to avoid shrinking (zero growth), it must introduce new products, that will generate sales equal to what is eroded. To grow, successful innovations have to be introduced requiring the huge R&D investment.

7. What world markets should the major pharmaceutical companies be targeting?

As we see in Exhibit 3, the United States is the biggest market for pharmaceuticals representing almost 50 percent of the global sales. Some students might argue that pharmaceutical companies should maintain their focus on the US market because of price controls in most other markets.

Despite the price controls, economies of scale through mass production could limit prices in the USA as well.
Nevertheless, as the demand for most medicine is inelastic, pharmaceutical companies should be targeting fast developing countries with large populations. The fact that Japan is the second largest market proves the value of this hypothesis, although it accounts for less than 1.5 percent of the global sales today. With a 9 percent growth rate and a population of almost 1.3 billion people, China seems to be the next logical target. The negative for China is the poor protection of intellectual property, but with its entry into the World Trade Organization (WTO) in 2001, this is expected to lessen.

8. What are the critical success factors (CSFs) for the pharmaceutical industry?

- Deep pockets to invest in R&D and succeed in the extended FDA approval process.
- Identification of therapeutic properties that will alleviate suffering.
- Drugs for chronic conditions offer greater opportunities.
- Speedy approval through the FDA process allows for greater profitability (the 20 year clock begins with submission to the FDA, not approval by the FDA).
- Balancing first-to-market benefits with costs associated with having to withdraw a marketed product.
- Avoiding generics for as long as possible.
- Educating consumers about the cost savings attributed to use of pharmaceuticals.
- Non-deceptive DTCA (direct to consumer advertising).
- Monitoring gene therapy that may eliminate the need for drugs for some diseases such as cystic fibrosis that tend to be chronic.
- Being on formularies. Both Medicare and formularies pressure prices on drugs in a manner that is similar to what has happened to physicians and hospitals.

Something that does NOT appear to be a CSF is industry concentration. Case Exhibit 4 illustrates that all but two of the top ten pharmaceutical companies that consolidated, lost market share. However, the three companies that did not merge, increased market share. Big may not be better in the pharmaceutical industry.