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The Journal appreciates the time and commitment of all those who generously give their time in reviewing and editing manuscripts. The following are those who have assisted in this volume.

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## **Notes To Authors**

Thank you for considering the *Journal of Applied Case Research* as an outlet for your work. We would be very pleased to review your manuscript. Please review our guidelines for submission found on the website at [www.swcrahome.org](http://www.swcrahome.org).

## Letter From The Editor

Dear SWCRA Members & Friends;

Volume 1 Number 1 of the *Journal of Applied Case Research* was published in 1997. Therefore, 2007 marks the Journal's 10<sup>th</sup> anniversary of publications. Much progress with the *Journal* has occurred over these ten years.

Most recently, *JACR* has transitioned to an on-line format. As cases are accepted for publication, they are uploaded to the *JACR* page of the SWCRA website. Currently, these teaching cases are available to all who visit the site. Access to teaching notes, though, requires membership in SWCRA.

The best measure of a case's worth is the extent to which it actually gets used as a vehicle for learning in the classroom. Please make good use of these cases, and let your colleagues know they are welcome to use these cases as well. To realize the greatest benefit of the cases, however, you should become a member, so you can access the teaching notes that reveal the insights within the cases. To join SWCRA, contact the Association's Treasurer.

I also encourage you to add to the pool of quality cases by submitting your work to *JACR* for review. Please see the Submission Guidelines on the *JACR* webpage.

Best Wishes,

Steven Maranville, Ph.D.  
Editor, *Journal of Applied Case Research*  
University of Houston-Downtown

# *Teaching Case*

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## **Journal of Applied Case Research**

Sponsored by the Southwest Case Research Association

**VistaCare Healthcare**

John J. Newbold  
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## **INTRODUCTION**

Since its founding in 1995 as a for-profit hospice entity, VistaCare had enjoyed tremendous growth. In 1997, VistaCare had grown from its initial 2 sites to 7 sites in 4 states. By the end of 2003, VistaCare operated 40 hospice sites in 14 states. And the stock price reflected this growth: From its IPO in December of 2002, where the stock debuted at \$12, it had risen to over \$40 by December of 2003. Recent operational issues negatively impacting revenue growth and profitability had left Chairman and CEO Rick Slager and his management team with the unenviable task of informing investors that the firm had recorded a net loss for the third quarter 2004 of \$6.2 million. In December of 2004, just one year after the stock had achieved its all-time high; it now wallowed at less than half that value.

What had happened in just a year's time? VistaCare had continued to invest in future growth by implementing aggressive marketing plans geared to spur the recruitment of patients for its ever-expanding number of hospices. But admissions growth had slowed. To make matters worse, VistaCare was plagued by unexpectedly high reimbursement charges from its primary source of revenue, the federal Medicare system. In effect, VistaCare had to pay back large amounts of monies received from Medicare because they had failed to effectively manage their business to comply with Medicare guidelines.

Rick Slager and his CFO, Mark Leibner, were in need of a viable operations plan to turn VistaCare's business around quickly. More specifically, Slager and Leibner needed to decide whether or not to continue the aggressive spending on marketing programs in the face of deteriorating company financial performance.

## **OVERVIEW OF THE HOSPICE INDUSTRY**

### **Hospice Care**

Hospice care is defined by the Hospice Association of America as:

“...comprehensive, palliative medical care (treatment to provide for the reduction or abatement of pain and other troubling symptoms, rather than treatment aimed at cure) and supportive social, emotional, and spiritual services to the terminally ill and their families, primarily in the patient's home. The hospice interdisciplinary team, composed of professionals and volunteers, coordinates an individualized plan of care for each patient and family.” (Hospice Association of America website 2005)

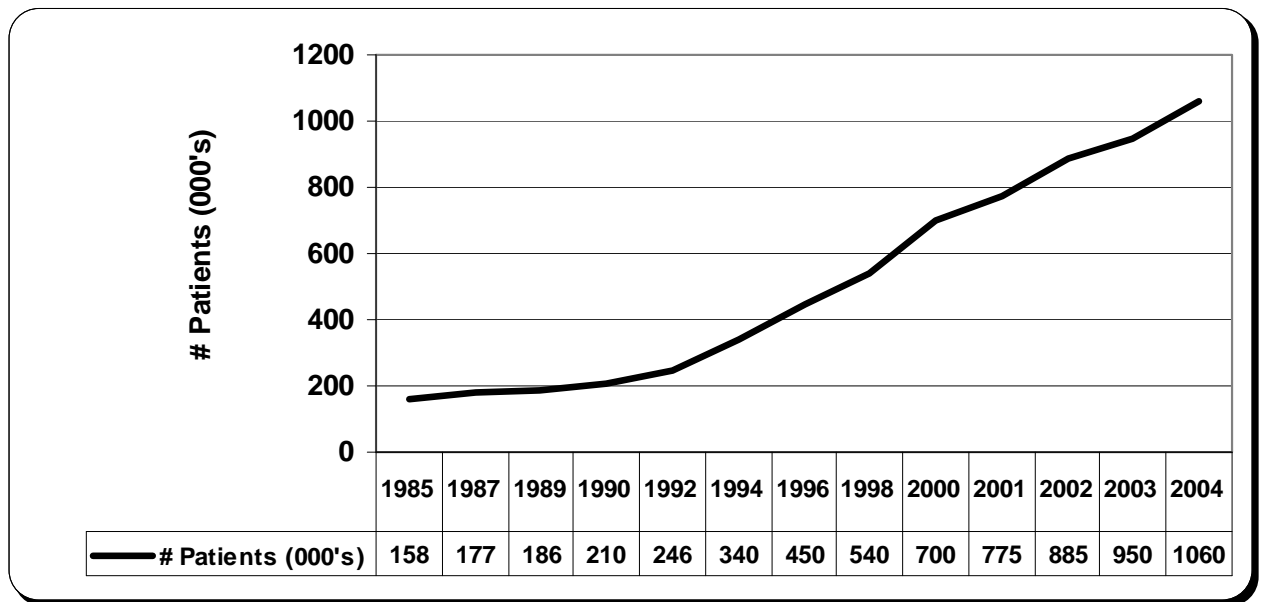
The palliative (pain-reducing) care provided by hospices differs from curative care which is traditionally provided by hospitals. A broad range of services, from traditional nursing care to respite care for family caregivers to bereavement services for family members is traditionally offered.

## The Institution of the Medicare Hospice Benefit Spurs Industry Growth

In 2004, the hospice industry in the US was a relatively small and fragmented component of the overall healthcare industry, generating aggregate annual revenues of about \$4.5 billion. Spending on hospice services amounted to less than one half of one percent of the \$1.4 trillion annual US healthcare spending and only 1.5% of annual Medicare spending (Shattuck Hammond Partners 2004).

In 1982, Congress enacted the Medicare Hospice Benefit on a provisional basis. In 1986, the provisional law was made permanent. Each state was also given the option of including hospice care in their Medicaid program. In addition, hospice care was made available to terminally ill patients in nursing homes. A significant jump in usage of hospices occurred at this time.

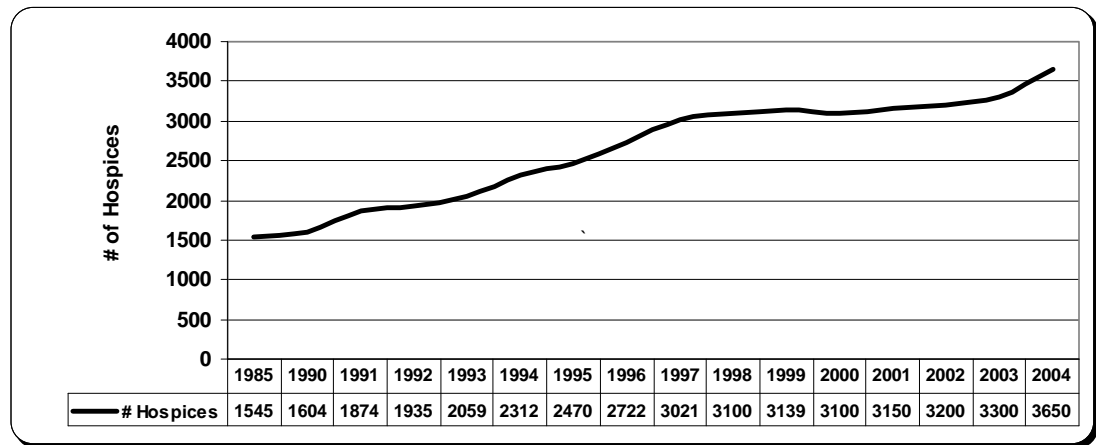
**Figure 1: Number of Hospice Patients: 1985 – 2004 (000's)**



(National Hospice and Palliative Care Organization (NHPCO) 2005)

In 1996, the federal government initiated a program (“Operation Restore Trust”) focused on preventing Medicare fraud across all provider groups. This increased level of regulatory scrutiny, while probably needed, likely inhibited referrals of patients and reduced average and median lengths of stay industry-wide. The Balanced Budget Act of 1997 further negatively impacted reimbursement rates, further dampening the growth rate of hospice sites. By setting aside fewer funds for hospice care reimbursement, the government provided less incentive for hospice providers, particularly those driven by the profit incentive, to open new facilities.

**Figure 2: Number of Hospices: 1985 – 2004**



(NHPCO 2005)

### **Factors Driving the Growth in Hospice Care Services in the US**

There were several factors driving growth in the hospice industry. Foremost was the overall aging trend in the US and the increasing size of the over 65 population. In addition, there had been an increasing role of advocacy groups in promoting hospice care over other end-of-life alternatives. Finally, The Center for Medicare and Medicaid Services (CMS) appeared to be promoting hospice care through its liberal policies for reimbursement. The CMS's favorable treatment of hospice care in their reimbursement policies was thought to be at least in part because hospice care was viewed as a lower cost alternative to traditional, hospital-based end-of-life care.

### **The Medicare Hospice Benefit**

In 2003, Medicare and Medicaid accounted for 97% of all hospice industry payments. Private insurance paid for an additional 3%. (NHPCO 2004)

Medicare has 3 key eligibility criteria for hospice care. First, the patient must have Medicare A coverage. Second, the patient's doctor and the hospice's medical director must use their best clinical judgment to certify that the patient is terminally ill with a life expectancy of six months or less, if the disease runs its normal course. Third, the patient must choose to receive hospice care rather than curative treatments for their illness. That is, the patient agrees that the future course of action is not to recover from the illness, but to mitigate the pain and suffering related to the inevitable advancement of the illness.

Medicare then pays the hospice a per diem rate, which is intended to cover virtually all expenses related to addressing the patient's terminal illness. Because patients require differing levels of care as they progress in their diseases, Medicare provides for four levels of care to meet their changing needs. These levels are summarized in Figure 3.



<u>Level of Care</u>	<u>Description</u>	<u>DAILY Rate (2005)</u>	<u>% of Total Medicare Payments</u>
Routine Home Care	Patient is at own home or nursing facility; hospice-led care-givers provide intermittent services.	\$121.98	95%
Continuous Home Care	Patient is at own home or nursing facility; hospice employees are providing care for blocks of 8 – 24 hours per day.	\$711.92	1%
Respite Care	Hospice employees relieve family member of certain care-giving duties for short periods of time to provide respite for the family care-giver.	\$126.18	0%
Inpatient Care	Patient is at a hospice- run facility being cared for continuously.	\$542.61	4%

**Figure 3: Hospice Reimbursement Rates by Service (2005)**  
(CMS 2005)

Typically, each October, Medicare adjusts its base hospice care reimbursement rates for the following year based on inflation and other economic factors.

Medicare reimbursements are made along the following guidelines:

- 1) Medicare beneficiaries must pay limited coinsurance: the smallest of 5% or \$5 for drugs and 5% of hospice payments for respite care.
- 2) Total annual co-payments for respite care cannot exceed the Medicare hospital deductible.
- 3) Medicare caps reimbursements to hospice programs in 2 ways:
  - a. Inpatient care days may not exceed 20% of all patient care days per provider. If the cap is reached, reimbursement continues, but at a reduced rate. This is referred to as “The 20/80 Rule”. This means that, when the government is reimbursing the hospice provider, they will not pay for inpatient days if they amount to more than 20% of the total number of days that the patient is under the care of the hospice provider. Since inpatient care is close to hospital care, and is the most expensive of the four forms of care, the government is vigilant about the potential abuse of this form of reimbursement.

In 2004, annual reimbursement per beneficiary was capped at \$19,635.67. This rate, which is updated every year, is multiplied by the number of new beneficiaries enrolled by the program during the fiscal year. If actual Medicare reimbursements to a program during the period exceed the total, the provider must repay the difference to Medicare. This aggregate reimbursement cap effectively serves as a corrective mechanism to programs with very long lengths of stay. This version of the cap is applicable on a site to site basis, not for hospice operations overall.

For example, a typical hospice site may have 100 patients who are each receiving one of the 4 levels of care as previously described. For that given year, they are “capped” at receiving \$1,963,567 for those 100 patients, or  $100 \times \$19,635.67$ . If the hospice somehow exceeds this amount, for that particular site, they will not be reimbursed for the amount over \$1,963,567.

The \$19,635.67 amount, divided by 365 days in a year, comes to only \$53.80 per day. But the government does not expect the patient at a hospice to have tenure much longer than 180 days (the six-month life expectancy requirement). This results in a daily reimbursement rate of \$108.08, which is much closer to the daily reimbursement rate for routine home care, which accounts for 95% of the claims.

- b. Prior to 1990, Medicare per-patient payments were limited to a 210 day maximum. From 1990-1997, payments were limited to a maximum of 4 6-month benefit periods, or roughly 720 days. Rules for maximum reimbursement have been further slackened: There are currently no limits to the number of days of care for which Medicare will pay. However, in order to continue to receive reimbursement a patient’s prognosis must be reaffirmed at 90 days, at 180 days, and every 60 days thereafter.

### **Hospice Patient Trends**

The typical patient in a hospice tended to be an older Caucasian who was most likely suffering from cancer. According to the National Hospice and Palliative Care Organization, 54% of all hospice patients were female, over 77% were Caucasian, and 65% were 75 years of age or older (NHPCO 2005).

Prior to 2004, the greatest increase had occurred in the number of beneficiaries with non-cancer diagnoses and those living in nursing homes and rural areas. Though cancer patients accounted for 46% of hospice admissions in 2004, this was down from 76% in 1992. Other ailments such as heart disease, dementia, debility, lung disease, kidney disease, and liver disease were becoming more common among patients admitted to hospice care.

## **Trends in Medicare-Certified Hospice Operations**

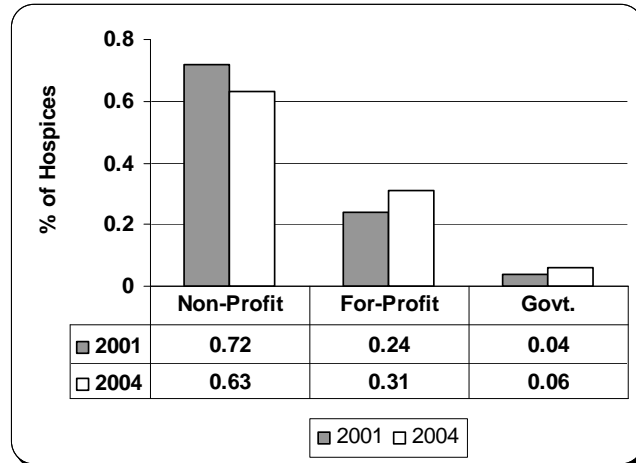
To be certified by Medicare, a hospice was required to provide a wide range of both core and non-core services. Core services, which include nursing services, medical social services, and bereavement, spiritual and dietary counseling, were to be provided by employees of the hospice. Non-core services, including home health aide or physician services, may be provided by hospice employees, or the hospice may have contracted to provide them. Medicare also required certified hospice programs to recruit and train volunteers to provide patient care or administrative services. Unpaid volunteers were required to provide a minimum of 5 % of total patient care hours provided by all paid hospice employees and contract staff of a hospice program.

Medicare regulations further specified that hospice providers could not make admission conditional on executed advanced directives, such as a “do not resuscitate” order, a living will, or a description of treatment desired or not desired. Beyond this specific stipulation, Medicare provided no other mandatory admission guidelines; hospice providers could provide care (or deny admission) to Medicare patients according to their individual philosophy of palliative care.

A hospice was allowed to refuse care to patients when the program was not equipped to provide the necessary services. For example, not all hospices had the ability to care for ventilator patients or to operate pediatric programs. Once a Medicare patient was admitted, the hospice could not discharge the eligible beneficiary at its own discretion, even if the care for the patient promised to be costly or inconvenient.

The hospice industry has traditionally been comprised of non-profit operations with an average of less than 50 patients at any given time. In 2004, nearly 63 % of all hospices were non-profit, with for-profit operations comprising 31%. However, as Figure 4 below shows, the trend had been toward growth in the for-profit area.

**Figure 4: Trends in Hospice Profit Status (2001 – 2004)**



(NHPCO 2005)

As of year-end 2003, 48% of hospices were free-standing entities, 30% were affiliated with hospitals and another 22% are affiliated with a home health agency or a nursing facility. The trend had been away from free-standing toward affiliation (NHPCO 2004).

The strategic rationale for a hospice to be a part of an integrated healthcare system was threefold. First, hospice was a critical and growing piece of the healthcare continuum and enabled acute care providers to offer patients an alternative to traditional end-of-life care situations. Second, hospice programs could act as a strong link to the community, given the large number of volunteers and the high level of emotional attachment. Finally, affiliated hospices offered “hard-wired” opportunities to transfer patients from high-cost acute care situations to the relatively lower-cost hospice environment, enhancing the financial performance of both entities.

Hospices had also traditionally skewed towards rural areas, most likely because of the relatively low penetration of other health-care alternatives in those areas. However, much of the growth in hospice care had been in the area of urban environments, where hospices were complementing other health care providers, such as hospitals. As of 2004, 38% of hospices were in rural areas, 24% in urban, and another 38% were considered to be operating in both urban and rural areas (NHPCO 2004).

### **For-Profit Hospices Grow in a Traditionally Non-Profit Industry**

Up until the institution of the Medicare Hospice Benefit in 1982, there was little incentive for for-profit hospices to enter the industry. The Medicare Hospice Benefit, along with the dramatic growth trends in patients seeking hospice care, has attracted for-profit players. If one measures by average daily census (ADC), eight of the top nine hospice providers in the US are for-profit.

**Figure 5: The Nine Largest Hospice Operations in the US (2004)**

	<b>Provider</b>	<b>Status</b>	<b>Est. ADC</b>	<b>Rev. (\$MM)</b>	<b>Industry Share</b>

1	Vitas Healthcare Corporation	Public; For-profit	8,500	\$490	10.9%
2	Odyssey Healthcare Inc.	Public; For profit	7,700	\$360	8.0%
3	VistaCare Inc.	Public; For profit	5,200	\$192	4.3%
4	Manor Care, Inc	Public; For profit	4,500	376*	8.4%
5	SouthernCare Hospice, Inc.	Private; For profit	3,500	180 **	4.0%
6	Beverly Enterprises, Inc	Public; For profit	2,000	\$87	1.9%
7	Trinity Hospice, Inc	Private; For profit	1,400	\$72	1.6%
8	Life Path	Private; Not For Profit	1,300	\$67	1.5%
9	Wellspring Hospice Care	Private; For profit	750	\$38	.9%

(Based on market of \$4.5 B)

\* =Hospice and Home Health Care

\*\* = estimated by Shattuck Hammond Partners LLC

## VISTACARE

### Origins and Growth

In 2004, VistaCare, Incorporated was the third largest provider of hospice services in the US. It was founded in 1995 by Barry Smith and Roseanne Berry in Phoenix, Arizona. Less than 10 years later, VistaCare had hospice operations in 45 facilities across 14 states, and served an overall average daily census of nearly 5,300 patients. Revenues had grown exponentially, approaching \$200 million for 2003. In 2004, despite its expansion in hospice sites, revenues had receded to just over \$150 million.

### VistaCare's Overall Business Strategies

VistaCare's business strategies revolved around the following imperatives:

- 1) Controlling operating costs,
- 2) Managing patient length of stay,
- 3) Establishing scale and geographic breadth, and
- 4) The development of referral partners

### Controlling Operating Costs

In November, 2003, VistaCare successfully completed a long-planned transition to a new billing system designed to streamline processes and prevent errors in applications for Medicare reimbursement which tend to delay timely payment. This system, called CareNation, had a number of hospice-specific applications which enabled them to track patient admission and certification, enroll patients in a nationwide network of pharmacies, monitor patient census and length of stay data, automate their bereavement communications, and process Medicare and private third-party payer reimbursement claims. Similarly, VistaCare also deployed a separate Pharmacy Cost Control System, which involved a flexible, proprietary disease and symptom-specific drug formulary that emphasized the use of generic drugs (if as effective as the brand-name alternative).

VistaCare maintained a commitment to reducing their patients' use of treatments that were needlessly expensive or clinically ineffective. Collectively, these internal systems helped VistaCare control operating costs.

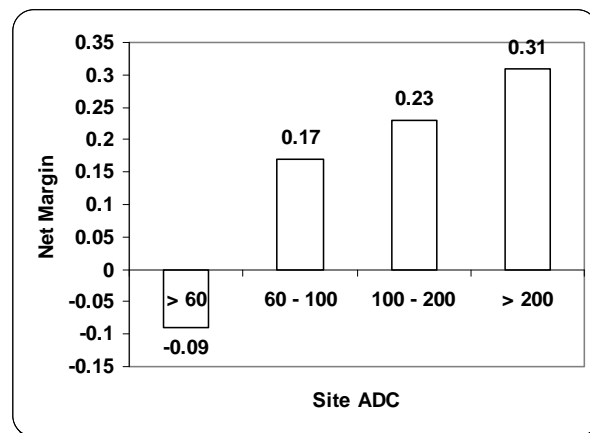
### Managing Patient Length of Stay

Patient length of stay appeared to have the most impact on net patient revenue. Patient care expenses were usually higher during the initial and latter days of care. During the initial days of care, expenses tended to be higher due to initial purchases of pharmaceuticals, medical equipment, supplies, and administrative costs. In the latter days of care, expenses tended to be high because patients required more services due to their deteriorating medical condition. For each patient, if length of stay was only a few days, the high costs were spread over fewer days of care which increased patient care expenses as a percentage of net patient revenue. Consequently, profitability was negatively impacted. Clearly, the ideal scenario for a for-profit hospice was to have each patient stay as long as possible so that the patient care expenses were spread over more days, positively impacting profitability. Of course, managing the mix of services provided could also have a positive impact on profitability. As will be seen later, some for-profit firms also engaged in a strategy of enriching their product mixes. In particular, some hospices sought to increase the amount of inpatient care provided.

### Establishing Scale and Geographic Breadth

The hospice business model was also highly sensitive to scale. Once the average daily census (ADC) breakeven point was reached (between 30 – 40 patients per month), operating margins in the 10% range were achievable and increased as the census rose. VistaCare's specific experience with scale effects are summarized in Figure 6 below.

**Figure 6: The VistaCare Experience: Net Margins by ADC: 2004**



(VistaCare Investor Day Presentation, May 17, 2005)

Hospice providers who achieved significant scale were able to negotiate volume discounts on the purchase of pharmaceuticals, durable medical equipment and medical

supplies. In addition, they were in a better position to enter into favorable contracts with private insurers, HMOs and pharmacy benefit managers. Finally, large hospice operations were better able to spread certain fixed costs (corporate overhead, IT infrastructure, and marketing spending) over large patient populations.

Having a broad footprint in a particular geography aided large for-profit hospices in receiving referrals from similarly broad-based health care providers. National and regional nursing home and assisted living communities often sought out the administrative and service consistency benefits resulting from working with a limited number of broad-based hospice service providers. Management at VistaCare referred to their geographic strategy as “building out regional density” (VistaCare Investor Day Presentation, May 17, 2005). A good example of this strategy could be found in the state of Georgia. VistaCare added 4 sites in Georgia in 2004 – 2005, essentially creating a cluster of sites around Atlanta covering 85% of the state population. VistaCare had similar clusters of operations throughout the Southeast, Southwest, Midwest and, to some degree, the East.

### **The Development of Referral Partnerships**

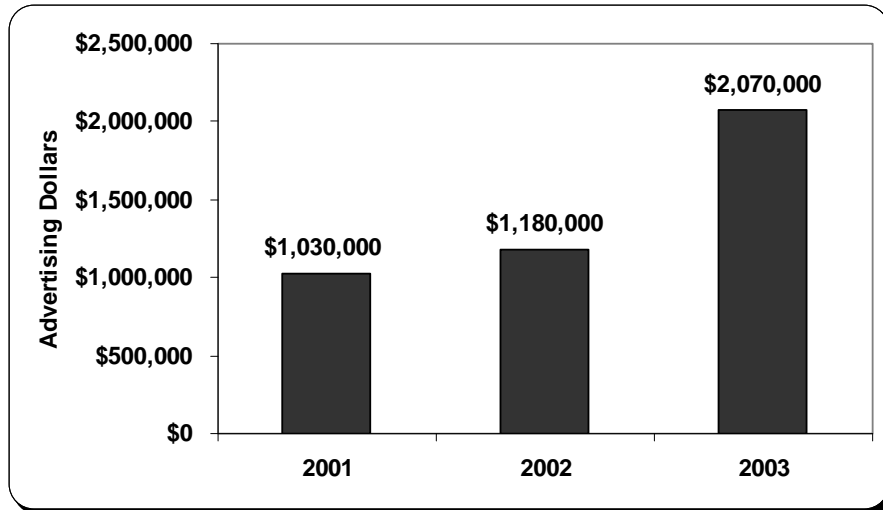
As previously mentioned, another trend toward aggressive marketing strategies in the hospice industry was to establish partnerships with hospitals and retirement communities. When these partnerships were established, the for-profit hospice relied on hospitals and retirement communities to generate referrals to their company. For example, when a person became terminally ill in a hospital or retirement community, a staff member from the organization would recommend that the patient seek hospice care with the partner hospice provider. These partnerships were a primary method used by for-profit hospices to increase admissions. For-profit hospices created marketing departments specifically designed to promote referral growth. As of May, 2005, VistaCare had over 150 hospital contracts, as well as similar relationships with long-term care providers and managed care providers. (VistaCare Investor Day Presentation, May 17, 2005).

## **THE EVOLUTION OF MARKETING PRACTICES AT VISTACARE**

### **Advertising and Promotions**

Traditionally, the marketing strategies of nonprofit hospices did not utilize many resources of the firm. However, the for-profit firms were dedicating increasing amounts of their budgets to marketing activities – particularly the recruitment of referral partners. Figure 7 below shows the increasing trend of advertising expenditures at VistaCare from 2001 – 2003.

**Figure 7: VistaCare Expenditures for Advertising (2001 – 2003)**



(VistaCare Annual Reports 2002, 2003, 2004)

As a point of differentiation from its larger competitors, VistaCare promoted their “Open Access Policy”, which meant they would accept anyone who was eligible for hospice care, regardless of the complexity of their medical needs. This “open access” policy was actually dictated by Medicare policy, but had not been stressed as explicitly by VistaCare’s leading competitors. The “Open Access Policy” had also been leveraged in the effort to convince patients and referrers to commit to hospice service in a more timely fashion (i.e., earlier in the progression of the terminal illness). Thus, the patient had a better chance of having a longer length of stay with the hospice, thereby augmenting the hospice’s business model.

### **Personal Selling**

As previously stated, VistaCare committed significant resources to establish personal selling teams to call on the various referring entities. Compensation plans were geared around numbers of referrals and types of patients obtained. In some cases, the teams specialized by type of client, such as nursing homes and oncology centers.

In June 2004, VistaCare created the new position of Vice President of Sales in their marketing department to further drive this critical aspect of their strategy. Through 2004, they continued to aggressively recruit qualified candidates to aid in the pursuit of future growth.

### **Products/Services Strategy**

In order to be certified by Medicare, marketers of hospice services were required to offer specific core and non-core services. However, some hospices recognized the value of differentiating their services to appeal to certain types of referrers. For example, certain national or regional health care providers appreciated the ability to work with a larger partner who could offer a consistent level of care and administration over a larger geographical footprint.



Further, hospices were beginning to differentiate themselves by specializing in services for specific diagnoses. Vitas Healthcare, the leading for-profit hospice organization in the industry, distinguished itself by specifically targeting patients that required general inpatient care and continuous home care. This strategy held several advantages. First, it allowed Vitas to attract higher reimbursement rates, thereby achieving higher profitability. Second, due to the relatively short lengths of stay of these patients (as they tended to be cancer-related), it created a buffer against the Medicare Cap by admitting relatively short length of stay patients to offset their longer length of stay patients. Finally, the strategy of offering high value inpatient services differentiated Vitas from their major competitors in the eyes of potential referral partners. By 2004, VistaCare had seen the wisdom of offering inpatient facilities and had identified the establishment of IPU (inpatient units) as a priority. In tandem with a regional density build-out strategy, VistaCare hoped to compete more effectively for referrals from large healthcare providers.

### **Distribution Strategy**

The major for-profit competitors saw rapid expansion and share growth as critical to their long-term success. All were using the following three methods of expansion to one degree or another: 1) “same store” census growth in existing operations, 2) acquisitions, and 3) the construction of new facilities. Since most of hospice care is provided in the patients’ places of residence and not a company-owned facility, capital costs to establish new facilities were relatively low. The acquisition costs for successful existing hospice operations far outstripped the roughly \$500,000 cost of establishing a hospice operation from the ground up. Thus, in 2004, the rate of mergers and acquisitions in the hospice industry was slowing.

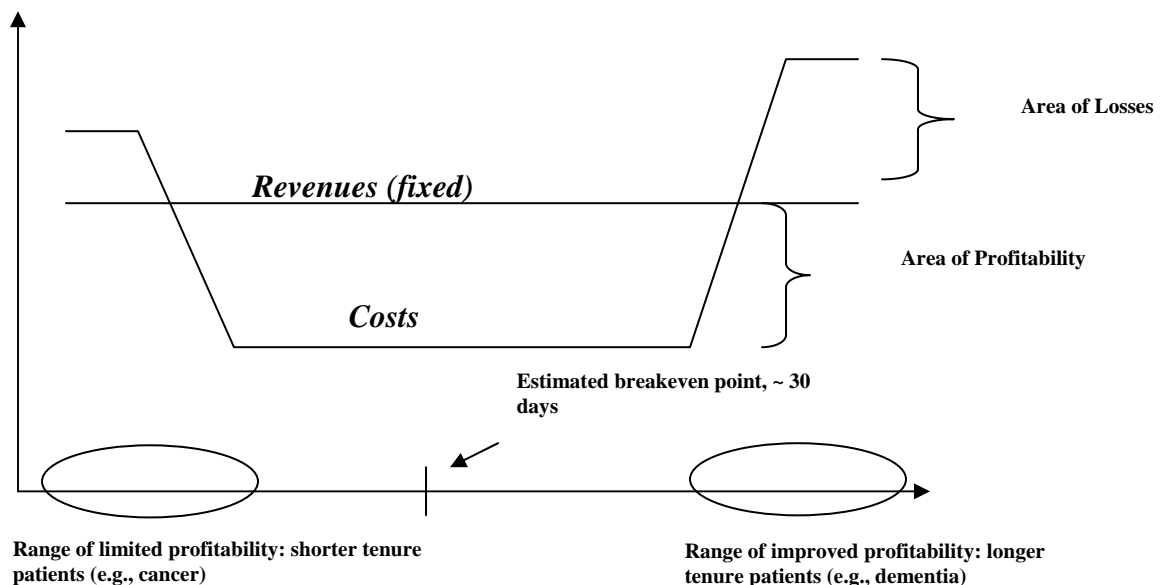
VistaCare was focusing on both rural areas and the fringes of metropolitan areas to expand their business. Prior to 2005, their strategy focused primarily on rural areas, where competition was relatively benign or non-existent, thereby improving the chances of ramping market share quickly.

Certification from Medicare was required to receive reimbursements from the government. Certification usually required that a hospice be up and running for a period of several months, after which time Medicare would inspect the operation and certify the hospice. This, of course, meant that a new hospice would have costs for several months with no income from Medicare, making the initial investment larger. To work around this issue, larger hospice operations made use of the stipulation that a hospice could operate within a 60 – mile radius of its certification. Thus, they used certified staff to establish hospices near the 60 – mile radius in order to operate under the other location’s certification until the new operation could become certified. This insured consistent cash flow from Medicare. Once the new operation became certified, they could repeat the process to expand their operations into another 60-mile service area. Utilizing this process could cut the start-up costs for new hospices by up to 50%. VistaCare referred to this as their “leapfrog” strategy.

## The Implications of a Fixed Pricing Environment

With over 90% of the revenues being obtained from Medicare and Medicaid, all hospice operators work under a fixed pricing system. Thus, the revenue function for a hospice operator is linear – a fixed per diem payment over time. The cost function, however, is not linear. The cost of a marginal day of care is relatively high at the onset of care, when there are initial costs of learning about the patient’s background, and when developing a plan for facilitating the move to a hospice environment. Similarly, costs are relatively high in the days immediately prior to death. Between the high costs at the start and at the end of the period of care, costs are lower (Huskamp, et al). This pattern of cost is the same regardless of diagnoses. A chart depicting this unique revenue to expenses relationship over time can be found in Figure 8 on the following page:

**Figure 8: Schematic of Fixed Revenue and U-Shaped Cost Function in Hospice Care**



The primary implication of the linear revenue function and the U-shaped cost function is as follows: Given the most typical hospice scenario, whereby a patient is receiving routine home care which is reimbursed at roughly \$120 per day, longer lengths of stay will yield higher profits.

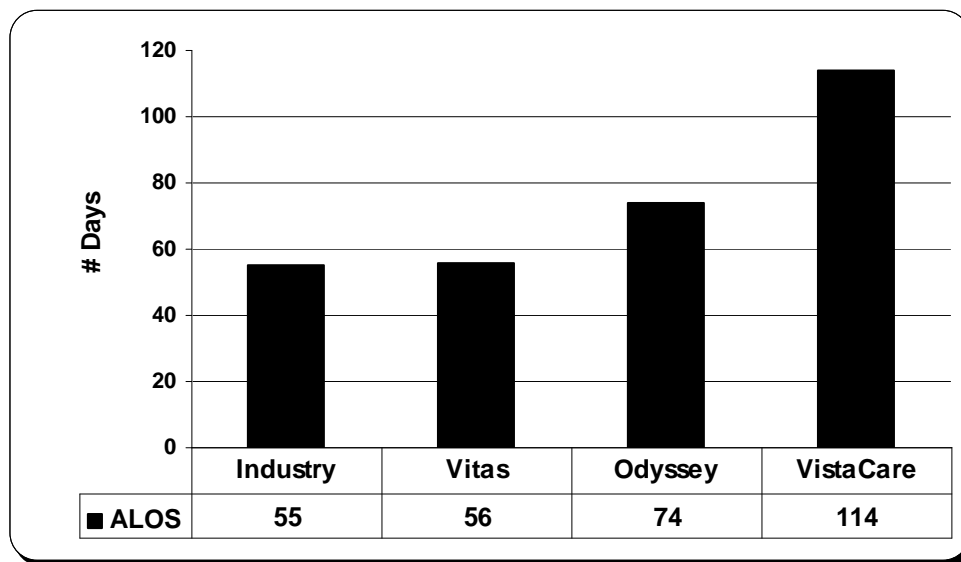
As previously discussed, another strategy being pursued by some hospice operations is to invest in the durable medical equipment that it utilized for inpatient care, which is

reimbursed at over \$500 per day. While the durable equipment and full-time care drive the cost function up, these costs can be amortized and spread over many patients, making this portion of the business profitable. It also serves to differentiate the hospice provider as an entity that serves the full spectrum of care.

Further, a patient’s diagnosis serves as a predictor of length of stay: Cancer patients tend to be referred late and have relatively short stays. In contrast, non-cancer patients tend to have longer lengths of stay. The cost/revenue dynamic is further complicated by the fact that the non-cancer patients tend to require more and more expensive types of medication and other services not traditionally used on a dying cancer patient.

Figure 9, on the following page, shows the average length of stay for VistaCare as well as for the other two major for-profit operations and the industry overall. It is interesting to note that VistaCare, which touts an “Open Access Policy”, has experienced considerably longer average lengths of stay.

**Figure 9: ALOS: Average Length of Patient Stay (2003)**



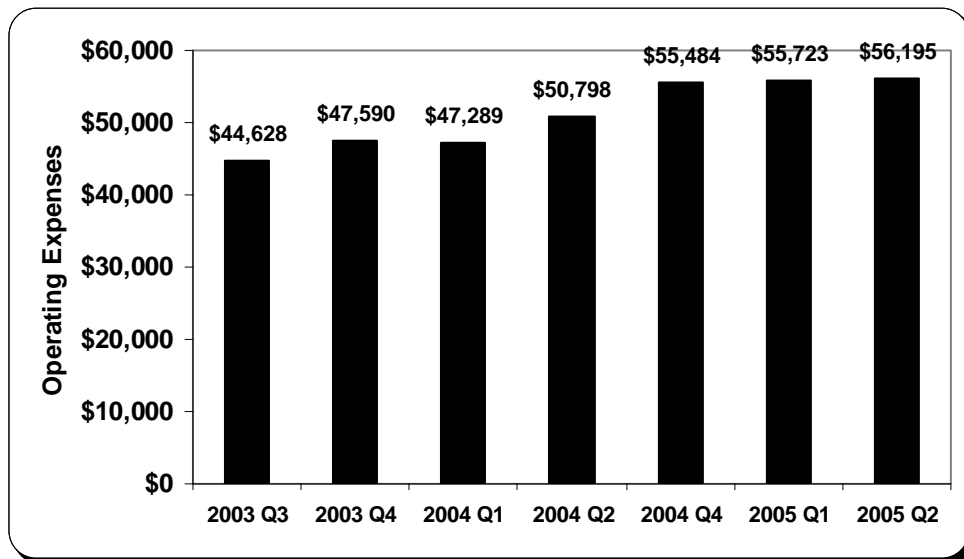
(NHPCO, Vitas, Odyssey, VistaCare Annual Reports 2004)

VistaCare must manage the type and number of patients in an environment where one is expected to take on all types of cases. This task is approached in the following two ways: First, marketing appeals are directed at the type of patients needed at the time to keep the mix of patients by diagnoses in an acceptable range. At times, this may mean directing efforts at oncology patients, but at other times it may mean directing efforts at non-cancer patients; Second, rapid census growth is viewed as a means of staying a step ahead of the Medicare Cap issue by attracting traditionally longer length of stay patients, and mitigating their impact by continuing to attract new patients with their inherently short tenures.

## VISTACARE’S OPERATIONAL ISSUES

The year 2003 saw VistaCare seeking to expand its marketing activities with the expectation of increasing its admissions, particularly in some of the new sites it was launching. Among the key marketing initiatives was a hospital referral initiative: VistaCare was rapidly expanding its personal selling sales force and investing in training by retaining the services of an outside training agency. In addition, VistaCare revised its compensation structure for sales reps to provide incentives for enrollment at the program (local) level. This investment in personal selling continued into 2004. The number of personal sales reps expanded from 90 in 2003 to 141 in 2004: a 57% increase. Figure 10 shows the upward trend in operating expenses from 2003 to 2005.

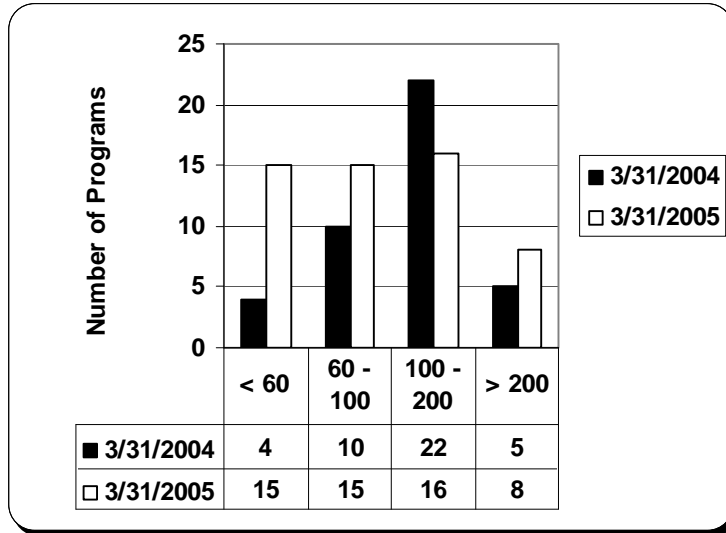
**Figure 10: VistaCare Quarterly Operating Expenses (2003 - 2005)**  
(\$ 000's)



(VistaCare 10Q Reports, 2003 - 2005)

2004 also saw a significant number of new sites becoming certified. As of March 31, 2004, VistaCare had 41 active sites. By March of 2005, there were 54 sites up and running. This amounts to an increase of 32%. Unfortunately, many of these new sites were operating at relatively low patient count (ADC: Average Daily Census) levels, as Figure 11 below attests.

**Figure 11: VistaCare Number of Sites by Site Size (2004 - 2005)**

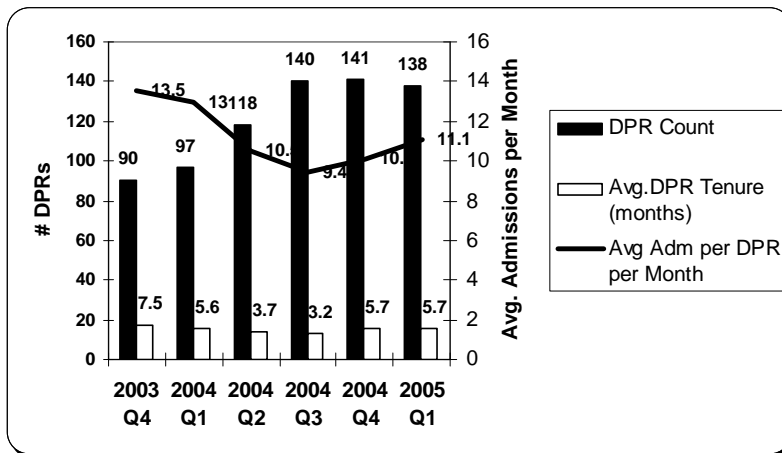


(VistaCare Investor Day Presentation, May 17, 2005).

For example, in examining figure 10 above, note that the number of hospice sites with patient counts less than 60 grew from 4 to 15 from March 2004 to March 2005. These low patient counts place pressure on the business model.

In addition, the new sales reps (DPRs: Directors of Patient Referrals) were not as productive in gaining referrals, due to the learning curve and the long sales cycle of relationship selling. Figure 12 shows the productivity of VistaCare’s DPRs based upon tenure in the job.

**Figure 12: VistaCare Quarterly DPR Numbers, Tenure and Productivity (2005)**

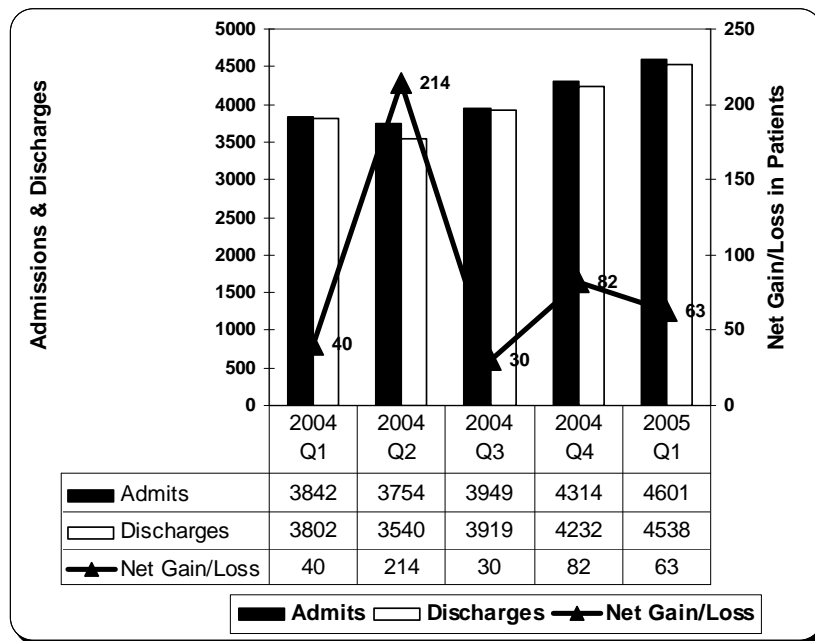


(VistaCare Investor Day Presentation, May 17, 2005).

Note that the average tenure of sales reps dipped from 7.5 months in Q4 2003 to 3.2 months in Q3 2004. Note also the swoon in average admissions per sales rep per month, which went from 13.5 per month in Q4 2003 to 8.4 per month in Q3 2004. In effect, VistaCare was bringing on new sales reps who, due to lack of experience, were less productive in obtaining referrals.

The result of this lack of sales force productivity resulted in a lack of net admissions growth in 2004, as is evidenced by Figure 13.

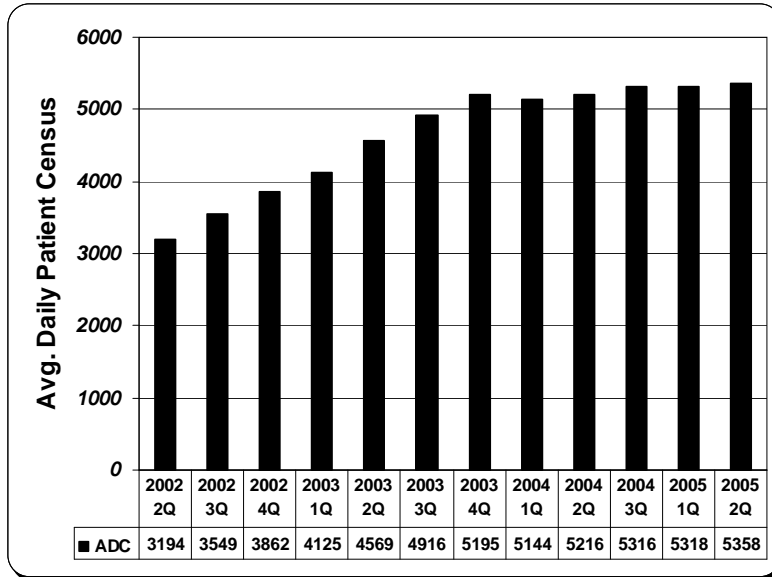
**Figure 13: VistaCare Quarterly Admits, Discharges and Net Position (2004 - 2005)**



(VistaCare Investor Day Presentation, May 17, 2005).

This dearth of net new admissions, in turn, led to a flattening of the Average Daily Census curve, as is shown by Figure 14.

**Figure 14: VistaCare Quarterly ADC (2002 - 2005)**

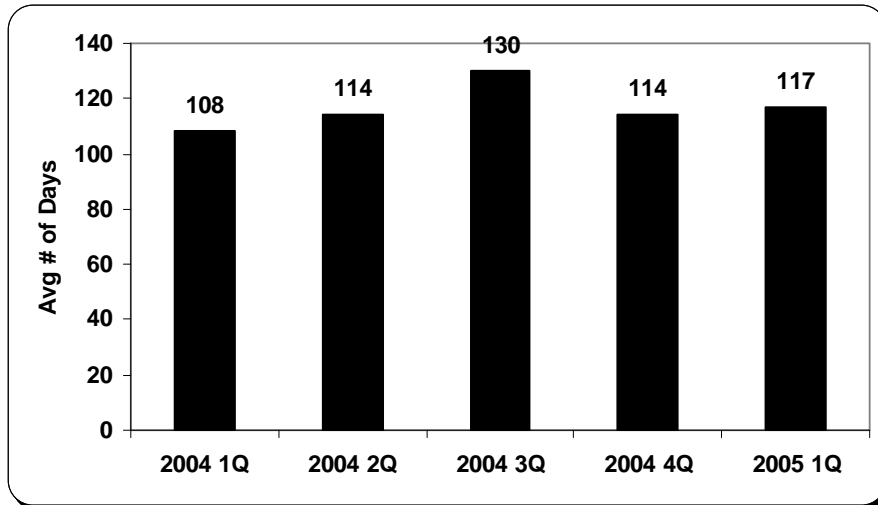


(VistaCare Investor Day Presentation, May 17, 2005)

To further exacerbate the situation, VistaCare had issues in regard to their patient mix. Whereas the industry average for cancer-related hospice patients in the patient mix was 49%, VistaCare’s mix of patients with cancer was running at 30%. Traditionally, VistaCare would specifically target non-cancer patients, as they would typically have longer average lengths of stay (ALOS), thereby boosting profitability. However, in the scenario of low ADC growth, the longer lengths of stay would prove to have an adverse impact upon the new sites, where lack of patient turnover would lead to issues with the Medicare Cap requirement. That is, in some of the newer sites, the patient mix became heavily weighted with patients with longer lengths of stay. Without a balance in the mix of shorter length of stay patients (e.g., cancer patients), these sites became susceptible to the Medicare Cap reimbursement guidelines, and VistaCare was forced to reimburse Medicare for amounts billed over the allowable amount.

As Figure 15 depicts, in Q3 of 2004, the average length of stay at VistaCare was surging to a high of 130 days -- over twice the industry average of 55 days.

**Figure 15: VistaCare Average Length of Stay (2004 - 2005)**



(VistaCare Investor Day Presentation, May 17, 2005).

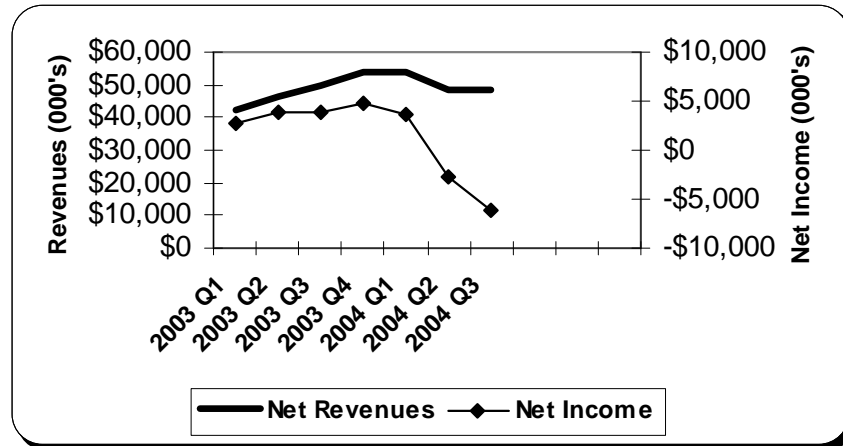
VistaCare also faced a significant issue in the form of the Medicare Cap Accrual. Medicare caps reimbursements per patient per year at a fixed level (in 2004, that figure was \$19,635.67). This rate, which is updated every year, is multiplied by the number of new beneficiaries enrolled by each individual site during the fiscal year. If actual Medicare reimbursements to an individual program during the period exceed the limit, the provider must repay the difference to Medicare. Since providers do not know if they have exceeded the limit until the end of the Medicare fiscal year (November 1), they must accrue accurately for this amount to avoid having an unexpected expense in the 4<sup>th</sup> quarter of the year. This can occur when hospices have patients with inordinately long lengths of stay. Assume the daily reimbursement rate for a typical hospice patient is about \$125 (this is close to the routine care reimbursement rate). A hospice with a patient who has accumulated more than 157 days in a given year would be “capped” at receiving the \$19,635.67 per the guideline. Any days beyond 157 would not be paid for by Medicare, and essentially come right off the bottom line of the hospice. The Medicare Cap is compiled in an aggregate manner for each individual hospice site, by simply dividing the total Medicare dollars reimbursed by the number of new patients admitted in the fiscal year. This means that the hospice can mitigate their cap accruals by taking on patients with relatively short lengths of stay. They can then dedicate the “unused” portion of the \$19,635.67 of a short length of stay patient as a “credit” of sorts against the patients who are over the cap amount. Thus, proper cap management entails strict attention to patient mix.

VistaCare ran into serious Medicare Cap accrual problems in 2004, brought upon by an imbalance in patient mix and the resulting inordinately high length of stay in some of their programs. VistaCare had Medicare Cap issues in 9 of their 44 programs in fiscal year 2004, or 20%. In 2Q 2004, they would surprise their stakeholders with an accrual of \$6.2 million, over 7 times the “normal” level of the previous quarter. The troubles continued: In 3Q 2004 they were forced to book an accrual of \$7.8 million. These expenses are essentially taken out of top-line revenues, severely impacting the bottom



line in those quarters, as Figure 16 attests. Refer to Appendix A for a more detailed profile of VistaCare’s Income statement from 2000 – 2004.

**Figure 16: VistaCare Quarterly Net Revenues & Net Income (2003 - 2004)**



(VistaCare 10Q Reports, 2003 - 2004)

In December of 2004, CEO Rick Slager, CFO Mark Leibner and the rest of the VistaCare management team likely sat down to develop a plan to restore revenue growth and profitability to their operation. They would have been looking for the proper strategy to articulate to their potential customers, suppliers and investors that would renew their confidence in VistaCare’s business going forward. In order to develop such a strategy, a number of issues were likely to be addressed:

- 1) What is the current situation in the industry? What is VistaCare’s place in the industry? What imperatives, if any, exist for revenue growth and profitability in both the short term and the long term?
- 2) What factors, both internal and external, had led them to their current situation? Which were controllable, and which were not?
- 3) What elements of the marketing program were working effectively for them and which were not? Which should be retained or augmented? Which, if any, could be cut?
- 4) What is the best manner to move forward that will minimize the likelihood of a downside earnings surprise in the future?

It was clear that action must be taken immediately. The next few months might determine whether VistaCare returned to its high-growth, high-profitability glory days or languished in operational difficulty while competitors gobbled up share in the rapidly-growing hospice industry.

**APPENDIX A: ANNUAL INCOME STATEMENTS FOR VISTACARE**

**VistaCare, Inc.**  
**Annual Income Statements: 5 Year Trend**  
 (Values in 000's)

	<u>12/31/2004</u>	<u>12/31/2003</u>	<u>12/31/2002</u>	<u>12/31/2001</u>	<u>12/31/2000</u>
<b>Total Revenue</b>	\$207,051	\$191,656	\$132,947	\$91,362	\$81,595
<b>Cost of Revenue</b>	\$135,204	<u>\$114,631</u>	<u>\$79,752</u>	<u>\$63,950</u>	<u>\$55,256</u>
<b>Gross Profit</b>	\$71,847	\$77,025	\$53,195	\$27,412	\$26,339
<b>Operating Expenses</b>					
<b>Sales, General and Admin.</b>	\$73,095	\$55,784	\$42,962	\$30,716	\$23,541
<b>Other Operating Items</b>	<u>\$4,060</u>	<u>\$1,963</u>	<u>\$1,349</u>	<u>\$1,990</u>	<u>\$1,797</u>
<b>Operating Income</b>	\$-4,402	\$19,278	\$8,884	(\$5,294)	\$1,001
<b>Add'l income/expense items</b>	\$967	\$309	(\$112)	(\$111)	\$194
<b>Earnings Before Interest and Tax</b>	\$-5,369	\$19,587	\$8,772	(\$5,405)	\$1,195
<b>Interest Expense</b>	0	\$126	\$935	\$1,157	\$1,497
<b>Earnings Before Tax</b>	-\$5,369	\$19,461	\$7,837	(\$6,562)	(\$302)
<b>Income Tax</b>	(\$1,845)	\$4,256	\$281	\$150	\$81
<b>Net Income-Cont. Operations</b>	<u>(\$3,524)</u>	<u>\$15,205</u>	<u>\$7,556</u>	<u>(\$6,712)</u>	<u>(\$383)</u>
<b>Net Income</b>	(\$3,524)	\$15,205	\$7,556	(\$6,712)	(\$383)
<b>Adjustments to Net Income</b>	<u>\$0</u>	<u>\$0</u>	<u>(\$4,052)</u>	<u>(\$3,839)</u>	<u>(\$3,482)</u>
<b>Net Income Applicable to Common Shareholders</b>	(\$4,232)	\$15,205	\$3,504	(\$10,551)	(\$3,865)

(VistaCare Annual Report 2004)

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# *Teaching Case*

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## **Journal of Applied Case Research**

Sponsored by the Southwest Case Research Association

### **Odyssey Healthcare**

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Sam Houston State University

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Accepted: December 2006

### **INTRODUCTION**

Richard Burnham thought he was easing out of the day-to-day management of Odyssey Healthcare, the hospice concern he co-founded. He had stepped down as CEO in January 2004 and turned the reins over to his cofounder, David Gasmire. Now, less than six months later, company performance issues and negative publicity were compelling him to weigh in on a turnaround plan.

Founded in 1995, Odyssey Healthcare had enjoyed tremendous growth for nearly 10 years. Odyssey had grown its base of business through “same store” growth, acquisitions and newly constructed operations to become one of the largest for-profit hospice organizations in the United States. The number of Odyssey hospices had more than doubled from 2001 – 2003, from 30 to 74.

However, as Burnham and Gasmire navigated into 2004, Odyssey began to experience some operations-related problems. In February 2004, Odyssey released its earnings for the fourth quarter of 2003. While the numbers for 2003 came in on target, Odyssey management advised investors that their earnings estimates for fiscal year 2004 were being lowered due to operational issues. Based upon this news, the stock price dropped 26% in a single day (Yu 2004). In April, 2004, Barron’s, a widely-read financial newspaper, wrote an unflattering article about Odyssey which strongly hinted at Odyssey engaging in less than ethical practices related to patient admissions, patient care and patient discharges (Ward 2004).

Immediate action was required. As Burnham prepared to meet with his friend and cofounder, CEO David Gasmire, he wrestled with a number of issues: What could be done to improve the operations of the firm and restore investor confidence? How could the organization ensure that individual hospice programs kept their eye on organizational goals while still behaving ethically?

## **THE HOSPICE INDUSTRY**

### **Hospice Care**

Hospice care has been defined by the Hospice Association of America as:

“...comprehensive, palliative medical care (treatment to provide for the reduction or abatement of pain and other troubling symptoms, rather than treatment aimed at cure) and supportive social, emotional, and spiritual services to the terminally ill and their families, primarily in the patient’s home. The hospice interdisciplinary team, composed of professionals and volunteers, coordinates an individualized plan of care for each patient and family.” (Hospice Association of America website 2005)

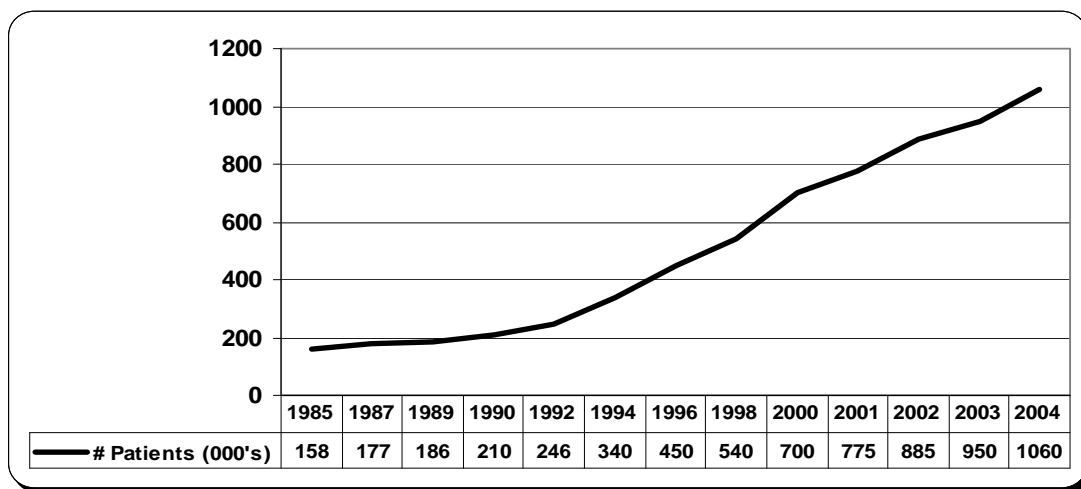
The palliative (pain reducing) care provided by hospices differed from curative care which was traditionally provided by hospitals in the sense that the primary focus was not on curing the patient. Rather, a holistic program was designed which was directed at all aspects of care which made the patient more comfortable and improved the quality of life. A broad range of services, from traditional nursing care to respite care for family caregivers to bereavement services for family members was traditionally offered.

### **The Institution of the Medicare Hospice Benefit Spurs Industry Growth**

In 2003, the hospice industry in the US was a relatively small and fragmented component of the overall healthcare industry, generating aggregate annual revenues of about \$4.5 billion. Spending on hospice services amounted to less than one half of one percent of the \$1.4 trillion in annual US healthcare spending. Further, hospice spending accounted for only 1.5% of annual Medicare spending (Shattuck Hammond Partners 2004).

In 1982, Congress enacted the Medicare Hospice Benefit on a provisional basis. In 1986, the provisional law was made permanent. Each state was given the option of including hospice care in their Medicaid program. In addition, hospice care was made available to terminally ill patients in nursing homes. A significant jump in usage of hospices occurred after 1990.

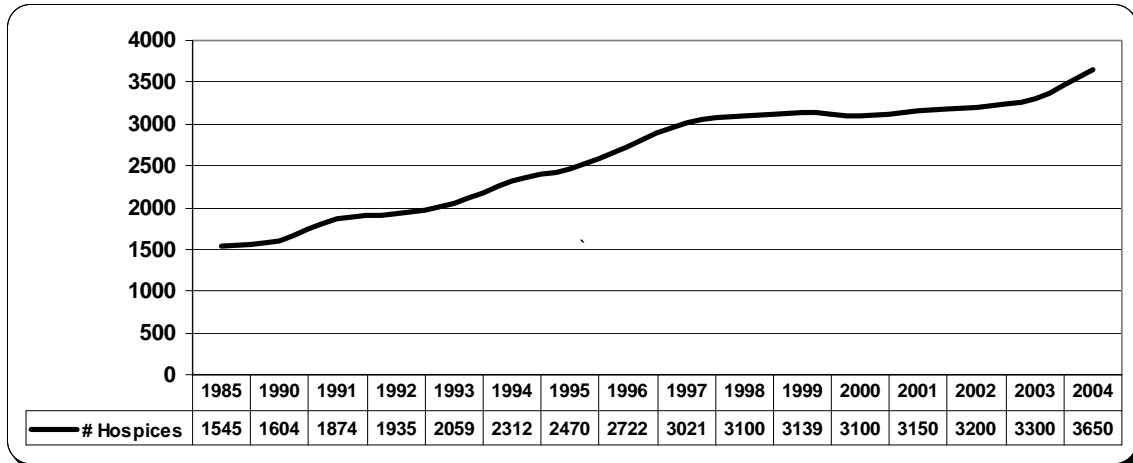
**Figure 1: Number of Hospice Patients: 1985 – 2004 (000's)**



(National Hospice and Palliative Care Organization (NHPCO) 2005)

In 1996, the federal government initiated a program (“Operation Restore Trust”) focused on preventing Medicare fraud across all provider groups. This increased level of regulatory scrutiny, while probably needed, likely inhibited referrals of patients and reduced average and median lengths of stay industry-wide. The Balanced Budget Act of 1997 further negatively impacted reimbursement rates, dampening the growth rate of hospice sites, as evidenced in Figure 2.

**Figure 2: Number of Hospices: 1985 – 2004**



(NHPCO 2005)

### **Factors Driving the Increasing Acceptance of Hospice Care Services in the US**

In 2004, there were several factors driving growth in the hospice industry. Foremost was the overall aging trend in the US and the increasing size of the over-65 population. In addition, there was an increasing role of advocacy groups in promoting hospice care over other end-of-life alternatives. Finally, The Center for Medicare and Medicaid Services appeared to be promoting hospice care through its liberal policies for reimbursement (CMS 2004, 2005). The CMS's favorable treatment of hospice care in their reimbursement policies was thought to be at least in part because hospice is viewed as a lower cost alternative to traditional, hospital-based end-of-life care.

### **Hospice Patient Trends**

The typical patient in a hospice tended to be an older Caucasian who was most likely suffering from cancer. They were just as likely to be male or female. According to the National Hospice and Palliative Care Organization, 54% of all hospice patients were female, over 80% were Caucasian, and 63% were 75 years of age or older (NHPCO 2004).

In the 10 years preceding 2004, the greatest increase occurred in the number of beneficiaries with non-cancer diagnoses and those living in nursing homes and rural areas. Though cancer patients accounted for 49% of hospice admissions in 2003, this was down from 76% in 1992. Other ailments such as heart disease, dementia, lung disease, kidney disease, and liver disease were becoming more common among patients admitted to hospice care (NHPCO 2005).

### **The Growth of For-Profit Medicare-Certified Hospice Operations**

Traditionally, the hospice industry had been comprised of non-profit operations with an average of less than 50 patients at any given site at any given time. In 2004, 63 % of all hospices were non-profit, with for-profit operations comprising 31%. Most of the growth in the industry was driven by the for-profit sector (NHPCO 2005).

At year-end 2003, 48% of hospices were free-standing entities, with 30% being affiliated with hospitals and another 22% affiliated with a home health agency or a nursing facility. The trend had been away from free-standing toward affiliation (NHPCO 2004). The strategic rationale for a hospice to be a part of an integrated healthcare system was threefold. First, hospice was a critical and growing piece of the healthcare continuum and enabled acute care providers to offer patients an alternative to traditional end-of-life care. Second, hospice programs could act as a strong link to the community, given the large number of volunteers and the high level of emotional attachment to patients. Finally, affiliated hospices offered “hard-wired” opportunities to transfer patients from high-cost acute care situations to the relatively lower-cost hospice environment, thereby enhancing the financial performance of both entities.

### **The Medicare Hospice Benefit**

In 2002, Medicare and Medicaid accounted for 86% of all hospice industry payments. Private insurance paid for an additional 11%. The rest was covered through Medicaid, self-pay, or other alternative payment methods (NHPCO 2004).

Medicare had three key eligibility criteria for hospice care. First, the patient was required to have Medicare A coverage. Second, the patient’s doctor and the hospice’s medical director were required to use their best clinical judgment to certify that the patient was terminally ill with a life expectancy of six months or less, if the disease ran its normal course. Third, the patient was required to choose to receive hospice care rather than curative treatments for their illness.

Medicare then paid the hospice a per diem rate, which was intended to cover virtually all expenses related to addressing the patient’s terminal illness. Because patients required differing levels of care as they progressed in their diseases, Medicare provided for four levels of care to meet their changing needs. Typically, each October, Medicare adjusted its base hospice care reimbursement rates for the following year based on inflation and other economic factors.

Medicare reimbursements were made along the following guidelines:

- 4) Medicare beneficiaries were required to pay limited coinsurance: the smallest of 5% or \$5 for drugs and 5% of hospice payments for respite care.
- 5) Total annual co-payments for respite care could not exceed the Medicare hospital deductible.



- 6) Medicare capped (i.e., limited) reimbursements to hospice programs in three ways:
  - a. Inpatient care days could not exceed 20% of all patient care days per provider. If the cap was reached, reimbursement continued, but at a reduced rate. This was referred to as “The 20/80 Rule”.
  - b. Annual reimbursements per beneficiary were capped at \$19,635.67 for FY 2004. This rate, which was updated every year, was multiplied by the number of new beneficiaries enrolled by the program during the fiscal year. If actual Medicare reimbursements to a program during the period exceeded the total, the provider was required to repay the difference to Medicare. This aggregate reimbursement cap effectively served as a corrective mechanism to programs with patients with inordinately long lengths of stay. This version of the cap was applicable on a per site basis, not for a firm’s hospice operations overall.
  - c. Prior to 1990, Medicare per-patient payments were limited to a 210 day maximum. From 1990-1997, payments were limited to a maximum of four 6-month benefit periods, or roughly 720 days. By 2004, rules for maximum reimbursement had been further slackened: There were no limits to the number of days of care for which Medicare would pay. However, in order to continue to receive reimbursements, a patient’s prognosis had to be reaffirmed at 90 days, at 180 days, and every 60 days thereafter.

In particular, the Medicare cap accruals posed a significant operational challenge for Odyssey. Medicare capped reimbursements per patient per year at a fixed level (in 2004, that figure was \$19,635.67). This rate, which was updated every year, was multiplied by the number of new beneficiaries enrolled by each individual site during the fiscal year. If actual Medicare reimbursements to an individual site during the period exceeded the limit, the provider was required to repay the difference to Medicare.

Since providers did not know if they had exceeded the limit until the end of the Medicare fiscal year (November 1), they struggled to accrue accurately for this amount. Thus, they often faced an unexpected Medicare cap expense in the 4<sup>th</sup> quarter of the year. This could occur when hospices had patients with inordinately long lengths of stay. Assume the daily reimbursement rate for a typical hospice patient is about \$125. A hospice with a patient who has accumulated more than 157 days in a given year would be “capped” at receiving the \$19,635.67 per the guideline. Any days beyond 157 would not be paid for by Medicare, and essentially come right off the bottom line of the hospice. The Medicare Cap is compiled in an aggregate manner for each individual hospice site, by simply dividing the total Medicare dollars reimbursed by the number of new patients admitted in the fiscal year. This means that the hospice could mitigate their cap accruals by taking on patients with relatively short lengths of stay. They could then dedicate the “unused”

portion of the \$19, 635.67 of a short length of stay patient as a “credit” of sorts against the patients who were over the cap amount. Thus, proper cap management entailed strict attention to patient mix.

## **ODYSSEY HEALTHCARE**

Odyssey was founded by Richard Burnham and David Gasmire, both former employees of another large, publicly held hospice organization – Vitas Healthcare. Burnham was a former regional manager for Vitas and Gasmire a former hospice site manager.

With headquarters in Dallas, Texas, Odyssey Healthcare, Incorporated operated 74 hospice care facilities in 30 states and employed over 4,000 healthcare workers in 2004. However, roughly half of those operations were located in California, Texas and Arizona. With an average daily census of 7700, they were the second largest hospice organization in the United States.

## **ODYSSEY’S BUSINESS STRATEGIES**

Odyssey Healthcare’s business strategies revolved around the following three imperatives: 1) Rapid expansion into new geographies with the ultimate objective to establish a broad geographic footprint, 2) Strict cost control and attention to the bottom line, and 3) A focus on marketing directed at increasing the admissions rate and average daily census (ADC), including the extensive training of their marketing, sales and operations personnel.

### **Rapid Expansion into New Geographies**

In organizing for rapid growth, Odyssey established eight regional territories. Each territory was headed by a Regional Vice President, who, in turn, managed teams of District Managers. At headquarters, Odyssey maintained a dedicated acquisitions team, as well as a dedicated expansion/startup team for de novo operations. With each new operating estimated to cost around \$1.6 million, Odyssey management indicated that a full 25% of that cost was dedicated to marketing expenses.

### **Increasing Scale and Geographic Breadth**

The hospice business model was also highly sensitive to scale. Once the average daily census (ADC) breakeven point was reached (between 30 – 40 patients per month), operating margins in the 10% range were achievable and increased as the census rose. Odyssey’s specific experience with scale effects are summarized in the Figure 3.

**Figure 3: Odyssey Average Daily Census and Net Margins: Q3 2004**

<b><u>AVERAGE DAILY CENSUS</u></b>	<b><u>NET MARGINS</u></b>
51 - 100	14.7%
100 - 200	27.3%
Over 200	31.9%
Overall	25.2%

(Odyssey Earnings Conference Call Transcript, Q3 2004)

Hospice providers who achieved significant scale were able to negotiate volume discounts on the purchase of pharmaceuticals, durable medical equipment and medical supplies. In addition, they were in a better position to enter into favorable contracts with private insurers HMOs and pharmacy benefit managers. Finally, large hospice operations were able to spread certain fixed costs (corporate overhead, IT infrastructure, and marketing spending) over a larger patient population.

Having a broad footprint in a particular geography aided large for-profit hospices in receiving referrals from similarly broad-based health care providers. National and regional nursing home and assisted living communities often sought the administrative and service consistency benefits resulting from working with a limited number of broad-based hospice service providers.

### **Controlling Operating Costs**

In 2003-2004, Odyssey struggled to adequately control their pharmaceutical costs. In many locations, they were paying local rates. In 2004, Odyssey completed an extensive project whereby a national formulary plan and an electronic drug adjudication system was implemented. This system provided better visibility and control over the drug side of the business. Odyssey also completed a switch-over to a new internal management IT infrastructure. The new software and hardware system was intended to improve the clinical and billing systems. It provided management at Odyssey with better real-time visibility into the day-to-day operations of the firm, such as the drug usage rate, patient length of stay and Medicare Cap accrual status reports

## **ODYSSEY'S MARKETING STRATEGIES**

### **Products/Services Strategy**

In order to be certified by Medicare, marketers of hospice services were required to offer specific core and non-core services. However, marketers at certain for-profit hospices recognized the value of differentiating their services to appeal to certain types of referrers. For example, certain national or regional health care providers appreciated the ability to work with a larger partner who could offer a consistent level of care and administration over a larger geographical footprint. Further, hospices were beginning to differentiate themselves by specializing in services for patients with specific diagnoses by investing in the durable medical equipment necessary to care for cancer patients with acute symptoms and a need for continuous care. Vitas, an Odyssey competitor, diverged in strategy by specifically pursuing patients that required general inpatient care and

continuous home care. This allowed Vitas to attract relatively short length of stay patients (as these patients tend to be cancer-related), achieve higher revenues (due to the relatively higher compensation levels called for by these services), and differentiate their offerings from those of Odyssey and other competitors. This change in strategy was reflected in Vitas' mix of business as shown in Figure 4.

**Figure 4: Patient Mix by Level of Care (2003)**

	<b>INDUSTRY</b>	<b>VITAS</b>	<b>ODYSSEY</b>	<b>VISTACARE</b>
<b>Routine Home Care</b>	96%	68%	90%	94%
<b>General Inpatient Care</b>	3%	16%	9%	6%
<b>Respite Care</b>	<1%	--	<1%	--
<b>Continuous Home Care</b>	<1%	16%	<1%	--

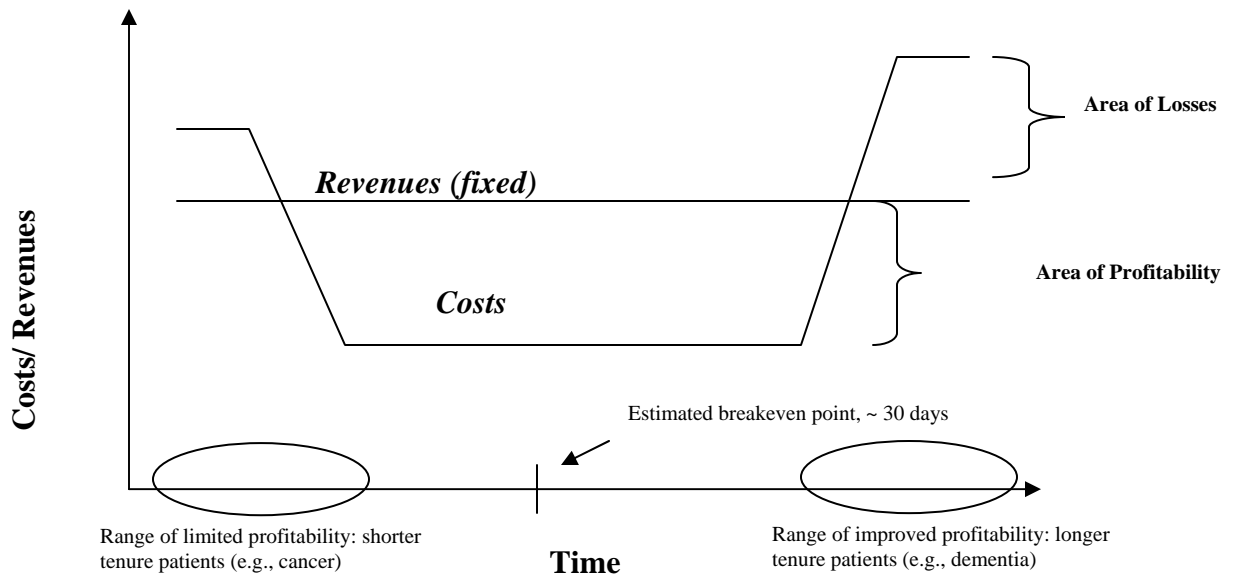
(NHPCO, Vitas, Odyssey, VistaCare Annual Reports 2004)

### **The Impact of Fixed Pricing on Odyssey's Target Market Strategy**

With over 90% of their revenues obtained from Medicare and Medicaid, all hospice operators worked under a fixed pricing system. Thus, the revenue function for a hospice operator was linear – a fixed per diem payment over time. The cost function, however, was not linear. The cost of a marginal day of care was relatively high at the onset of care, when there were initial costs of learning about the patient's background, and when the hospice developed a plan for facilitating the move to a hospice environment. Similarly, costs were relatively high in the days immediately prior to death. Between the high costs at the start and at the end of the period of care, costs were lower (Huskamp, et al 2001). This pattern of cost was the same regardless of diagnosis. The important implication of the linear revenue function and the U-shaped cost function was that longer lengths of stay would yield higher profits.

Further, a patient's diagnosis served as a predictor of length of stay: Cancer patients tended to be referred late and have relatively short stays. In contrast, non-cancer patients tended to have longer lengths of stay. For these reasons, there had been a natural tendency of for-profit hospices to target *non-cancer* patients for admissions. Figure 5 illustrates the impact of the "U-shaped" cost function and the fixed pricing environment on hospice profitability.

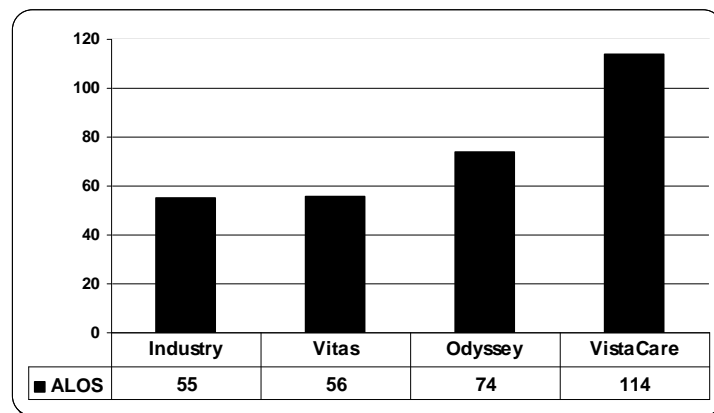
**Figure 5: Schematic of Fixed Revenue and U-Shaped Cost Function in Hospice Care**



### Managing Patient Length of Stay

Patient length of stay appeared to have the most impact on net patient revenue. For each patient, if length of stay was only a few days, the high costs were spread over fewer days of care, which increased patient care expenses as a percentage of net patient revenue. Consequently, profitability was negatively impacted. Clearly, the ideal scenario for a for-profit hospice was to have each patient stay as long as possible so that the patient care expenses were spread over more days, positively impacting profitability. As a result, Odyssey had a relatively high length of stay compared to the industry, as Figure 6 attests.

**Figure 6: Average Length of Stay (2003)**



(NHPCO, Vitas, Odyssey, VistaCare Annual Reports 2004)

Thus, Odyssey was faced with a challenge of managing the type and number of their patients in an environment where they were expected to take on all types of cases.

This objective was approached in the following two ways. First, marketing appeals were directed at the type of patients needed at the time to keep the mix of patients by diagnoses in an acceptable range. Second, rapid census growth was viewed as a means of staying a step ahead of the Medicare cap issue by attracting traditionally longer length of stay patients, and mitigating their potential negative impact on their business model (via larger than anticipated Medicare Cap accruals) by continuing to attract new patients with inherently short tenures. Thus, on a per site basis, the average length of stay used for the Medicare cap accrual calculation could be managed.

### **Driving Admissions Growth through Personal Selling**

By May 2004, Odyssey had added 17 new hospice sites in just the past 12 months. To assist in ramping up the patient counts in these nascent programs, Odyssey dedicated an increasing share of its operational budget to establish personal selling teams to call on the various referring entities. In some cases, the teams specialized by type of client, such as nursing homes and cancer centers. These referral representatives were referred to as “Community Education Reps” or CERS. In 2004, Odyssey employed more than 200 CERS. They had over 70 hospice sites, with the number of CERS per site fluctuating between 2 and 6 depending on the market conditions of each individual site.

In January 2004, Odyssey hired Bill Ward to fill the newly created position of Senior Vice President, Sales and Marketing. In addition to managing the overall sales and marketing function, Mr. Ward also took the lead in establishing strategic relationships with large referring partners, such as regional hospitals and other regional/national healthcare providers.

Compensation plans were geared around numbers of referrals and types of patients obtained. In January 2004, the compensation plan was modified. Base salaries were set slightly higher than market (i.e., other hospices in each area). Bonuses were established to be awarded after each quarter based upon growth over the previous quarter. A minimum expectation of four new admissions per week was established. Bonuses were established to incent CERS to raise their averages as the year progressed, with an incentive awarded at the end of the year if the average admissions/week reached a certain target level.

In 2003, Odyssey expanded their training and support staff to include two professionals whose sole responsibility was to educate their field sales representatives who called on their referral sources. This corporate function was referred to as The Support Center. The primary recipients of the training were the CERS, the local patient care managers, and the general managers of each individual hospice facility. In 2004, faced with a slowing admissions trend, Odyssey accelerated their training schedule for these individuals.

### **Compliance and Oversight**

Odyssey’s Annual Report for 2004 delineated their compliance program as follows:

- 1) The appointment of a compliance officer and committee,
  - 2) The adoption of a corporate code of business conduct and ethics,
  - 3) Employee education and training,
  - 4) The implementation of an internal system for reporting concerns on a confidential, anonymous basis,
  - 5) Ongoing internal auditing and monitoring programs, and
  - 6) A means for enforcing the compliance program policies.
- (Odyssey Annual Report 2004)

Odyssey placed heavy emphasis on compliance with Medicare rules and regulations. Kathy Ventre, Senior Vice President of Clinical and Regulatory Affairs reported directly to the CEO and regularly reported to the Board of Directors. She headed up a team of twelve clinicians whose primary objective was to ensure that all of Odyssey's hospices remained Medicare compliant. Of the twelve clinicians, one clinician was assigned to each of the eight sales regions. The remaining four clinicians monitored activities at all start-ups and new acquisitions. In addition to this central staff, each of the individual hospices also employed one full-time clinician.

Medicare regularly sampled paperwork submitted by its certified sites for compliance to its rules and standards. In the first quarter of 2004, 17 of Odyssey's 70+ sites had been scrutinized by Medicare: All had passed.

A summary of key excerpts from Odyssey's Corporate Code of Business Conduct and Ethics can be found in the Appendix to this case.

### **ODYSSEY'S EARNINGS MISS**

In February of 2004, Odyssey management advised investors that their earnings estimates for the fiscal year 2004 were being lowered. The primary drivers of Odyssey's reduced profit outlook included: 1) higher than anticipated costs in the form of newly acquired hospices, 2) greater pharmacy and salary expenses, and 3) greater than anticipated costs in the form of Medicare cap accruals.

On the operations front, admissions growth was slowing, apparently due to a potential lack of productivity of a relatively new sales force. This slow-down in admissions was exacerbated by new challenges from competition. Net income was squeezed by increasing marketing expenses and issues with Medicare Cap accruals at selected sites. In 2003, the total reduction to net revenues based upon Medicare Cap accruals was \$1.3 million. In 2004, this figure was expected to more than double, which was largely responsible for the reduced earnings outlook. The exponentially growing Medicare Cap

accruals were caused by extremely long average length of stays in combination with a dearth of new admissions at selected sites. Whereas the industry average for cancer-related hospice patients in the patient mix was 49%, Odyssey's overall mix of patients with cancer was running at 35%. Traditionally, Odyssey would specifically target non-cancer patients, as they would typically have longer average lengths of stay, thereby boosting profitability. However, in the scenario of low census growth, the longer lengths of stay proved to have an adverse impact upon some of the newer sites, where lack of patient turnover had led to issues with the Medicare cap requirement.

### **ADVERSE PUBLICITY**

The last thing Odyssey needed on the heels of their February 2004 earnings announcement was to have an unfavorable article come out in a prominent business periodical. Yet on April 12, 2004, *Barron's* featured an article by reporter Sandra Ward entitled: "Troubling Odyssey, Questions Arise About Hospice Company's Patient Care, Level of Medicare Payments". On the surface, the article appeared to be about operational problems associated with Odyssey's aggressive growth. However, the article intimated that Odyssey may have been engaging in less-than-ethical marketing practices. Consider the following excerpt:

"There are also suggestions that some of Odyssey's strong growth is the result of providing a level of care and services below the standards set forth under government guidelines, including providing adequate bereavement services for patients' families. A son tells *Barron's* of Odyssey's ignoring calls from a nursing home as the staff sought the assistance of the hospice firm with which he'd contracted. Some former nurses and marketing representatives tell *Barron's* of patients being kicked out of Odyssey programs after 90 days upon being 'reevaluated' or because they required hospital care. Former staffers complain about lack of access to supplies, and caseloads that are heavier than industry norms. The company's CEO, David Gasmire, says Odyssey follows all federal guidelines."

The article went on to imply that Odyssey may have been skirting Medicare requirements for admission into hospice care:

"In a business almost entirely dependent upon Medicare for reimbursement for revenues, adherence to guidelines is crucial. People familiar with the Medicare system say that exceeding the reimbursement cap is very unusual and is considered a serious breach of accepted practice by the Centers for Medicare and Medicaid Services, as well as by the insurance intermediaries who handle Medicare claims. Such breaches raise red flags about admittance procedures and the possibility that ineligible patients are being accepted into hospice programs, which are supposed to admit only those whom doctors believe have no more than six months to live."



Toward the end of the article, the author highlighted the tension caused by the incursion of for-profit firms in a traditionally non-profit industry:

“In a business expanding as fast as the hospice industry and at a company expanding as quickly as Odyssey, growing pains are to be expected. Nonetheless, there is mounting concern within the industry that the quest to show profit growth and stock price gains can sometimes conflict sharply with the needs of dying patients and their families. Nonprofit hospices increasingly complain that they are shouldering a heavier burden than the for-profits – caring for a higher proportion of expensive-to-care-for patients and providing services that should be available at all hospices.

Says Dorothy Deremo, president and chief executive of Detroit-based Hospice of Michigan: ‘For-profit organizations in health care have a different social contract: to deliver a return on investment and improve the equity of their stockholders. The social contract for the not-for-profit is....to return value to our shareholders who are the patients, the families, and the community-at-large’”.

Despite the intimations of the Barron’s article, at the time of its publication, Odyssey was not under investigation by the U.S. Department of Health and Human Services’ Inspector General’s Office, the watchdog agency for the Centers for Medicare and Medicaid Services.

### **ODYSSEY MANAGEMENT MULLS NEXT STEPS**

In May of 2004, Odyssey Chairman Richard Burnham and CEO David Gasmire were struggling with significant operational issues as well as the challenge of fending off a high-profile article intimating there were ethical issues with their operations. Key issues for them to consider included:

- 1) What, if anything, could Odyssey do to promote a corporate culture where the ethical issues were better balanced with its business objectives? Was a change in leadership needed to signal a new direction in terms of ethical conduct?
- 2) What was the relationship between effectively managing the business to turn a profit and the adherence to ethical concerns? Did meeting the needs of one preclude meeting the needs of the other?
- 3) Where was the line drawn between ethical and unethical practice in the delivery of hospice services? Did adherence to Medicare guidelines constitute ethical behavior? Or were firms such as Odyssey somehow held to a broader standard?

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## **APPENDIX**

### **SELECTED EXCERPTS: ODYSSEY HEALTHCARE CORPORATE CODE OF BUSINESS CONDUCT AND ETHICS**

(April 29, 2004)

**The following are excerpts from Odyssey's Corporate Code of Business conduct and Ethics, as adopted April 29, 2004. For a complete version of this document please refer to the following hyperlink:**

[http://media.corporate-ir.net/media\\_files/NSD/ODSY/cgov/Business\\_Conductupdated.pdf](http://media.corporate-ir.net/media_files/NSD/ODSY/cgov/Business_Conductupdated.pdf)

### **Under "General Policy"**

Along with legal compliance, all Associates should observe high standards of business and personal ethics when performing assigned duties. This requires using honesty and integrity when dealing with other Company Associates, the public, the business community, stockholders, patients and their families, suppliers and governmental and regulatory authorities.

***Fraud and Abuse Laws.*** All Associates shall refrain from conduct that may violate fraud and abuse laws. These laws prohibit:

- direct, indirect or disguised payments in exchange for the referral of business or patients;
- the submission of false, fraudulent or misleading claims, including claims for services not rendered, claims which characterize the service differently than the service actually rendered, or claims which do not otherwise comply with applicable program or contractual requirements; and
- making false representations to any person or entity in order to gain or retain participation in a program or to obtain payment for any service.

### **Quality of Services**

Each Employee must provide high quality services in the performance of their responsibilities for the Company. Patients and other individuals in the Company's care have a fundamental right to considerate care in a manner that safeguards their personal dignity and respects their cultural values. It is the right of such individuals to receive accurate and timely information regarding their health, diagnosis, prognosis and information necessary to make informed decisions and choices regarding treatment.

# *Teaching Case*

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## **Journal of Applied Case Research**

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### **A New Day Dawns for Vietnamese FDI**

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Accepted: April 2007

#### INTRODUCTION

On February 28<sup>th</sup>, 2006 Intel Corporation announced its decision to invest \$300 million to create a semiconductor assembly and testing facility in Vietnam. Intel Chairman Craig Barrett while in Ho Chi Minh City (formerly known as Saigon) stated, “We applaud the progress the country has made in building up their technology

infrastructure and support of education programs to advance the capabilities of the local workforce.”

The Intel investment represents the largest U.S. non-oil investment in Vietnam. Prior U.S. investment had mainly been in low-tech manufacturing such as shoes, food processing and textiles. Vietnam has experienced a sizable, ongoing increase in FDI in recent years, and political leaders hope to expand an economy and improve living standards shattered by wars and poor prior economic performance. While Vietnam has a number of attractive features to foreign investors, some analysts question the desirability of investing in a country that has only recently experienced political stability and economic freedom.

## VIETNAM

Located in Southeast Asia, **(Exhibit 1)** Vietnam has attracted the attention of Western governments since at least the 19<sup>th</sup> Century. In 1858 the French colonized Vietnam. After internal fighting in an eight-year war, the French signed the Geneva Agreement in 1954 which led to their withdrawal from the country and the division of Vietnam into the communist north and noncommunist south. The Geneva Agreement required elections to be held for unification, however, the government in the south refused to participate and proclaimed itself the Republic of Vietnam. Armed conflict between the communist north and noncommunist south started shortly thereafter and intensified as the decade progressed.

U.S. involvement commenced in 1961 as President Kennedy sent U.S. military advisors to Vietnam. In 1965 President Johnson sent military combat forces to Vietnam. The war in Vietnam escalated, and without a clear sign of victory the American public grew increasingly tired of the conflict. In 1973 a peace agreement was reached and the U.S. withdrew its military forces. Within two years the communist government from the north invaded the south and unified the country into the Socialist Republic of Vietnam. Many Americans felt the United States had lost the war in Vietnam and still harbor negative views and sentiments about the country.

With its population and economy suffering under the strains of a socialist economic system, the Communist Party of Vietnam - the only political party permitted in the country - instituted a program of economic liberalizations and structural reforms in 1986. The program, referred to as *doi moi* (renovation) signaled the country was ready to move towards a market economy.

The cornerstone of the *doi moi* was an export-led economic growth strategy, a strategy that had already been pursued with reasonable success by the so-called “Asian Tigers.” Vietnam sought to position itself as a lower cost location than countries such as Taiwan, Hong Kong and Singapore for targeted manufacturing and assembly operations. Under the *doi moi* economic sectors and industries with potential for significant export growth were targeted and given preferential treatment in the forms of tax breaks and subsidies. Foreign investment was steered to the preferential sectors to provide the capital necessary to support expansion. Finally, Vietnam instituted a controlled, fixed exchange rate policy designed to maintain an undervalued currency in order to promote exports.

While the country has moved towards a market economy, Vietnam still remains a communist country. The Propaganda and Training Department still controls newspapers, books, and even tourism companies to insure that the political ideology of the communist party is maintained.

Although the government of Vietnam is still communist, the economy has become more capitalistic. The government, however, still maintains significant control over the economy and operates many state-owned enterprises. The Propaganda and Training Department continues to control newspapers, books, and even tourism companies to ensure the political ideology of the communist party remains intact. Government bureaucracy and corruption are seen as impediments to further economic growth.

## FDI AND ECONOMIC OPPORTUNITIES IN VIETNAM

In the late 1980s foreign investment began to flow into Vietnam as economic liberalization began to take shape. Lured by the prospects of cheap labor and untapped markets for consumer and industrial goods, foreign investors made their way to Vietnam in hopes of finding a new “Asian Tiger.” The initial inflow of foreign capital was motivated by economic reform (*doi moi*) and the prospects of an underdeveloped market. Vietnam also benefited from a trend in FDI being directed towards emerging markets and increased intra-regional investment and trade in Southeast Asia. The enthusiasm for FDI in Vietnam, however, didn’t last long, as communist bureaucracy and corruption began to make the country a less attractive market. Many early investors retreated from Vietnam and FDI peaked in 1996. The Asian financial crisis of 1997 further dampened foreign investor interest. Subsequent to the liberalization of the economy, Vietnam began to experience significant inflows of foreign direct investment and rapid economic growth. Real GDP expanded at a robust 9.00 percent annual rate from 1993 to 1997. Per capita income more than doubled, rising from about \$810 in 1987 to roughly \$1750 in 1997 (**Exhibit 2**). Many Western companies raced into Vietnam during this period due to its low labor costs, the preferential treatment provided by the government and the view that Vietnam was an untapped market for industrial and consumer goods. With the sudden drop in foreign investment in 1997, Vietnamese leaders knew a different direction in policy was needed.

Vietnam responded to the problems experienced by foreign investors and made some necessary changes. These changes re-affirmed its commitment to economic liberalization and international integration, and allowed it to become a member of the ASEAN Free Trade Area. In December, 2001 Vietnam signed a bilateral trade agreement with the United States and started the process of applying for membership in the World Trade Organization. Once again, FDI has begun to make its way back into Vietnam. With rising labor costs in China, increased trade agreements with the United States and the EU, and the expected entry into the World Trade Organization (WTO), Vietnam attracted foreign investment at record rates. By the end of 2004, Vietnam had over 5,000 FDI projects, worth more than \$46 billion. Vietnam attracted a record \$1.3 billion in FDI in the first two months of 2006. Vietnam in 2005 attracted more FDI, as a percent of GDP, than China and appeared to have reversed the investment decline (**Exhibit 3**).

Economic growth has also accelerated in Vietnam. After slowing to an annual growth rate of less than 7.00 percent from 1998 to 2004, real GDP advanced by about 8.00 percent in 2005. Per capita income reached \$3,000. Moreover, there are a number of reasons to expect economic growth, per capita income and FDI to continue to expand in coming years. Factory workers in Vietnam earn on average \$55 a month and are considered to be hardworking and dedicated employees. Vietnam has a young population, with two-thirds of its 84 million inhabitants in the prime working ages of 16 to 64. It has a literacy rate of 96%, and a growing middle class. English is favored as a second language providing an advantage to global commerce. Vietnam also offers lower production costs, not only due to low labor rates, but also because of additional lower operating costs including land, rents, and shipping expenses.

International investors consider Vietnam's political environment to be an increasingly stable one. Although Vietnam has a communist form of government, it has provided stability, unlike its neighbor Thailand which experienced a bloodless coup in September, 2006 and announced plans to put in place capital and foreign ownership controls. Vietnam has not suffered from the internal Islamic terrorist attacks which have occurred in Thailand and the Philippines. Vietnam also offers an attractive alternative to firms who seek to diversify their supply sources in the region. These and other factors have prompted A.T. Kearney, the international consulting firm, to rank Vietnam twentieth of the top twenty-five countries in its *2004 Offshore Location Attractiveness Index*. Kearney's index ranked Vietnam the second highest, trailing only India, in categories such as compensation costs, infrastructure costs, and tax and regulatory costs. However, Kearney's index placed Vietnam at the low range of the rankings in categories related to people skills and availability, and business environment. According to the Kearney Index Vietnam's attractiveness ranked it ahead of countries such as Russia, Spain and Ireland but behind countries such as Malaysia, Thailand and the Philippines (**Exhibit 4**).

The decision by Intel to invest in Vietnam is seen by some as confirmation that Vietnam has arrived as a major international player in the global sourcing game. Intel chose Vietnam over Thailand, the Philippines, Malaysia, and China mainly due to its low production costs. As Chairman Barrett stated, when responding to why Intel chose Vietnam, "Cost is always a driving force." Intel continues to operate manufacturing facilities in China, Malaysia, the Philippines, and Costa Rica. It appears likely that Intel will continue to invest in Vietnam. According to Barrett, "We consider this to be a small step in a long journey of involvement in Vietnam."

Intel is not the only large, multi-national technology company showing interest in Vietnam. Canon is building a manufacturing plant in Vietnam to produce ink jet printers and Fujitsu is already producing circuit boards for personal computers and telephones in the country. Nidec plans to build two plants to manufacture electronic components, and Sparton of Michigan, from the United States, makes chemical diagnostic equipment in Vietnam. Intel's facility will be located in the Saigon High Tech Park in Ho Chi Minh City, where a number of foreign software firms are currently operating.

## CHALLENGES

While it appears that Vietnam may have a new day dawning for foreign investment, the country still has a number of difficulties that may make the future less certain. Vietnam remains a one-party communist country, and some of the problems that early investors experienced still are present. Although the country has become more capitalistic the government maintains significant control over the economy and operates many state-owned enterprises. Corruption and government bureaucracy continue to be problems, as well as a poor infrastructure, and restrictive laws concerning business operations. The region is also perhaps more vulnerable to an outbreak of the deadly H5N1 (bird flu) virus which is expected to cause economic turmoil, especially in countries ill-prepared for its arrival.

Vietnam imposes export taxes on some products and maintains high import tariffs on products that the government desires to be produced locally. Both export and import taxes have been reduced or eliminated in recent years, however, the government has a history of making policy changes quickly in order to achieve its objectives in international trade. The government maintains tight control over FDI, and this regulation is fragmented and sometimes ambiguous. Vietnam still is a developing country and its rule of law is considered weak by many observers. Vietnam ranks 99<sup>th</sup> out of 155 countries tracked by the World Bank in terms of the ease of doing business. Particular concerns include restrictions on hiring and firing employees, protection of foreign assets, and contract enforcement. The Fraser Institute, in its *Economic Freedom of the World, 2003* report ranked Vietnam 103<sup>rd</sup> of 127 countries – the lowest of all evaluated Southeast Asian nations except Myanmar. The Fraser Institute scored Vietnam low in areas related to the size of government, security of property rights, and access to sound money but considerably higher in categories dealing with freedom to trade internationally and regulation of credit, labor and business. Vietnam must continue to compete with other countries in the region in order to attract foreign investment. Compared to Thailand, for example, Vietnam is considered to be more corrupt, maintains more restrictions on foreign investment, and has a weaker rule of law and contract enforcement, a weaker currency, and a less desirable quality of life for expatriate managers.

## DISCUSSION QUESTIONS:

1. Compare the attractiveness of Vietnam (as a host country for FDI) with other Southeast Asian nations. What factors make it more and less attractive compared to other Southeast Asian nations?
2. Do some types of FDI in Vietnam make more sense than others for international investors?
3. Case Exhibit 2 presents information on GDP in Vietnam measured by the Purchasing Power Parity method and also using the Official Exchange Rate. Using Purchasing Power Parity GDP is about \$253 billion for 2005 while it is only about \$45 billion when the Official Exchange Rate is used to measure

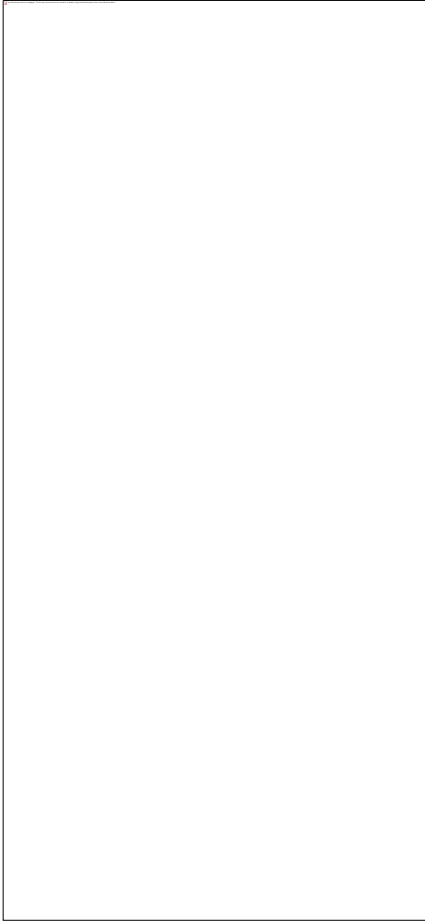


GDP. What could account for such a wide disparity in the measure of GDP for Vietnam?

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**EXHIBIT 1**  
**MAP of VIETNAM**



**MAP OF SOUTHEAST ASIA**



**Source: Reproduced from CIA FACTBOOK**

## EXHIBIT 2

### Demographic, Economic, Political Information for Vietnam, Cambodia, Singapore and Thailand

<b>COUNTRY</b>	<b>Vietnam</b>	<b>Cambodia</b>	<b>Thailand</b>	<b>Singapore</b>
<b>CATEGORY</b>				
<u>Demographic</u>				
Population (millions)	84.4	13.8	65	4.5
Growth Rate (%)	1.8	1.0	0.7	1.4
Male/Female (%)	59/41	49/51	50/50	50/50
Age Structure (%)				
0-14	27	36	22	16
15-64	67	61	70	76
.>65	3	6	8	8
Life Expectancy at birth (yrs.)	59	71	72	82
<u>Labor</u>				
Labor Force (millions)	45	7	36	2.4
Sector Employment (%)				
Agriculture	57	75	49	0
Industry	37	NA	14	36
Services	6	NA	37	64
Unemployment Rate	2.0	2.5	2.1	3.1
Literacy (% 15+ can read & write)	90	74	93	93
<u>Economy</u>				
GDP (USD billions) <sup>1</sup>	259	37	586	139
GDP (USD billions)	48.3	5.1	197	122
Growth Rate (%)	7.8	5.8	4.4	7.4
GDP per Capita (USD)	3,100	2,600	9,100	30,900
GDP by Sector (%)				
Agriculture	20	35	10	0
Industry	42	30	45	34
Services	38	35	29	66
Investment (% GDP)	33	19	29	22
Inflation Rate (%)	8	5	5	1

<sup>1</sup> The first measure of GDP uses the Purchasing Power Parity (PPP) method; the second measure uses the Official Exchange Rate. GDP per capita is based on PPP.

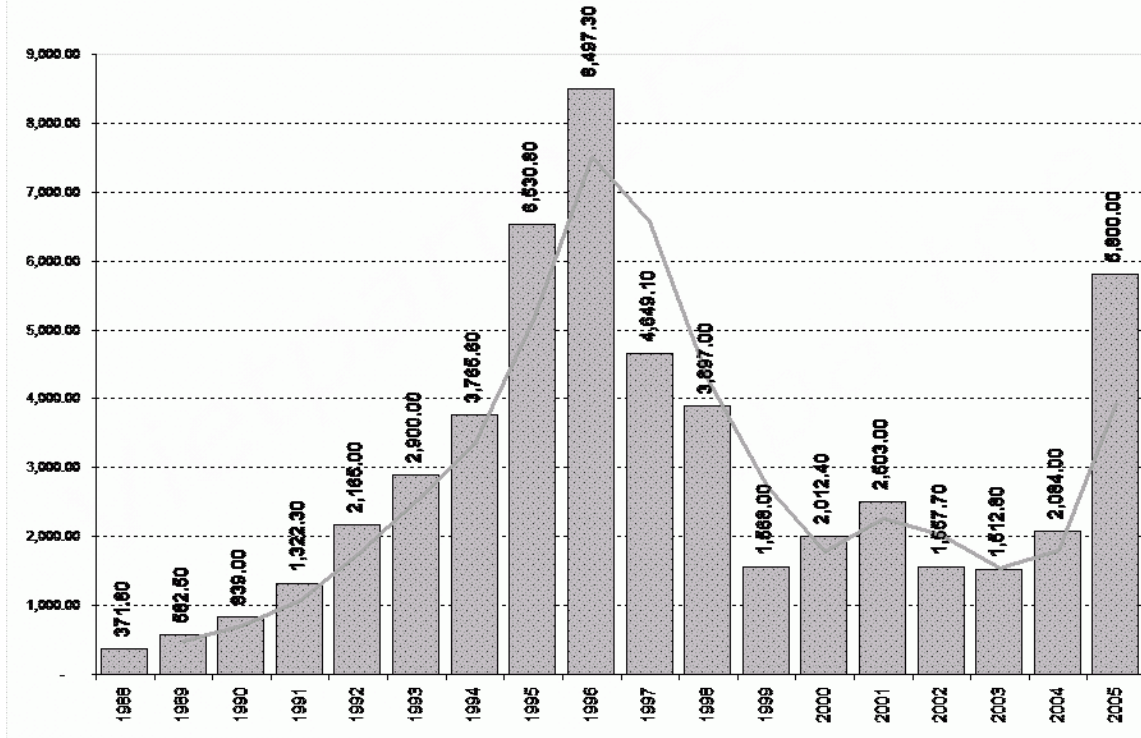
**EXHIBIT 2, CONTINUED**

<b>COUNTRY</b>	<b>Vietnam</b>	<b>Cambodia</b>	<b>Thailand</b>	<b>Singapore</b>
<b>CATEGORY</b>				
<b><u>Political</u></b>				
<b>Government Type</b>	Communist	Multiparty Democracy	Constitutional Monarchy	Parliamentary Republic
<b>Legal System</b>	Communist & French Civil Law	Civil Law	Civil Law	Based on English Common Law
<b>Number Political Parties</b>	1	4	5	4
<b>Government Revenues (USD)</b>	15.4 billion	.73 billion	40.3 billion	19.7 billion
<b>Government Expenditures (USD)</b>	16.6 billion	.93 billion	40.3 billion	19.9 billion
<b><u>International Trade</u></b>				
<b>Currency</b>	Dong	Riel	Baht	Singapore Dollar
<b>Currency per USD (2006-2002)</b>	16,037 – 15,280	4,119-3912	38.2-42.96	1.595-1.79
<b>Exports (USD billions)</b>	40	3.3	124	284
<b>Imports (USD billions)</b>	39	4.5	119	246
<b>Major Exports</b>	oil marine products rice coffee	clothing timber rubber rice	textiles footwear fishing products jewelry	machinery & equipment consumer goods chemicals mineral fuels
<b>Export Partners</b>	U.S. Japan China	U.S. Hong Kong Germany	U.S. Japan China	Malaysia U.S. Indonesia
<b>Imports</b>	machinery petroleum products fertilizers steel products	petroleum gold machinery motor vehicles	capital goods consumer goods fuels raw materials	machinery & equip. mineral fuels chemicals foodstuffs
<b>Import Partners</b>	China Singapore Taiwan	Hong Kong China France	Japan China U.S.	Malaysia U.S. China

Source: CIA World Fact Book

### EXHIBIT 3 FDI Vietnam

FDI Registered Capital 1998 - 2005 (mil. \$US)

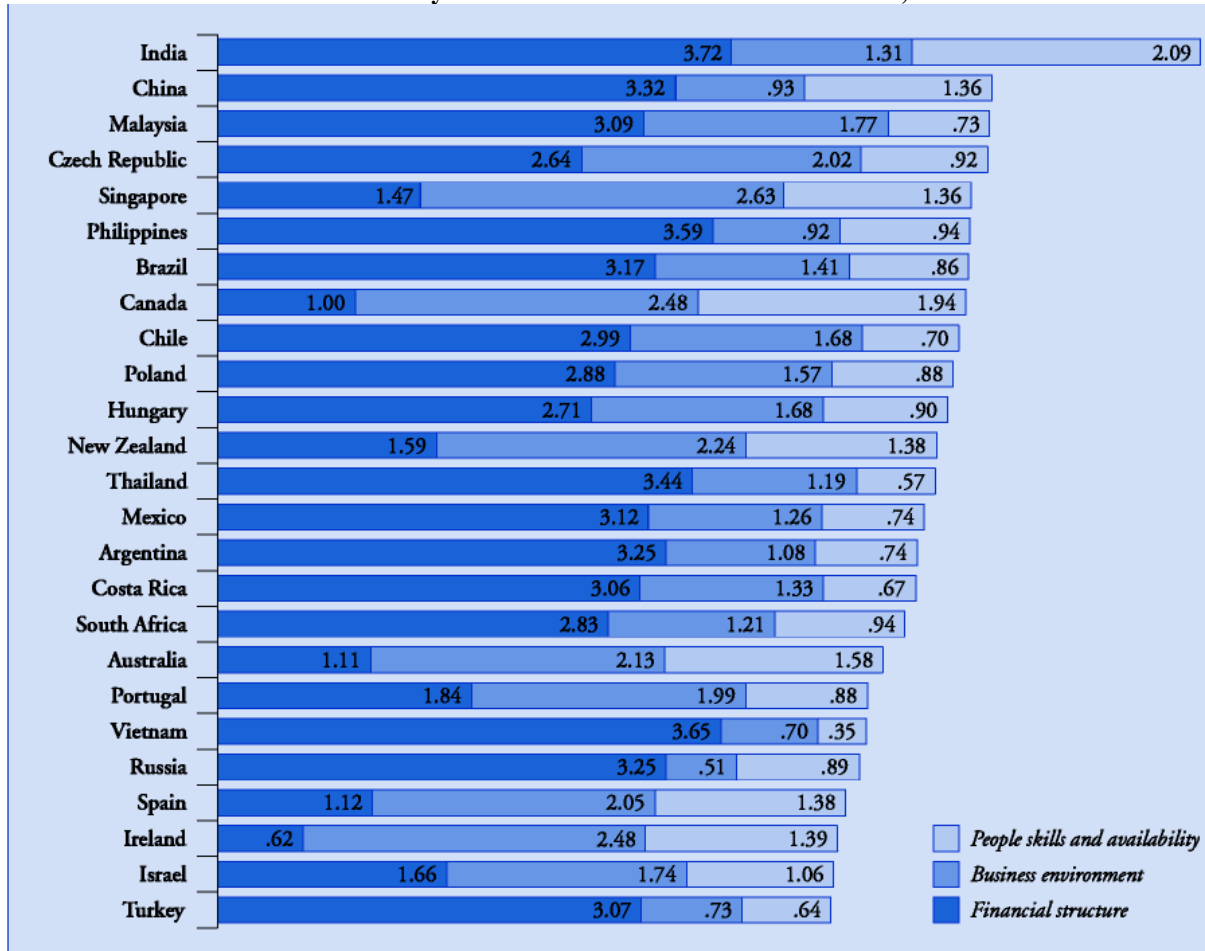


Source: Vietpartners.com

Note: The numbers in the bars are index numbers. The weight distribution for the three categories is 40:30:30, meaning that financial structure is rated on a scale of 1 to 4 and that business environment and people skill and availability are on a scale of 1 to 3.

Source: A.T. Kearney

**EXHIBIT 3**  
**A.T. Kearney Offshore Location Attractiveness Index, 2004**



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**Columbia Medical Center  
and the  
Cocaine-Addicted Pharmacist**

Charles M. Carson, Samford University  
Alan R. Spies, Samford University  
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## **Columbia Medical Center and the Cocaine-Addicted Pharmacist**

### **INTRODUCTION**

Carmen Estrada had seen a lot of eye opening events in her time as Human Resources Director at the Columbia Medical Center – East hospital in El Paso, TX, none of which had prepared her for handling Tom Zenor. As she looked through his personnel file she wondered how Tom went from a promising young pharmacist, to cocaine addict, to possibly suing his employer for alleged Americans With Disabilities Act (ADA) violations.

### **BACKGROUND**

Tom Zenor was hired to work as a pharmacist for Columbia Medical Center-East Hospital in El Paso in 1991. Two years later, in 1993, Zenor was provided a copy of the Hospital's Drug Free/Alcohol-Free Workplace Policy. Another interesting fact occurred later in 1993; Tom Zenor became addicted to cocaine.

As Estrada continued to peruse Zenor's personnel file she recalled several key incidents that led to Zenor's dismissal. During his first three years with Columbia, Zenor had positive yearly performance evaluations. That changed with his evaluation for the 1994 year (year ended July 8, 1994). The results of this evaluation were not discussed with Zenor until October of 1994. The 1994 evaluation revealed performance that was below average. This rating resulted in Zenor being placed on a two month probation. Zenor's pharmacy director, Eduardo Ramirez had a brief discussion with Zenor about his performance evaluation and probationary situation. Ramirez informed Tom that if his performance did not significantly improve over the next two months of the probationary period, he was running a real risk of being discharged. Zenor acknowledged the need for improved performance and subsequently successfully completed the two month probationary period.

The threat of discharge, however, did not stop Zenor from his cocaine use. Zenor left the pharmacy on the morning of August 15, 1995 after working the night shift and injected himself with cocaine. Later the same day, Zenor was preparing to return to work but he experienced dizziness and had trouble walking. Zenor then phoned the pharmacy director, Ramirez, with the news that he was not feeling well and would not be able to work that night. Ramirez questioned Zenor about the reason for his absence and he got the shocking reply that Zenor had injected himself with cocaine earlier in the day and was not handling it well.

Ramirez held the phone in stunned silence, not sure what to do next. He eventually asked Zenor if he planned on going into the employee assistance program for help with his substance abuse problem. Zenor replied that he needed help to beat his addiction and that he would enter the program. A shaken Ramirez instructed Tom to contact Evelyn Torres, Ramirez's supervisor, with this news. After a phone conversation with Zenor, Torres



advised Tom to contact Tom's personal physician. Zenor was admitted to R.E. Thomason General Hospital for emergency treatment and was transferred to the El Paso Alcohol and Drug Abuse Service Detox Center the next morning. Zenor had no contact with anyone at Columbia Medical Center until August 23, 1995. Surprisingly, no one at the medical center knew where Tom Zenor was or had been for eight days.

As Carmen came towards the end of Zenor's file she recalled her first conversation with Tom, which was Tom's first contact with any representative or employee of Columbia Medical Center, while he was in the detox center. During the conversation Zenor informed Carmen that he was about to get out of detox but that his doctors and counselors wanted him to transfer to a rehab center and enter a program. Tom then asked if his job would be safe until he was able to return to work.

Carmen informed Zenor that his job would be safe until he completed his rehabilitation program. She also informed Tom that he was eligible for a twelve week leave of absence under the Family Medical Leave Act (FMLA).

Carmen looked at Tom's FMLA paperwork in his file. She also read a note in the file that Tom had checked into Landmark Adult Intensive Residential Services Center following his stay in detox, which was not affiliated with the Hospital's employee assistance program.

During Tom's stay at Landmark, Carmen, Eduardo and other hospital administrators and lawyers met and discussed the Zenor situation. They believed that terminating Tom was the best thing for the hospital and pharmacy to do, due in no small part to the availability of pharmaceutical cocaine in the hospital's pharmacy. However, they also knew that they were opening up the possibility for Tom to sue the hospital. The decision was made to terminate Tom at the end of his twelve week FMLA leave.

### **AMERICANS WITH DISABILITIES ACT**

In discussing the potential lawsuit they thought about which claims Zenor might make against the hospital. The area about which they were most concerned was the Americans with Disabilities Act (ADA) and whether or not a court would consider Tom's cocaine addiction a disability. If it was considered a disability, Columbia was likely in a great deal of legal hot water.

From various training seminars and her years of experience Carmen knew some key elements of the ADA that would likely be addressed in a potential suit by Zenor. First, she knew that Title I of the ADA only protected *qualified* individuals from employment discrimination. While Tom Zenor was certainly a qualified, licensed pharmacist when he was hired, there was some question in her mind as to whether or not he was still qualified. She made a note of this and continued to think about some other key areas of the ADA.

Carmen recalled that the ADA provided a specific definition of what is considered a disability. However, she was frustrated that she could not remember the specifics of that definition. Carmen recalled that she had attended an ADA seminar and quickly found her notes from the seminar. Those notes stated that the Equal Opportunity Employment Commission (EEOC) had defined “major life activities as caring for one’s self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working” (EEOC/Robinson et al., 2002: 168). She felt good about that definition until the last word; “working.”

In Carmen’s mind, something was missing. She kept thinking that there was something in the ADA that addressed drug use and rehabilitation programs. However, she could not find any quick answers in any of her training materials. Tired of searching for a needle in a haystack, Carmen pulled out her copy of the ADA (Exhibit 1) and began reading, searching, and hoping to find something that they could use to protect Columbia from the lawsuit that was likely to come.

**EXHIBIT 1**

Source: <http://www.usdoj.gov/crt/ada/pubs/ada.txt>

Exhibit 1 contains excerpts from Title I of the Americans With Disabilities Act of 1990

AMERICANS WITH DISABILITIES ACT of 1990

S. 933

One Hundred First Congress of the United States of America  
AT THE SECOND SESSION  
Begun and held at the City of Washington on Tuesday, the twenty-third day of January, one thousand nine hundred and ninety

An Act

To establish a clear and comprehensive prohibition of discrimination on the basis of disability.

=====

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) Short Title.--This Act may be cited as the "Americans with Disabilities Act of 1990".

(b) Table of Contents.--The table of contents is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings and purposes.
- Sec. 3. Definitions.

TITLE I--EMPLOYMENT

- Sec. 101. Definitions.
- Sec. 102. Discrimination.
- Sec. 103. Defenses.
- Sec. 104. Illegal use of drugs and alcohol.
- Sec. 105. Posting notices.
- Sec. 106. Regulations.
- Sec. 107. Enforcement.
- Sec. 108. Effective date.

SEC. 2. FINDINGS AND PURPOSES.

(a) Findings.--The Congress finds that--

(1) some 43,000,000 Americans have one or more physical or mental disabilities, and this number is increasing as the population as a whole is growing older;

(2) historically, society has tended to isolate and segregate individuals with disabilities, and, despite some improvements, such forms of discrimination against individuals with disabilities continue to be a serious and pervasive social problem;

(3) discrimination against individuals with disabilities persists in such critical areas as employment, housing, public accommodations, education, transportation, communication, recreation, institutionalization, health services, voting, and access to public services;

(4) unlike individuals who have experienced discrimination on the basis of race, color, sex, national origin, religion, or age, individuals who have experienced discrimination on the basis of disability have often had no legal recourse to redress such discrimination;

(5) individuals with disabilities continually encounter various forms of discrimination, including outright intentional exclusion, the discriminatory effects of architectural, transportation, and communication barriers, overprotective rules and policies, failure to make modifications to existing facilities and practices, exclusionary qualification standards and criteria, segregation, and relegation to lesser services, programs, activities, benefits, jobs, or other opportunities;

(6) census data, national polls, and other studies have documented that people with disabilities, as a group, occupy an inferior status in our society, and are severely disadvantaged socially, vocationally, economically, and educationally;

(7) individuals with disabilities are a discrete and insular minority who have been faced with restrictions and limitations, subjected to a history of purposeful unequal treatment, and relegated to a position of political powerlessness in our society, based on characteristics that are beyond the control of such individuals and resulting from stereotypic assumptions not truly indicative of the individual ability of such individuals to participate in, and contribute to, society;

(8) the Nation's proper goals regarding individuals with disabilities are to assure equality of opportunity, full participation, independent living, and economic self-sufficiency for such individuals; and

(9) the continuing existence of unfair and unnecessary discrimination and prejudice denies people with disabilities the opportunity to compete on an equal basis and to pursue those opportunities for which our free society is justifiably famous, and costs the United States billions of dollars in unnecessary expenses resulting from dependency and nonproductivity.

(b) Purpose.--It is the purpose of this Act--

(1) to provide a clear and comprehensive national mandate for the elimination of discrimination against individuals with disabilities;

(2) to provide clear, strong, consistent, enforceable standards addressing discrimination against individuals with disabilities;

(3) to ensure that the Federal Government plays a central role in enforcing the standards established in this Act on behalf of individuals with disabilities; and

(4) to invoke the sweep of congressional authority, including the power to enforce the fourteenth amendment and to regulate commerce, in order to address the major areas of discrimination faced day-to-day by people with disabilities.

### SEC. 3. DEFINITIONS.

As used in this Act:

(1) Auxiliary aids and services.--The term "auxiliary aids and services" includes--

(A) qualified interpreters or other effective methods of making aurally delivered materials available to individuals with hearing impairments;

(B) qualified readers, taped texts, or other effective methods of making visually delivered materials available to individuals with visual impairments;

(C) acquisition or modification of equipment or devices;

and

(D) other similar services and actions.

(2) Disability.--The term "disability" means, with respect to an individual--

(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual;

(B) a record of such an impairment; or

(C) being regarded as having such an impairment.

(3) State.--The term "State" means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, American Samoa, the Virgin Islands, the Trust Territory of the Pacific Islands, and the Commonwealth of the Northern Mariana Islands.

### SEC. 101. DEFINITIONS.

As used in this title:

(1) Commission.--The term "Commission" means the Equal Employment Opportunity Commission established by section 705 of the Civil Rights Act of 1964 (42 U.S.C. 2000e-4).

(2) Covered entity.--The term "covered entity" means an employer, employment agency, labor organization, or joint labor-management committee.

(3) Direct threat.--The term "direct threat" means a significant risk to the health or safety of others that cannot be eliminated by reasonable accommodation.

(4) Employee.--The term "employee" means an individual employed by an employer.

(5) Employer.--

(A) In general.--The term "employer" means a person engaged in an industry affecting commerce who has 15 or more employees for each working day in each of 20 or more calendar weeks in the current or preceding calendar year, and any agent of such person, except that, for two years following the effective date of this title, an employer means a person engaged in an industry affecting commerce who has 25 or more employees for each working day in each of 20 or more calendar weeks in the current or preceding year, and any agent of such person.

(B) Exceptions.--The term "employer" does not include--

(i) the United States, a corporation wholly owned by the government of the United States, or an Indian tribe; or

(ii) a bona fide private membership club (other than a labor organization) that is exempt from taxation under section 501(c) of the Internal Revenue Code of 1986.

(6) Illegal use of drugs.--

(A) In general.--The term "illegal use of drugs" means the use of drugs, the possession or distribution of which is unlawful under the Controlled Substances Act (21 U.S.C. 812). Such term does not include the use of a drug taken under supervision by a licensed health care professional, or other uses authorized by the Controlled Substances Act or other provisions of Federal law.

(B) Drugs.--The term "drug" means a controlled substance, as defined in schedules I through V of section 202 of the Controlled Substances Act.

(7) Person, etc.--The terms "person", "labor organization", "employment agency", "commerce", and "industry affecting commerce", shall have the same meaning given such terms in section 701 of the Civil Rights Act of 1964 (42 U.S.C. 2000e).

(8) Qualified individual with a disability.--The term "qualified individual with a disability" means an individual with a disability who, with or without reasonable accommodation, can perform the essential functions of the employment position that such individual holds or desires. For the purposes of this title, consideration shall be given to the employer's judgment as to what functions of a job are essential, and if an employer has prepared a written description before advertising or interviewing applicants for the job, this description shall be considered evidence of the essential functions of the job.

(9) Reasonable accommodation.--The term "reasonable accommodation" may include--

(A) making existing facilities used by employees readily accessible to and usable by individuals with disabilities; and

(B) job restructuring, part-time or modified work schedules, reassignment to a vacant position, acquisition or modification of equipment or devices, appropriate adjustment or modifications of examinations, training materials or policies, the provision of qualified readers or interpreters, and other similar accommodations for individuals with disabilities.

(10) Undue hardship.--

(A) In general.--The term "undue hardship" means an action requiring significant difficulty or expense, when considered in light of the factors set forth in subparagraph (B).

(B) Factors to be considered.--In determining whether an accommodation would impose an undue hardship on a covered entity, factors to be considered include--

(i) the nature and cost of the accommodation needed under this Act;

(ii) the overall financial resources of the facility or facilities involved in the provision of the reasonable accommodation; the number of persons employed at such facility; the effect on expenses and resources, or the impact otherwise of such accommodation upon the operation of the facility;

(iii) the overall financial resources of the covered entity; the overall size of the business of a covered entity with respect to the number of its employees; the number, type, and location of its facilities; and

(iv) the type of operation or operations of the covered entity, including the composition, structure, and functions of the workforce of such entity; the geographic separateness, administrative, or fiscal relationship of the facility or facilities in question to the covered entity.

SEC. 102. DISCRIMINATION.

(a) General Rule.--No covered entity shall discriminate against a qualified individual with a disability because of the disability of such individual in regard to job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, and other terms, conditions, and privileges of employment.

(b) Construction.--As used in subsection (a), the term "discriminate" includes--

(1) limiting, segregating, or classifying a job applicant or employee in a way that adversely affects the opportunities or status of such applicant or employee because of the disability of such applicant or employee;

(2) participating in a contractual or other arrangement or relationship that has the effect of subjecting a covered entity's qualified applicant or employee with a disability to the discrimination prohibited by this title (such relationship includes a relationship with an employment or referral agency, labor union, an organization providing fringe benefits to an employee of the covered entity, or an organization providing training and apprenticeship programs);

(3) utilizing standards, criteria, or methods of administration--

(A) that have the effect of discrimination on the basis of disability; or

(B) that perpetuate the discrimination of others who are subject to common administrative control;

(4) excluding or otherwise denying equal jobs or benefits to a qualified individual because of the known disability of an individual with whom the qualified individual is known to have a relationship or association;

(5)(A) not making reasonable accommodations to the known physical or mental limitations of an otherwise qualified individual with a disability who is an applicant or employee, unless such covered entity can demonstrate that the accommodation would impose an undue hardship on the operation of the business of such covered entity; or

(B) denying employment opportunities to a job applicant or employee who is an otherwise qualified individual with a disability, if such denial is based on the need of such covered entity to make reasonable accommodation to the physical or mental impairments of the employee or applicant;

(6) using qualification standards, employment tests or other selection criteria that screen out or tend to screen out an individual with a disability or a class of individuals with disabilities unless the standard, test or other selection criteria, as used by the covered entity, is shown to be job-related for the position in question and is consistent with business necessity; and

(7) failing to select and administer tests concerning employment in the most effective manner to ensure that, when such test is administered to a job applicant or employee who has a disability that impairs sensory, manual, or speaking skills, such test results accurately reflect the skills, aptitude, or whatever other factor of such applicant or employee that such test purports to measure, rather

than reflecting the impaired sensory, manual, or speaking skills of such employee or applicant (except where such skills are the factors that the test purports to measure).

(c) Medical Examinations and Inquiries.--

(1) In general.--The prohibition against discrimination as referred to in subsection (a) shall include medical examinations and inquiries.

(2) Preemployment.--

(A) Prohibited examination or inquiry.--Except as provided in paragraph (3), a covered entity shall not conduct a medical examination or make inquiries of a job applicant as to whether such applicant is an individual with a disability or as to the nature or severity of such disability.

(B) Acceptable inquiry.--A covered entity may make preemployment inquiries into the ability of an applicant to perform job-related functions.

(3) Employment entrance examination.--A covered entity may require a medical examination after an offer of employment has been made to a job applicant and prior to the commencement of the employment duties of such applicant, and may condition an offer of employment on the results of such examination, if--

(A) all entering employees are subjected to such an examination regardless of disability;

(B) information obtained regarding the medical condition or history of the applicant is collected and maintained on separate forms and in separate medical files and is treated as a confidential medical record, except that--

(i) supervisors and managers may be informed regarding necessary restrictions on the work or duties of the employee and necessary accommodations;

(ii) first aid and safety personnel may be informed, when appropriate, if the disability might require emergency treatment; and

(iii) government officials investigating compliance with this Act shall be provided relevant information on request; and

(C) the results of such examination are used only in accordance with this title.

(4) Examination and inquiry.--

(A) Prohibited examinations and inquiries.--A covered entity shall not require a medical examination and shall not make inquiries of an employee as to whether such employee is an individual with a disability or as to the nature or severity of the disability, unless such examination or inquiry is shown to be job-related and consistent with business necessity.

(B) Acceptable examinations and inquiries.--A covered entity may conduct voluntary medical examinations, including voluntary medical histories, which are part of an employee health program available to employees at that work site. A covered entity may make inquiries into the ability of an employee to perform job-related functions.

(C) Requirement.--Information obtained under subparagraph (B) regarding the medical condition or history of any employee are subject to the requirements of subparagraphs (B) and (C) of paragraph (3).

SEC. 103. DEFENSES.



(a) In General.--It may be a defense to a charge of discrimination under this Act that an alleged application of qualification standards, tests, or selection criteria that screen out or tend to screen out or otherwise deny a job or benefit to an individual with a disability has been shown to be job-related and consistent with business necessity, and such performance cannot be accomplished by reasonable accommodation, as required under this title.

(b) Qualification Standards.--The term "qualification standards" may include a requirement that an individual shall not pose a direct threat to the health or safety of other individuals in the workplace.

(c) Religious Entities.--

(1) In general.--This title shall not prohibit a religious corporation, association, educational institution, or society from giving preference in employment to individuals of a particular religion to perform work connected with the carrying on by such corporation, association, educational institution, or society of its activities.

(2) Religious tenets requirement.--Under this title, a religious organization may require that all applicants and employees conform to the religious tenets of such organization.

(d) List of Infectious and Communicable Diseases.--

(1) In general.--The Secretary of Health and Human Services, not later than 6 months after the date of enactment of this Act, shall--

(A) review all infectious and communicable diseases which may be transmitted through handling the food supply;

(B) publish a list of infectious and communicable diseases which are transmitted through handling the food supply;

(C) publish the methods by which such diseases are transmitted; and

(D) widely disseminate such information regarding the list of diseases and their modes of transmissibility to the general public.

Such list shall be updated annually.

(2) Applications.--In any case in which an individual has an infectious or communicable disease that is transmitted to others through the handling of food, that is included on the list developed by the Secretary of Health and Human Services under paragraph (1), and which cannot be eliminated by reasonable accommodation, a covered entity may refuse to assign or continue to assign such individual to a job involving food handling.

(3) Construction.--Nothing in this Act shall be construed to preempt, modify, or amend any State, county, or local law, ordinance, or regulation applicable to food handling which is designed to protect the public health from individuals who pose a significant risk to the health or safety of others, which cannot be eliminated by reasonable accommodation, pursuant to the list of infectious or communicable diseases and the modes of transmissibility published by the Secretary of Health and Human Services.

#### SEC. 104. ILLEGAL USE OF DRUGS AND ALCOHOL.

(a) Qualified Individual With a Disability.--For purposes of this title, the term "qualified individual with a disability" shall not include any employee or applicant who is currently engaging in the illegal use of drugs, when the covered entity acts on the basis of such use.

(b) Rules of Construction.--Nothing in subsection (a) shall be construed to exclude as a qualified individual with a disability an individual who--

(1) has successfully completed a supervised drug rehabilitation program and is no longer engaging in the illegal use of drugs, or has otherwise been rehabilitated successfully and is no longer engaging in such use;

(2) is participating in a supervised rehabilitation program and is no longer engaging in such use; or

(3) is erroneously regarded as engaging in such use, but is not engaging in such use; except that it shall not be a violation of this Act for a covered entity to adopt or administer reasonable policies or procedures, including but not limited to drug testing, designed to ensure that an individual described in paragraph (1) or (2) is no longer engaging in the illegal use of drugs.

(c) Authority of Covered Entity.--A covered entity--

(1) may prohibit the illegal use of drugs and the use of alcohol at the workplace by all employees;

(2) may require that employees shall not be under the influence of alcohol or be engaging in the illegal use of drugs at the workplace;

(3) may require that employees behave in conformance with the requirements established under the Drug-Free Workplace Act of 1988 (41 U.S.C. 701 et seq.);

(4) may hold an employee who engages in the illegal use of drugs or who is an alcoholic to the same qualification standards for employment or job performance and behavior that such entity holds other employees, even if any unsatisfactory performance or behavior is related to the drug use or alcoholism of such employee; and

(5) may, with respect to Federal regulations regarding alcohol and the illegal use of drugs, require that--

(A) employees comply with the standards established in such regulations of the Department of Defense, if the employees of the covered entity are employed in an industry subject to such regulations, including complying with regulations (if any) that apply to employment in sensitive positions in such an industry, in the case of employees of the covered entity who are employed in such positions (as defined in the regulations of the Department of Defense);

(B) employees comply with the standards established in such regulations of the Nuclear Regulatory Commission, if the employees of the covered entity are employed in an industry subject to such regulations, including complying with regulations (if any) that apply to employment in sensitive positions in such an industry, in the case of employees of the covered entity who are employed in such positions (as defined in the regulations of the Nuclear Regulatory Commission); and

(C) employees comply with the standards established in such regulations of the Department of Transportation, if the employees of the covered entity are employed in a transportation industry subject to such regulations, including complying with such regulations (if any) that apply to employment in sensitive positions in such an industry, in the case of employees of the covered entity who are employed in such positions (as defined in the regulations of the Department of Transportation).

(d) Drug Testing.--

(1) In general.--For purposes of this title, a test to determine the illegal use of drugs shall not be considered a medical examination.

(2) Construction.--Nothing in this title shall be construed to

encourage, prohibit, or authorize the conducting of drug testing for the illegal use of drugs by job applicants or employees or making employment decisions based on such test results.

(e) Transportation Employees.--Nothing in this title shall be construed to encourage, prohibit, restrict, or authorize the otherwise lawful exercise by entities subject to the jurisdiction of the Department of Transportation of authority to--

(1) test employees of such entities in, and applicants for, positions involving safety-sensitive duties for the illegal use of drugs and for on-duty impairment by alcohol; and

(2) remove such persons who test positive for illegal use of drugs and on-duty impairment by alcohol pursuant to paragraph (1) from safety-sensitive duties in implementing subsection (c).

#### SEC. 105. POSTING NOTICES.

Every employer, employment agency, labor organization, or joint labor-management committee covered under this title shall post notices in an accessible format to applicants, employees, and members describing the applicable provisions of this Act, in the manner prescribed by section 711 of the Civil Rights Act of 1964 (42 U.S.C. 2000e-10).

#### SEC. 106. REGULATIONS.

Not later than 1 year after the date of enactment of this Act, the Commission shall issue regulations in an accessible format to carry out this title in accordance with subchapter II of chapter 5 of title 5, United States Code.

#### SEC. 107. ENFORCEMENT.

(a) Powers, Remedies, and Procedures.--The powers, remedies, and procedures set forth in sections 705, 706, 707, 709, and 710 of the Civil Rights Act of 1964 (42 U.S.C. 2000e-4, 2000e-5, 2000e-6, 2000e-8, and 2000e-9) shall be the powers, remedies, and procedures this title provides to the Commission, to the Attorney General, or to any person alleging discrimination on the basis of disability in violation of any provision of this Act, or regulations promulgated under section 106, concerning employment.

(b) Coordination.--The agencies with enforcement authority for actions which allege employment discrimination under this title and under the Rehabilitation Act of 1973 shall develop procedures to ensure that administrative complaints filed under this title and under the Rehabilitation Act of 1973 are dealt with in a manner that avoids duplication of effort and prevents imposition of inconsistent or conflicting standards for the same requirements under this title and the Rehabilitation Act of 1973. The Commission, the Attorney General, and the Office of Federal Contract Compliance Programs shall establish such coordinating mechanisms (similar to provisions contained in the joint regulations promulgated by the Commission and the Attorney General at part 42 of title 28 and part 1691 of title 29, Code of Federal Regulations, and the Memorandum of Understanding between the Commission and the Office of Federal Contract Compliance Programs dated January 16, 1981 (46 Fed. Reg. 7435, January 23, 1981)) in regulations implementing this title and Rehabilitation Act of 1973 not later than 18 months after the date of enactment of this Act.

#### SEC. 108. EFFECTIVE DATE.

This title shall become effective 24 months after the date of enactment.

# *Teaching Case*

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## **Journal of Applied Case Research**

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### **Procter & Gamble: Country Cost Of Capital**

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## **PROCTER & GAMBLE: COUNTRY COST OF CAPITAL**

In mid-1996, as Procter & Gamble (P&G) continued expanding its business into new regions around the globe, Russell Hughes, P&G's Associate Director for Investment Analysis, was considering a question he had just been asked: "As we are putting more money into non-G7 countries, China, Russia, and so on, why are we not reflecting different hurdle rates?" The questioner was Corporate Treasurer, Chad Delaney, and the outcome was the beginning of discussions between Corporate Finance and Treasury on how to calculate P&G's weighted average cost of capital across countries.

### **BACKGROUND – PROCTER & GAMBLE**

Procter & Gamble (P&G) began as a small, family-operated soap and candle company in 1837. By 1859 sales reached \$1 million, and in 1879 the company developed Ivory Soap. It was incorporated in Cincinnati, Ohio in 1890, by which time it was selling more than thirty different types of soap. In 1996, P&G was manufacturing and marketing some of the world's most recognizable brands, including Tide, Pampers, Bounty, Pantene, Vicks, Pringles, and Crest.

P&G built its first manufacturing facility outside the U.S. in 1915 in Canada and established its first overseas subsidiary in 1930 with the purchase of a soap manufacturer in England (see **Table 1**). Though P&G established an operation in the Philippines in 1935, the internationalization process began in earnest after the Second World War. In 1948, operations began in Mexico and an Overseas Division was established. In 1960, P&G opened its first office in Germany and in 1961 opened one in Saudi Arabia. It began manufacturing and selling in Japan much later, entering the country with an acquisition in 1973. Despite these efforts, P&G still considered itself a domestic company and focused relatively little attention on the global market.

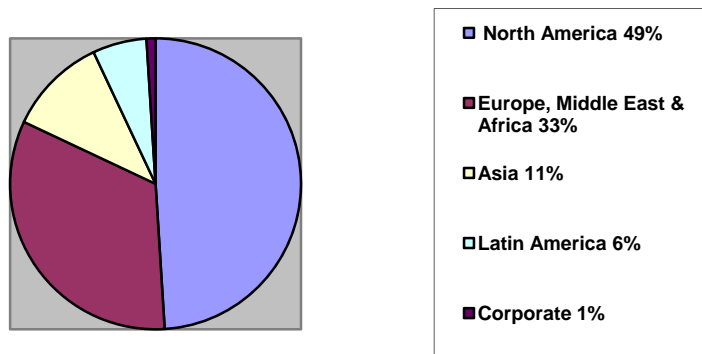
By the 1980s, P&G's strong position in the U.S., the availability of improved transportation and communication technologies, and continued economic growth in foreign markets led senior managers to focus greater attention on international markets. As noted by Hughes, "We needed to be where the world's consumers were," and the U.S. accounted for only 5% of the world's population. Based in part on the success of its Mexican subsidiary, P&G bought a soap business in Brazil and expanded into Colombia, Chile, Peru, and Argentina in the late 1980s and early 1990s. It also expanded its business in Japan and in 1988 started a joint venture to manufacture products in China. In 1991, P&G initiated operations in Eastern Europe – Czechoslovakia, Hungary, and Poland – and Russia.

**TABLE 1: Procter & Gamble (P&G) Entry Into Selected Major Markets**

<b>Year</b>	<b>Region</b>
1915	Canada
1930	United Kingdom
1935	Philippines
1948	Mexico
1950	Venezuela
1954	France
1956	Italy, Peru
1960	Germany
1961	Saudi Arabia
1968	Spain
1973	Japan
1983	Chile
1985	Australia, India, New Zealand, Taiwan
1987	Turkey, Colombia, Central America
1988	China, Brazil
1989	South Korea
1990	Argentina, Ukraine
1991	Russia, Poland, Czechoslovakia, Hungary, Pakistan
1992	Romania
1993	* over 50% of P&G revenues are earned outside the U.S. *
1995	Vietnam

By 1993, P&G’s global sales were greater than \$30 billion, with more than half coming from outside the U.S. The growing importance of P&G’s international sales and desire to help it compete more effectively on a global basis led the company in 1995 to replace its organizational structure. Two regions - U.S. and International – were replaced by four – North America, Latin America, Asia, and Europe/Middle East/Africa – with all four regions reporting to the Chief Operating Officer (see Tables 2 and 3).

**TABLE 2: Net Sales by Geographic Segment\***



\*source: Procter & Gamble Company’s Annual Report, 1996

**TABLE 3: Geographic Segment Information\***

		North America	Europe, Mid. East, and Africa	Asia	Latin America	Corp.	Total
Net Sales	<b>1996</b>	<b>\$17,133</b>	<b>\$11,719</b>	<b>\$3,790</b>	<b>\$2,173</b>	<b>\$ 469</b>	<b>\$35,284</b>
	1995	16,233	11,017	3,617	2,178	437	33,482
	1994	15,164	9,738	3,133	2,250	100	30,385
Net Earnings	<b>1996<sup>1</sup></b>	<b>2,220</b>	<b>767</b>	<b>222</b>	<b>218</b>	<b>(381)</b>	<b>3,046</b>
	1995	1,872	675	199	213	(314)	2,645
	1994	1,713	581	132	157	(372)	2,211
Identifiable Assets	<b>1996</b>	<b>11,894</b>	<b>6,895</b>	<b>2,882</b>	<b>1,445</b>	<b>4,614</b>	<b>27,730</b>
	1995	11,375	7,446	3,311	1,305	4,688	28,125
	1994	10,699	5,576	2,690	1,302	5,268	25,535

<sup>1</sup> Includes a gain on the sale of the Company's share of a health care joint venture: North America - \$120 after tax, Health Care - \$185 before tax.

\*source: Procter & Gamble Company's Annual Report, 1996

### **ESTIMATING THE WEIGHTED AVERAGE COST OF CAPITAL PRIOR TO 1996**

In making investment decisions around the world, P&G relied on weighted average cost of capital (WACC) adjustments that were based on qualitative analyses. Because P&G products had similar risk characteristics, calculating a division or project WACC was not considered necessary. Investments in areas outside the United States were assigned a cost of capital essentially twice the company-wide WACC regardless of geographic region or type of project. Although the process was informal, it did provide a risk premium for international projects that compensated the company for the relative uncertainty of international investment in more volatile areas (see **Tables 4 and 5**).

**TABLE 4: Consolidated Statements of Earnings\***

(Amounts in Millions Except Per Share Amounts)

Years Ended June 30	1996	1995	1994
<b>Net Sales</b>	<b>\$35,284</b>	\$33,482	\$30,385
Cost of products sold	20,762	19,561	17,338
Marketing, research, and administrative expenses	9,707	9,677	9,377
<b>Operating Income</b>	<b>4,815</b>	4,244	3,670
Interest expense	484	488	482
Other income, net	338	244	158
<b>Earnings Before Income Taxes</b>	<b>4,669</b>	4,000	3,346
Incomes taxes	1,623	1,355	1,135
<b>Net Earnings</b>	<b>\$ 3,046</b>	\$ 2,645	\$ 2,211
<b>Net Earnings Per Common Share</b>	<b>\$ 4.29</b>	\$ 3.71	\$ 3.09
<b>Dividends Per Common Share</b>	<b>\$ 1.60</b>	\$ 1.40	\$ 1.24
<b>Average Common Shares Outstanding</b>	<b>686.3</b>	686.0	683.1

\*source: Procter &amp; Gamble Company's Annual Report, 1996

**TABLE 5: Financial Highlights\***

(Millions of Dollars Except Per Share Amounts)

	1996	1995	1994
Net Sales	35,284	33,482	30,385
Operating Income	4,815	4,244	3,670
Net Earnings/(Loss)	3,046	2,645	2,211
Net Earnings Margin	8.6%	7.9%	7.3%
Net Earnings/(Loss) Per Common Share	4.29	3.71	3.09
Dividends Per Common Share	1.60	1.40	1.24
Research and Development Expense	1,221	1,148	964
Advertising Expense	3,254	3,284	2,996
Total Assets	27,730	28,125	25,535
Capital Expenditures	2,179	2,146	1,841
Long-Term Debt	4,670	5,161	4,980
Shareholders' Equity	11,722	10,589	8,832
Cash Flow From Operations	4,158	3,568	3,649

\*source: Procter &amp; Gamble Company's Annual Report, 1996

**NOTE:**

\* P&amp;G's before-tax cost of debt was 8% and its cost of equity capital was 11.5%

\* Debt fair market value as of June 30, 1996 is \$5,014 million; tax rate=35%

\* P&amp;G stock price for 1995-1996 high=\$93.88, low=\$79.38; June 28, 1996 close=\$90.62



Prior to 1996, major innovative financial methodology came from the regions. For example, Michael Brown, Treasurer for Latin America, felt sure that a more specific adjustment to WACC was necessary to reflect the differential risk among the countries in Latin America. As a consequence, in the early 1990s P&G financial managers in Latin America began discussing how to adjust the WACC there to reflect country risk. Of course, managers in the region were not equally enthusiastic about the project; country risk varied greatly in the region, and an adjustment to WACC for country risk would force a higher hurdle rate for some managers than others.

### **CHANGING INVESTMENT OPPORTUNITIES**

Although P&G had operations throughout the world, the traditionally risk-averse company was just beginning to feel the impact of venturing into more volatile markets. Early international investment had been concentrated in relatively stable regions, primarily Mexico, Europe, and Japan. Though Latin America was considered relatively risky, the region in 1993 contributed only seven to eight percent of P&G's earnings, so exposure was relatively modest.

As a result of its initiatives to increase overseas sales in the late 1980s and early 1990s, as well as the increasing realization of risk associated with ventures in Latin America and Eastern Europe, it became clear that new, global markets were offering P&G not only the potential for both greater profits, but also substantial risk.

### **RISK AND THE GLOBAL COST OF CAPITAL: 1996**

Treasury had established working relationships with several investment banks and through these relationships had learned in the early 1990s about new techniques that substantially improved the cost of capital methodology. Delaney, as Corporate Treasurer, was aware of them. But Treasury and Corporate Finance worked independently at P&G so Hughes, as Director for Investment Analysis within Corporate Finance, was not. It was at this point in mid-1996 that Delaney approached Hughes to propose reassessing how P&G determined the country cost of capital. Hughes noted that, "What we realized ... is that there had been a lot of development in financial instruments and so on that had taken place that we just frankly weren't aware of that let us quantify country risk more specifically than we had been able to do when we looked at this several years ago."

Hughes began spending time with Treasury and investment bankers from JP Morgan and Goldman Sachs to learn about quantifying country risk in a more rigorous, mathematical way. Both Goldman Sachs and JP Morgan recommended that P&G develop a more systematic approach to estimating risk premiums for different markets. Dennis Driscoll, who worked for Hughes on the project, recommended using sovereign spreads in the emerging bond market as a proxy for country risk, with the spread defined as the difference between the yield to maturity on a particular country's dollar-denominated bonds and the yields of US-Treasury bonds with comparable maturities. Driscoll knew this was already being done by Latin American financial managers, who had found, for

example, that there might be as much of a differential as 8% on U.S. debt versus 45% or more on Brazilian debt (see **Tables 6 and 7**).

**TABLE 6: Moody's and Standard & Poor's Ratings Symbols for Long-term Debt**

	<b>Investment-Grade Ratings</b>				<b>Speculative-Grade Ratings</b>	
<b>Moody's</b>	Aaa	Aa1	A1	Baa1	Ba1	B1
		Aa2	A2	Baa2	Ba2	B2
		Aa3	A3	Baa3	Ba3	B3
<b>S &amp; P's</b>	AAA	AA+	A+	BBB+	BB+	B+
		AA	A	BBB	BB	B
		AA-	A-	BBB-	BB-	B-

**TABLE 7: Country Risk and Sovereign Credit Ratings, mid-1996**

Country	Sources			
	Institutional Investor Country Credit Rating (March 1996)	Moody's (May 1996)	S&P (May 1996)	Euromoney (March 1996)
Argentina	38.4	B1	BB-	57.24
Belgium	79.5	Aa1	AA+	93.11
Brazil	35.8	B1	B+	55.39
Chile	59.2	Baa1	A-	79.79
China	56.4	A3	BBB	70.81
Colombia	46.7	Baa3	BBB-	62.56
Germany	91.5	Aaa	AAA	96.64
Hong Kong	65.4	A3	A	85.39
India	45.8	Baa3	BB+	66.68
Indonesia	51.8	Baa3	BBB	73.23
Japan	91.0	Aaa	AAA	97.19
Kazakhstan	19.2	-	-	35.88
Korea	72.0	A1	AA-	85.04
Mexico	41.2	Ba2	BB	58.78
Peru	27.2	B2	BB-	47.51
Philippines	38.1	Ba2	BB	63.53
Poland	40.2	Baa3	BBB-	56.53
Romania	30.9	-	-	51.95
Russia	19.9	-	-	40.60
Ukraine	16.7	-	-	31.17
Venezuela	30.1	Ba2	B	44.68
United Kingdom	88.2	Aaa	AAA	95.85
United States	90.9	Aaa	AAA	97.17

Driscoll proposed to Hughes that P&G use sovereign debt spreads as a measure of risk globally, adding “Emerging markets have a whole new set of rules, versus Europe or Canada ... the portfolio effect can spread our risk successfully while we go global.” As a result, P&G decided to begin adjusting the WACC for countries upward based on sovereign debt spreads (see Table 8). Although the new procedure would differentiate investments geographically, some in the company were concerned that it would result in higher costs of capital in more volatile countries, thus discriminating against investments in them. Because developing countries generally have more volatile economies, and volatility creates opportunity, forcing a higher cost of capital there would likely result in missed opportunities.

**TABLE 8: Spreads between dollar-denominated sovereign debt and comparable U.S. government bonds, mid-1996**

<b>Country</b>	<b>Sovereign spread (basis points)*</b>
Argentina	718
Belgium	-
Brazil	610
Chile	-
China	-
Colombia	150
Germany	-
Hong Kong	-
India	-
Indonesia	100
Japan	-
Kazakhstan	-
Korea	-
Mexico	597
Peru	434
Philippines	226
Poland	185
Romania	-
Russia	765
Ukraine	-
Venezuela	811

\*Source: Bloomberg

### **WHERE DO WE GO FROM HERE?**

As Corporate Finance began developing the methodology for quantifying the adjustment to the WACC discount rate, Hughes and his colleagues were mindful of both the benefits of increasing the accuracy of estimating hurdle-rates and the potential costs of missing profitable opportunities in developing countries. Should they adjust the cost of capital based on sovereign debt spread country by country, or by categories of countries? If the latter, how many categories should they create?

# *Teaching Case*

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## Journal of Applied Case Research

Sponsored by the Southwest Case Research Association

### **Kellogg's Healthier Cereals: An Ethical Dilemma?**

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The genesis of this case was the result of a class project. The author would like to thank Marco Guzman, Matty Horton, Shayla Impson, Chris Taylor and Courtney Williams for their contributions to this case.

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#### INTRODUCTION

Vicki thought of herself as a good mother. She planned her grocery purchases and attempted to provide nutritional food for her husband and son. Her three-year-old son, Chaden, was a “picky” eater, so finding healthy foods that he would eat was a challenge, especially at breakfast. About the only food that Chaden would eat for breakfast was cereal. He was particularly fond of Kellogg's Frosty Flakes and thought “Tony the Tiger” was super. She had even made Chaden a “Tony the Tiger” costume for

Halloween. Vicki could usually get Chaden to eat breakfast when she said that “Tony the Tiger” was proud of him for eating a bowl of Frosty Flakes and milk.

Vicki was concerned, however, with the sugar content of Frosty Flakes. She had recently returned to school to pursue a degree in early childhood education and had researched the impact of sugar on children’s health, especially childhood obesity. She was relieved when Kellogg’s introduced a low-sugar version of its Frosty Flakes. Vicki was pleased that Chaden’s favorite cereal was now a healthy choice. Or was it?

## **KELLOGG’S**

### **The Beginning**

During the late 1800’s and early 1900’s, two brothers, Dr. John Harvey Kellogg and Will Keith Kellogg, began experimenting with a healthy meal supplement for the Battle Creek Sanitorium, a hospital and health spa. Patients were required to exercise daily and follow a strict diet that excluded any intake of caffeine, alcohol, tobacco and meat. The Kellogg family began working with foods that were high in grain content. They also attempted to develop a substitute for coffee and a type of granola and peanut butter to replace the stale and tasteless bread offered at the sanitorium.

While experimenting with grain products to develop a healthy substitute for protein, the Kellogg family found that wheat could be converted into brown flakes that were light and crispy. The process involved cooking the wheat, moving it through granola rollers, forming the wheat into thin sheets and finally baking it. The Kellogg brothers were unaware that they had formed not only a new healthy food substitute but also a new industry. The new flakes became an instant hit with the patients of the sanitorium. When patients went home, they wanted to continue eating the crispy flakes. As a result of this demand for the new product, John formed Sanitas Nut Food Company, where his younger brother, Will, began producing the flake cereal so that patients’ requests could be met by mail order.

Within a short decade, over 40 factories began producing wheat flaked cereal and began expanding the product line. In response to the increased competition, Will continued experimenting for new versions of corn flakes. Though his older brother was satisfied with one type of flaked cereal, Will saw great potential in the growing market and went into business for himself. In order to keep his competitive advantage, Will added a malt flavor to his corn flakes to distinguish them from other flake cereal. While he believed that people might be initially attracted to food because of its nutritional values, he was convinced that consumers wanted food products that were not only healthy but also fresh and flavorful. He also believed that consumers wanted value and convenience for their food expenditures.

In 1906, Will used his talent to create The Battle Creek Toasted Corn Flake Company. He spent a lot of time and money developing good advertising techniques to promote his cereal products. One of the most prominent advertisements included an expensive full-page advertisement in the 1906 July issue of *The Ladies Home Journal*. Will saw his sales increase dramatically from only 33 cases of cereal per day to over 2900 cases of cereal per day. His well-known advertisements helped to promote “The Original and Best” Kellogg’s Corn Flakes to sales that exceeded over a million cases by the end of 1909.

Along with the importance of advertising, Will also found packaging an important aspect of the company's success. He packaged his cereal in "waxtite" to help keep the cereal fresh. He also added nutritional messages, recipes and product information to the side and back of the cereal packages. Kellogg's became the first food company to voluntarily print nutritional information, including sugar content on the side of its products. In the 1970s, Kellogg was the first marketer to press the Food and Drug Administration to allow companies to use food-related health claims. During the early to mid 1900s the company brought to market several new cereal products, including Kellogg's All-Bran, Special K, Corn Pops, Frosted Flakes, Honey Smacks, and their now famous Rice Krispies. This same time period also saw Kellogg's begin global operations in Canada, Australia, and England. Today, consumers can purchase Kellogg's cereals in over 160 countries.

### **Kellogg's Advertising Techniques**

Kellogg's has used a variety of advertising techniques, including television, newspaper, radio, magazines, and sporting events, to promote its numerous products. In late 2004, Kellogg's joined NASCAR with the number 5 car driven by Kyle Bush. Kellogg's advertisements have provided consumers with insights into its products as well as notification of new products and improvements to existing products.

On its corporate web site, Kellogg's has stated that its advertisements are socially responsible and that the company is committed to conveying the truth in its advertising rather than misleading consumers. Kellogg's goal has been to place ads in programs that support and communicate standards of good taste and fair practice. Kellogg's has suggested that its advertisements provide accurate information, comply with any Federal, state, and local laws or regulations, and avoid any violent content and racial or sexist themes.

Children have been a primary focus for Kellogg's advertisements. For example, in 1912, Kellogg's placed an advertisement in New York City's Times Square that used animation to portray a child smiling when they had Kellogg's and frowning when they did not. To capture children's interests, Kellogg's has used age-appropriate ads, including computer games and characters such as Tony the Tiger, Snap! Crackle! Pop! and Ernie Keebler. The company began utilizing characters as an advertising tool during the 1950's and 60's when the baby-boomer generation started elementary school. To appeal to children's taste, cereal such as Corn Pops, Frosted Flakes, and Honey Smacks made their debut.

## **CHILDHOOD OBESITY AND INDUSTRY PRACTICES**

The U. S. Department of Health and Human Services (DHHS) has stated that childhood obesity is the fastest growing cause of disease in children. The health of many children in the U.S is being negatively affected by less active lifestyles related to playing video games and watching television for several hours each day. When children with these types of lifestyles increase their sugar consumption, weight gain may become a by-product. Some children that have excess body weight have developed symptoms associated with diabetes, heart disease and asthma as well as emotional and mental health problems.

In order to combat childhood obesity, children must increase their daily physical activity, expand their knowledge of a healthy lifestyle and practice healthy eating habits. One suggestion given to combat childhood obesity has been to decrease daily sugar intake, which is often impacted by the consumption of children's cereal. Children need to be educated about the nutritional value of their diet, not just the color of or character on a cereal box.

The food processing industry has been slow to react to the warning signs that the growing concern and national discourse over childhood obesity could lead to litigation. However, in the last few years, Kraft Foods, General Mills and PepsiCo have made concentrated efforts to inform the public about the proactive changes that they have made to their product portfolios and advertising practices. In contrast, during this same time period, Kellogg has stood by its existing products and strategies, including its aggressive advertising and toy giveaways aimed at children. Part of this advertising campaign included the marketing of healthier versions of some of its product line, including low sugar versions of Frosted Flakes and Froot Loops.

### **HEALTHIER OR MISLEADING?**

Vicki's belief about Kellogg's healthier Frosty Flakes was short lived. She recently read an article about Mary Hardee, a mother of two from San Diego, suing Kellogg's over a deceiving cereal label. Vicki noted that Mary's research indicated that Kellogg's was replacing the sugar on Frosted Flakes with refined carbohydrates, which the body treats the same as sugar; thus, there was no real difference between traditional Frosty Flakes and the new "low-sugar" Frosty Flakes. The article stated that Hardee appeared on Good Morning America and told the host that Kellogg's was deceiving...parents think that they are buying something healthier for their children, only to find out that they are not. Vicki was disappointed that Kellogg's mislead consumers. Or did they?



# *Teaching Case*

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## **Journal of Applied Case Research**

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**Hana Biosciences, Inc.: A Case Study  
In Biopharmaceutical Entrepreneurship**

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# **HANA BIOSCIENCES, INC.: A CASE STUDY IN BIOPHARMACEUTICAL ENTREPRENEURSHIP\***

## **ABSTRACT**

Hana Biosciences is a South San Francisco-based development stage biopharmaceutical company committed to advancing cancer care. Despite breakthroughs in biological insights in the last twenty-five years, translating scientific progress into increased biopharmaceutical industry productivity has been elusive, as capital costs continue to rise and product development timelines lengthen. On average, it takes over \$1.0 billion and 12 years to progress a product candidate from target identification to marketing approval. This case considers decisions faced by a biopharmaceutical start-up as the company works to build its product pipeline and establish commercial capabilities.

## **THE ROAD TO HANA**

Hana Biosciences (NASDAQ: HNAB) is a South San Francisco-based biopharmaceutical company committed to advancing cancer care. It was founded in 2003, nearly three decades after the inception of the biotechnology industry. The name Hana means “health” in Hawaiian, the birthplace of Mark Ahn, founder and CEO of the company. The name also evokes the fabled road to Hana, a 56-mile trip full of sharp twists and turns on the island of Maui. The drive can be nauseating at times, but offers a glimpse of paradise if one can withstand the journey. Early on, the management team often used this “road to Hana” as a metaphor for their biopharmaceutical start-up. In the first three years, the team discovered that they were more correct than they could have ever possibly imagined.

Hana assembled an experienced management team whose members came primarily from large biotechnology and traditional pharmaceutical companies such as Genentech, Amgen, Gilead, and Bristol-Myers Squibb, as well as from academia. Their backgrounds and professional passions were particularly focused on developing and commercializing new drugs for the treatment and supportive care of cancer patients. Most of the team members previously worked on multiple oncology products, including blockbuster drugs with over \$1 billion in annual sales, such as Amgen’s Epogen, Genentech’s Rituxan and Novartis’s Gleevac. Prior to starting Hana, many team members had already been based in the South San Francisco area, working at a cluster of biotechnology companies surrounding industry pioneer, Genentech. The Bay area location also made it easier to recruit talent, since Northern California offered the world’s largest concentration of biotech companies, as well as leading research institutions such as Stanford, UCSF and UC Berkeley. In addition, proximity to Silicon Valley venture capitalists provided access to the most active group of early stage biotech investors.

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As Hana founders surveyed the operating environment of the biopharmaceutical industry, they sought to take a realistic view of the key trends and orthodoxies that drove the industry. Biotechnology has been an industry built on promise, but the reality has been a few spectacular successes that brought life-saving drugs to patients and outstanding returns to shareholders (i.e., Amgen, Biogen-Idec, Genentech, Genzyme, and Gilead) punctuated by many more wrenching setbacks, with financial losses to match. Despite the collective breadth and backgrounds of team members, Hana's management team faced a number of challenging fundamental questions facing nearly all start-up biopharmaceutical companies: "Does the biotechnology industry need yet another small, pre-revenue, unprofitable company to add to the hundreds of such companies already in existence? What will make Hana Biosciences' value proposition unique and sustainable? Does this team possess the necessary core competencies, technology, and access to capital to build a sustainable company?"

## **BIOPHARMACEUTICAL INDUSTRY**

Since the US FDA approved the first biotechnology drug (recombinant insulin, developed by Genentech and licensed to Eli Lilly and Company) in 1982, the biopharmaceutical industry has had 254 drugs approved for 385 indications with over \$40 billion in sales. In addition, over 300 drugs are currently in clinical development targeting over 200 diseases. The industry employs over 200,000 people and spends over \$20 billion annually on research and development.<sup>1</sup>

Despite this tremendous investment, productivity over the years has been decreasing, with higher drug development costs and longer clinical development timelines. The average drug takes over \$1.0 billion and 12 years to go from laboratory to approval (see Appendix 1). Part of the reason for these large costs is the high failure rate of product candidates in clinical trials. For the drug candidates that progress from animal testing into human clinical trials, the overall success rate is 11%. In other words, nine out of ten products entering clinical trials will fail, and some disease areas are even more challenging (i.e., oncology success rates are approximately 5%). Furthermore, getting approval is no guarantee of commercial success. To date, only 4 out of 10 products that reach the market achieve profitability. This lack of development productivity (either increasing the value created or decreasing the time required to create value) has taken its toll on financial performance of the industry. Out of the nearly 350 publicly traded biopharmaceutical companies, fewer than 10 reached sustainable profitability.<sup>1,2,3,4,5</sup>

Despite the formidable odds in drug development, the excitement surrounding biomedical enterprises remains high. Fundamental forces shaping the biotechnology industry in the first decade of 21<sup>st</sup> century include: (1) The gap between the low cost of creating a biotech company around an exciting scientific discovery and the extremely high costs of converting novel technologies into approved drugs; (2) Steady evolution of the perception of value by investors in the biopharmaceutical industry value chain; (3) The irregular nature of biotechnology financial markets increases operating risk and uncertainty; and (4) Despite intense competitive pressure, product pipelines remain

highly valued because large multinational pharmaceutical companies increasingly need more products given declining productivity and pernicious attrition rates.

**First, a persistent issue is the gap between the low cost of creating a biotech company around an exciting scientific discovery and the extremely high costs of converting novel technologies into approved drugs.** Ever-broadening access to molecular biology tools, rapidly growing body of knowledge about basic biological processes, and use of information-based research technologies in academic laboratories and research institutes made it easy to create a new company by spinning the basic technology out of academia. Academic research is more likely to result in breakthrough innovation due to the large numbers of scientists, resources, and patience with the scientific process. While the core competency of academia is basic research (defined as laboratory-based target validation and lead optimization), however, most universities are not resourced to translate discoveries from the lab to clinical studies. This process of translational development from the lab typically includes process development and manufacturing, toxicology testing, regulatory filings with the FDA (US Food and Drug Administration), and mobilizing physician investigators to enroll patients into early stage clinical studies. Fueled by the expanded access to research tools and biological insights from the human genome and by venture capital firms willing to invest in novel science, the excitement of creating new companies has resulted in large numbers of small, undercapitalized startups focused on discovery of novel drug targets but lacking resources needed to convert these targets into drug candidates and to validate them in the clinic.

**Second, another fundamental factor is the steady evolution of the perception of value by investors in the biopharmaceutical industry value chain.** In three decades, biopharmaceutical industry investors went from ascribing value solely to platform technologies to requiring clinical stage product candidates to expecting revenues and finally, to demanding sustainable profitability (see figure 1). That is, as in all other industries based on technological breakthroughs, investors in biopharmaceutical companies increasingly demand commercially realizable opportunities to justify additional capital.<sup>6</sup> In the early 1990s, the highest market valuations went to companies with technology platforms which *may* potentially lead to biologic targets (i.e., Human Genome Sciences, a biotech start-up, granted GlaxoSmithKline, a top 10 pharmaceutical company, access to its gene-based drug technology in a partnership valued at \$125 million). Over the next decade, the “sweet spot” of venture capitalists and financial markets steadily migrated through the value chain:

- from valuing novel drug targets (i.e., Bayer, a big pharma company, paid five-year old Millennium Pharmaceuticals over \$1.0 billion to deliver 225 drug targets over 5 years);
- to focusing on product leads (i.e., Hoffman-La Roche acquired a 60% stake in Genentech in exchange for right of first refusal to all Genentech products outside the US);
- to acquiring development candidates in clinical trials (i.e., Amgen entered into an alliance with Abgenix to co-development monoclonal antibodies over five years

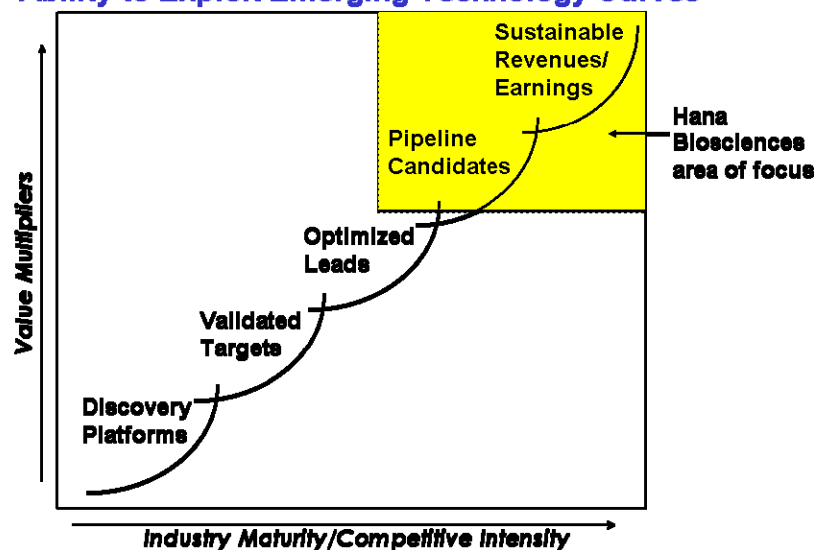
which led to Vectibix, then subsequently acquired the company for \$2.2 billion after positive Phase III clinical trial results to obtain full ownership and eliminate future royalties);

- to paying for revenues from approved products that led to increased merger and acquisition activity, with Pfizer acquiring Agouron, Johnson & Johnson acquiring Centocor, etc.

Further, distinctions between traditional Big Pharma companies and smaller biotechs have increasingly blurred due to alliances and converging research interests. This trend is increasing competitive intensity in the marketplace, as multiple players pursue drugs with the same mechanisms of action in overlapping indications (i.e., multi-kinase inhibitors Sutent by Pfizer and Nexavar by Onyx/Bayer in renal cell cancer; or EGFR inhibitors Tarceva by Genentech/OSI, Erbitux by Bristol-Meyers Squibb/Imclone, and Vectibix by Amgen). The result of increasing competitiveness for the same molecular targets is shorter periods of effective intellectual property exclusivity and profit margin pressure.

Figure 1

### Biopharmaceutical Industry Architecture is Driven by the Ability to Exploit Emerging Technology Curves



Third, the irregular nature of biotechnology financial markets increases operating risk and uncertainty. As a result of large capital requirements, long lead times, and episodic successes and failures, biotech financing cycles have been characterized by periods of high euphoria, only to be followed by deep disillusionment after a cluster of high-profile product failures that seemed to occur regularly.<sup>7</sup> This subjects early-stage companies to high degrees of financing risks, regardless of their operational progress. While the industry has matured, the predominant venture capital financing model—one product platform or one product, a few investors who provide seed capital, and a long incubation period leading to sale or an IPO (initial public offering)—has not markedly changed, despite reduced numbers of exits and modest overall risk-adjusted rates of return.<sup>8</sup> Recently, the early stage financing environment has entered a

period of dramatic realignment due to the entry of hedge funds into earlier rounds of funding for private and small publicly traded companies.

**Fourth, despite intense competitive pressure, product pipelines remain highly valued because large multinational pharmaceutical companies increasingly need more products given declining productivity and pernicious attrition rates.** The incessant need for pipeline products is accentuated by increasingly narrow molecular targets, large development and commercial infrastructures, and patent expirations. Moreover, the stock market appears to be quite efficient at discerning the qualitative differences amongst biopharmaceutical companies in terms of market valuations and price-earnings multiples (see Appendix 2). Thus, the conventional wisdom that new product pipelines are the lifeblood of the biopharmaceutical industry is well founded in historical operating experience and market valuations.<sup>9,10</sup>

Thus, large biopharmaceuticals often turn to small biotechnology companies to augment their pipelines. It estimated that in the last five years, 30-50% of new molecular entities (NMEs) came from in-licensing versus internal development. As a result, the number of pharma-biotech alliances has risen from just 69 in 1993 to 502 in 2004.<sup>11</sup>

While the increased value of in-licensing is often spurned as a failure of internal development, it frequently serves as a source of innovation and energy for both. Namely, big pharmaceuticals can allow internal and external programs to compete, and then choose which to move forward after proof-of-principle studies are completed.<sup>12</sup> The paradox is that despite the need for pipeline products, in-licensing is generally viewed as a failure within large companies due to the “not invented here” syndrome (or persistent corporate or institutional culture that avoids using research or knowledge because of its different origins). A recent industry report by the GAO concluded:

*Recent scientific advances have raised expectations that an increasing number of new and innovative drugs would soon be developed to more effectively prevent, treat, and cure serious illnesses...Although the pharmaceutical industry reported substantial increases in annual research and development costs, the number of NDAs submitted to, and approved by, FDA has not been commensurate with these investments. From 1993 through 2004, industry reported annual inflation-adjusted research and development expenses steadily increased from nearly \$16 billion to nearly \$40 billion--a 147 percent increase. In contrast, the number of NDAs submitted annually to FDA increased at a slower rate--38 percent over this period. Similarly, the number of NDAs submitted to FDA for NMEs increased by only 7 percent over this period... According to experts, several factors have hampered drug development. These include limitations on the scientific understanding of how to translate research discoveries into safe and effective drugs, business decisions by the pharmaceutical industry, uncertainty regarding regulatory standards for determining whether a drug should be approved, and certain intellectual property protections.<sup>13</sup>*

## STRATEGY FOCUSED ON CANCER CARE

Given these trends and the strengths of the team, Hana Bioscience's focus on cancer care addresses large unmet needs, focused market segment, and builds on team strengths. Hana's management believed that focusing on one physician specialty or therapeutic area was required to achieve critical mass to build a sustainable business. Hana chose cancer care which represented a niche market segment with significant unmet medical need, pricing power, and a focused commercial scope that can be addressed by an emerging company.

Cancer is a group of diseases characterized by either the runaway growth of cells or the failure of cells to die normally. Often, cancer cells spread to distant parts of the body, where they can form new tumors. Cancer is caused by a series of mutations, or alterations, in genes that control cells' ability to grow and divide. Some mutations are inherited; others arise from environmental factors such as smoking or exposure to chemicals, radiation, or viruses that damage cells' DNA. The mutations cause cells to divide relentlessly or lose their normal ability to die.

Each year, nearly 1.4 million new cases of cancer are diagnosed in the United States. Cancer is the second leading cause of death (after heart disease) in the United States, with one in four deaths in the US expected to be due to cancer. For all forms of cancer combined, the 5-year relative survival rate is 64%.<sup>14</sup> Despite the fact that the cancer mortality rate in the U.S. has risen steadily for the past 50 years, scientific advances appear to have begun to turn the tide. According to the National Center for Health Statistics, 2003 was the first year since 1930 that annual cancer deaths declined—the start of what researchers hope will be a long-term decline in cancer mortality.

Major treatments for cancer include surgery, radiotherapy, and chemotherapy. There are many different drugs that are used to treat cancer, including cytotoxics or antineoplastics, hormones, and biologics. Major categories include chemotherapy, targeted agents, radiotherapy, and supportive care.

Chemotherapy refers to anticancer drugs that destroy cancer cells by stopping them from multiplying. Healthy cells can also be harmed with the use of cytotoxic chemotherapy, especially those that divide quickly. Harm to healthy cells is what causes side effects. These cells usually repair themselves after chemotherapy. Cytotoxic agents act primarily on macromolecular synthesis, repair or activity, which affects the production or function of DNA, RNA or protein. Although there are many cytotoxic agents, there is a considerable amount of overlap in their mechanisms of action. As such, the choice of a particular agent or group of agents is generally not a consequence of a prior prediction of anti-tumor activity by the drug, but instead the result of empirical clinical trials.

Targeted anticancer therapies have been developed as a result of biologic insights to create products with increasingly specific molecular targeting to enhance efficacy and reduce toxicity. Most of these targeted therapies must be used in combination with

chemotherapy. Over 100 targeted anticancer agents are already on the market or in development, with the leading eight targeted therapies (Avastin, Rituxan, Herceptin, Erbitux, Gleevec, Tarceva, Sutent, and Nexavar) having estimated sales of more than \$7.5 billion in 2006. Further, targeted therapies clearly dominate cancer pipelines with over 100 drugs in clinical development.<sup>15</sup>

Radiotherapy, also called radiation therapy, is the treatment of cancer and other diseases with ionizing radiation. Ionizing radiation deposits energy that injures or destroys cells in the area being treated - the target tissue - by damaging their genetic material, making it impossible for these cells to continue growing. Although radiation damages both cancer cells and normal cells, the latter are able to repair themselves and regain proper function. Radiotherapy may be used to treat localized solid tumors, such as cancers of the skin, tongue, larynx, brain, breast, or uterine cervix. It can also be used to treat leukemia and lymphoma (cancers of the blood-forming cells and lymphatic system, respectively).

Supportive care is another key area of the oncology market. As noted, the treatment of a cancer may include the use of chemotherapy, radiation therapy, biologic response modifiers, surgery, or some combination of all of these or other therapeutic options. All of these treatment options are directed at killing or eradicating the cancer that exists in the patient's body. Unfortunately, the delivery of many cancer therapies adversely affects the body's normal organs. The undesired consequence of harming an organ not involved with cancer is referred to as a complication of treatment or a side effect which not only cause discomfort, but may also limit a patient's ability to achieve the best outcome from treatment by preventing the delivery of therapy at its optimal dose and time. Common side effects include anemia, fatigue, hair-loss, reduction in blood platelets and white and red blood cells, bone pain, and nausea and vomiting.

The cost of cancer to the healthcare system is significant. The National Institute of Health (NIH) estimates that the overall cost of cancer in 2004 was \$189.8 billion. This cost includes \$69.4 billion in direct medical expenses, \$16.9 billion in indirect morbidity costs, and \$103.5 billion in indirect mortality costs.

According to Reuters, the global cancer market is estimated at \$40 billion in 2005. In addition to being a large market, cancer care is also a highly concentrated market which makes it ideal for a small company to commercialize. Oncologists represent only 1% or 8,400 out of 635,000 total physicians in the US (often further concentrated in major metropolitan areas where specialists practice in teams). Thus, oncologists as a physician group can be promoted to by a specialty sales force (versus primary care therapeutics in areas such as cardiovascular which require thousands of sales representatives to adequately address).

## **BUILDING HANA'S STRATEGY, STRUCTURE, CULTURE, AND FINANCING**

Reflecting on these trends in the biotech industry generally and cancer care specifically, Hana set out to develop a unique strategy relative to competitors to gain and



maintain competitive advantage, market share, and profitability. Hana decided to: (1) Focus exclusively in oncology to capture operating efficiencies, leverage core competencies, and address the passion of team members in advancing cancer care, (2) Depend on in-licensing and business development to build a diversified, stratified pipeline of oncology product candidates, (3) Concentrate on translational development and pursue a no-research, development-only (NRDO) approach to accelerate time-to-commercialization, (4) rapidly obtain a stock market listing to gain access to public capital markets by merging with an existing public entity.

First, Hana decided to focus exclusively in oncology to capture operating efficiencies, leverage core competencies, and address the passion of team members in advancing cancer care in areas of unmet medical need. Moreover, oncology is also a highly concentrated, niche market which can be commercialized by a small company with premium pricing leading to rapid value creation. In order to execute on a no-research, development-only model, the company decided it needed to be outstanding at finding new drugs through business development to build and nurture its product pipeline.

Second, the company decided to depend on in-licensing and business development to build a diversified, stratified pipeline of oncology product candidates to accelerate growth and speed-to-commercialization. Given high attrition rates in clinical development, Hana needed to be able to continuously and efficiently screen, acquire, and integrate new products and technologies into the company to achieve its ambitious objectives.

Third, the company established business development criteria with an aim to diversify risk by acquiring multiple technologies in oncology which have targets that are well validated, characterized mechanisms of action, and have strong intellectual property rights. Instead of focusing on only one product or technology platform, the management team bet that investors would support building multi-product revenue opportunities that would help Hana fund development of other follow-on technologies. They calculated that this approach would also allow Hana to establish a sales organization that would create recognition for the company as an innovator among oncologists and research institutions, which would further enhance competitiveness for business development efforts.

Finally, instead of pursuing basic research that would bind the company exclusively to one technology platform, Hana decided it's core competency was translational research to accelerate time-to-commercialization. Typically, academia achieves breakthrough discoveries through target validation and lead optimization versus translational research which is aimed at efficiently moving a product candidate from the lab to clinical development. Hana's team was built to collaborate with academia and to conduct translational research studies, such as toxicology and pharmacokinetics, to allow a timely progression to clinical trials. Of significance, the largest valuation multiples are realized between the lab and the clinic, providing a high value-added business model conducting activities that academia and research institutes are not typically capable of performing. Mark Ahn, President and CEO explained Hana's business strategy:

*Hana's business model is tightly focused strategically on oncology. We are technologically agnostic, just like the physicians and patients we serve. We aim to serially acquire novel, late pre-clinical and early clinical oncology leads from academia and research institutes, as we have demonstrated to date. This will allow us to accelerate growth and speed to commercialization by starting with actual product leads versus targets. It also will allow us to exploit development cost efficiencies from our therapeutic focus in oncology, and to realize transformational valuation multiples from the lab to the clinic to proof of principle and beyond. We believe there's a large gap to be an efficient, research cooperative from which we can drive a sustainable, high value-added business and growth for our investors.*<sup>16</sup>

**While many small companies become cults of the founders' personality, the management team felt strongly that sustainable growth in a highly complex life science business required careful attention to building a cohesive team-based culture.** The culture was crafted by the first four employees and is continuously revisited and discussed at meetings to ensure consistency and relevance as the company grows. Hana's approach was to frame culture as "How we get things done" and a belief that striving to be part of something larger than oneself is a universal human value. Moreover, the leadership team felt that having a unifying culture would also provide guidance to all levels of the organization making challenging and complex multifunctional decisions.

Hana's unique culture was formed around four elements. First, "Enhancing the lives of patients through bold and continuous innovation" represents a unifying theme irrespective of the functional expertise of a particular team member. This was crafted with a belief that advancing cancer care was challenging, significant, and worth the effort of those who committed their professional lives to improving treatments. It was also based on the belief that achieving significance was a fundamental human goal and a guiding force for decision making. For example, everyone is expected to place patient welfare first which makes safety paramount to all other issues such as timelines, milestones or financial pressures facing the company.

Second, another element of Hana's high performance culture "developing extraordinary team members who can realize their full potential, talent and imagination" reflected the high expectations for performance and specialized knowledge each individual team member. Regardless of the expertise of any individual on the team, Hana also signaled that teamwork was absolutely required.

The third aspect of Hana's culture is, "creating high performing teams that are committed to the unlimited success of one another, as well as our patients, partners, and shareholders." This reflects the critical level of collaboration required in order to be efficient and effective at moving multiple products at multiple stages of development forward simultaneously. In an environment of high performing knowledge workers with highly specialized skills, the management team strongly believes that developing a tight knit group who cares deeply about one another and fiercely committed to a common mission will ultimately determine the success or failure of Hana.

The fourth and final element of Hana's culture, "seeking goodness and grace in others with the highest standards of integrity," signaled the founding team's belief in the fundamental good nature of others. It was also a reflection of the unlimited power and energetic commitment required to be successful in advancing cancer care. This element of company culture was inspired by a line by poet John Keats, "*I am certain of nothing but the holiness of the heart's affection and the truth of imagination.*"

Combining these four elements, Hana summarizes their mission and strategy as P<sup>3</sup>C (People, Products, Pipeline, and Culture) as follows:

***Hana Biosciences, Inc. (NASDAQ: HNAB) is a South San Francisco, CA-based biopharmaceutical company that acquires, develops, and commercializes innovative products to advance cancer care. We are committed to creating value by building a world-class team, accelerating the development of lead product candidates, expanding our pipeline by being the alliance partner of choice, and nurturing a unique company culture. We are committed to P<sup>3</sup>C:***

- ***People:*** Building a world-class team with leading core competencies in cancer drug development and commercialization.
- ***Products:*** Acquiring and accelerating the development and commercialization of innovative oncology product candidates.
- ***Pipeline:*** Expanding our pipeline by being the partner of choice for suppliers, researchers, and alliance partners.
- ***Culture:*** Nurturing a unique company culture focused on patients, developing extraordinary team members, creating high performing teams, and seeking goodness and grace in others with the highest standards of integrity.

Source: Hana Biosciences company presentation, [www.hanabiosciences.com](http://www.hanabiosciences.com)

**Another critical element of Hana's business model is obtaining financing to achieve and accelerate its corporate goals.** The traditional financing approach of obtaining venture capital seed funding was dismissed because venture investors typically want Board of Directors' control, as well as focus on a single asset or platform to gain a value multiplier which can be realized through a sale, IPO or other exit strategy.<sup>17</sup> This is predominantly the case because most venture capital funds have 10 year life spans at the end of which all investments must be liquidated and returned to investors. Thus, the primacy of focus for venture capitalists effectively dissuades portfolio companies from internal diversification (since they are already diversified through multiple investments and need to be able to raise additional investment funds).<sup>18</sup>

Instead, Hana completed a reverse-merger with an illiquid, publicly traded over-the-counter (OTC) company only 15 months after inception to gain access to public capital markets early in the company's development. Essentially, management bet that generating broad investor interest in Hana stock based on its strategy and progress would outweigh the substantial costs of being a publicly traded company (i.e., Sarbanes-Oxley, SEC requirements, audits, etc).

Hana moved from the OTC (over-the-counter) market to the Amex (American Stock Exchange) after eight months, then to the NASDAQ six months afterwards while raising successive rounds of financing with increasingly larger banks and investors. In the first year since going public, Hana stock volume went from 3,000 shares a day for the first 3 months to over 200,000 shares a day. The company obtained biotechnology analyst research coverage from nine different investment banks, raised over \$75 million with successively larger investors, and progressed from about 40 initial investors to over 3,000 shareholders.

Most importantly, from the perspective of Hana management, operational flexibility was greatly enhanced which allowed the company to use its stock currency to rapidly build a stratified and diversified pipeline. “In less than three years, Hana licensed multiple products never worrying about how the addition was going to impact the exit strategy of any one of our investors,” John Iparraguirre, Vice President and CFO reflected. “While we experienced major investor turnover along the way, the changes have led to very healthy shifts in our investor base from venture stage to early public stage funds.”

In sum, Hana’s management was focused on building a premium oncology company by building a strong, experienced team, accelerating the development of lead product candidates, expanding their pipeline by being the alliance partner of choice for academic and research organizations, and nurturing a unique company culture. With the company’s unique strategy, structure, culture, and financing approach, Ahn explained the company’s five-year vision:

*Our vision is very clear. Our intent is, by 2010, to be a fully integrated biopharmaceutical company with at least two innovative drugs in the market, reach \$100 million in revenues, and aim for at least five product pipeline candidates. All of these goals are driven by a unique culture, which is focused, relentless, and flexible.*

## CASE A: SHOULD HANA BIOSCIENCES DOUBLE ITS PIPELINE THROUGH PRODUCT ACQUISITION?

After two years from private to public company, Hana Biosciences entered 2006 with significant momentum. The small cap biotech company went from one person start-up to completing two financings, obtaining a public listing on the American Stock Exchange (and about to apply for a NASDAQ listing), and attaining investment bank equity research coverage from six leading biotech analysts. This was all on the basis of acquiring and developing three pre-clinical stage products: Zensana (ondansetron HCl) Oral Spray, Talvesta (talotrexin), and Ropidoxuridine (IPdR) respectively.

On the basis of its three product pipeline, the company developed strong support from the biotechnology financial analyst community placing a uniform “buy” rating on Hana’s stock. Investors appeared to be signaling that focus and execution on the products already in the company were expected to continue expanding value.<sup>20</sup> Oppenheimer, for example, initiated research coverage of Hana with:

*We are initiating coverage of Hana Biosciences, Inc. with a Buy rating and a 12-month target price of \$15 based on a risk-adjusted net present value (rNPV) analysis and supported by a real-options analysis. As a relatively undiscovered story with three oncology candidates, an impressive management team, and multiple milestones expected over the next six months, we believe Hana is a compelling opportunity for risk-tolerant investors.*

*In our opinion, Zensana is a significantly underappreciated asset that alone is worth \$7-\$8 per share. This anti-emetic oral spray has the same active ingredient as GlaxoSmithKline’s Zofran (ondansetron), which generated \$1.2 billion in sales in 2005... We believe Talotrexin holds the most upside potential of Hana’s three product candidates. The drug is designed as an improved version of an established class of cytotoxic therapies (antifolates), has demonstrated promising preclinical and early clinical results, and is poised to deliver significant news flow over the coming year...IPdR, the third clinical candidate in Hana’s stable, is an orally available prodrug of IUdR, which is being developed as a radiosensitizer in various solid tumors and brain cancers.<sup>21</sup>*

However, just when Hana Biosciences appeared set to tightly focus on assets already in the pipeline, the team stumbled across an intriguing set of distressed products known as targeted sphingosomal cancer therapeutics which were originally developed by researchers at the University of British Columbia and currently in the possession of Inex Pharmaceuticals, a financially troubled Canadian biotech company.

Sphingosomal encapsulation is a new generation liposomal drug delivery platform, which significantly increases tumor targeting and duration of exposure for cell-cycle specific anticancer agents. When used in unencapsulated form, chemotherapeutic drugs diffuse indiscriminately throughout the body, diluting drug effectiveness and causing toxic side effects in the patient’s healthy tissues. The proprietary sphingosomal

formulation technology permits the loading of a high concentration of therapeutic agent inside the lipid envelope, promotes accumulation of the drug in tumors, and prolongs the release of the drug at disease sites. As a result, compared to free drugs, agents encapsulated in sphingosomes have been shown to deliver more of the therapeutic agent to a targeted disease site over a longer period of time, thus increasing the efficacy of the drug without increasing the toxicity in healthy, non-targeted tissues.<sup>22</sup>

There were three drugs using the sphingosomal encapsulation: Marqibo™ (sphingosomal vincristine), Alocrest™ (sphingosomal vinorelbine), and Sphingosomal topotecan. The lead drug in the portfolio was Marqibo™, a novel, targeted sphingosomal formulation of vincristine that has shown promising Phase II anticancer activity in patients with non-Hodgkin's lymphoma (NHL) and acute lymphoblastic leukemia (ALL). Due to selective targeting, Marqibo™ delivers ten times more drug into the tumor than does unencapsulated vincristine. Based on clinical results in over 600 patients to date, Marqibo™ will enter pivotal trials by year end 2006.

In addition, the remaining products in the licensing opportunity included Alocrest, a targeted formulation of a microtubule inhibitor that is approved for use as a single agent or in combination with cisplatin for the first-line treatment of unresectable, advanced non-small cell lung cancer. The third product was Sphingosomal Topotecan, a proprietary, targeted formulation of a topoisomerase I inhibitor that is approved for use in relapsed small-cell lung cancer and in relapsed ovarian cancer. Both of these products were scheduled to enter human clinical trials within a year.

While the targeted sphingosomal encapsulated anticancer agents were scientifically exciting, the Hana management team was concerned that a prior rejection by the FDA would be controversial for investors. Further, the lead licensing candidate, Marqibo, had itself become a political issue and particularly infamous example of denying access to life saving technologies despite widely acknowledged problems with clinical study conduct. As noted in a terse *Wall Street Journal* editorial entitled "Pazdur's Revenge" published after the FDA denied Marqibo's first new drug application:

*At issue was a therapy called Marqibo for aggressive non-Hodgkins lymphoma for patients who relapse following initial treatment... there was plenty of evidence before the panel to suggest it might have been a valuable addition to the anti-cancer arsenal, given how much variability there is in the way individual patients respond to different drugs.*

*And since there are no other drugs approved for relapsed non-Hodgkins, it should have been eligible for accelerated approval. But Dr. Pazdur [FDA oncology drug chief] explained that since there are a number of drugs for other conditions being used "off-label" to treat relapsed non-Hodgkins, there was no great urgency concerning Marqibo.*

*Just as worrying as the fate of this individual therapy was the apparent relish with which some of the panelists dismissed the efforts of Marqibo's makers at the Enzon*

*company and fired back at the patient activists who've been uppity enough to suggest faster access to developmental drugs...*<sup>23</sup>

The management team called a Board teleconference at 6 am to consider the opportunity. Sitting around the conference table with a box of Starbucks coffee and Krispy Kreme donuts, Ahn began, “Good morning and thanks for convening on such short notice. In the course of routine business development due diligence on a completely different preclinical compound in CLL [chronic lymphocytic leukemia], we literally stumbled on a unique situation and opportunity to license three targeted sphingosomal agents developed by Dr. Pieter Cullis at the University of British Columbia, then subsequently developed by Inex Pharmaceuticals in Vancouver. The initial efforts were unsuccessful not because of drug performance in clinical trials, but due to a number of clinical trial deviations which we believe can be readily addressed with a quality clinical trial.”

Alex Tkachenko, Vice President, Corporate Development and Strategic Planning provided an overview of the proposed licensing deal terms. “We can license these assets on very favorable terms with built in flexibility for Hana. Of the \$11.5 million up-front payment, we pay Inex \$1.5 million in cash and the remainder in Hana stock. Additional milestones can be paid in stock or cash at our choosing. Further, single digit royalty rates provide high margins if we can get these drugs approved.”

“Vincristine is a standard chemotherapeutic agent used in most lymphoma and leukemia regimens in approximately 60,000 patients annually. Vincristine’s activity is limited by it’s short half-life and it’s inability to be dose escalated beyond a 2 mg total dose because of neurotoxicity,” offered Greg Berk, Vice President and Chief Medical officer, as well as a hematologist-oncologist who treated many leukemia patients. “Not only does Marqibo have a significantly longer half-life, but phase I and II studies with Marqibo have shown that patients can tolerate doses which are 100% greater than conventional vincristine. The result of the improved pharmacokinetic profile and dose intensity is improved efficacy.”

Fred Vitale, Vice President and Chief Business Officer went further, “Marqibo is an attractive drug for Hana to commercialize because only 1,500 hematologist-oncologists will need to be targeted to maximize revenues.”

“Inex needs this deal to survive. They have no access to the capital markets because their balance sheet is upside down. This deal gives them a way to eliminate their debt and restart their company around other technology platforms, added John Iparraguirre, Vice President and Chief Financial Officer. However, he cautioned, “a pivotal trial program for Marqibo would cost *at least* an extra \$20 million that we don’t currently have in the budget or in the bank. This license will require us to raise capital and dilute current shareholders in order to develop these assets.”

After a great deal of debate and several cups of coffee, it was clear Board members were concerned about the impact on Hana’s strategic direction and operational focus. As

one Board member soberly pointed out, “liposomal encapsulation is nothing new. Successes in this area have been very limited despite several efforts to expand the therapeutic index of chemotherapy agents.” Another stated, “We shouldn’t dilute our operational focus. Wall Street may also believe that we don’t have confidence in the products we already have.” Yet another Board member said, “Marqibo was turned down by the FDA. Should we double our pipeline and substantially increase our operating costs when Marqibo still has a cloud over it?” Finally someone asked the CEO, “Mark, what *exactly* are you and the management team requesting?”

As the management team looked at each other and the Voicepoint teleconferencing device located on the meeting room table, Ahn replied “We would like to proceed with licensing the Inex targeted chemotherapy agents as negotiated. We believe that these agents would substantially add to our portfolio while leveraging our core capabilities, carry low-to-moderate development risk with rapid cycle times, and will ultimately be accretive to Hana shareholders.” An uncomfortable silence of about 30 seconds elapsed as Board members were considering the initiative...

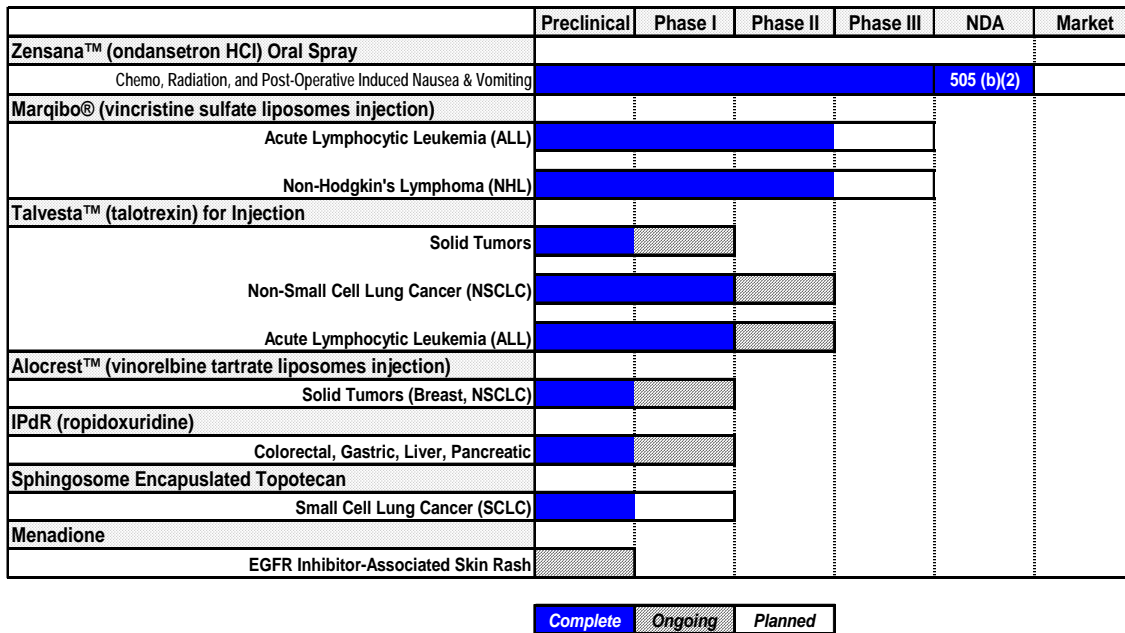


## CASE B: SHOULD HANA BIOSCIENCES PURSUE COMMERCIALIZATION OR PARTNER TO LOWER RISK?

As the New Year opened, the management team met to assess the prior year and discuss challenges ahead. As they reflected on Hana’s first full year as a public company, Mark Ahn, President and CEO remarked, “during the year we met and exceeded our objectives in terms of building and moving the pipeline forward. We strengthened the core capabilities of the team in key functional areas such as clinical, regulatory and manufacturing. We achieved these goals on time and on budget. We also built shareholder value through our progress. Last year’s achievements included completing pivotal trials and filing a new drug approval application for Zensana™, strengthening our pipeline with the addition of four drug candidates, and expanding investor reach with a NASDAQ listing.”

As a result of a significant business development effort, Hana built a fully integrated, diversified pipeline of seven products (see figure 2). With a full pipeline of 7 products, five of which were already in clinical trials, Hana proved it could build a pipeline but still lacked revenues and commercialization.

**Figure 2: Hana’s pipeline of seven product candidates**



As the management team gathered to reflect on the budget and goals for the following year, however, they quickly realized that current resources were insufficient to complete the bold strategic gambit which the company had communicated to investors. The firm’s three primary goals—commercialize Zensana, execute a pivotal clinical trial leading to approval for Marqibo, and move Talvesta forward in Ph II clinical trials—alone surpassed the cash balance on hand for the company and required difficult strategic choices for the management team.

Hana expected to commercially launch Zensana in the United States in the first half of 2007. The company anticipated that revenues from Zensana would help offset at least a portion of development costs and reduce dependence on external financing. Additionally, they planned to assemble a specialized oncology sales force of approximately 30 people that could educate oncologists and nurses in using Zensana. Moreover, they intended to leverage this sales force in commercializing future oncology products.

Fred Vitale, Vice President and Chief Business offer stated emphatically, “We only have one chance to launch Zensana. This is not a pay-as-you go business. Let’s spend the money for a rapid launch and give this product a chance to be successful.”

John Iparraguirre, Vice President and CFO replied, “I don’t want to be overly cautious, but how are we going to pay for the launch of Zensana and effectively develop the rest of the pipeline? We simply don’t have the budget to do everything.”

### **About Zensana**

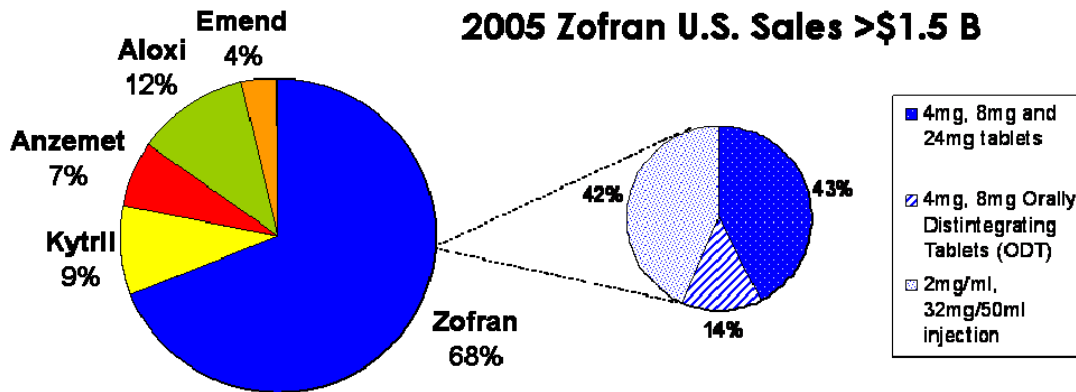
Zensana™ (ondansetron HCl) oral spray is the first multidose oral spray 5-HT<sub>3</sub> antagonist. Zensana™ utilizes a micro mist spray technology to deliver full doses of ondansetron to patients receiving emetogenic chemotherapy. Ondansetron is approved to prevent chemotherapy and radiation-induced, and post-operative nausea and vomiting. Many patients receiving chemo and radiation therapy experience dysphagia or have difficulty swallowing oral medicines. Drug delivery via a spray is convenient and offers a desirable alternative to tablets and other forms of ondansetron.

Zensana appeared to present an attractive commercial opportunity in a competitively intense market (see figure 3). The management of chemotherapy-induced nausea and vomiting (CINV), radiation-induced nausea and vomiting (RINV), and post-operative nausea and vomiting (PONV) is a critical aspect of cancer patient care. It is estimated that approximately 70-80% of 500,000 patients receiving chemotherapy per year are addressable with antiemetic therapies.

Since the introduction of Zofran® (ondansetron), the 5-HT<sub>3</sub> class of treatment has grown to approximately \$2.0 billion in the US alone with the introduction of three other US marketed antiemetics – Kytril (granisetron) from Roche, Anzemet (dolasetron) from Sanofi-Aventis, and most recently, Aloxi (palonosetron) from MGI Pharma. 2005 US sales for branded Zofran® were approximately \$1.5 billion, which represented 68% market share of the total antiemetic market.

Figure 3

## Zensana™: Market Potential for Antiemetics



Source: IMS (2006)

In addition to the currently branded antiemetics, there will be generic versions of ondansetron after Zofran goes off patent in December 2006. Dr. Reddy's Lab, Par Pharmaceuticals, Mayne Pharmaceuticals, and Teva Pharmaceuticals, have all submitted generic applications for the three formulations of ondansetron. After the launch of the generics, each will have 180 day exclusivity for the sale of their respectively approved formulations before multiple versions can be launched.

Market research was conducted to survey physician and payor utilization, as well as perceptions of current and emerging antiemetics. Despite the competitive intensity, a survey of hematologists-oncologists concluded 90% or 9 out of 10 oncologists believe Zensana™ is more convenient for their patients than a tablet for the prevention of chemo-induced nausea and vomiting. In addition, the survey indicated that oncologists would use Zensana™ (ondansetron oral spray) *prior* to chemotherapy in at least 25% of their patients. In addition, 66% of oncologists surveyed responded that they would prescribe Zensana™ (ondansetron oral spray) *after* chemotherapy to >50% of their patients treated with moderate-to-highly emetogenic chemotherapy. Thus, while the primary use of Zensana™ will be in the post-chemotherapy setting, there is also a significant upside opportunity to use Zensana™ for the entire treatment cycle. Finally, Zensana's product profile appeared to offer an attractive alternative to existing formulations by concluding that 48% of physicians agree that *the* most important product attribute for oral 5-HT3s' is: "[product] can be used easily by patients who are experiencing nausea & vomiting, in contrast to swallowing a tablet."

Despite the favorable target product profile of Zensana, several financial analysts questioned the wisdom of Hana launching the product versus finding an established alliance partner who already possessed significant commercial infrastructure required to successfully launch a biopharmaceutical drug.

*This is a great management team facing a tough launch in the form of Zensana. We actually find this launch fascinating since factors completely out of Hana's control could turn it into a nightmare. While we think the odds of that are slim, it will be interesting to see how good management really is by determining how fast they pull the plug...Of more specific interest for Zensana are the potential outlicensing deals for indications other than oncology. A good deal or two could really benefit the company.*<sup>24</sup>

Another analyst worried that competitive intensity as a result of multiple branded and generic products would significantly reduce the pricing power of Zensana and lead to modest launch performance.

*HNAB stock has been relatively weak during the last couple of weeks. We believe one of the main reasons is the approval/launch of several generic versions of Zofran (ondansetron) by as many as seven different companies. Hana has Zensana, which is an oral spray version of Zofran with a unique method of delivery that works by going directly into the blood through the oral cavity and avoiding first pass metabolism. The seven companies involved in the impending generic war are Abraxis BioScience (ABBI), Boehringer Ingelheim, Dr. Reddy Laboratories (RDY), Hospira (HSP), PAR Pharmaceutical (PRX), Teva Pharmaceutical (TEVA) and Wockhardt. Details of the different generic versions are provided in the table below.*

*We continue to believe that it would be in the best interest of Hana to partner Zensana. Currently, the company is in the midst of pre-launch activities for Zensana including building out a sales force in preparation for expected approval on April 30 (PDUFA date).*<sup>25</sup>

While Zensana presented an attractive commercial opportunity, Hana was faced with a critical decision of whether to partner the product with a company who already had an established commercial presence to lower risk or go it alone and build commercialization capabilities. Launching Zensana independently, however, forced other tradeoffs in the company's pipeline development. Of particular concern to management was allocating resources to accelerate the conduct of a large multinational trial for Marqibo, which could lead to approval of a larger and more competitive drug compared to Zensana. Given its current cash position, the management team considered its options to build value—launch Zensana and delay the Marqibo clinical trial, find an alliance partner to launch Zensana, conduct the Marqibo trial and delay the launch of Zensana, or do a dilutive financing and attempt to conduct the entire strategy alone.

“The market clearly sees that if we launch Zensana ourselves we'll need to raise significant capital and be dilutive to shareholders to simultaneously develop the rest of our pipeline. This is why our stock is weak,” observed CFO John Iparraguirre. “Licensing out Zensana lowers operational and financial risk. Hana would not have to raise money for an additional two years and we can complete the critical pivotal trial with Marqibo, as well as make significant progress with the remainder of the pipeline.”

Fred Vitale, Chief Commercial Officer emphatically countered, “We have earned the right to launch Zensana. Building our commercial presence and executing on our clinical progress is precisely why we started this company and the market will reward us for a successful launch. Let’s not quit while the prize is in our grasp.”

Hana could stay the course to keep all assets in the company and bet that operational execution would allow it to continue to raise additional financing on favorable terms. On the other hand, several small companies recently gained FDA approval only to experience poor product launches leading to drastic reductions in market value and operational flexibility. Ahn reflected, “One misstep with Zensana may jeopardize the entire company, but if we can pull off a successful launch we have the opportunity to become one of the very few sustainable, fully integrated biopharmaceutical companies.”

## APPENDIX A: BIOPHARMACEUTICAL DRUG DEVELOPMENT

The average development costs per product are over \$1.0 billion and 12 years from research to approval. Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved. For the drugs that progress into human clinical trials the overall attrition rates is 11%, with oncology at 5% (although biopharmaceuticals tend to have a lower overall clinical approval success rate compared to traditional pharmaceutical firm products).<sup>26,27</sup>

The table below provides an outline of the drug development process, success rate of drugs and the length of time each step takes.

**Figure 4: Drug Development**

Clinical Trials									
	Preclinical Testing		Phase I	Phase II	Phase III		FDA		Phase IV
Years	3.5		1	2	3		2.5	12 Total	
Test Population	Laboratory and animal studies	File IND at FDA	20 to 80 healthy volunteers	100 to 300 patient volunteers	1000 to 3000 patient volunteers	File NDA at FDA	Review process / Approval		Additional Post marketing testing required by FDA
Purpose	Assess safety and biological activity		Determine safety and dosage	Evaluate effectiveness, look for side effects	Verify effectiveness, monitor adverse reactions from long-term use				
Success Rate	5,000 compounds evaluated		5 enter trials						

New biopharmaceutical products generally progress through the following steps: (1) pre-clinical testing to establish biological activity against the targeted disease, (2) Investigational New Drug Application (IND) filing to allow human clinical trials, (3) Phase I, II and III clinical trials to establish statistically significant safety and efficacy, and (4) New Drug Application (NDA) for approval for a specific type and stage of disease.<sup>26</sup>

Further, under the Food and Drug Administration Modernization Act of 1997 (FDAMA), the FDA has established a number of processes—Fast Track, Priority Review, and Accelerated Approval—to accelerate the review of medicines which treat life threatening unmet medical needs such as cancer.<sup>28</sup> Fast Track review refers to a process for scheduling meetings to seek FDA input into development plans, option of submitting a New Drug Application in sections rather than all components simultaneously, and the option of requesting evaluation of studies using surrogate endpoints. Priority Review is a designation for an application that accelerates the review

period to 6 months for FDA action versus the standard review period of 10 months (i.e., Ethyol (amifostine) to reduce post-radiation xerostomia for head and neck cancer where the radiation port includes a substantial portion of the parotid glands by US Biosciences). Accelerated Approval or Subpart H Approval is a program which allows the FDA evaluation to be performed on the basis of a surrogate marker (a measurement intended to substitute for the clinical measurement of interest, usually prolongation of survival) that is considered likely to predict patient benefit (i.e., Velcade (bortezomib) for the treatment of multiple myeloma patients who have received at least two prior therapies and have demonstrated disease progression on the last therapy by Millennium Pharmaceutical).

## APPENDIX B: FINANCIAL ANALYST EARNINGS MODEL<sup>29</sup>

(\$ in thousands, except per share data)

FY ending December 31	2004A	2005A	2006E	2007E	2008E	2009E	2010E
Revenue							
Zensana	\$ -	\$ -	\$ -	\$ 27,202	\$ 93,645	\$ 227,147	\$ 350,902
Marqibo	-	-	-	-	-	24,347	75,293
Talvesta	-	-	-	-	-	2,915	137,296
IPdR	-	-	-	-	-	-	42,418
<b>Total Revenue</b>	-	-	-	<b>27,202</b>	<b>93,645</b>	<b>254,410</b>	<b>605,909</b>
Total COGS (1)	-	-	-	6,392	22,007	57,841	118,515
<b>Gross Profit</b>	-	-	-	<b>20,809</b>	<b>71,638</b>	<b>196,569</b>	<b>487,394</b>
Operating Expenses							
Research & Development (2)	4,547	6,366	21,052	29,568	39,420	47,974	61,495
Licensing & Milestone (3)	-	50	2,050	8,050	9,050	9,050	9,050
Sales & Marketing (4)	-	-	440	4,352	9,365	11,600	11,888
General & Administrative (5)	2,809	3,793	10,642	16,174	13,967	12,721	30,295
Total Operating Expenses	7,355	10,209	34,184	58,144	71,802	81,344	112,729
<b>Operating Income</b>	<b>(7,355)</b>	<b>(10,209)</b>	<b>(34,184)</b>	<b>(37,334)</b>	<b>(163)</b>	<b>115,225</b>	<b>374,665</b>
Other income (expenses)							
Interest income (6)	26	186	1,151	694	864	3,171	8,683
Depreciation and Amortization	-	-	-	-	-	-	-
Other income (expenses)	(1)	(20)	(22)	(24)	(26)	(29)	(32)
Income (Loss) Before Tax	(7,330)	(10,043)	(33,054)	(36,664)	675	118,367	383,316
Tax (7)	-	-	-	-	-	(12,300)	(145,660)
<b>Net Income (Loss)</b>	<b>\$ (7,330)</b>	<b>\$ (10,043)</b>	<b>\$ (33,054)</b>	<b>\$ (36,664)</b>	<b>\$ 675</b>	<b>\$ 106,068</b>	<b>\$ 237,656</b>
Shares Outstanding (8)	10,792	17,662	28,743	28,743	28,743	28,743	28,743
Fully-Diluted Shares (8)	13,149	22,564	34,592	34,592	34,592	34,592	34,592
<b>EPS - Basic</b>	<b>\$ (0.80)</b>	<b>\$ (0.57)</b>	<b>\$ (1.15)</b>	<b>\$ (1.28)</b>	<b>\$ 0.02</b>	<b>\$ 3.69</b>	<b>\$ 8.27</b>
<b>EPS - Diluted</b>	<b>\$ (0.80)</b>	<b>\$ (0.57)</b>	<b>\$ (1.15)</b>	<b>\$ (1.28)</b>	<b>\$ 0.02</b>	<b>\$ 3.07</b>	<b>\$ 6.87</b>
P/E Ratio (price as of close 9/26/06)	N/M	N/M	N/M	N/M	N/M	2.26	1.01

MARGIN ANALYSIS	2004A	2005A	2006E	2007E	2008E	2009E	2010E
Gross Margin	NM	NM	NM	77%	77%	77%	80%
COGS	NM	NM	NM	24%	24%	23%	20%
G & A	NM	NM	NM	59%	15%	5%	5%
R & D	NM	NM	NM	109%	42%	19%	10%
Operating Income	NM	NM	NM	NM	0%	45%	62%
Net Income	NM	NM	NM	NM	1%	42%	39%

YOY GROWTH ANALYSIS	2004A	2005A	2006E	2007E	2008E	2009E	2010E
Revenue	NM	NM	NM	NM	244%	172%	138%
COGS	NM	NM	NM	NM	244%	163%	105%
R & D	NM	40%	231%	40%	33%	22%	28%
G & A	NM	35%	181%	52%	-14%	-9%	138%
Operating Income	NM	NM	NM	NM	NM	NM	225%
EPS	NM	NM	NM	NM	NM	NM	124%



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