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Full Length Research Paper

Risk management in the development of new products in the pharmaceutical industry

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One of the greatest challenges facing the pharmaceutical industry is the process of selecting which new products to develop. In this study, the product development and investment decision problem was examined. A hypothetical case of new product investment in either Product A and/or Product B by a hypothetical company called Healthcare Company was investigated. As employed in previous empirical studies, the NPV framework was utilized to examine the strategies for new product development. Additionally, the stochastic dominance methodology was employed to help with further examination of the dominant strategy. Three investment scenarios were investigated in this article: 100% of investment devoted to only one of the products and an equal investment in each of the drugs. The results suggested that the healthcare company should only invest in one of the pharmaceutical drugs. All of the methods utilized in this study yielded consistent outcomes.

Keywords: Stochastic dominance, net present value, new product development.

INTRODUCTION

Deciding which new products to develop is a major challenge for many pharmaceutical companies with an excess of opportunities but limited resources. Project-prioritization and new product-portfolio selection has long been the domain of the new product arm of the corpo-ration (Blau et al., 2000). Pharmaceutical product deve-lopment as any other management tasks requires impor-tant decisions about the tradeoffs between the available resources as managers decide which drugs to bring to the market (Ogawa and Piller, 2006).

Assuming a fixed research and development budget, the management problem includes deciding which new products to develop, continue to research, terminate, and invest in. In making these decisions, managers face tradeoffs between risks, returns, and time horizons for future payoffs. In theory, such tradeoffs are easily tackled by optimization problems; however, the complexity and uncertainty of the new drug development process make the solution hard to obtain and force the management to employ less complicated and therefore less precise methods of new product identification (Gino and Pisano, 2006).

There are several methods of new product develop-ment identification process. These methods include net present value of income (NPV) analysis, system engi-neering approach, and real option valuation analysis. All of the above methods account for the financial impact of chosen alternatives (Grabowski and Vernon, 1998; Blau et al., 2000; Smit and Trigeorgis, 2006). There are also other methods, which do not take into account the financial aspect of new product development and analyze consumers' preferences for different product alternatives. These models are usually based on consumer theory and involve discrete choice models determining the most preferred product attribute mix (Dakin et al., 2006). For the purpose of this article, only the former type of models is discussed as the proposed method extension involves accounting for the financial aspect of new product development.

In past studies, cash flows, expected returns, and net present value of income were the key variables in the decision-making process of the new drug development and investment. According to Grabowski and Vernon (1998), the rapid growth in RandD development and investment had a strong impact on cash flows and internal rates of return. The relationship between invest-ment and cash-flow statements provided marketing and financial managers with a working framework for resource-allocation decisions. However, NPV of income was still the subject to change and depended on a range of prices and operating costs associated with the invest-ment and development of new pharmaceutical products (AMA, 1969).

Demand, drug prices, as well as develop-ment and operating costs are the source of uncertainty within the framework. Modeling this uncertainty was the primary struggle of previous studies (Grabowski and Vernon, 1998).

Recently, new product development analysis has used a system engineering approach, which includes capacity planning and development management in the analysis. This approach not only focuses on the cash flows and NPV framework, but also on FDA approvals and clinical trails successes (Rogers et al., 2004). The new additions to the model account for the uncertainty associated with the dynamics of the pharmaceutical market. For example, Blau et al. (2000) developed a probabilistic simulation model of a pharmaceutical product development pipeline to prioritize candidate drugs based on their risk/reward ratios. Their framework captured the complexity of new pharmaceuticals development by incorporating probability of success of clinical trails into the NPV conceptual framework (Blau et al., 2000; Lave et al., 2007). Submarinian et al. (2003) and Gino and Pisano (2006) formulated a simulation-optimization framework that combined mathematical programming with discrete choice simulation to account for planning and scheduling uncertainty. Although these models account for high level of complexity regarding new product development, they tend to be time consuming, not easily executable by marketing executives, and geared towards more specialized industries (eg. pharmaceutical industry) where federal guidelines need to be validated before new product production (Baker, 2002).

Rogers et al. (2004) criticized the above engineering approach even further for not accounting the uncertainty factor within the financial markets in the project's risk estimation process. They proposed a real option valuetion (ROV) model to track the uncertainty in the value of a project in development through market-traded securities to minimizes the risk for the specified level of return (Rogers et al., 2004) . The ROV framework captures the value of the adaptive resources and capabilities, enabling a company to adapt and re-deploy assets, develop and exploit synergies, and gain competitive advantage in bringing a pharmaceutical product to market (Smit and Trigeorgis, 2006).

The focus of this article is to introduce a new way of decision-making process with regards to the new drug development by employment of a NPV model which includes stochastic dominance method, accounting for the uncertainty within the financial markets. Differently from Rogers' et al. (2004) ROV model, which tracked the uncertainty through market- traded securities, this method models the distribution of each NPV component and therefore accounts for the uncertainty in drug prices, as well as development and operating costs. In addition, the stochastic dominance methodology, as an intuitive and easily implemented tool, is uniquely suited to the objecttives of new product development decision. Stochastic dominance is a generalization of utility theory that eliminates the explicit specification of firm's utility function and employs general mathematical statements about product's return on investment and risk aversion to develop the optimal investment decision rule for selecting the new product alternative (Heyer, 1995; Post and Versijp, 2007).

As a result, the objective of this study is to identify which new drug a hypothetical pharmaceutical company, healthcare company, should develop by utilizing the stochastic dominance methodology in combination with the existing framework of NPV. As mentioned earlier, deciding which new products to develop is a major challenge for many pharmaceutical companies. Consequently, studying the proposed process of new drug development may provide additional insights into the practice and identify new and simple ways of the investment strategy detection. In this investigation, a hypothetical situation is analyzed to identify the best pharmaceutical candidate for development by employing the predictive powers of the NPV model and stochastic dominance analysis. The data and the pharmaceutical company were created for this exercise.

EMPIRICAL ANALYSIS

Problem description

As mentioned earlier, the focus of this study is to determine which product or products the pharmaceutical company, healthcare company, should develop in order to maximize their return on investment. In order to perform the analysis, a hypothetical pharmaceutical company called healthcare company is considered. The company has 4 million dollars for a new drug investment. There are two-potential drugs (Product A and Product B) in which the company can invest in and three possible scenarios of investment:

i) 4 million dollars to develop and produce Product B;
ii) 2 million dollars for production of each product;
iii) 4 million dollars to develop and produce Product A.
The healthcare company is faced with uncertainty in the product pricing, demand, and cost.

Data inputs

The data employed in this investigation is based on data employed by Blau et al. (2000) and Rogers et al. (2004). These two articles used the hypothetical data in order to analyze the NPV of income using a system engineering approach. For the purpose of this analysis, the data was manipulated to fit the assumptions of this framework.

The following describes the data employed for this analysis. Five-year time-series for predicted sales (Sales) and unit price (Price per Package) for each new drug (Product A and Product B) are utilized in the study. These two drugs data are correlated with each other. The corre-

Table 1. Input for New Drug Candidate PRODUCT A and PRODUCT B

		PRODUCT A			PRODUCT B		
NPV for PRODUCT B with $4 Million of Investment	**Year**	**Price per Package $**	**Sales**	**Investment $**	**Price per Package $**	**Sales**	**Investment $**
	Year 0			0			4,000,000
	Year 1	8	0		4.3	1,675,000	
	Year 2	5	0		4	1,700,000	
	Year 3	5.5	0		3.5	1,800,000	
	Year 4	6	0		3	1,900,000	
	Year 5	6.5	0		2.5	1,950,000	
NPV for PRODUCT A and PRODUCT B with $2 Million of Investment Each		**Price per Package $**	**Sales**	**Investment $**	**Price per Package $**	**Sales**	**Investment $**
	Year 0			2,000,000			2,000,000
	Year 1	8	200,000		4.3	837,500	
	Year 2	5	250,000		4	850,000	
	Year 3	5.5	350,000		3.5	900,000	
	Year 4	6	400,000		3	950,000	
	Year 5	6.2	425,000		2.5	975,000	
NPV for PRODUCT A with$4 Million of Investment		**Price per Package $**	**Sales**	**Investment$**	**Price per Package $**	**Sales**	**Investment $**
	Year 0			4,000,000			0
	Year 1	8	400,000		4.3	0	
	Year 2	5	500,000		4	0	
	Year 3	5.5	700,000		3.5	0	
	Year 4	6	800,000		3	0	
	Year 5	6.2	850,000		2.5	0	
Taxes		32%					
Discount Rate	5%						
Cost of Revenues	55%						
Operating Cost	20%						

correlation matrix is presented in the Appendix. These sales and price values are converted into a net income value for each year, which is then combined with investment information to compute NPV of income for the new drugs portfolios (Goldman, 2002). Differently from other reviewed articles, the probability of clinical trails success and FDA approvals are not included in this analysis.

The several assumptions are made with regards to taxes, discount rate, cost of revenues, and operating costs. The above variables are included in the income calculations. Although the two cost variables (Revenues and Operations) change each year, their average values are utilized to describe their uncertainty. The following assumptions are employed in NPV computations: taxes rate is 32%, discount rate is 5%, cost of revenues constitutes 55% of gross revenues, and operating costs are 20% of gross income (Goldman, 2002). Finally, probability distributions are used to describe the uncertainty surrounding the input variables. Both the price per package and sales has a triangle probability distribution. The input data and assumptions are provided in Table 1. Price per package and sales values represent the value most likely to occur.

METHODOLOGY

This article methodology is based on net present value (NPV) calculations discussed earlier. NPV was cited as one of the most important factors driving new product development and investment decisions (Grabowski and Vernon, 1998). In addition to the cash flows/NPV analysis, the stochastic dominance methodology is utilized. Although it was not mentioned by previous studies as a possible tactic, the stochastic dominance procedures identify the dominant strategy for the presented level of investment. In order to perform the NPV analysis, Excel's add-ons software Simetar and Crystal Ball are employed. In order to determine the drug in which the healthcare

company should invest, the NPV of income data is simulated. The NPV calculations for each scenario are presented in the Appendix. Similarly to Blau et al. (2000) as well as Rogers et al. (2004) approaches, the simulation procedure has a Monte Carlo sampling method, a random number generator Excel LGC, and 1,000 itera-tions. The NPV data are simulated for each of the three scenarios. In addition, the sensitivity analysis is per-formed to evaluate the range of output in response to changes in one of the input variables over constant values of other inputs as well as to identify the key factors responsible for the results variation (Goldman, 2002; Post and Versijp, 2007). The open loop technique of sensitivity analysis is employed. As a result, the realized value of the input in question has an effect on the value of output achieved, but does not alter the product decision (Bosch, 2007; Post and Versijp, 2007).

In order to determine the preferable drug of investment, the NPV simulated data for each scenario is analyzed using the stochastic dominance methodology. Stochastic dominance is a procedure characterized by preferences between risky prospects (Bennet, 2007; Bosch, 2007). First Degree Stochastic Dominance (FSD), Generalized Stochastic Dominance (GSD), Stochastic Efficiency with Respect to a Function (SERF), and Risk Premium are employed to identify the product in which the healthcare company should invest. The second order Stochastic Dominance is not utilized in this study due to Simetar's calculation problems.

First Degree Stochastic Dominance informs which NPV distribution dominates. If a decision maker prefers NPV distribution for scenario 1 [$f(x)$] to NPV distribution for scenario 2 [$g(x)$] and scenario 3 [$h(x)$], then $f(x)$ dominates $g(x)$ and h[x] by FSD. As a result, the cumulative probability distribution function of NPV for scenario 1 ($F[x]$) is less or equal to cumulative probability distribution function of NPV for scenario 2 ($G[x]$) and 3 ($H(x)$) (Bennet, 2007; Bosch, 2007).

The second method employed is the Generalized Stochastic Dominance (GSD), which predicts choices given a bound on risk preferences. GSD is based on minimization of the following equation:

$$\int_0^1 [G(x) - F(x)]^* U'(x)\, dx$$

where G(x) and F(x) are the cumulative probability distribution functions of NPV for scenario 2 and 1, U'(x)dx is the first derivative of an utility function for a given risk aversion interval consisting of lower and upper coefficients of absolute risk aversion [coefficient of absolute risk aversion is defined as $\Pi(x) = -(U''(x))/(U'(x))$, where U is the utility function and x is the inputs of U (Bosch, 2007)]. As a result, two risky prospects are compared for a risk aversion interval, r1 and r2 (McCarl, 1990; Davidson and Duclos, 2006). The risk aversion interval used in this analysis is [0.000; 0.001].

A refinement of GSD, Stochastic Efficiency with Respect to a Function (SERF), is also used in this analysis. SERF uses certainty equivalent [Certainty Equivalent – the amount with certainty having the same utility as the risky prospect (Bosch, 2007)] for the comparison of alternative NPV distributions. For a given risk aversion interval, r1 and r2, the certainty equivalent of NPV for all scenarios are computed for any number of risk aversion coefficients. The alternative with the highest or equal highest certainty equivalent values in the risk aversion range is the dominant distribution. The most important difference between SERF and GSD is SERF being more discriminating, because it eliminates a distribution dominated by a combination of other NPV distributions. GSD, on the other hand, eliminates only a distribution dominated at every point of the risk aversion interval (Bosch, 2007; Hardacker et al., 2004; Davidson and Duclos, 2006).

The final stochastic dominance method utilized for this analysis is a Risk Premium method. Risk Premium is the difference between certainty equivalents of alternatives at a given coefficient of absolute risk aversion. It measures by how much one distribution is preferred to another. The difference between certainty equivalents is the risk premium indicating the minimum amount by which the less preferred distribution would have to be increased to make it equally preferred to the dominant alternative (Bosch, 2007).

The software used to perform the analysis is Excel add-ons Simetar and Crystal Ball. Crystal Ball, widely used in system engineering, enhances Excel by creating probability distributions that describe the uncertainty surrounding the input variables (Goldman, 2002) . Recently, Crystal Ball was found useful in economic analysis of risk, especially for performing Monte Carlo simulations (Clemen, 1996). As a result, it is utilized to define the probability distributions of each input, to perform NPV Monte Carlo simulations for each scenario, and to carry out sensitivity analysis. On the other hand, Simetar is employed to perform the stochastic dominance analysis that determines the drug candidate to be invested in by Healthcare Company.

RESULTS

In this section, the results of the analysis are discussed based on the Monte Carlo simulations of NPV and stochastic dominance analysis for three-investment strategies. The NPV data was simulated using Monte Carlo simulation with 1,000 iterations. The summary statistics for each investment scenario is presented in Table 2. As presented below, the mean NPV of income was the highest when 4 million dollars is invested in drug Product B. The mean NVP in this case is $2,609,537. Investment of 2 million dollars in each of the products yielded mean NPV of $1,352,790 and mean NPV was the smallest for investment only in Product A. The standard deviation was also the highest for NPV for Product B with smallest for NPV for Product A. As a result, based solely on the Monte Carlo simulations of NPV, investing in Product B

Table 2. Summary statistics for scenarios with three investment strategies

	NPV for PRODUCT A with $4 Million of Investment	NPV for PRODUCT A and PRODUCT B with $2 Million of Investment Each	NPV for PRODUCT B with $4 Million of Investment
Mean $	95,783	1,352,790	2,609,537
Standard Deviation $	111,120	136,838	175,512
Max $	486,624	1,781,493	3,121,545
Min $	-305,598	908,751	2,008,667
CV	116.01	10.12	6.73

Table 3. First degree stochastic dominance results

Scenario	NPV for PRODUCT A and PRODUCT B with $2 Million of Investment Each	NPV for PRODUCT A with $4 Million of Investment	NPV for PRODUCT B with $4 Million of Investment
NPV for PRODUCT A and PRODUCT B with $2 Million of Investment Each		FDD	
NPV for PRODUCT A with $4 Million of Investment			
NPV for PRODUCT B with $4 Million of Investment	FDD	FDD	

Note: FDD means first order dominated distribution.

Table 4. Generalized stochastic dominance results

Lower risk aversion coefficient (*r1*)	0.000
Name	Level of Preference
NPV for PRODUCT B with $4 Million of Investment	Most Preferred
NPV for PRODUCT A and PRODUCT B with $2 Million of Investment Each	2nd Most Preferred
NPV for PRODUCT A with $4 Million of Investment	3rd Most Preferred
Lower risk aversion coefficient (*r2*)	0.001
Name	Level of Preference
NPV for PRODUCT B with $4 Million of Investment	Most Preferred
NPV for PRODUCT A and PRODUCT B with $2 Million of Investment Each	2nd Most Preferred
NPV for PRODUCT A with $4 Million of Investment	3rd Most Preferred

yielded the highest investment returns for the healthcare company. Additionally, the Internal Rate of Return (IRR) for this investment strategy was also the highest, with a mean IRR of 28%.

The sensitivity analysis was performed to evaluate key output variables of a simulation analysis and their effect when input variables change in specified amounts (Bosch, 2007). The effect of input variables as price per-package and Sales on the variability of NPV was investi-gated. Based on the analysis, Price per Package had an impact of 9.3 to 12.3% and Sales has an impact of 9.4 to 10.8% on the variability of NPV. As a result, when price per package rises by 1%, the NPV will change between 9.3 and 12.3%. An increase of 1% in sales results in 9.4 to 10.8% increase in NPV. The largest impact of Price per Package on NPV was under scenario of investment only in Product B and largest variability in NPV from change in sales was under scenario of investment only in Product A. These results are presented in the Appendix. In summary, based on the results presented in the above simulation of NPV as well as stochastic dominance ana-lysis, it is easy to conclude that the distribution of NPV for Product B with 4 million dollars of investment yielded the highest NPV of income, as well as it was the most effi-cient and dominant strategy among the three invest-ment scenarios. Furthermore, all of the methods employ- ed in this study yielded consistent results. Even GSD and SERF, which usually differ in final outcomes, lead to the same conclusions. Consequently, healthcare company should invest in the development and production of a

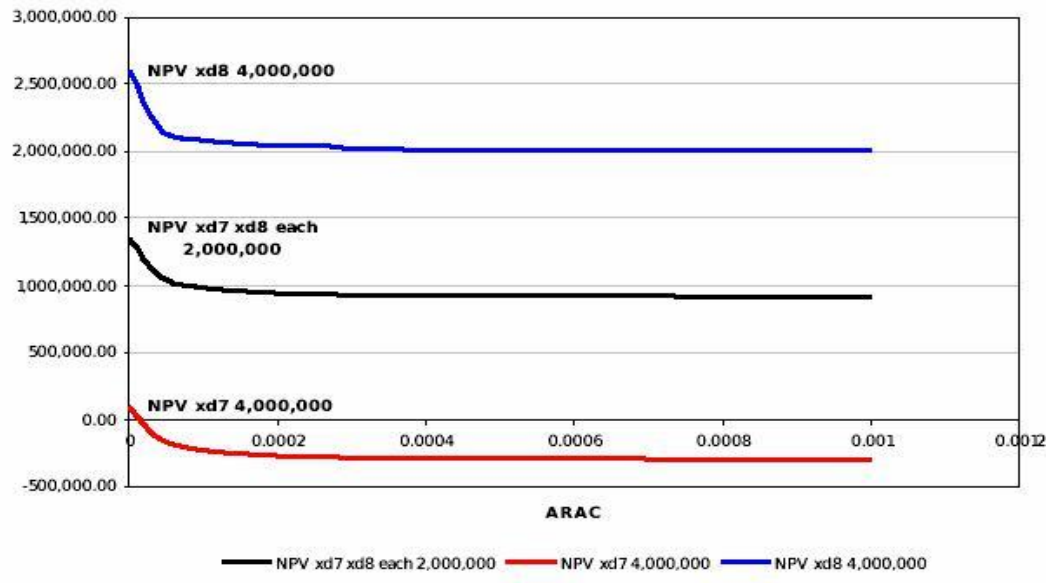

Figure 1. Sochastic Efficiency with Respect to A Function (SERF) under a Neg.Exponential Utility Function

drug Product B.

Conclusion

Deciding which new products to develop is a major challenge for many pharmaceutical companies with an excess of opportunities but limited resources (Blau et al., 2000). Previous studies employed a simple cash flow and NPV analysis, as well as more complicated system engineering approaches to solve the new pharmaceuticals development problem (Grabowski and Vernon, 1998; Rogers et al., 2004). This study extended the new product identification knowledge by combining the NPV analysis with the stochastic dominance method to identify the product with the highest return on investment for hypothetical healthcare company. Based on the NPV and stochastic dominance results, the healthcare company should invest only in Product B as it would provide the highest return on investment.

The inclusion of stochastic dominance accounts for the financial markets uncertainty within the project's risk estimation as suggested by Rodgers et al. (2004). In addition, although stochastic dominance is a relatively crude method, it highlights the practical simplicity of measuring returns on investment for each alternative (Heyer, 1995; Post and Versijp, 2007). Finally, when making a well informed new development product investment decision, it is important to acquire information on each product's return on investment based on different scenarios and different methods. Stochastic dominance employed together with the NPV analysis should become yet another measure of future product success employed by pharmaceutical companies as well as other industries in their decision making process.

Although the methodology employed in this analysis yields consistent outcomes, improvements could be made to the conceptual framework of the study. The proposed model does not account for clinical trials probability of success and FDA approvals. These factors should be included in the model to improve the model predictions and therefore allow for more efficient resource allocation and future profitability and success of chosen pharmaceutical product. Furthermore, extending the number of drugs investigated, introducing scheduling and planning components as well as accounting for the uncertainty within the financial markets, would present more precisely the dilemma faced by pharmaceutical companies and account for the variables affecting the dynamic structure of the pharmaceutical market.

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APPENDIX

Table 6. Correlation Matrix for Drugs Product A and Product B

	Cost/Package PRODUCT A	Cost/Package PRODUCT	BSales of PRODUCT A	Sales of PRODUCT B
Cost/Package PRODUCT A	1	0.36	-0.45	-0.30
Cost/Package PRODUCT B	0.36	1	-0.97	-0.99
Sales of PRODUCT A	-0.45	-0.97	1	0.98
Sales of PRODUCT B	-0.30	-0.99	0.98	1

Table 7. The NPV Calculations for PRODUCT B with 4 Million Dollars of R and D Investment.

Drug: PRODUCT B						
Input	**Year 0**	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Price per Package $		4.3	4	3.5	3	2.5
Sales		1,675,000	1,700,000	1,800,000	1,900,000	1,950,000
Gross Revenues $		7,202,500	6,800,000	6,300,000	5,700,000	4,875,000
Cost of Revenues $		3,961,375	3,740,000	3,465,000	3,135,000	2,681,250
Gross Income $		3,241,125	3,060,000	2,835,000	256,5000	2,193,750
Operating Costs $		648,225	612,000	567,000	513,000	438,750
Net Income Before Taxes $		2,592,900	2,448,000	2,268,000	2,052,000	1,755,000
Taxes $		829,728	783,360	725,760	656,640	561,600
Initial Investment $	-4,000,000					
Net Income $	-4,000,000	1,763,72	1,664,640	1,542,240	1,395,360	1,193,400
NPV $	2,604,360					
IRR	28%					

Table 8. The NPV Calculations PRODUCT A and PRODUCT B with each 2 Million Dollars of R&D Investment

Inputs	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Drug: PRODUCT A						
Price per Package $		8	5	5.5	6	6.5
Sales		200,000	250,000	350,000	400,000	425,000
Drug: PRODUCT B						
Price per Package $		4.3	4	3.5	3	2.5
Sales		837,500	850,000	900,000	950,000	975,000
Gross Revenues $		5,221,202	4,656,126	5,031,338	5,244,601	4,972,422
Cost of Revenues $		2,871,662	2,560,869	2,767,236	2,884,531	2,734,832
Gross Income $		2,349,542	2,095,257	2,264,102	2,360,070	2,237,590
Operating Costs $		469,908	419,051	452,820	472,014	447,518
Net Income Before Taxes $		1,879,633	1,676,205	1,811,282	1,888,056	1,790,072
Taxes $		601,483	536,386	579,610	604,178	572,823
Initial Investment $	-4,000,000					
Net Income $	-4,000,000	1,278,150	1,139,820	1,231,671	1,283,878	1,217,249
NPV $	1,325,096					
IRR	17%					

Table 9. The NPV Calculations for PRODUCT A with 4 Million Dollars of R and D Investment.

Input	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
Price per Package $		8	5	5.5	6	6.5
Sales		400,000	500,000	700,000	800,000	900,000
Gross Revenues $		3,000,000	3,000,000	4,000,000	5,000,000	5,000,000
Cost of Revenues $		2,000,000	1,000,000	2,000,000	3,000,000	3,000,000
Gross Income $		1,000,000	1,000,000	2,000,000	2,000,000	2,000,000
Operating Costs $		300,000	200,000	338,641	400,000	500,000
Net Income Before Taxes $		1,000,000	900,000	1,000,000	2,000,000	2,000,000
Taxes $		400,000	300,000	433,460	600,000	600,000
Initial Investment $	-4,000,000					
Net Income $	-4,000,000	800,000	600,000	921,103	1,000,000	1,000,000
NPV $	45,832					
IRR	5%					

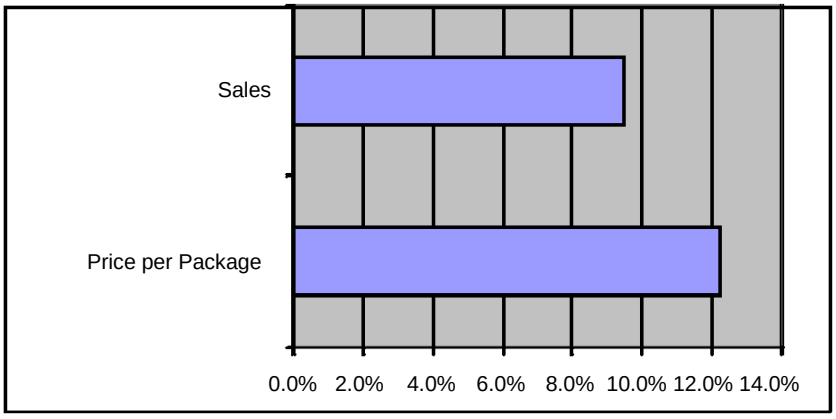

Figure 2. Sensitivity Analysis: NPV for PRODUCT B with $4 Million of Investment

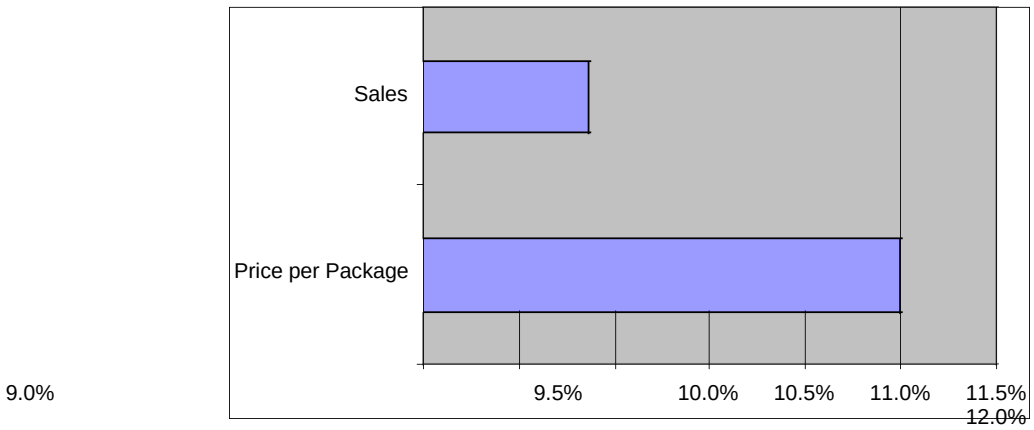

Figure 3. Sensitivity Analysis: NPV for PRODUCT A and PRODUCT B with $2 Million of Investment Each

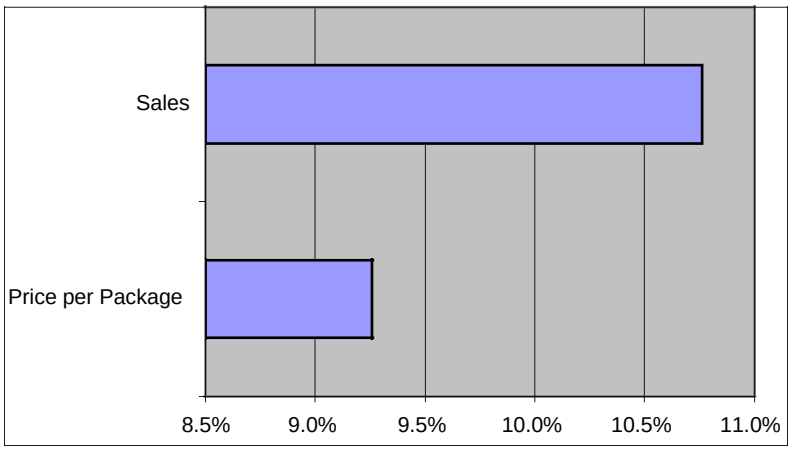

Figure 4. Sensitivity Analysis: NPV for PRODUCT A $4 Million of Investment.