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# DECISION ANALYSIS AND STRATEGIC MANAGEMENT OF RESEARCH AND DEVELOPMENT: A COMPARISON BETWEEN APPLICATIONS IN ELECTRONICS AND ETHICAL PHARMACEUTICALS


## Abstract

The process of strategic management of research and development is contrasted through the application of decision analysis in the evaluation of R&D projects--one in an electronics company, and one in a pharmaceutical company.

Issues considered include the different character of applied R & D in each industry resulting from, for example, the shorter product life cycles that apply to the electronics industry compared to the much longer life-cycles in the pharmaceutical industry. The difference of time horizon between the two industries suggests that different decision criteria might be adopted in project evaluation. Decision-makers in both industries express a need for flexible decision and performance criteria in relation to strategy dialogue about alternative project-options.

Implementation problems encountered include: long term discounting, the nature of the preference function for long-term cash flow streams, issues in making assessments of uncertainty in relation to long-term future time horizons, and the management of research portfolios.

The Nature of the R & D Decision Process and Strategic Management

Industries such as electronics and ethical pharmaceuticals are heavily dependent for their success upon the productivity of research and development. In both fields, the strategy for development of new products has been undergoing significant changes over the past twenty years. (Bemelmans (1978), Balthasar et al. (1978), Harrigan (1983)) The explosion of scientific knowledge in these areas has led to more rational and productive approaches for carrying out research.

In the ethical pharmaceutical area, for example, less use is being made of traditional methods for finding new drugs, which involved screening at random chemical components to discover safe, therapeutic products. Such methods have been largely superseded by approaches which involve initial specification of the characteristics required in a new drug. Use is then made of newly developed scientific information on the molecular biology of disease and the processes of drug action to design, in a custom-built sense, the molecular structure of the desired compound.

In the electronics industry, rapid technological developments in micro-electronics and micro-circuitry have shortened the life cycle of many end-products, and have increased the risks involved in research activity.

The common strategic reaction of many pharmaceutical companies has been to concentrate upon a selected number of research areas--typically say, from three to six therapeutic classes. By restricting these areas initially, the company is able to build up expertise, strength and an identifiable market position, and then later extend

research into closely related and integrated product areas. This trend has been hastened by the increasing costs of research activity and the uncertainty about eventual sales. Some new drugs are reputed to require investments in excess of $50 m. - $75 m.

Those decision processes which might lead to a new applied research product in the pharmaceutical and electronic areas are characterized in this paper. Some or all of the following steps in the decision process have to be identified. These include the generation of ideas, screening, analysis of projects considered for selection, physical development of the product, test marketing, production and marketing. Special attention is focussed on the role of strategic decision analysis at the project analysis and evaluation stage, as it can potentially handle the influence of risk and uncertainty, multiple objectives, the sequential character of research and development, as well as promote the interactions necessary between R & D, finance, marketing and production for effective strategic management. This role is examined in relation to two case studies drawn from electronics and pharmaceuticals, and the problems and strategic issues in implementation are highlighted.

## Case A: Policy Options in an Electronics Company

### Background

Firm A has interests in the applications of microelectronics to computers and analytical instrumentation. It has followed industry trends by integrating backward and forwards to maintain a competitive strength, not only in semi-conductor manufacture but increasingly also in end products. Its strategic management emphasis is to undertake

R & D in order to provide the strategic base for the company's long term growth. It stresses leadership and high quality in its research activities, and requires that R & D generates the competitive edge to enable the firm to finance its long-term growth as far as possible from internally generated funds.

A range of possible R & D project areas appear frequently for evaluation and feasibility screening. As a conscious policy the research and development group work closely with marketing staff and production engineers, and thus keep abreast both of market needs and potential production improvements, i.e., applied design projects. Idea development is regarded as a very important process. Regular project review and brainstorming meetings are held by the research staff who are divided into groups by area of R&D expertise.

Once a new product idea has been generated, its potential progress is monitored in a process involving the following steps:

1) Investigation
2) Laboratory Prototype
3) Production Prototype
4) Pilot Run

Decision Analysis

Only the investigation phase is dealt with in this paper because it is then that decisions about the adoption of projects are made. It comprises three relatively distinct stages. First, a preliminary product survey, during which a broad definition of the potential technical and end market features of the project is required. Second, a detailed design study involving a thorough evaluation of possible project

designs. Third, a project proposal which firms up the technical and economic framework for the project.

The following discussion concentrates on two decision analysis models used for screening a set of R & D policy areas. As the company was a private enterprise, the financial worth of each project needed to be assessed from the outset. The first model uses a form of risk simulation [Hertz and Thomas (1983)] to sensitize decision-makers to the existence of risk and for financial forecasting of return, cost and revenue factors. The second involves a multi-dimensional, multi-attributed utility model which has as one of its attributes a financial worth measure. Thus, the mean/variance analysis provided by the risk simulation approach had the purpose of offering a firmer basis for assessments on this attribute.

These models were evaluated in the context of a meeting held to assess ten new project areas for the company. The areas were appraised by four senior engineers from the company.

It was decided to adopt the simulation approach because distributions of IRR (internal rates of return) could easily be obtained, and these were used in conjunction with the net present value (NPV). A structural flow chart for the risk analysis procedure is shown in Appendix 1. Net cash flows per period were generally assumed to be independent although certain meaningful patterns of dependence were present in the model structure. Probabilistic assessments for such underlying project variables as cost and sales volume were obtained using the fractile assessment approach (Moore and Thomas (1976)). Each of the four decision-makers made assessments based upon differing assumptions about project areas.

Problems arose in measurement in two situations. First, there were difficulties involved in obtaining probability assessments from appropriate decision-makers, mainly because of the large number of assessments required, and the complexity of each project. The decision analyst's presence was usually required by engineers to enable them to sharpen and better understand the probability assessment process. Second, they had some difficulty in making assessments for future events such as sales in the later years of the project. The analyst encouraged them to graph optimistic and pessimistic scenarios for sales volume over time and use such scenarios as a frame of reference for subsequent assessments.

The attributes used in the subsequent Churchman-Ackoff multiattributed model (see Appendix 2) were generated in a Delphi process by the four senior engineers. They were: profitability, growth and diversity of the product line, offensive research mounted to anticipate competition, increased market share, maintenance of technical capability, increase in company research image (quality) and development of research staff skills. The relative weighting for these attributes was developed using the approach suggested by Edwards (1976).

Discussion of Results of Models in Firm A

In terms of the risk-simulation model Tables 2, 3, 4 and 5 and the associated graphs (Figures 1-4) show that where more than one decision maker was responsible for evaluating a project, the measures of IRR, NPV and payback differ, and often quite markedly. Figures 1 to 4 show for each decision-maker respectively a graph of standard deviation of his estimate against the net present value at a discount rate of 10%.

Table 1 displays options for dealing with the projects according to each decision-maker's valuation--the higher the ratio the greater the potential value of the project.

Insert Tables 1-5 and Figures 1-4 about here

There appears to be support for screening out project 2 and taking a much closer look at 4, 5, 7, 10.

The results from use of the Churchman-Ackoff model are given in Table 6. The agreement between decision-makers is poor (Table 7). The attempt in Table 8 to produce a consensus ranking is, in fact, a linear additive equal weighting scheme for the set of judges. It shows that projects 2, 7, 10 are less favored project areas whereas 8, 3, 1 and 5 are more favored.

Insert Tables 6-8 about here

Although there is some agreement among the screening procedures about either good or bad project areas, there is a considerable grey area in between, where factors such as other attributes not included in the evaluation, problem assumptions, and so on, may be important.

## Implementation and Further Screening of Areas

The pilot study of screening procedures in Company A highlighted as many problems as it did solutions. Some of them are listed below:

(i) The screening process models used inevitably lead to a consensus problem in reconciling the separately produced criteria from each individual. However, it is more appropriate to use consensus estimates of probability or value obtained through a group dialogue process as inputs for the NPV model. This seems more valuable than

efforts to thrash out a consensus view about the single most relevant decision criterion.

(ii) The ten project areas had been screened initially by a "team" scenario process. There was much subsequent discussion about how and under what assumptions the derived product-market areas were obtained. It could be argued that an entirely different, indeed diametrically opposite, view of future scenarios (and associated product market concepts) should have been introduced at an early stage in the dialogue about options resulting perhaps in the generation of a wider set of project options.

(iii) A's future depends upon strategic risk-taking and continuing investment in R & D possibilities. Therefore, it was felt that the top corporate management should give research management guidelines concerning the company's preferred risk/return profile for the portfolio of R & D investment possibilities. Further, it is essential that the firm should indicate clearly its goals for R&D and that trade offs between respective rates of return and their risk exposure characteristics be identified. For example, should the corporate policy require that each project earn better than some pre-specified target level or should flexibility be built into the evaluation process?

In reviewing these problems it was decided to adopt the following changes. First, that increased initial effort in the process should be directed towards a more <u>focussed</u> questioning of assumptions, scenarios, product/market concepts. Some extreme scenarios were to be included in the agenda for debate and dialogue, and team members were asked to examine, challenge and take "devil's advocate" positions about project

assumptions. Notice that this decision makes the inquiry system more complex and multi-dimensional in accordance with Churchman's (1971) conflict-based Kantian and Hegelian forms of inquiry system. That is, several views about the problem are held and consensus is achieved through group dialogue and debate. Second, it was decided that the decision-making unit should be the team rather than the individual. Emphasis was placed upon the value of achieving consensus judgments about problem structure and about the assessments of probabilities and values, by obtaining the widest possible "airing" of views and assumptions. It could also be argued that strategic assumptions analyses (Mason and Mitroff (1981)) are probably more valuable than forced consensus processes of the Delphi type in achieving some meaningful "closure" for consensus judgments. Third, it was decided that the multi-attributed screen could be carried out more sensibly in association with a sensitivity analysis of a certainty model, before the strategic risk analysis was carried out. Strategic risk analysis need then be focussed only on those options which pass through the dialogue process of project structuring and multiattributed (MAUT) screening. It was also decided that the MAUT screening process should be modified to provide more rapid feedback about options on the lines suggested by Humphreys and Wisudha (1979), Sarin (1977) and Slevidge (1976).

It is appropriate at this point to review the role of the certainty model and sensitivity analysis (see Rappoport (1967)). Basically, the certainty model involves calculating NPV for a project using single, most likely estimates for annual cash flows. Sensitivity analysis with such a certainty model investigates the effect that a

small change in each of the variables would have on the NPV measure. It, therefore, identifies the variables whose uncertainty would have the largest effect on the NPV. It is further argued that the advantages of the certainty model, with sensitivity analysis back-up, lie in relation to the simplicity, speed and economy of the process. The process can quickly highlight projects or research areas with high risk or loss potential and, thus, allow managerial effort to be focussed upon those research areas which promise well for the organization's future. Such an emphasis would make more sense of both the subsequent application of multi-attribute screening approaches, and a detailed strategic risk analysis.

When this process was implemented, a further MAUT analysis was carried out on an augmented project set. This resulted in two further options being added to the project set 8, 3, 1 and 5 already considered as candidates for the strategic risk analysis. The output from this risk analysis was then discussed in great detail, at both the corporate level and at the R & D team level. The consensus view was that all of areas should be examined further, both in terms of their projected fit within the portfolio of activities, and also in relation to "dovetailing" corporate goals and objectives (such as the risk/reward trade-off) with the "projected" results of the portfolio.

This dialogue process simply recognizes that there is no single "best" criterion, or set of criteria, by which strategic management of the firm's R & D and growth process should be handled. Some managers still argued that the ability to keep abreast of the long-term technological futures was more important than such purely short-term

financial issues as risks, returns and timing of cash flows. Their concern was with the common top management focus upon short-term financial results. However, there was agreement that some "balance" between high risk, high return and low risk, low return activities was worthwhile, provided that the organization's financial objectives had a medium to long term focus. Corporate management then reviewed the project set and decided to go for all of the finally screened areas. The decision was based on the view that they offered both the potential for longer-term skills strategic development and also the attainment of satisfactory short to medium term financial results.

Case B: Project Evaluation of Ethical Pharmaceuticals Company

Firm B is a research oriented pharmaceutical company specializing in ethical pharmaceuticals (prescription drugs) rather than "over-the-counter" proprietary products. It competes in that segment of the industry in which the main competitive requirement is heavy spending on R & D activity, directed specifically towards the development of new ethical drugs or compounds. This is in contrast to the so-called "generic" segment (non-branded), in which R & D efforts are largely directed towards improving manufacturing efficiency (i.e., competition on the basis of low-cost manufacture).

Approximately 10% of Firm B's sales volume is invested in R & D and a key performance measure in that area is the ability to produce a regular flow of ethical pharmaceuticals which can be successfully marketed. However, firms such as B have to accept that only 10-20% of new compounds ever achieve significant technical success, quite apart

from ultimate commercial success. That is, the risks and costs of continued research activity are high. Therefore, strategic management of the research portfolio should ensure a sound cash flow balance between new and existing products. Existing products should be positioned to generate positive net cash flows in order to provide a strong basis for internal funding of those in the developmental stage and those new R & D activities directed towards medium to long term growth.

Lengthy time horizons are common in pharmaceutical R & D. It may take from ten to twelve years to develop a drug from initial formulation to the point of sale[1]--that is, around ten years after a patent on a new product or process is granted. Since patent life is seventeen years (in the United States)[2] the firm typically has protection against significant competition in the three to six years of initial "growth" sales in the product's life cycle. Thus, companies may be able to establish a leadership base for continued medium to long-term cash flow generation. The product life of a drug in the market-place may normally be from fifteen to twenty years. This may be extended if the product's uniqueness in quality and branding can be maintained.

In the pharmaceutical R & D process, the stages through to registration can be characterized as follows. The initial phase of <u>screening</u> involves the search for potentially useful compounds in the firm's areas of therapeutic concentration. This stage can take upwards of one year, and depends upon the form of exploration and synthesis required

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[1] Cross-licensing and joint-venture arrangements may reduce the developmental time period.

[2] This patent period may be lengthened by pending legislation in the U.S. Congress and House of Representatives.

to generate a potential project candidate. For example, there is a strong contrast between random screening processes and those based on molecular biology.

The next two stages involve the development of the product to the pre-clinical decision point. This development phase involves pharmacological and toxicological studies of the new compound to determine the extent of chemical viability in the designated therapeutic class.

At the preclinical decision point, the issue is whether to test the drug compound in animals in order to determine safety and therapeutic efficiency. If the preclinical stage is successfully completed, then clinical trials are undertaken on a limited basis with human subjects. During the course of these clinical studies the firm also carries out further long-term toxicological trials, and examines suitable production process development.

Success at the clinical stage allows the company to apply for drug registration by national country drug authorities. Some countries are considerably more stringent than others, and often require extremely detailed technical, therapeutic and clinical research information. Registration, once achieved, allows the firm to market the drug to doctors and health authorities.

Two features about this development and product life cycle process should be noted prior to a discussion of the case study. First, that the probability of technical success is low--typically in the range 0.1 to 0.2 as a historical relative frequency. Second, that technical success does not necessarily guarantee commercial success. Evidence available suggests that the probability of commercial success is around

50%, implying that only 5-10% of compounds overall can be commercially successful.

## The Contrapil Case Study

### Introduction

The case deals only with the application of decision analysis to the process of evaluating a single project within a given research therapy area in Firm B. However, it was part of a pilot implementation of the use of decision analysis in the strategic management of the research and development process as a whole in which both individual projects and research area portfolios were appraised.

This case study illustrates the use of licensing, a joint-venture strategy, as one of the many strategies that larger pharmaceutical companies use in order to shorten the length of the development time horizon of an individual research project. Pharmaceutical companies employ experts to identify valuable compounds developed by smaller companies, with a view to licensing the compounds for end-use. The advantage of the joint-venture arrangement to the smaller company is that it can transfer the responsibility for the potentially costly pre-clinical, clinical and registration stages to the larger company.

Contrapil should be viewed as an example of the application of decision analysis to the evaluation of the individual research project in the clinical pharmaceutical area.

### Background

The following case study describes the proliferation of problems which confronted a pharmaceutical company when it was offered the

opportunity of purchasing a license to develop a specified substance, which, for the purpose of this analysis, is known by the name "Contrapil." The preliminary negotiations commenced in March 1969 with Benco Ltd wishing to sell the license and Sappho Ltd as the potential purchaser. The drug itself belonged to that group generally known as oestrogens, a group in which the amount of work undertaken by the prospective buyer was usually minimal. At the time of the potential sale all of the pharmacological stages of development had been undertaken by the Benco research laboratories.

Initial discussions were between Benco and Sappho's Licensing Departments with Benco stipulating that they should receive approximately $70-$100 per kilogramme of the substance sold by Sappho. The Licensing Department had to calculate the economic worth of the substance and of advise the company as to whether or not it should purchase the license. It was felt that the decision-making process would benefit from the combined expertise offered by different Departments within the company. Top management formed a general review team which comprised members from the Licensing Department, general research experts, hormone specialists, and a decision analyst.

At this initial stage, the team were faced with two obvious questions. Firstly, what was the likelihood of the successful completion of toxicological and teratological trials within a short-term period of two to three years? Secondly, what was the probability of the completion of clinical trials within a further two year period, thereby creating a possible launch target of 1974-5?

As already stated, membership of the Review Team was broadly based in order to produce a spread of expertise, but the resulting dispersion of knowledge brought about a lack of consensus in certain areas under consideration. For example, at the time of these preliminary discussions, the amount of previous research work which would be of assistance to the team in their evaluation of the potential success of future toxicological trials was small. However, such work as had already been done was sufficient to allow estimates of some of the key parameters to be made. The research director was sure that there was a strong relationship between use of the drug and the development of breast tumors in certain circumstances. He concluded that there was a 75% chance of the drug failing the toxicological testing stage. If this happened, he estimated that at least another two years of intensive drug modification and re-testing would be essential before success could be expected. The initial launch date would then be delayed until 1977-8 at the earliest. In contrast the hormone specialists were convinced that the likelihood of the drug failing the toxicological stage would be as low as 20%.

Decision Analysis

Both sets of experts remained adamant about their subjective assessments. However, compromise was eventually reached when it was agreed to submit the question to analysis by the decision analyst. The analyst subsequently suggested that it would be helpful to follow through the consequences of both of the rival assessments. The decision trees (Figures 5, 6, 7) which he eventually produced are based on the following estimates.

Insert Figures 5, 6, and 7 about here

The current estimate for the total costs of toxicological and teratological trials on the substance had been assessed as: low $1,000,000; high $2,500,000; and most likely $1,500,000. Should toxicological failure occur, however, it was predicted that there would be a massive escalation of total toxicological testing leading to a new range of costs: low $4,000,000; high $9,000,000; with a most likely value of $6,000,000. Such trials would be essential should there be the slightest suspicion that any relationship existed between use of the drug and carcinogenic effect.

It was anticipated that the likely costs incurred at the clinical stage would be in the range of low $1,000,000; high $1,300,000 and most likely value of $1,100,000. In comparison to the earlier disagreement, there was general unanimity that the probability of the likely success of the clinical trials could be as low as 0.6; high 0.75 and most likely value of 0.7. If these additional trials indicated the necessity to embark on further toxicological trials then such work would be a required supplement to the clinical trials, with a simultaneous increase in expenditure. Identifying the outcomes of these supplementary trials in terms of estimated probability of success, it was agreed that the likely range would extend from a low of 0.5 to a high of 0.7, with a most likely value of 0.6. Inclusive of the added costs incurred by the additional clinical trials, then the distribution for the total clinical trials' expenditure was predicted as ranging from: low $4,500,000; high $7,500,000; with a most likely value of $6,000,000.

It was thought prudent next to look at the developmental costs in terms of such expenditure being a proportion of the cost of a daily dose of 75 mgs. This calculation was considered a crucial part of any attempt to determine the profit contribution per daily dosage. For a daily dose of 75 mgs, it was estimated that the development costs ranged from a low of $0.04 per dose to a high of $0.075, with a most likely value of $0.06. If further toxicological trials were needed, such values could be expected to rise by approximately 20%. The materials cost of the substance was given as $0.0075 per 75 mgs and the production cost (exclusive of research and development) was assessed as being $0.05 per 75 mgs. It was predicted that the marketed drug could sell at a price in the range of low $0.15 per 75 mgs, to a high of $0.30 per 75 mgs, with a most likely value of $0.25.

Tables 10 and 11 respectively show the estimated sales forecasts for the drug, given the following assumptions. First, a sales horizon of ten years; second, developmental phases of either five or seven years, the latter to include the extra toxicological trials that might be necessary.

Insert tables 10 and 11 about here

Decision trees (Figures 5, 6, 7) were constructed from these estimates of costs and revenues. The conclusion was reached that unless the probability of success at the first decision point was greater than 0.4 the project would produce a negative net present value to the company. That is, if the research director's estimate of 0.25 were correct, then the product class would have to be modified. Attention was then focussed upon the problems inherent in the procedures of

registration and launch. Experience indicated that the process of registration was by no means standardized across countries; for example registration was easier to obtain in some countries than it was in others. In the United States of America, Japan and the United Kingdom, stringent Governmental controls regarding the approval of drugs made these markets relatively less attractive in the early stages of launch. The strong tendency towards the centralized buying of drugs in Sweden also made that country an unattractive market. Indeed, in all the above examples, it was expected that registration would be extremely difficult without more evidence of further toxicological and clinical testing.

Given such limitations, and in view of the desire to set a prospective launch date of 1974-5 to 1975-6, it was decided to assess the advantages and disadvantages of potential alternative markets. It was agreed that the initial launch should be in a market which would probably offer ready acceptance for registration. The introductory launch would be limited in size. However, if the sales figures were favorable and the drug could be seen as a potentially commercially successful product, then the launch would be extended to other countries. Given the constraints outlined above, it was anticipated that penetration into certain markets, for example the United States of America, would be highly unlikely until 1980 at the very earliest. Unfortunately, as the patent from Benco had an expiry date of 1985, any such late launch would bring with it incumbent problems for Sappho.

The group discussion was then summarized. It was agreed to ask the commercial and licensing directors firstly, to assess the

situation in terms of the potential risks; secondly to choose between the alternative strategies facing Sappho, and finally, to determine the economic worth of the license. (Notes on the details of Figures 5, 6 and 7 are given in Appendix 3.)

Discussion of Case B

The issues raised in the course of this pilot exercise are summarized below:

Big Decision Trees

Though engineers and researchers were used to network planning for the control of R & D activity, they nevertheless felt that there was a danger that the decision trees for project evaluation could quickly become very complex and "bushy." They expressed the view that the problem should be structured in sufficient detail so that the project was clearly identified and understood by all research staff. However, it was felt the tree should be as simple as possible, in order to function as a means of comparing the research project analyzed with alternative options.

Time Problem

The research managers felt that decision analysis could sometimes be an unduly time consuming process. Even with a "pruned" problem structure, they felt that the processes of financial modelling and assessment of uncertain quantities would absorb large amounts of research managers' time. The caveat to this observation was the belief that there were potentially plenty of opportunities to simplify the strategic decision analysis. In particular, since many research areas

require shared research investment and experience, decision analytic modelling of research area portfolios is often more appropriate and effective. That is, creative strategic management of R&D involves aggregating projects into therapeutic research areas and then examining portfolios of R & D activity derived from the research areas in terms of strategic decision analysis. Therefore, at the corporate level, R&D policy formulation requires the choice of resarch areas recognizing the interdependencies such as shared experience and resources between certain research areas.

## Assessment and Estimation Problems

### Probability Assessments

Problems were encountered in assessing probabilities of development success and commercial success. In addition, the company found great difficulty in assessing cost distributions for clinical trials and sales distributions for the end-product.

### Estimation of Inflation Rates

A matter for concern which was not resolved was how to allow for inflation in the estimates of project costs and sales volumes, which is imperative because of the long-term nature of the process of developing ethical pharmaceuticals. (See also Wilson (1981))

### Portfolio Problems

Many issues were raised both about the therapeutic area portfolios and the overall research portfolios. In the case of the former, questions were raised about how to set priorities to projects within areas, and about the factors which should govern the assessment of

resource requirements (e.g., technical capabilities, skills, financial resources) to each. Questions about the overall research portfolios revolved around the appropriate allocation of resources amongst research areas so that portfolio balance might be achieved. That is, how to obtain a sound mix between new and existing projects and satisfactory cash flow generation to provide base funding for those projects. Further, there should be a balance between time preference and risk preference goals. Thus, some short-term low risk projects are needed to generate sufficient cash to sustain the promise of the high risk, high cost, high potential projects.

Need for Flexible Criteria

The need for flexible criteria for performance evaluation of portfolios and projects was stressed. It was argued that projects should be examined in terms of a wide range of measures that recognize the long-term nature of the R & D process rather than in terms of a single measure such as NPV. For example, managers found great difficulty in using risk-adjusted rates of return for long-term discounting because they gave much greater weight to costs than revenues and often produced negative NPV's. They argued that the use of probabilistic and scenario projections of such variables as sales projections, cost projections, cash flow profiles would enable them to better understand the nature of projects and portfolios.

Modifications to the Initial Decision Analysis Model

In reviewing the use of decision analysis, the research management and director of pharmaceutical planning at Firm B decided that some

changes were required. First, it was agreed that significant managerial effort should be spent in identifying strategic research areas (or therapeutic classes) in which the company should concentrate its R & D activity. Senior research managers and engineers would discuss the costs and benefits of potential research areas, and, as a by-product project engineers would be asked to suggest a range of specific within-area projects for investigation and evaluation. It was felt that more attention should be focussed on the rationale and assumptions underlying participation in given research areas since this would be extremely valuable for communication amongst the research staff.

Second, it was felt that potential portfolios of strategic research areas and projects within them should not be evaluated in terms of a single criterion, particularly NPV. They argued for the use of risk analysis [see Hertz and Thomas (1983)] in deriving a number of performance measures for planning such as cash flow profiles, sales profiles, and capacity profiles to monitor the flow of projects in relation to the potential of the R & D and production processes for drugs. They felt that such profiles would enable managers to better understand the impact of uncertainty and also avoid concentration on simplistic discounting criteria.

Third, it was felt that sensitivity analysis and sensible forms of multi-attributed screening could definitely help the managerial group to define and identify areas of concentration for research activity.

These modifications were incorporated into the subsequent portfolio evaluation and review process. Managers found them useful. They appreciated the ability to view the problem and the output in a number

of different ways. An additional feature was incorporated into the analysis; review points for R & D decision-making were made to correspond with the control points in the PERT network planning diagrams. This drew favorable comment because it was seen that strategic management involved not only initial evaluation but also re-evaluation, performance control and project implementation. This recognition of an ongoing, flexible decision process which had the ability to adapt to change was probably the most significant factor to emerge from the management group in the firm.

General Issues and Conclusions from the Two Cases

Although the nature of research and development is different in the two cases, certain common findings emerge from the attempts to apply decision analysis procedures. These will be summarized under the headings of assessment problems, discounting processes, the need for flexible decision criteria, and the process of policy dialogue.

Assessment problems were undoubtedly more complex in the pharmaceutical situation. In both cases, however, assessors had difficulty in confronting future events. A simple assessment aid which proved to be very useful involved drawing on graph paper the scenario of future values for the uncertain variable, say sales, over the project's time horizon. Assessors were asked to draw only best and worst scenarios in order to avoid the potential problem of "anchoring" around most likely or "average" values. In pilot studies it was found that assessors exhibited "too tight" distributions if they were asked to provide "most likely" scenario as well as optimistic and pessimistic

scenarios. This phenomenon of tightness is consistent with the studies of Alpert and Raiffa (1969) and the "anchoring" and "adjustment" cognitive heuristics postulated by Tversky and Kahneman (1974).

Discounting processes must be applied cautiously to R & D projects. In particular, if applied routinely to very long-term R & D projects as in ethical pharmaceuticals, few individual projects may be justified using ROI or NPV criteria.

Further, there may be problems in introducing risk adjustment into the discounting process. By using a fixed risk-adjusted rate over a long-term horizon, the assumption is that there is some fixed, "average" risk for which allowance has to be made. Yet a project may be subject to different degrees of risk at different periods during a project's life. A more appropriate approach is to put considerable effort into assessing cost and benefit risk profiles over the project's life. For example, if there is a risk in the pharmaceutical industry that price rises may be constrained because of government regulation, then revenue projections should reflect this. Similarly, cost projections must allow for contingencies such as technological cost savings being eroded by labor cost rises resulting from union bargaining. It is recommended, therefore, that risk analysis be used to generate profiles of cost, revenues, cash flows and capacities. This form of analysis would encourage the development of an awareness about the influence of risk and uncertainty on the project (and indeed portfolio for aggregations of projects). Further if NPV distributions are derived, then a risk-free discount rate (e.g., the return on a government bond of equivalent maturity) should be used in the calculations.

It should also be noted that "balancing" risk preference and time preference considerations becomes important in R & D portfolio management. What should be the mix between long and short-term projects, and those with high and low technical risks? In essence, which projects generate cash and which consume cash? In these firms it was found that research managers appreciated being presented with cash flow profiles of possible portfolios. They found that these gave them a means of understanding cash flow impacts on their portfolios, and alerted them to situations of potential risk.

In both contexts, partly because of technological uncertainties, there was a perceived need for flexible decision criteria. Corporate managers wanted multiple performance measures for projects and portfolios. Examples given were cost profiles, sales profiles, net cash flow profiles, production and R & D capacity profiles and profitability (e.g.) NPV profiles (for a further example in another context see Thomas (1982)). They preferred being presented with this set of measures than being asked to estimate corporate utility functions over a lengthy time horizon. In essence, they baulked at utility function assessments, and preferred being presented with profiles of relevant performance indicator variables estimated up to the planning horizons identified in each firm. Another reason often given was the need to adapt quickly to strategic changes resulting not only from technology, but also from the impacts of competitive pressures.

The word-policy dialogue has been used several times in the paper to express the choice process concerning projects and portfolios. Both

firms felt that the process of strategic management of R & D was critical to the growth of the firm; it was complex, dynamic and characterized by lengthy time-horizons. The decision analytic role in this process turned out to be different from that often identified in very simple applications of its comprehensively rational framework. Rather than determining the "best" strategy, it was seen that the role of decision analysis was to provide output (e.g., decision tree analysis, risk analysis, multi-attributed screens) which enabled managers to develop a better understanding of the R & D system and engage in dialogue about the dynamic character of the system being studied. Indeed, it is argued that choice emerges from adaptive consideration of alternative policies presented in terms of a time-stream of indicator variables, rather than in terms of a single criterion such as expected utility.

The view held in this paper is that the policy dialogue framework proved to be extremely useful in both firms for handling conflicting viewpoints. In both cases, the character of the problem formulation process in R&D adapted to changing views of the problem. The initial decision analysis framework changed to a more complex policy dialogue form involving the resolution of debate and dialogue about alternative viewpoints and "passes" of the analytic framework. The strategy adopted in both cases resulted from continued review, updating and consensus through group discussion.

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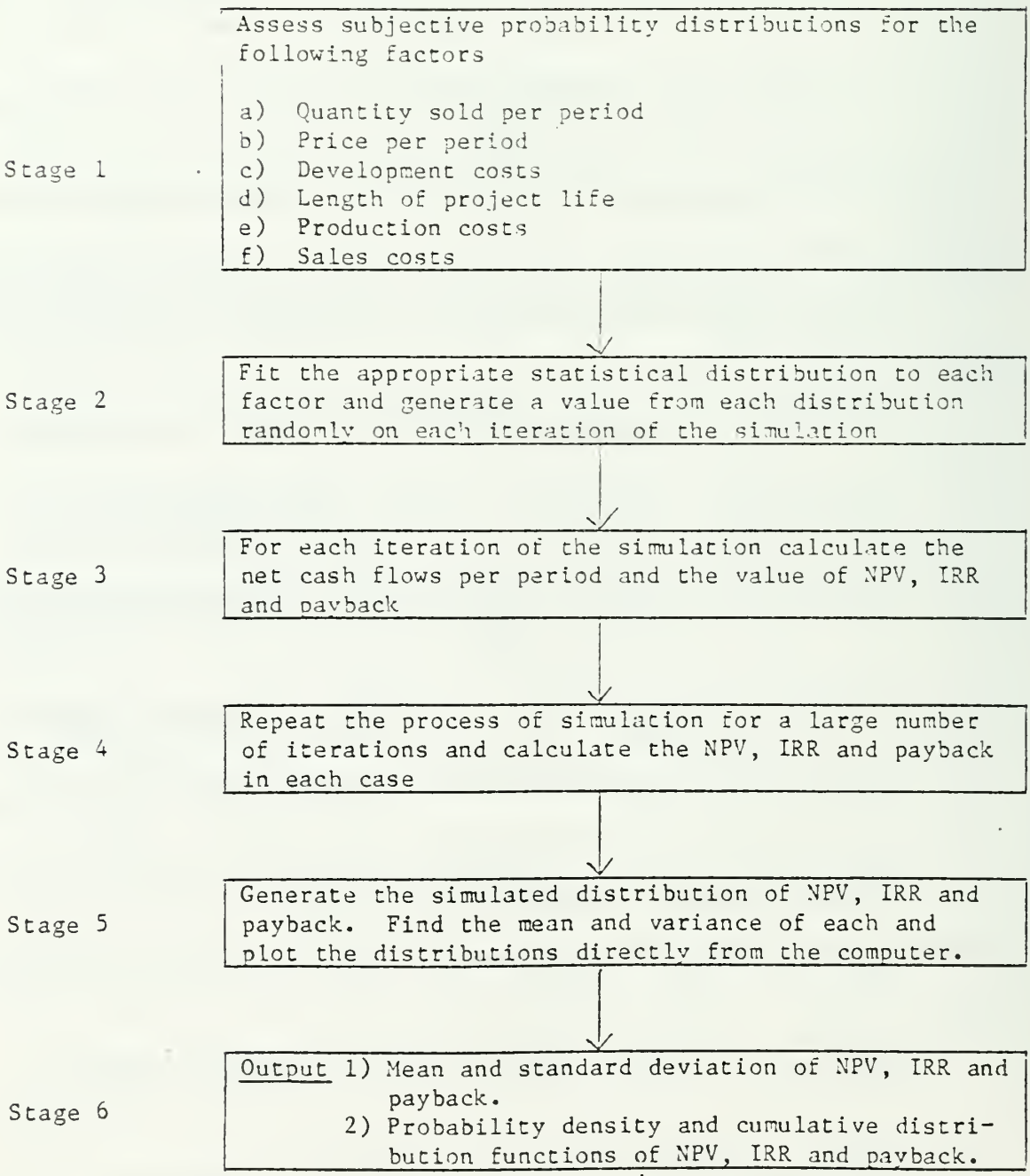
APPENDIX 1

CASE STUDY A: THE ELECTRONICS COMPANY




Readers are referred to D. B. Hertz, "Risk Analysis in Capital Investment," 1964, Harvard Business Review for a further discussion of this program, or D. B. Hertz and H. Thomas (op. cit.).

APPENDIX 2

Churchman-Ackoff model for multi-dimensional objectives

The following is a concise description of the Churchman-Ackoff model for evaluating a set of projects on a basis of multiple objectives.

1. Suppose that at some moment in time, the decision-maker assigns a relevant set of objectives ($O_1$...., $O_n$) for his decision problem.

2. Suppose also that he has a number of alternative research projects ($R_1$...., $R_k$) which need to be evaluated.

3. The decision-maker then constructs a (k x n) matrix with alternative projects as rows and objectives as columns.

| | $O_1$ | ... | $O_n$ |
|---|---|---|---|
| Weights | $W_1$ | ... | $W_n$ |
| $R_1$ | | ... | |
| . | | ... | |
| . | | ... | |
| . | | ... | |
| $R_k$ | | | |

4. The cells in the matrix are assigned values between 0 and 1 according to the extent to which each $R_i$ satisfies each of the objectives.

Appendix 2 (continued)

5. The decision maker is also asked to estimate a positive weight $W_i$ to each objective subject to the restriction that

$$\sum_{i=1}^{n} W_i = 1$$

in order to establish the priority between objectives. Let W be the (n x 1) column vector of weights.

6. A weighted objective score is then calculated for each project $R_i$ by obtaining the (k x 1) row vector S by matrix multiplication, i.e.,

$$S = M \times W$$

$$(k \times 1) = (k \times n)\ (n \times 1)$$

This weighted projective score is the criterion by which preliminary project decisions should be made.

Readers are referred to C. W. Churchman, "Introduction to Operations Research," 1951, Wiley for fuller details of this multi-dimensional model.

TABLE 1 - PROJECT RATING

(based on benefit/cost ratio, i.e., ratio of net present value to standard deviation at discount rate of 10%)

| Project | DECISION-MAKER | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| 1 | ✓ | | | |
| 2 | X | X | | X |
| 3 | ✓ | ✓ | | |
| 4 | ? | ✓ | | |
| 5 | X | ✓ | | |
| 6 | | | ✓ | ✓ |
| 7 | | | ✓ | ? |
| 8 | ✓ | | | |
| 9 | | | ✓ | |
| 10 | ✓ | | | ? |

Note: [✓ - OK, X - Stop, ? - Further Discussion]

TABLE 2

ESTIMATES MADE BY DECISION-MAKER 1

| PROJECT | INTERNAL RATE OF RETURN (IRR) [MEAN (S.D.)] | PAYBACK YEARS [MEAN (S.D.)] | NPV AT 10%[1] ($) [MEAN (S.D.)] | NPV AT 25%[2] ($) [MEAN] |
|---|---|---|---|---|
| 1 | 126.40<br>(3.95) | 2.53<br>(0.04) | 224750<br>(7745) | 114536 |
| 2 | 139.0<br>(13.1) | 1.68<br>(0.1) | 285,500<br>(21560) | 172650 |
| 3 | 242.3<br>(8.5) | 2.25<br>(0.02) | 847170<br>(27415) | 451070 |
| 4 | 61.1<br>(3.4) | 3.40<br>(0.1) | 30025<br>(1575) | 12410 |
| 5 | 85.5<br>(3.5) | 2.72<br>(0.1) | 145650<br>(7500) | 72645 |
| 8 | 500<br>(25) | 1.07<br>(0.01) | 375,725<br>(23,500) | 265,650 |
| 10 | 516.5<br>(31.5) | 1.21<br>(0.02) | 285,730<br>(12,250) | 215,250 |

NOTE

1. The means and standard deviations in this column were obtained using a risk-free rate (pre-tax) of 10% in the denominator and distributions for net cash flow in the numerator.

2. Obtained using expected net cash flows in the numerator and a risk-adjusted rate (pre-tax) of 25% in the denominator.

(These notes apply for all subsequent tables.)

Figure 1

Estimates of NPV Made by Decision-Maker 1
(Discount rate - 10%)

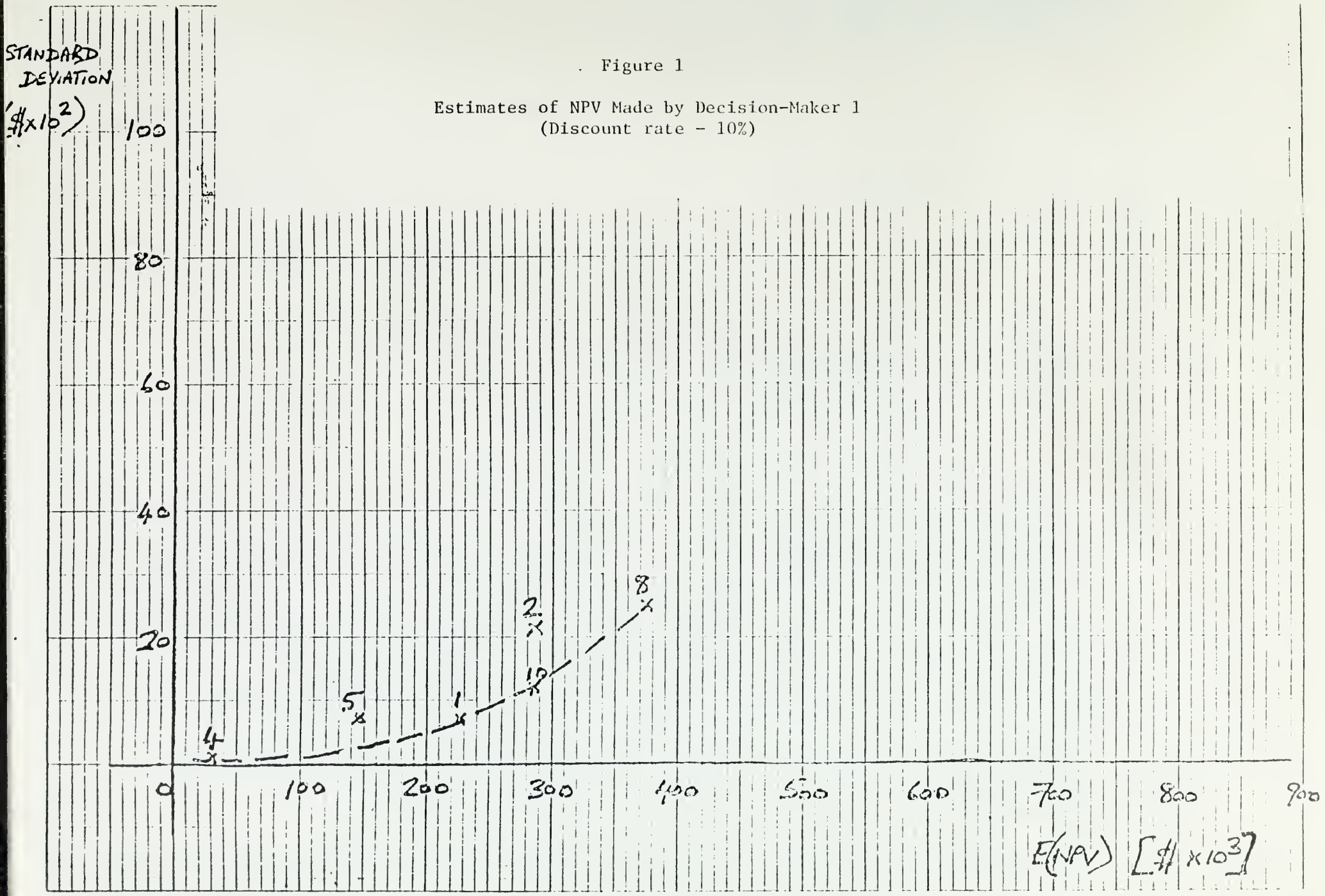


TABLE 3

ESTIMATES MADE BY DECISION-MAKER 2

| PROJECT | IRR (%) [MEAN (S.D.)] | PAYBACK (YEARS) [MEAN (S.D.)] | NPV at 10% ($) [MEAN (S.D.)] | NPV at 25% ($) [MEAN] |
|---|---|---|---|---|
| 2 | 72.6 (13.6) | 2.3 (0.15) | 111,230 (15,750) | 52630 |
| 3 | 233.8 (6.7) | 2.3 (0.02) | 782200 (27120) | 416870 |
| 4 | 178.5 (8.1) | 2.4 (0.03) | 129690 (4130) | 67870 |
| 5 | 92.4 (3.3) | 2.7 (0.1) | 227220 (8800) | 110970 |

NOTE: See note to Table 2.

Figure 2

Estimates of NPV Made by Decision-Maker 2

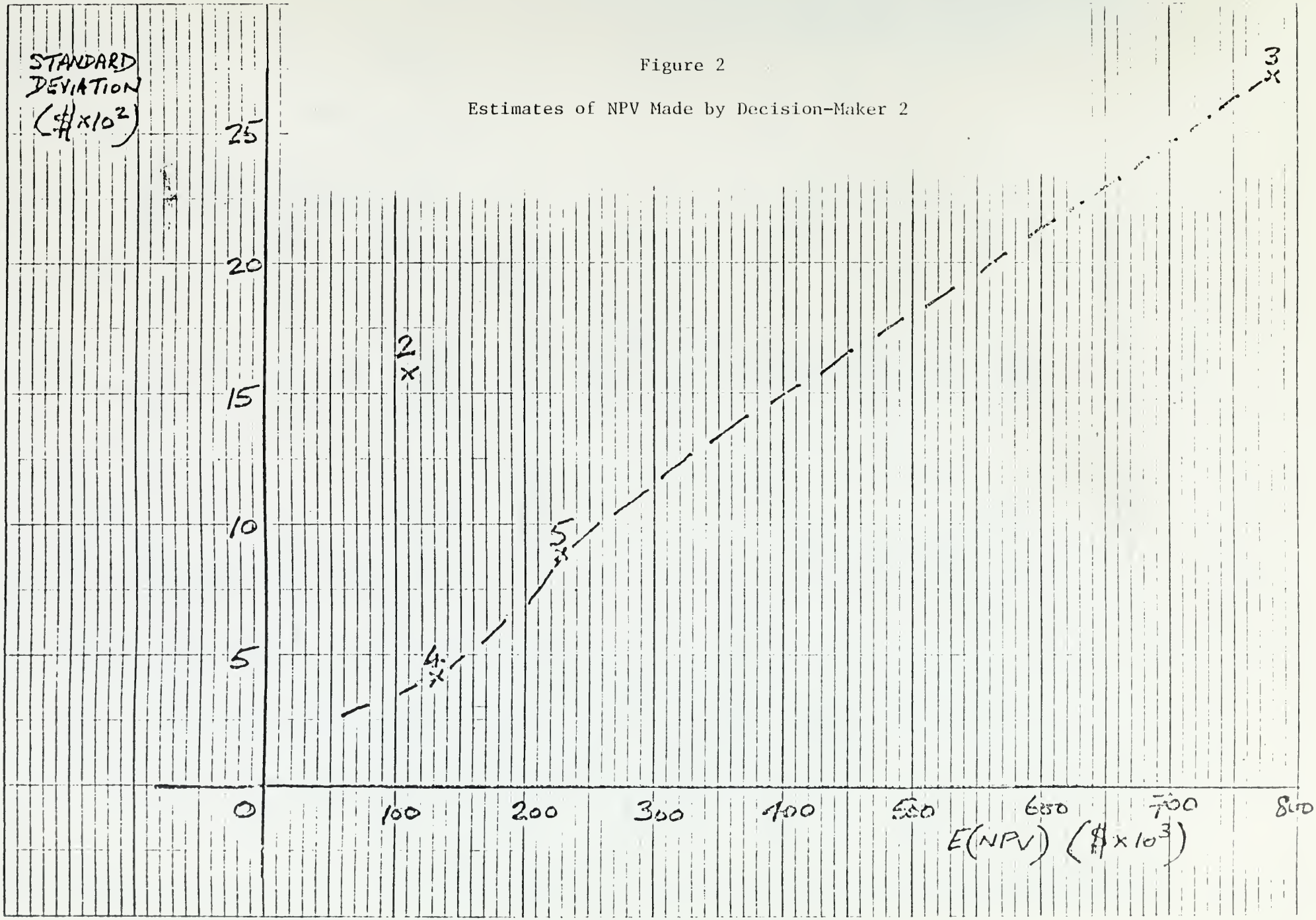


TABLE 4.

ESTIMATES MADE BY DECISION-MAKER 3

| PROJECT | IRR (%) [MEAN (S.D.)] | PAYBACK (YEARS) [MEAN (S.D.)] | NPV at 10% ($) [MEAN (S.D.)] | NPV at 25% ($) [MEAN] |
|---|---|---|---|---|
| 6 | 65.7<br>(10.9) | 3.0<br>(0.25) | 485735<br>(99760) | 281390 |
| 7 | 40.0<br>(10.0) | 2.8<br>(0.3) | 42250<br>(15600) | 23250 |
| 9 | 51.0<br>(15.0) | 3.2<br>(0.6) | 126,250<br>(21,000) | 81100 |

NOTE: See note to Table 1.

TABLE 5

ESTIMATES MADE BY DECISION-MAKER 4

| PROJECT | IRR ($) [MEAN (S.D.)] | PAYBACK (YEARS) [MEAN (S.D.)] | NPV at 10% ($) [MEAN (S.D.)] | NPV at 25% ($) [MEAN] |
|---|---|---|---|---|
| 2 | 10.4<br>(5.7) | 3.25<br>(0.6) | 3050<br>(12420) | -13,370 |
| 6 | 105.5<br>(6.5) | 2.58<br>(0.08) | 951,324<br>(80,535) | 515250 |
| 7 | 28.3<br>(5.4) | 3<br>(0.2) | 18120<br>(9520) | 3180 |
| 10 | 44.3<br>(13.7) | 2.5<br>(0.2) | 40160<br>(10300) | 22150 |

NOTE: See note to Table 1.

Figure 3

Estimates of NPV Made by
Decision-Maker 3

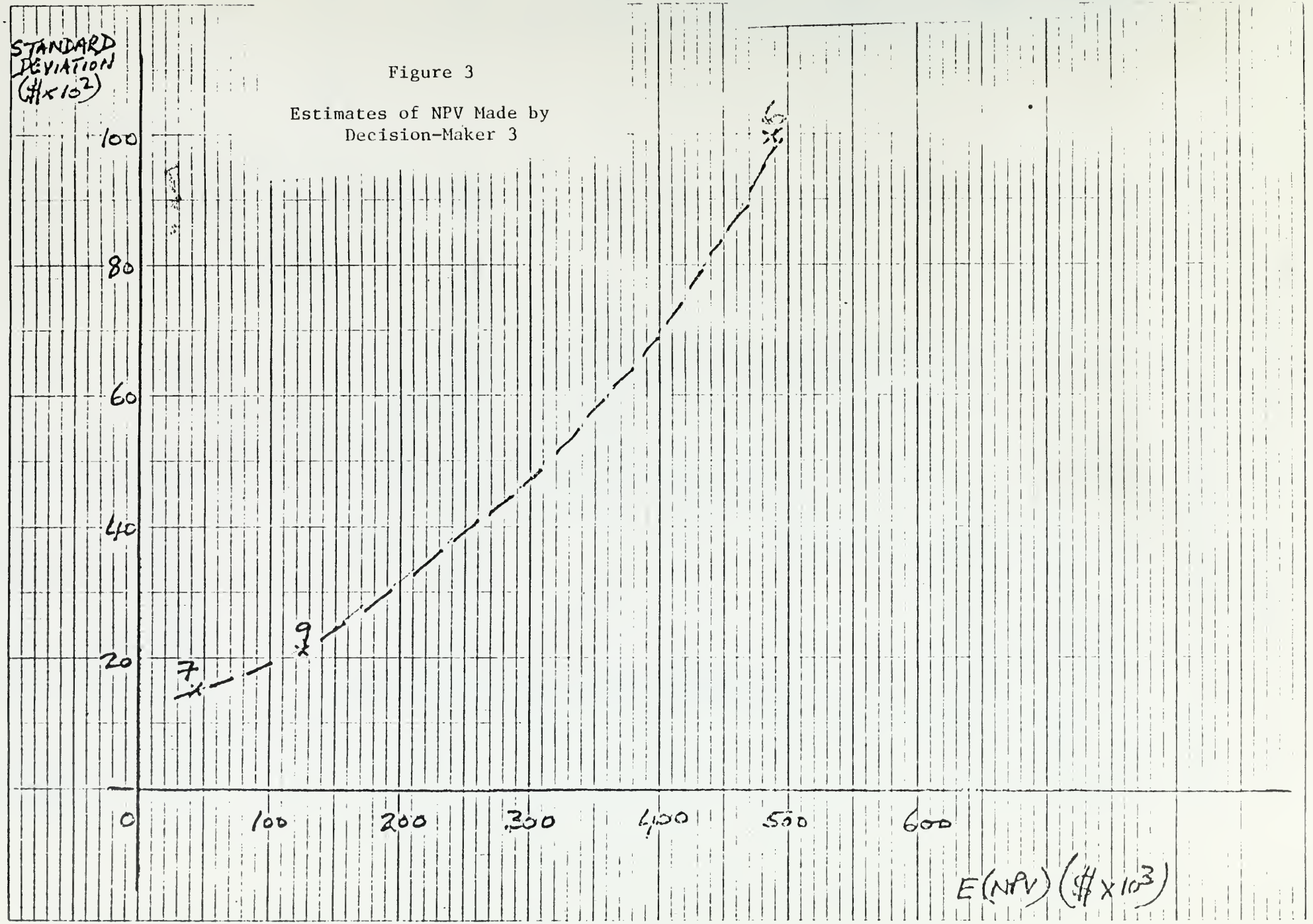


Figure 4

Estimates of NPV Made by Decision-Maker 4

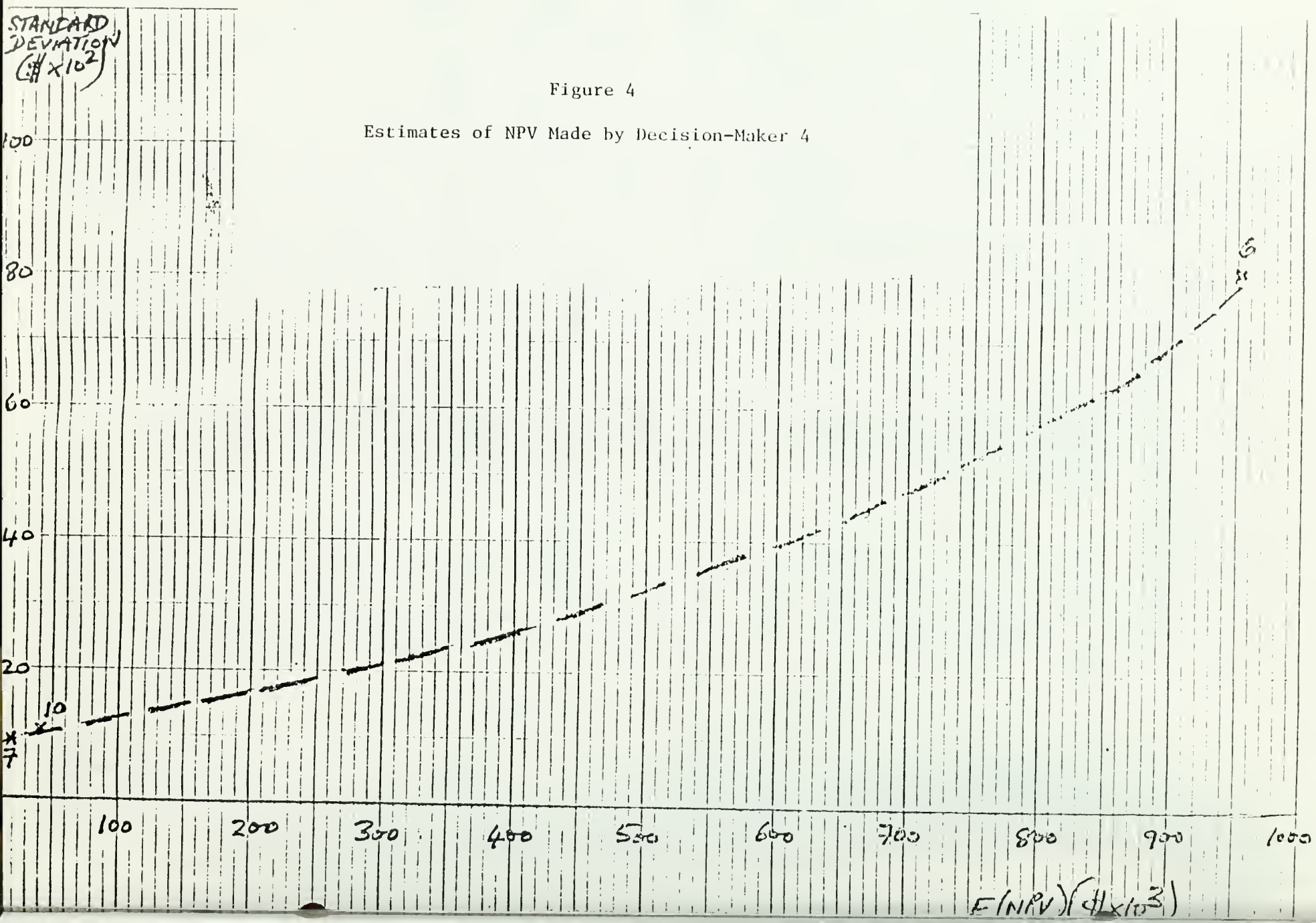


TABLE 6

PROJECT SCORES OVER SEVEN OBJECTIVES
(According to Churchman-Ackoff Model)

| | DECISION-MAKER | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | | 2 | | 3 | | 4 | |
| Project | Score | Rank | Score | Rank | Score | Rank | Score | Rank |
| 1 | 28.34 | 5 = | 42.59 | 2 | 30.40 | 5 | 39.68 | 4 = |
| 2 | 23.51 | 7 | 31.03 | 7 | 35.15 | 3 | 19.93 | 8 |
| 3 | 38.91 | 2 | 35.34 | 4 | 37.31 | 2 | 41.85 | 3 |
| 4 | 18.35 | 8 | 32.14 | 6 | — | | 57.54 | 2 |
| 5 | 28.34 | 5 = | 39.64 | 3 | -- | | 39.68 | 4 = |
| 6 | 31.20 | 4 | 28.88 | 8 | 31.62 | 4 | 38.28 | 6 |
| 7 | -- | | 12.29 | 10 | 40.11 | 1 | 16.26 | 9 |
| 8 | 44.57 | 1 | 44.25 | 1 | -- | | 58.60 | 1 |
| 9 | -- | | 34.97 | 5 | 23.09 | 6 | — | |
| 10 | 35.95 | 3 | 23.51 | 9 | — | | 24.92 | 7 |

NOTE: Scores expressed as percentages.

TABLE 7

SPEARMAN RANK CORRELATION COEFFICIENTS
BETWEEN DECISION-MAKER PROJECT RANKINGS IN TABLE 6

| | DECISION MAKER | | | |
|---|---|---|---|---|
| Decision-Maker | 1 | 2 | 3 | 4 |
| 1 | 1 | | | |
| 2 | 0.4 | 1 | | |
| 3 | -0.24 | -0.37 | 1 | |
| 4 | 0.63 | 0.63 | -0.42 | 1 |

NOTE: The entries in the tables are the correlations between the project ratings of different decision-makers. The sign indicates a positive or negative relationship.

Figure 6

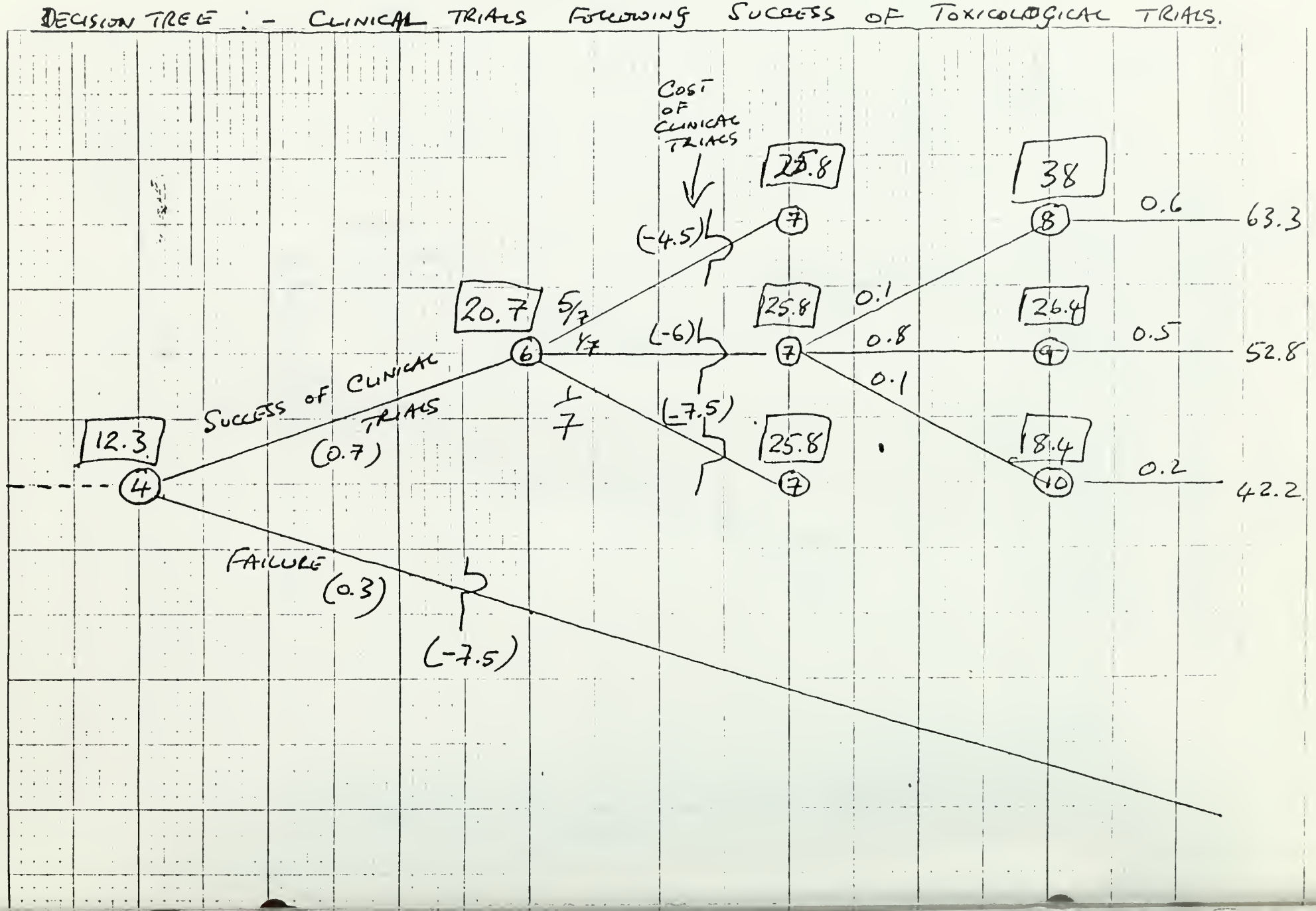
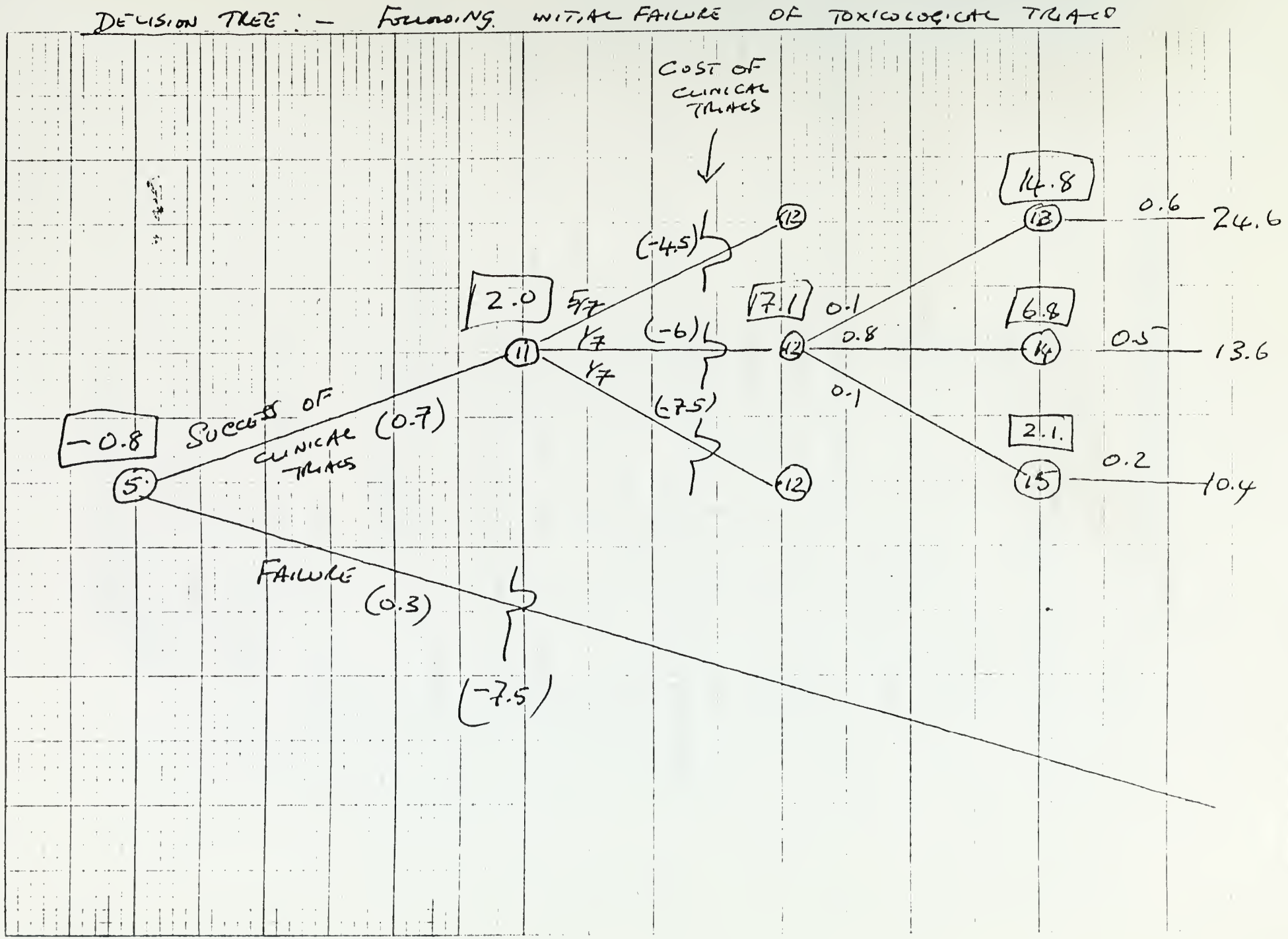

DECISION TREE :- CLINICAL TRIALS FOLLOWING SUCCESS OF TOXICOLOGICAL TRIALS.
COST OF CLINICAL TRIALS
12.3
4
SUCCESS OF CLINICAL TRIALS
(0.7)
FAILURE
(0.3)
(-7.5)
20.7
6
5/7
2/7
(-4.5)
(-6)
(-7.5)
25.8
7
25.8
7
25.8
7
38
8
26.4
9
18.4
10
0.1
0.8
0.1
0.6
0.5
0.2
63.3
52.8
42.2

Figure 7


DECISION TREE :- FOLLOWING INITIAL FAILURE OF TOXICOLOGICAL TRIALS
COST OF CLINICAL TRIALS
-0.8
SUCCESS OF CLINICAL TRIALS (0.7)
FAILURE (0.3)
(-7.5)
2.0
5/7
2/7
(-4.5)
(-6)
(-7.5)
7.1
0.1
0.8
0.1
14.8
0.6
24.6
6.8
0.5
13.6
2.1.
0.2
10.4

## Notes on the Decision Trees in Figures 5, 6 and 7

1. Note that costs have been deducted at the appropriate nodes on the tree, and not gathered up into terminal values. This is because of the way in which the tree has been split up into symmetrical branches.
2. Outcomes as High, Medium or Low chances have been assigned the probabilities 0.1, 0.8, 0.1.
3. In the clinical trials (Nodes 4-6-7 & 5-11-12), it has been assumed that expenditure will continue up to 7.5 M or success, whichever is achieved first. Hence, the probability of failure is 0.3; that of success before 4.5 M expended, 0.5; etc.
4. Profitability is mainly a function of selling price. Moreover, for simplicity, it has been assumed that those circumstances which were deemed to favor a High Sales Revenue were also considered to be associated with a high selling price. Hence the single branches emanating from nodes 8,9,10,13,14,15.

   Profitability = Price - Costs (development, production & raw material)

   = Price/dose - 0.12

   Hence for High Sales:

   Profit/Price = 18/30 = 0.6

   for Medium Sales:

   Profit/Price = 13/25 = 0.5

   for Low Sales:

   Profit/Price = 3/15 = 0.2

## Notes on the Decision Trees in Figures 5, 6 and 7

5. Discounting the future sales @ 18% to present values at 1974

| | | |
|---|---|---|
| Case 1 | High | = 63.3 |
| | Medium | = 52.8 |
| | Low | = 42.2 |
| Case 2 | High | = 24.6 |
| | Medium | = 13.6 |
| | Low | = 10.4 |

Note: Account has been taken in Case 2 of the fact that the revenues are delayed by 2 years.

TABLE 10

SALES FORECAST

Case I

Development time of five years

| | SALES ($ MILLION) | | |
|---|---|---|---|
| | Low | Most likely | High |
| Year 1 | 6 | 7 | 9 |
| Year 2 | 9 | 10 | 12 |
| Year 3 | 11 | 14 | 17 |
| Year 4 | 16 | 18 | 21 |
| Year 5 | 19 | 20 | 25 |
| Year 6 | 14 | 15 | 17 |
| Year 7 | 10 | 11 | 12 |
| Year 8 | 4 | 7 | 8 |
| Year 9 | 2 | 5 | 6 |
| Year 10 | 1 | 5 | 6 |

TABLE 11

SALES FORECAST

Case 2

Development time of seven years

| | SALES ($MILLION) | | |
|---|---|---|---|
| | Low | Most likely | High |
| Year 1 | 1.0 | 2 | 3 |
| Year 2 | 3.0 | 4 | 6 |
| Year 3 | 4.0 | 5 | 9 |
| Year 4 | 5.0 | 6 | 11 |
| Year 5 | 7.0 | 8 | 15 |
| Year 6 | 4.0 | 5 | 10 |
| Year 7 | 3.0 | 4 | 8 |
| Year 8 | 2.0 | 3 | 6 |
| Year 9 | 1.0 | 2 | 5 |
| Year 10 | 0.5 | 1 | 3 |

APPENDIX 3

## DECISION ANALYSIS OF THE CONTRAPIL CASE

1) The decision analysis was decomposed into a number of decision trees as shown in Figures 5, 6 and 7.

2) The following outline the assumptions made in the analysis.

3) The "first-pass" conclusion of the analysis is that, for a positive expected NPV at the initial decision point, p, the probability of success must be greater than 0.4.

This follows from the equality (node 1).

$$10.7\ p = (1 - p) \times 6.9$$

$$p = \frac{6.9}{17.6} = 0.4.$$