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Case Article

Idiopathic Pulmonary Fibrosis

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This article describes a case in which decisions are made by two biopharmaceutical firms in pursuit of FDA approval of a drug to treat idiopathic pulmonary fibrosis (IPF). The case contains information on each firm's estimates of costs, revenues and likelihood of success, as well as average values for these available from the scientific literature. The case provides an opportunity to apply decision analysis in the form of decision trees to various decision problems and to perform sensitivity analysis. It can be used as an introduction or as an application of decision trees after an introduction. The students are first exposed to one firm's simple decision based on expert opinion, which is then modified by the inclusion of data. The advantage of expressing information in a tree diagram becomes apparent. The tree diagram is then examined to expose hedging strategies, one of which introduces the second larger firm as a potential licensee. The second firm presents its own view of the decision process based on its own expertise, thus allowing for a rich discussion of sensitivity analysis. Students are to evaluate the first firm's approach to decision making and whether the second firm should be a licensee or not.

Keywords: cases; teaching decision analysis; visualization; teaching modeling; decision trees; sensitivity analysis.

History: Received: January 2015; accepted: December 2015.

Introduction

Idiopathic pulmonary fibrosis (IPF) is a severe, progressive disease that destroys the lungs within five years of onset. Marnac is an entrepreneurial biopharmaceutical firm focused on the discovery and development of drugs to treat autoimmune, inflammatory and fibrotic disorders such as multiple sclerosis. By 1999, Marnac had a number of drugs in the pipeline with potential efficacy in IPF. It had reduced its consideration to pursuing FDA approval of one of two drugs, a steroid and pirfenidone, a non-steroid, to treat IPF. This initial decision provides a starting point for an investigation of how decisions can be represented graphically by trees and how examination of the resultant tree may offer insights that may not otherwise be apparent. Having selected to pursue FDA approval of pirfenidone, Marnac needs to estimate the individual costs and likelihood of passing the various stages of the FDA approval process. Rather than rely solely on in-house expertise, Marnac turns to the scientific literature to obtain average estimates for these values. Students can be assigned to create a decision tree for this more detailed decision that provides a richer structure for insights such as hedging. In particular, Marnac considers licensing pirfenidone to a larger biopharmaceutical

firm, InterMune. InterMune has more experience in pursuing FDA approval and has its own view of the decision whether to accept the license for pirfenidone.

Target Audience

This case may be used at the undergraduate level or at the MBA level in an introductory quantitative course or microeconomics course that covers decision analysis. It can be used with a software-based course or a course in which decision trees are manually drawn. An understanding of Bayes' theorem is not necessary. This case may be used as an introduction to decision visualization using decision trees or as an application of decision trees to view decision-making from different perspectives for students who have been exposed to the basics of decision trees.

This case has been used in the required quantitative core course in our MBA programs as well as in the second course in our required two-course undergraduate quantitative core. This case has evolved from a series of mini-cases which have been continually modified since 2012 by four faculty and interaction with over 700 MBA and undergraduate students. The MBA course in which the case is used is concerned with identifying variation, measuring it and managing it to make informed

decisions. Topics include: numerical and graphical description of data, confidence intervals, hypothesis testing, regression, decision analysis and simulation. Applications to economics, finance, marketing and operations illustrate the use of these quantitative tools in applied contexts. The course utilizes spreadsheet, statistical and simulation software. The course emphasizes communicating in-context interpretations of the results of analysis in written, visual and oral form.

The undergraduate course in which the case is used is the second in our required sequence and explores decision-making problems in a managerial context using algebraic, spreadsheet, graphical and statistical models. The focus is on understanding basic mathematical and modeling principles through the analysis of real data. Topics include introductions to regression, time series analysis, linear programming, decision analysis and simulation. The prerequisite is our first required quantitative course, which provides a foundation in introductory statistics and use of spreadsheets-concepts that are extended and reinforced throughout the second course.

The case has proven equally useful for all our students as part of their core requirements. It may be utilized in a single 90 minute class or in a two 90 minute class sequence. This case is revisited by our required core Managerial Economics course as part of its discussion of decision theory.

Learning Objectives

Using a 90 minute class to analyze this case with pre-assignments, students should be able to:

- Structure managerial decisions including uncertainties from an introduction to decision trees with only one decision and two alternatives to more complicated decision situations including hedging strategies and multiple decisions.
- Structure managerial decisions including future uncertainties using decision trees to seek insights uncovered by a thoughtful examination of the graphical representation of decisions and to expose potential hedging strategies.
- Solve decision trees and create risk profiles for all alternatives thereby allowing an examination of the tradeoffs between expected value and risk as well as consideration of an “allowable loss.”
- Understand the methodologies for incorporating risk and uncertainty into making managerial decisions.

Additional learning objectives utilizing two 90 minute classes to analyze this case with pre-assignments, students should be able to:

- Run and interpret a sensitivity analysis on decision trees to measure the effects of uncertainty and variation on decision outcomes.
- Communicate risk quantitatively.

- Understand that when running sensitivity analysis on probabilities, two conditions must be addressed and explicitly accounted for: the probabilities must sum to one, and the probabilities must always be between zero and one.

Classroom Experience

In our MBA course, the students are treated more as “consumers of statistics” than as “producers of statistics” whereas our undergraduate course has more emphasis on production. The case exposes the difference between how the decision to pursue FDA approval for a drug to treat IPF is viewed by a small, entrepreneurial company, Marnac, in contrast to how it is viewed by the larger company, InterMune. This is especially relevant due to the common use of maximizing expected monetary value as the selection criterion for a course of action. Additionally, in our MBA course, students with negotiation experience bring insights into how the licensing agreement itself can be influenced by the two different views of the decision’s payoffs and probabilities.

We have used this case, or parts thereof, as a basis for class discussion in both instances where this case is useful to introduce decision analysis and as a follow-up application of decision analysis after a class in which decision analysis already has been introduced. In both instances the case has proven successful, although in the former more care must be taken in class to tease out the relevant information. Details of this approach are given in the Teaching Note (available as restricted instructor materials at <https://www.informs.org/IOL-Home/Pubs/ITE/Access-Restricted-Materials>).

There are three areas where students have had difficulty. The first area is why Marnac would pursue pirfenidone when the steroid option appears to be less risky. It is interesting to note that, as of the date of this writing, there are no successful steroid-based treatments of IPF. The second challenging area is the difference between the views of the decision by Marnac and by InterMune. This provides an opportunity to discuss how having data or the lack thereof can color a decision maker’s view. Lastly, some students, especially when this case is used as an introduction, find diagramming and interpreting InterMune’s multistage decision problem difficult. The instructor can refer back to Marnac’s original, simple, one-decision, two-alternative tree and show the similarities to each sub-tree part of the multistage tree.

On the other hand, most students get a deep appreciation of the powerful insights decision analysis provides by examining the sensitivity analysis output once the structure of the tree has been codified.

Conclusion

This case provides the capstone application of the decision analysis section of our courses. Parallels are

drawn from the one-way sensitivity analysis involving the uncertainties in the tree's inputs to the interpretation of significant slopes in multiple regression. Identifying which of the uncertainties in the tree's input values have the biggest effect on the expected value is reinforced by the examination of how the uncertainties represented in the choice of distribution in a simulation have the biggest effect on the simulation's output. This parallelism reinforces the conceptual ideas and provides for an opportunity to review the seemingly disparate topics of our required courses.

Our quantitative core courses are not case-based courses. Use of this case provides a real example of how essentially the same decision is viewed by a

small company versus a large company as well as how decisions are updated with the use of available data and expert opinion. The use of sensitivity analysis deepens the appreciation and understanding of the analysis of decisions.

Supplemental Material

Supplemental material to this paper is available at <http://dx.doi.org/10.1287/ited.2016.0155ca>.

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