Chapter 11
Data-Driven Decision Making for New Drugs:
A Collaborative Learning Experience

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ABSTRACT

Two courses, advanced decision-making and pharmaceutical marketing, were combined in a collaborative process to mimic how the pharmaceutical industry determines the potential of new drugs. Integrated student teams worked together to complete semester-long projects and taught each other their respective knowledge areas—marketing and statistics. Real-world data for medical and pharmacy claims payments were "cleaned" and mined by students to analyze usage and cost patterns for anti-hypertensive and anti-hypercholesterolemia drugs currently on the market. Analyses included merging the medical and pharmaceutical data records to derive individual electronic patient records, which were the basis of financial projections for the new drugs. Importantly, the single patient record is congruent with the needs of the stakeholders currently working to reform U.S. healthcare delivery.

INTRODUCTION

Academic enrollment during this recession is increasing but there are more unemployed college graduates seeking employment than high school dropouts (Grummon, 2009). Therefore, the time is right to augment the business student's learning so they are equipped with appropriate skill sets to meet their employer's needs, such as techniques for data analysis. This is particularly true for students pursuing employment within the pharmaceutical industry and/or those industries involved with the drug development process where development of new prescription medicines takes about 10 years

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Figure 1. "P" stakeholders in U.S. healthcare delivery

Phase 0	↑	Phase I	Phase II	Phase III	↑	FDA Review	Phase IV
Pre-Clinical Testing to assess safety & biological activity Years: 3-6	File IND with FDA	Determine safety & dosage on ≈50 healthy volunteers Years: 1-2	Evaluate effectiveness; look for side effects on ≈300 patient volunteers Years: 2	Confirm efficacy; monitor adverse reactions on 1000-3000 patient volunteers Years: 3-4	File NDA With FDA	Review and approval Years:1-3	Post-marketing testing and surveillance Years: until patent expiration

to gain marketing approval in the United States (U.S.) and costs close to a billion dollars (Dimasi & Paquette, 2004).

Concurrently, America is making a genuine attempt at healthcare reform and, while there is disagreement in Congress about how to accomplish it, any sustainable reform will involve an integration of data from all the stakeholders in U.S. healthcare delivery (Connolly, 2009):

- Patients, whose healthcare needs increase along with their increased life spans,
- Product manufacturers to include, pharmaceuticals, medical devices and diagnostics,
- Payers, private and government programs, e.g., Medicare,
- Providers to include hospitals and doctors, of which there is a considerable shortage to meet patients' needs (Halsey, 2009),
- Policy Makers/Regulators, such as the Food & Drug Administration (FDA),

Within pharmaceutical companies making the appropriate decisions about the therapeutic viability of a potential new drug takes a team of professionals with different educational backgrounds to assess the safety and efficacy of a potential new drug. Based on these clinical studies, the team projects profitability based on clinical advantages, such as improved efficacy or reduced side effects, and how it compares to currently available therapeutic alternatives. The patterns of use and costs of medications are most accurately captured in the actual claims data used by healthcare payers to pay providers. But these data often contain inaccuracies that must be addressed before the can be analyzed.

Replicating this process as part of an undergraduate course is challenging but conceivable when students who possess complementary skill sets work together and real-world data are available (Berg, 2003). We created such a situation when we integrated a pharmaceutical marketing research course with an advanced decision-making course.

This paper will discuss the process we used to combine the learning efforts of both classes and to generate results into a format that has application for making informed decisions about the drug development process and implications for sustainable healthcare reform. The next section reviews the literature and positions our work to address research questions about integrating classes and the value of business intelligence. Following the literature review, we will describe our research methodology and review and discuss our findings. Finally, we will give our conclusions and present implications for future research.