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Perceptions Regarding Knowledge Management: An Exploration of Characteristics and Components of Knowledge Management with Application in the Pharmaceutical Industry

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PERCEPTIONS REGARDING KNOWLEDGE MANAGEMENT: AN EXPLORATION OF CHARACTERISTICS AND COMPONENTS OF KNOWLEDGE MANAGEMENT WITH APPLICATION IN THE PHARMACEUTICAL INDUSTRY

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ChapterI

INTRODUCTION

Scholars have explored the transfer of tacit knowledge in organizations and proposed unified frameworks for mobilizing knowledge. They have also studied impediments to maintaining competitive advantages in knowledge management (De Leo, 1994; Itami, 1987). Tremendous financial resources have been dedicated to create and deliver a single, universal *haute vulgarisation*[1] using empirical studies and modeling tools. Unfortunately, none are known by this author to have delivered to the business world a complete system.

Examining the management of knowledge is the focus of this study, a review of the literature related to this topic. Specifically, stratagems used in the technology-intensive corporate settings of pharmaceutical development will be explored. A comparison of models used to depict key knowledge management tenets will also be developed in order to provide a reference for the reader to draw conclusions.

Lupton and Miller (1996) describe "design history" in the context of visual literacy as requiring an understanding "not as a catalogue of styles or a canon of formal rules, but as a complex enterprise that engages political, economic, and intellectual culture" (p.62). This author concurs that the whole of understanding and the entirety of management of what is considered valuable in the context of business and indeed life, rests on perceptions that come from every facet of our experience.

Consideration for visual literacy and a review of the awareness of artistry and visual manipulation as a part of knowledge management will also be briefly discussed in this study.

Research Question

Does a single model of knowledge management exist that when properly applied, provides a clear indication or likelihood of economic value to the development of a new pharmaceutical product?

Need for the Study

A large amount of research is being generated and a considerable financial investment is being made by corporate America (the pharmaceutical industry included) in examining business processes. Kofman and Senge (cited in Chawla & Renesch, 1995) argue that there exist areas of dysfunction in knowledge management: "Organizations are microcosms of the larger society... We believe that there are three fundamental problems with our current paradigm: fragmentation, competition, and reactiveness"(p. 61). This author believes that a fragmented effort to understand and manage knowledge without a process is currently occurring in corporate America. A system of effort is required.

A considerable amount of research has been conducted on how human beings (infants and adults) learn (Bronson, 1982; Day, 1975; 1982; Gorman & Fisher, 1998; Messaris, 1994).A considerable amount of research has been conducted on the psychology of illustrations (Chawla & Renesch, 1995; Willows & Houghton, 1987). An even broader and more eclectic area, the science of spatial intelligence and human cognitive extension, is just now being researched and continues to grow logarithmically in lockstep with computer technology. McClamrock (1995) examines philosophical implications of perception by understanding of brain states. "Accepting some notion of the supervenience of the mental on the physical, the intrinsic character of these

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[1] High popularization – effective presentation of a difficult subject to a general audience.

conscious experiences is entirely determined by the biophysical character of underlying brain states" (p. 166).

Objective

The author wishes to add to the heterogeneous body of information that is known as knowledge management, attempting to offer a synopsis of fundamental approaches to understanding knowledge management as a system and produce a suggested and more clear vision of how a well designed system can lead to greater understanding in the business area of pharmaceutical product development and marketing.

This author believes that developing a sound process to recognize, collect, manipulate, and manage information and knowledge as well as to prosper (by transference) from owning it, is a requirement for business survival.

Definition of Terms

1. Knowledge: A fluid mix of framed experience, values, contextual information, and expert insight that provides a framework for evaluating and incorporating new experiences and information (Davenport & Prusak, 1998, p.2). That which enables people to assign a meaning to data and thereby generate information (Liebowitx & Wilcox, 1997, p. 37). The accumulation and integration of information received and processed by the recipient (Meadow & Young, 1997, p. 701).

2. Knowledge Modeling: Pictorial displays of knowledge flow in an organization.

3. Data: A set of discrete, objective facts about events (Davenport & Prusak, 1998, p.2). Symbols which have not yet been interpreted (Liebowitz & Wilcox, 1997, p. 37). A set of symbols with little or no meaning to the recipient (Meadow & Young, 1997, p.701).

4. Information: A message, usually in the form of a document or an audible or visible communication, meant to change the way the receiver perceives something; to have an impact on his judgment and behavior. Data that make a difference (Davenport & Prusak, 1998, p.3). A set of symbols that does have meaning or significance to their recipient (Meadow & Young, 1997, p. 701). Information is power, a world currency upon which fortunes are made and lost (Wurman, 1990, p.36). Data that has been assigned a meaning (Liebowitz & Wilcox, 1997, p.37). That which modifies knowledge structure (Brookes, 1977, p. 57).

5. Knowledge Management: The explicit control and management of knowledge within an organization aimed at achieving the company's objectives. Knowledge management entails formulating a strategic policy for development and application of knowledge; executing the knowledge policy with the support of all parties within the organization, and improving the organization where knowledge is not optimally used or is not adapted for changing circumstances (Liebowitz & Wilcox, 1997, p.43).

6. Tacit Knowledge: Knowledge that is not amenable to simple formalization; knowledge that is not codifiable (De Leo, 1994).

7. Cognitive Knowledge: (or know-what) the basic mastery of a discipline that professionals achieve through extensive training and certification (Klein, 1998, p. 88).

8. Visual Literacy: The ability to create and understand concepts depicted with little or no written text.

9. Medical Informatics: The study, invention, and implementation of structures and algorithms to improve communication, understanding and management of medical information (Zakaria, 1998).

10. Management Value-added: The remaining profits after all business costs are accounted for, including taxes, shareholder equity and adjustments for accounting peculiarities influenced by the tax code (Strassmann, 1996, p. 9).

11. Return-on-Management: Management Value-added costs plus the cost of management (Strassmann, p.9).

12. Information Productivity (IP) Index: The cost of sales, general & administrative (SG&A) subtracted from the Return-on-management costs (Strassmann, p.9).

13. Codification Strategy: Strategy in which knowledge is codified and stored in databases, where it can be accessed and used easily by anyone in the company (Hansen, Nohira, & Tierney, p. 107).

14. Personalization Strategy: Strategy in which knowledge is closely tied to the person who developed it and is shared mainly through direct person-to-person contacts (Hansen, et al., p. 107).

Limitations

This study is limited to reviewing contemporary literature sources of knowledge management practices that have real or potential application used within the pharmaceutical industry. Knowledge management in any industry, much less that within the pharmaceutical industry, is a fairly new concept. Although successful programs used in other business disciplines will be mentioned, the scope of this study and final research is restricted to theories

and practices applicable to the pharmaceutical industry over the last 10 years. The author, who has extensive professional experience in medical diagnostics and pharmaceuticals, will make the determination as to what appears applicable.

Chapter II

DEVELOPMENT OF THIS STUDY

General Perceptions Regarding Visual Display and Cognition

Edward Tufte (1983) speaks of the self-promoting graphic and refers to it as "the duck" (p.116). When a graphic depiction is overrun with conventions available through computerization and embellished with decorative forms, the overall design purveys graphical style rather than quantitative information. Similarly, Venturi (1996a), an architect, describes Las Vegas, Nevada in 1968 as "a landscape of symbol in space rather than form in space—it's two-dimensional signs, not buildings, providing identity in the amorphous sprawl (p. 124)." Venturi uses the themes of Las Vegas both architecturally and urbanistically as metaphors for the visual environment. Venturi (1996b)also proffers that "architecture is necessarily complex and contradictory in its inclusion of the traditional Vitruvian elements of commodity, firmness and delight" (1996, p. 16). A review of contemporary literature on the subject of knowledge management and graphical depiction provides an overview of general perceptions regarding knowledge management. The architectural definitions of our surroundings, geographical space, urban form and our general habitats are the subject of several authors in addition to Venturi (Droege, 1997, Shapiro & Varian, 1998). Droege (1997) in particular maintains that the environment, as modified and created by people, is driven by the use of available information including the creation of information and its managed exchange.

Shapiro and Varian (1998) similarly treat the subject of the impact of technology on information exchange and management not by examining the contemporary pressures of the world wide web, but by examining the impact of the telephone and the early proliferation of electricity in the late 1800s.

Papert (1993) writes of other more traditional impacts on information exchange when he discusses cybernetics[2] in his book The Children's Machine. He writes that traditional study in the nature and grounds of knowledge as being inferior if it lacks precision (p. 185). This author maintains that "managed vagueness" is presented as having a great value in the scope of knowledge management even if traditional epistemology is contrary.

Standardized Nomenclature

Meadow and Yuan (1997) present a compilation of definitions commonly used in the field of information and attempt to organize and derive a standard lexicon for information scientists. The authors specifically attempt to propose standard usage for "data, information, knowledge, impact, and development" (p.697). Frustration over a lack of a common basis for referring to these key concepts is the reason for their study. The authors are not promoting any single definition or a singularly correct definition. Rather, they wish to create and promote a standard that all researchers can adopt. By adopting a standard, commonality can be established and respective fields of study will become more cohesive in their approach to scientific study. This study has merit in that the scope of knowledge management is expanding without any apparent self-management.

Verkasalo (1995) addresses knowledge utilization processes in the business environment. Verkasalo describes "contour" with respect to familiarity of a knowledge base (p. 2). Although referring to navigation within a hypertext document, he illustrates the desired interactive discussion between the subjects author and reader which is only facilitated by recognition and acceptance of standardized terms.

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[2] Cybernetics – The science of communication and control theory that is concerned especially with the comparative study of automatic control systems (the nervous system and brain and mechanical-electrical communication

Technical Communication

Shannon (1948) wrote an often-quoted section of the 1948 Bell System Technical Journal entitled "A Mathematical Theory of Communication." This section purports that communication systems can be classified into three main categories: discrete, continuous and mixed. A discrete system is one in which the message and the signal are a sequence of discrete symbols, where the message is a sequence of letters and the signal is a sequence of dots, dashes and spaces, as in telegraphy. A continuous system is one in which the message and the signal are treated as continuous functions, radio and television. A mixed system is defined as one in which both discrete and continuous variables appear.

Although Shannon's fundamental theories are purely engineering based, they are used today as the basis for emergent theories on communication noise and systems theories on how human being successfully share information. It is interesting to note that Shannon was not concerned with psychological dimensions of meaning and reaction inherent in many models.

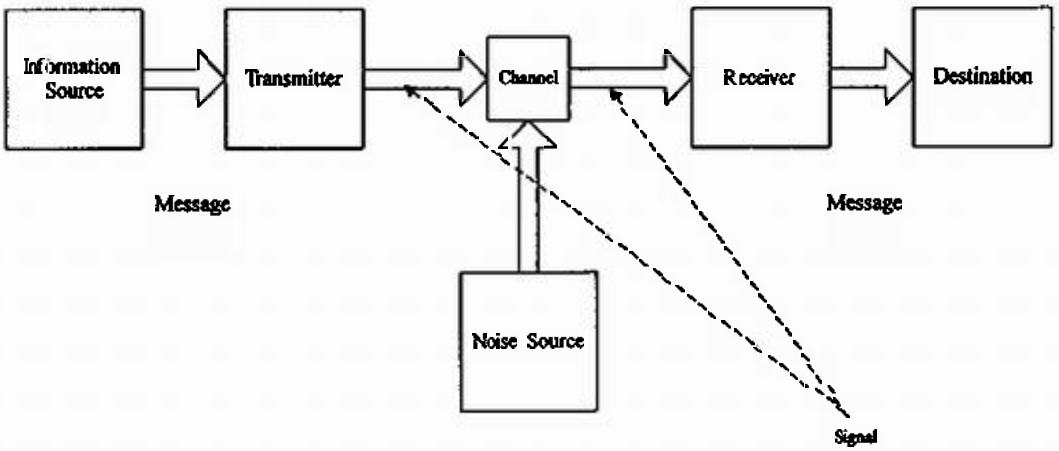

Figure 1. Shannon's Schematic Diagram of a General Communication System

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systems).

Visual Information and Making Decisions

Tufte (1997) writes "Our thinking is filled with assessments of quantity, an approximate or exact sense of number, amount, size, scale." He further describes that "in scientific work, both order-of-magnitude reasoning and precise measurements are pervasive."(p.13). Tufte asks the question: "How are such quantities represented in visual expressions of ideas, experience, and evidence? How are moving images, photographs, diagrams, maps, and charts to be scaled and labeled? An what makes images quantitatively eloquent?" (p.13).

Although not classically eloquent, causal theories regarding the 1854 London Cholera epidemic and the 1986 Space Shuttle Challenger accident are discussed by Tufte. In both cases, he states that descriptive narration is not a causal explanation. He applauds the efforts of Dr. John Snow who mapped knowledge of the physical proximations of drinking water wells to the deaths from cholera. This was an early example of recasting single dimensions of data into a "two dimensional spatial comparison." (p. 30).

Perceptions of three-dimensional space are more easily identified by children than the perception of two-dimensional space and three-dimensional illusion (Hurlbert, 1977). Hurlbert supports his conclusion by drawing on the fact that children are usually slow to accept perspective and that is why it is an infrequent addition to their drawings (p. 137).

Bizarre imagery has been studied extensively by researchers (e.g., Einstein & McDaniel cited in McDaniel & Pressley, 1987) as a potentially effective means for memorization (p. 78). Various materials including prose and lists of information have been studied in the overall effort of improving memory in a wide variety of situations. The results of many studies show contradictory results as to the true effectiveness of bizarre imagery (see Andreoff & Yarmey,

1976, cited in McDaniel, 1987). Bizarre imagery as a part of imagery mnemonics, is characterized by the use of unusual models or symbolism that appears unrelated to the subject or process at-hand. This author concludes that memorization and recall are important considerations in the design of an effective knowledge management system.

Vidal-Abarca (cited in van Hout-Wolters & Schnotz, 1992) explores the awareness of text structure and the skill sets of elementary school students and derives that "getting the main idea" occurs in cases dependent on whether the main idea was explicit or implicit in the body of text passages of varying lengths (p. 48). This study reflects a carefully chosen exploration of uncovering information in expository prose and the ranking of key ideas in a text study.

Information as Process

A study by Brookes (1977) resulted in the development of a fundamental equation that highlights that information and presentation of information is highly subjective to the individual seeking it. Brookes views information as a process in the following equation (cited in Cole, 1997, p. 55): $[\Delta I] + [K] \Rightarrow [K + \Delta K]$.The equation explains that the information user's state of knowledge about a particular subject is modified in the process of knowledge exposure. Knowledge structure (K) is modified as a result of exposure to information (ΔI). Cole (1997) uses Brookes equation to postulate that "information must modify knowledge structure (criterion 1)" (p.55).

Following Cole, Park (1997) studied the concept of relevance and judgments based on relevance in the information retrieval and retention process. Cole studied and presents a model of relevance that explains criteria useful in studying how human being search and establish value of

selected information. He concludes that " for effective information retrieval, three things need to be effective: document representation, problem presentation, and the notion of relevance" (p.340).

Knowledge Management

Knowledge management is a burgeoning field of study. A great deal has been written in the last several years as businesses attempt to reconsider their processes. That sentiment in well reflected in the following statement by Y. Malhotra (1998):

> Knowledge management caters to the critical issues of organizational adaptation, survival, and competence in face of increasing discontinuous environmental change...Essentially, it embodies organizational processes that seek synergistic combination of data and information processing capacity of information technologies, and the creative and innovative capacity of human beings. (p. 58)

Malhotra (1997) also writes that in order to develop a "richer conceptualization of knowledge management", a more comprehensive assessment of human ideals, values and emotions must also be considered. This together in combination with tacit knowledge will allow explicit forms of knowledge to be realized. (p. 294). Malhotra also writes that "the current model of inquiring systems, apparently may have a greater role in combination which involves combining different bodies of explicit knowledge, and internalization which involves knowledge transfer through verbalizing or diagramming into documents, manuals, and stories" (p.294).

De Leo (1994) studied the extent to which organizations are able to transfer knowledge within organizational boundaries or operating units. He termed this "tacit knowledge transfer" (p. xiii). The focus of the 1994 study was to proffer an assessment strategy to be used to allow organizations to better manage their unarticulated knowledge (essentially tacit) in comparison to rival firms. De Leo points out that "organizational knowledge tends to be sticky, i.e., it does not easily move from firm to firm" (p. 171). This author believes that no apparent indicators exist to measure whether or not mobilization of information and management of content is consistently occurring in corporations. De Leo does state that tacit knowledge doesn't require conversion into an explicit form in order to be disseminated within an organizations boundary. Rather, he argues that "tacit knowledge remains tacit because of the presence of firm-idiosyncratic mechanisms which allow operating units to share knowledge without having to specify the details" (p. 186).

Demarest (1995) asserts that two primary paths have emerged that will govern a firm's strategic decisions on knowledge management; on either design-centered process flow or cost-centered price leadership (p. 1). He states within the context of knowledge management that "design-centered firms will select empowerment paradigms for the IT-based automation of knowledge work; cost –centered firms will select control paradigms for IT-based knowledge work (p. 1)." Demarest posits that the similarities between the early craft-workers, employed in the factories of the industrial age and today's knowledge worker are striking. The "factoring system" of the industrial age is again present in that knowledge workers "control the means of production in information-intense businesses" (p. 10).

Hansen, et al (1999) describe the need for organizations to adopt a single strategy and adopt a secondary strategy devoting only a portion of resources to the latter. Without such a strategy of focusing on either a codification strategy or a personalization strategy, and using

either one to complement the primary strategy in a supporting role, firms risk failing both (p. 112).

Hyperinformation

Harvey Molotch (cited by Roszak in Rana, 19), currently professor of Sociology at the University of Santa Barbara, California, tells us that "A world of information so clear that we would know where to go, and so rich that it would deliver answers, would be a fool's paradise because it would not allow the risk of being wrong"(p.74). He also tells us of the state of hyperinformation. A state in which "any added increment requires a finite quantum of information be shed in order to make sense of things" (p.75). He further describes the drain of information overload experienced by today's human being, in addition to the responsibilities of knowing about health, food, music, fashion, etc.

In his 1990 book, Information Anxiety, Richard Saul Wurman radically reclassified information and began a trend in lock step with computer technology, of creating one of the first hyperlinked books. He models his structures of communication after "the quirkiness of conversations and associated ideas" (foreword by Naisbitt in Information Anxiety, p.28). Wurman also conceptualizes the explosion in the amount of information that is put forth for an individual to digest and act upon. He states "The glut has begun to obscure the radical distinctions between data and information, between facts and knowledge" (p.37).

The focus for this literature review is governed by this author's wish to add to the heterogeneous body of information that is known as knowledge management, attempting to offer a synopsis of fundamental approaches to understanding knowledge management as a system and produce a clearer vision of how a well designed system can lead to greater understanding in the

business area of pharmaceutical product development and marketing. "What we need is a language that would allow us the power and ability to demand learning, safety, mobility, and communication. What we have is a vocabulary that encourages makeshift solutions that distract us from real problems" (Wurman, 1990, p.124).

According to a study by The Delphi Group in Boston, over 600 corporate users surveyed, had investments in knowledge management projects (Fusara, 1998, p.8). In the same article, Robert D. Aaron, president of Aaron Smith Associates, Inc. reports that "what will kill knowledge management is the lack of being able to tie it to discernible achievements in the company" (p. 8). This author concurs with that assertion and will seek to identify characteristics and components of knowledge management that possess either real or potential application within the pharmaceutical industry.

This author has purposely selected publications from sociology, graphic design, illustration, computer science, anthropology and architecture and related journals and manuscripts in addition to texts and journal articles on pharmaceutical development in an effort to offer insight into the development of new thoughts on knowledge management. Available, relevant literature was obtained from a variety of locations including current contents of Walsh Library (Seton Hall University), Rutgers University Libraries, various on-line catalogues in the arts and humanities that recognize and contain literature on knowledge management; data management and cataloging; pictorial displays of knowledge; form and functions in printed literature; graphic elements and their use in all media forms.

Chapter III

DRUG DISCOVERY ACTIVITIES

Background

Does a single model of knowledge management exist that when properly applied, provides a clear indication or likelihood of economic value in the development of a new pharmaceutical product? This author seeks to answer this question through a review of select literature from pharmaceutical companies employing some form of knowledge management program or process that is reported to be a valuable business process.

Drug Science and Understanding Drug Effects

Weatherall (1990) comments that Jonathan Pereia (1804-1853), the father of the Royal Pharmaceutical Society of Great Britain was responsible for describing the first recognizable schema for medicinal knowledge management (p. 19). The categories included the sensible qualities of medicines; natural historical properties, chemical properties and dynamical properties (p.19). Sensible qualities referred to the color, taste and odor of medicines. Natural historical properties referred to the botanical characteristics of plants and their potential therapeutic benefits. Chemical properties described performance characteristics of complex organic compounds based crudely on similar or dissimilar chemical or medicinal applications. Finally, dynamical properties described the effects of administration of early medicines to animals (p.21). Periea's treatise describing these characteristics and modes of management was published in 1839 and entitled Elements of Material Medica and Therapeutics.

Fundamentals of Drug Research

Schwartzman (1976) defines drug research as "a trial-and-error process organized on the basis of a series of provisional hypotheses systematically refined by feedback from empirical tests (p.48)." The delivery of a safe and effective drug requires a complex interaction of several entities during the research phase. The typical participants are pharmacologists, clinicians, medicinal chemists and laboratorians. Each participant must be in constant communication throughout the development process as each participant is responsible for managing the effects of their respective areas. Management of such complex knowledge becomes increasingly difficult in light of the fact that inadequate animal models may exist and as such, clinical evaluations in humans can take several years.

The decision by a drug manufacturer to undertake research in a particular therapeutic area typically involves typically a 10-year commitment to build core competencies. This has classically been done without complete assurance that of safety, effectiveness or economic return to offset development costs (Schwartzman, p.57). Figure 2 provides a brief visual of the pharmaceutical research process.

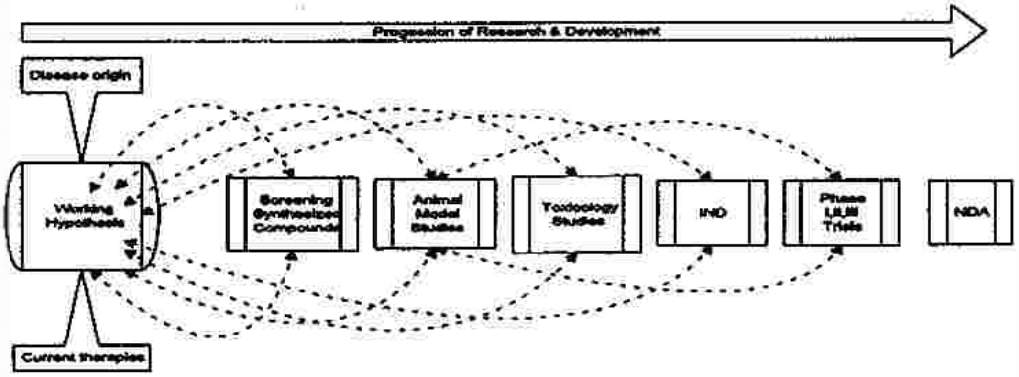

Figure 2. R&D Steps in the Development of a Typical Drug Compound

Current therapies and treatment regimens are examined together with postulates on a disease origin. Together these two elements constitute the working hypothesis. High throughput screening (HTS) of multiple synthesized compounds is conducted to isolate one or more stable, active compounds. At this point the researcher has begun formulating biopharmacologic study protocols in an effort to understand physiochemical properties of the potential drug product and the pharmacological effect. Animal model studies are begun after the relationship is understood. Toxicology studies then ensue to understand the relationship between therapeutic dosage and toxic levels of drug, it's delivery route and excretion rate. An IND or Investigational New Drug application is filed with the Food and Drug Administration (FDA) based upon successful outcomes in the previous steps. Successive phases of clinical trials are commenced each building upon positive outcomes. Phase I includes clinical pharmacology and toxicology; phase 2 examines initial clinical effectiveness; and phase 3 researches the treatment effectiveness. Finally, the NDA or New Drug Application is submitted to the FDA. The NDA is reviewed by one of several divisions responsible for specific classes of drugs. Each of these dependent steps depicted in Figure 2 are displayed with dotted-line arrows to illustrate the forward and backward dependencies that evolve throughout the process.

Economic Valuation of Computerization and Knowledge Management

Strassmann (1996) researched that expenditure for computers averaged less than 0.4% of revenue and less than 2.5% of overhead costs (p. 2). He also states that value from information technologies can be extracted only by operating executives who have harmonized their organizations to earn profits. (p. 5). A more disciplined business cycle is being entered into

today that requires higher performance and better use of resources, including knowledge management. Strassmann also points out that to understand the effective use of information resources, one needs to rank a company's Information Productivity or IP™. Strassmann created a model ranking in 1996 using Standard Industrial Classification or SIC codes for select pharmaceutical companies. In conjunction with other public information regarding the respective companies' financial performances, he was able to create a table in local currency that compares various pharmaceutical companies against equity, income, SG & A and IP (p. 10). Although not conclusive in the findings that high IP is a direct correlation with high equity and income performance, the study does respect that excessive assets and excessive SG & A can influence IP ranking (p.9). Finally, Strassmann points out that relying only on capital-based productivity indicators such as Return on investment (ROI) and Return on Equity (ROE) is necessary to judge organizational health (p.12).

Prediction of Effects in Pharmaceutical Development

Drug development is a complex and extremely risky process involving the dissection of specific biological mechanisms at a variety of effect levels and subsequently creating a model of a disease or affliction process with potential points of intervention.

Several companies (e.g., Molecular Simulations, Inc., or MSI) have emerged in recent years that provide software that enables the user to model complex interactions and simulate processes that otherwise would require more extensive studies on safety, reliability and efficacy.

In a study by Ernst and Young LLP (1998), Hoffmann-LaRoche, one of the world's largest pharmaceutical companies, described their revised methodology of handling NDAs or New Drug Applications. In the case study, Hoffmann-LaRoche organized the large amount of

data normally submitted for an NDA into two new conceptual frameworks, Question Tree and Knowledge Link (p. 3). By doing so, a more fundamental approach of presenting information was successfully obtained that mimics Piaget's creation of the terms assimilation and accommodation in the study of how children learn that was discovered many years earlier (Papert, 1993, p. 41). The Question Tree process began with providing the answers to traditional questions of drug safety, efficacy and quality. Branching out from each question are maps of sub-questions that all point to sources to answers. Avoiding the passive stance of creating simply a knowledge map, the creators of this framework sought to instill an active sense of contribution on behalf of persons who had knowledge to offer to the Knowledge Link. The Knowledge Link provided guidance to knowledge creators as to whom and at what point a person or group should share their knowledge (Ernst & Young LLP, 1998, p.5). Assimilation is a term created by Piaget to describe the process of a person changing their representation of the world to fit a their way of thinking; accommodation refers to adaptation of a person's ways of thinking to fit the worldview (Piaget, 1993, p. 41).

In a pharmaceutical industry survey conducted in 1997, Pike created a briefing on corporate activity and major trends in the pharmaceutical industry. The key drivers for a large number of corporate acquisitions concluded in 1997 were cited as: a search for critical mass (via broadened product portfolio and enhanced geographic range); the achievement of cost savings (through consolidation of functions and systems including R&D and Sales); and to strengthen financial their position (through divestiture of non-core businesses) (p.3). The authors hold that "even the biggest pharmaceutical companies are considered to be too small to maintain their competitive position in a geographic market or specific therapeutic area" (p.11). With estimated worldwide sales of pharmaceuticals reaching US$357 billion by the year 2000, manufacturers

are struggling to maintain their competitive positions in both horizontal and vertical markets (p.4). Pike et.al., depicts the factors that can exert pressure on a pharmaceutical company in the figure 3. These pressure the authors maintain, are significant enough that in principle it is feasible for a pharmaceutical company to "outsource all its activities to leave just a skeleton consisting of financial and management functions, i.e., a virtual pharmaceutical company" (p.19). R&D cost efficiency and Information technology are two large factors that influence development under the umbrella of operations.

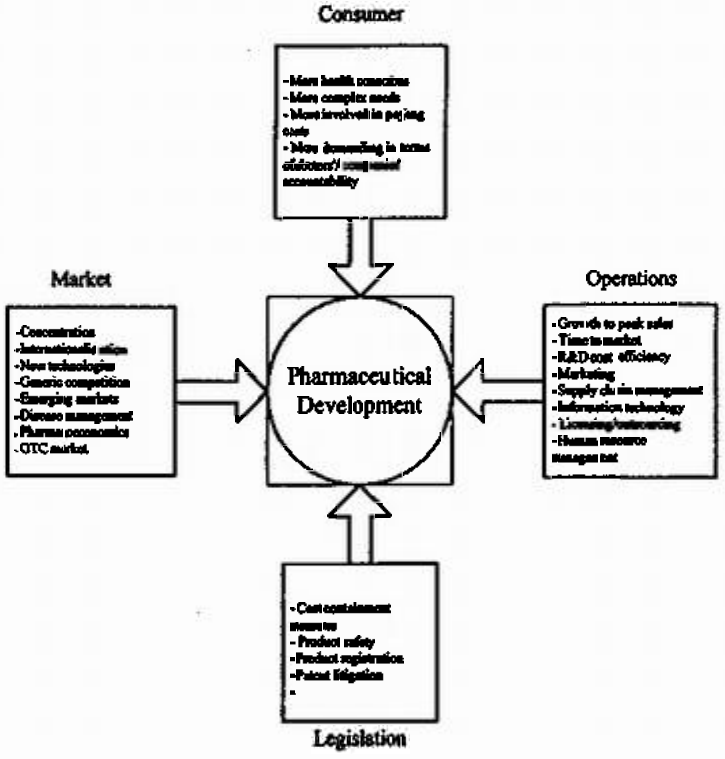

Figure 3. Typical Pressures on Pharmaceutical Company Performance

Pharmaceutical R&D Costs and Innovation

According to a study by PricewaterhouseCoopers (1998), the pharmaceutical industry is experiencing symptoms of stress: the cost of research and development; a slowdown in sales; and

general costs of innovation (p. 3). Worldwide costs of research and development are expected to reach nearly $39 billion. U.S.-based companies are projecting to invest nearly $21.1 billion. A decade prior, total research and development dollars in the U.S. were $6.5 billion. The study reports that the largest and historically the most profitable pharmaceutical organizations "have no choice but to adopt a new strategic, tactical and operational management model consistent with the fundamental drivers of this new paradigm– and do so fast" (p.5).

The drug development process is changing from a previous strategy of an iterative/intuitive approach that might yield a single compound once the development process is complete to a systematic/predictive approach where the development process includes and plans for the possibilities of surrogate pharmacogenomics and potential diagnostic applications as an outgrowth of the development of a disease-specific compound. A pharmaceutical industry "traditionally characterized by indecision must now become much more decisive" (PricewaterhouseCoopers, 1998, p. 110). Rappaport (1998) makes similar commentary on development strategies in drug discovery by referring to drug discovery as one of several "meta domains" (p. 1). His reference stems from the observation that the inherent development processes underlying drug discovery and development result from the creation of many domains of information and activities. Further, he postulates that discovery activities are only a single portion of the discovery process; what "matters beyond the analytical skills of the researcher is the available information and the ability to focus one's attention on a rich set of possibilities, the believability of data and theories, the decision-making strategies between different approaches..."(p. 2).

The field of 3D chemical database systems is explored by VanDrie (1998) in his study which traces the historical development of analyzing which molecules may be active against

which human receptors. He discusses several unresolved issues in methods development but relates one key element that is common in this author's research. The fact that VanDrie (cited in Hansen, Nohira & Tierney, 1999) makes the conclusion that "3D database searching and de novo design/experimentation are complementary, with neither obviating the other" (p. 10) is profound in relation to the fact that over-arching corporate knowledge management researchers found that a singular management strategy breeds the most successes.

Chapter IV

CAPABILITIES AND ADVANTAGES

Introduction

As stated earlier, the focus of this literature review is to examine various authors' management of knowledge in the context of pharmaceutical development. It has become apparent that a single model of knowledge management does not exist, that when properly applied, can provide a clear indication or likelihood of economic value in the development of a new pharmaceutical product. Many models do exist, however, focusing on those activities that can be linked to the economic transaction is key. This is also known as the value proposition. The discovery of a key value proposition (O'Dell & Grayson, 1998) is important to focus knowledge management initiatives so that resources are not haphazard in their use. Defined as "the logical link between action and payoff" (p. 31), value propositions are divided into the categories of customer intimacy, product-to-market excellence or operational excellence (p. 31).

Knowledge Management Strategies

Fisher and Fisher (1998) report that during their interview of several individuals employed in knowledge management capacities, hierarchy was discussed and described as vestigial of the industrial age and "no longer a valuable practice or requirement for providing clarity of purpose and directing an uneducated workforce" (p. 121). The conceptual bottleneck is no longer a reality in organizations that allow for distributed information that can include information that was typically only available to management. On the contrary, Nonaka states that "the value of any one person's contribution is determined less by his or her location in the

organizational hierarchy than by the importance of the information he or she provides to the entire knowledge-creating system" (p. 39). Knowledge-creating systems are the norm at Vertex Pharmaceuticals. At Vertex Pharmaceuticals, the company uses a product development process called structure-based rational drug design (SBRDD). SBRDD "combines the mature technology of synthesizing drugs with the nascent biotechnology techniques" to create the proteins and enzymes that are produced naturally in the body (Leonard, 1998, p. 68). Vertex subsequently uses computer knowledge modeling to as a substitute for traditional protein synthesis and screening used typically by researchers. This "mixing of methodological preferences" is valuable in the complex field of drug development.

Table 1 lists the criteria used in examining the models of knowledge management. In an attempt to develop one's own process to recognize, collect, manipulate, and manage information and knowledge, as well as to prosper (by transference) from owning it, one needs to establish criteria that enable easy recognition. Van Doren (1991) states that knowledge never can be certain. It is "always intrusive" he writes and "no matter how hard we try, our very effort to know fully and completely gets in the way" (p. 340).

Table I

Criterion Used to Categorize Models of Knowledge Management

Criterion	Description
Simplistic	Containing minimal descriptive elements.
Clear	Containing succinct descriptive elements.
Relevant	Containing descriptive elements that provide

	tactical guidance.
Tacit-Tacit Exchange	Easily communicated verbally from one person to the next through observation, imitation and practice.
Tacit-Explicit Exchange	Characterized as articulated knowledge that is readily converted into action.
Explicit-Tacit Exchange	Characterized as the action of integrating and converting stated knowledge into new tacit knowledge.
Explicit-Explicit	Characterized as the combination of articulated knowledge to form new articulated knowledge.

Table 2

Comparison of Select Knowledge Management Strategies

Type	Description
Codification Strategy (Hansen, et al., 1999)	Knowledge coded and stored for company-wide retrieval.
Personalization Strategy (Hansen, et al., 1999)	Knowledge closely tied to originator; shared through direct person-to-person contact.
Corporate Health Pyramid (Germeraad & Morrison, 1998)	Intellectual assets are categorized and managed based on corporate needs matched to corporate strategy; resembles Maslow's Hierachy of Needs.

Knowledge Narration (Weinberger, 1998)	Knowledge should be managed through narrative order because "stories are how we make sense of things (p. 3)"
Empowerment Strategy (Demarest, 1995)	"Ennobling and enriching the work environment, enhancing the scope of control of the worker, creating conditions of satisfaction on both sides of the economic transaction (p. 5)."
Control Strategy (Demarest, 1995)	"The deployment of information technology to render the firm's service interfaces utterly regular, uniform and predictable (p. 6-7)."
Knowledge Chain (Frappaolo & Koulopoulos, 1999)	A series of four labeled cells describing Awareness and Responsiveness juxtaposed to Internal and External elements of knowledge.

Table 2 attempts to offer a synopsis of select strategies that can be applied to enhance economic value through management of key knowledge. Each strategy can be viewed as a descriptor of knowledge states, often involving a single variable, yet playing an important role in both the theory of economic growth and in empirical research on R&D and profitability.

According to Ghosal and Bartlett (cited in Klein, 1998), who studied trust and renewal tactics in companies undergoing transformation, an organization's goal is to maintain momentum (p. 155). Citing an organizations need to maintain an identity and framework for operation

directly after multiple difficult business periods, the authors present that "an internal context to support front-line operations and the collaborative team-based behaviors for supporting resource linkages and best-practice transfers across individual entities" (p. 155) is at odds with individual initiatives. This author supports that selection criteria for applying one or more strategies is best matched to considerations of an organization's phase of development.

Considering phases of development in an organization in light of capabilities is critical according to a study by Baghai, Coley and White (1999). These authors maintain that in addition to what they term "organizational skill," three other classes of resources are required for effective knowledge management: privileged assets, growth-enabling skills and special relationships (p. 100). The authors' strategy for management of knowledge describes privileged assets as "physical or intangible assets that are hard to replicate and confer competitive advantage to the owner;" growth-enabled skills are described as "skills in acquisition, deal structuring, financing and risk management;" and special relationships are described as "ties with existing customers and suppliers (that) provide growth opportunities and should be nurtured" (pp. 100-101). The authors describe a carefully written schema for combining these resources and creating a competitive advantage that is amenable to the pharmaceutical industry which has a typically large catalogue of privileged assets generated by research and or acquisition. Weill & Broadbent (1998) maintain that this combination of knowledge culture with "expertise-centered management" focuses on human expertise for achieving business advantages over the competition (p. 199).

Chapter V

HEURISTIC FRAMES OF REFERENCE

Subject Quadrant

It has become apparent that a single model of knowledge management does not exist, that when properly applied, can provide a clear indication or likelihood of economic value in the development of a new pharmaceutical product. Each model presented and discussed offers a framework for improved performance in light of economic pressures. According to O'Dell and Grayson (1998), the choice of value proposition, indeed the management of valuable knowledge, depends on "value levers in a particular market" (p. 224). Value levers being those business propositions that present a higher return over investment costs.

Figure 4 below illustrates an adaptation of a well-known figure created by J. Luft in 1961. Adapted for the pharmaceutical industry, this author is attempting to identify a succinct model that provides development activity direction.

Four quadrants are presented in a 2x2 matrix that compares subject knowledge (facts, figures, methods) with a organization's self-knowledge about knowledge. There exist four areas of self-knowledge about the subject knowledge. There are certain facts, that a pharmaceutical corporation involved in drug discovery knows, namely codified, explicit knowledge regarding the compounds it has studied (via High Throughput Screening). Also, studies using surrogate compounds in combination with making use of know in silico libraries (for testing toxicity, metabolism and bioavailability) constitutes a high degree of garnered knowledge with a low degree of exact outcomes knowledge (i.e., "known to be unknown."). Functional genomics and

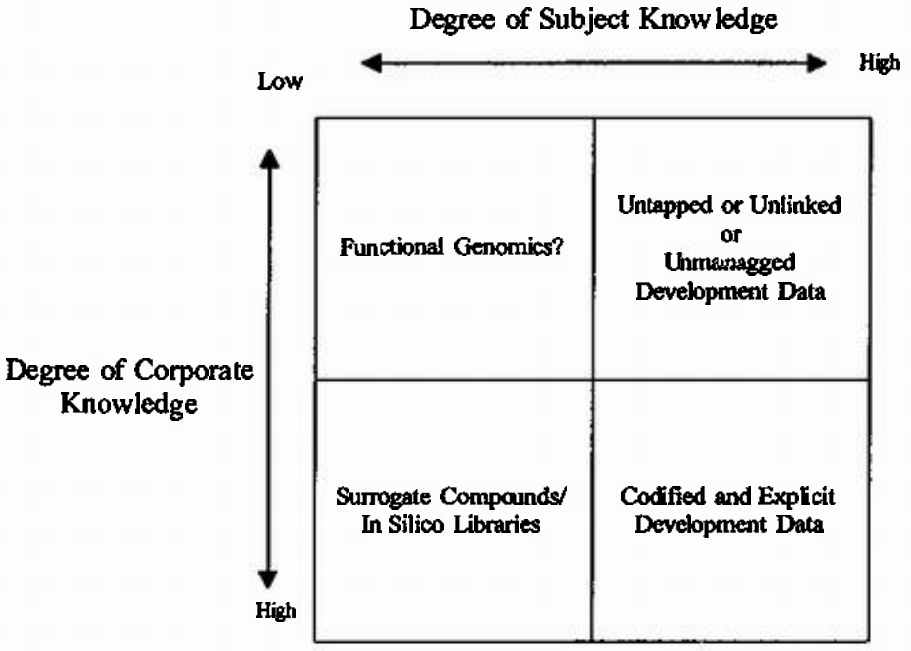

Figure 4. Self-knowledge and Pharmaceutical Development Direction

human genome analysis represent a quadrant of low subject knowledge on behalf of science as a whole. According to a recent publication by PriceWaterhouseCoopers (1998) entitled Pharma 2005, "transferring skills traditionally associated with preclinicals into late stage discovery, and skills traditionally associated with clinicals into early development is only an interim measure...preclinical stage will soon be a bridge nobody needs" (p. 12). The fundamental message is that past practices relying on iterative and intuitive approaches to drug discovery will evolve into systematic and predictive modeling in this authors opinion.

According to an interview published by Tufts University Center for the Study of Drug Development (Tufts University CSDD, 1998), the measures used to access productivity in drug development include "development costs, development times, and technical success rates. Not one of these measures fully defines productivity in drug development but they are all indicators

of some aspect of productivity" (p. 2). Less onerous ways to increase sales and gain access to promising technologies are through diversification (and acquisition). In a study by Pike, King and Barsi (1998), the following key drivers we listed as being responsible for corporate acquisition in 1997: search for critical mass; achievement of cost savings; and strengthening of financial positions (p. 3).

Spatial Influences on Knowledge Management

Encouraging collaboration amongst knowledge workers can be facilitated in many ways. Certainly shared visions and goals, together with financial rewards for participants promote positive efforts toward success. Morris (1999) describes efforts by pharmaceutical companies to stimulate collaboration through evocative physical surroundings; surroundings that increase spontaneous interaction. Morris cites that "the probability of once-a-week communication between researchers drops to less than five percent when their offices or labs are located more than 100 feet apart" (p. 34). He further states the "the best of new R & D faculties follow design strategies intended to optimize face-to-face interactions between co-workers" (p. 34.).

Baumard (1998) describes the efforts of Intel Corporation and other successful firms that not only focus on continuous improvement plans, but also focus on the maintenance of an innovative environment. Intel is described as having developed "war rooms" and openly encourages crisscrossed organizational boundary relationships (p. 1).

Chapter VI

CONCLUSION AND RECOMMENDATIONS

It is this author's opinion that the field of knowledge management in the pharmaceutical industry is currently at an infantile stage. William Gilbert (1544-1603) the English physician who was fascinated by lodestone (now known as the mineral magnetite which possesses natural magnetism) never understood exactly how magnetism worked, yet he made a blind connection to the rotation of the planets around the sun being a form of magnetic force. No one else understood the implications of this suggestion at the time (VanDoren, 1991). Like Gilbert's assumptions, the current state of knowledge management is equally speculative. This author found it difficult to draw exacting conclusions based upon the body of scientific information labeled as knowledge management treatises because of the tendency of authors to speculate rather than publish implicit facts regarding pharmaceutical development, most likely due to confidentiality. The rapid evolution of technology solutions in the form of generational computer databases and physical/logical communication technologies is creating tremendous challenges as well as advantages for the pharmaceutical researcher. Presumably all researchers in pharmaceutical development are using such tools. The challenges are not limited to drug research but also include providing high-quality health-education for consumers as direct-to-consumer marketing becomes more prevalent.

Developing a system effort, coordinated across development groups appears to be a requirement for project success. This assumption is supported both in apparent literature on human behavior as well as in studies in operational excellence.

Future Study

Although the conclusions from the research and data are not definitive, the author offers some recommendations to those interested in pursuing more detailed information regarding knowledge management practices in the pharmaceutical industry.

Paramount to further focused study of specific pharmaceutical classes of drugs or specific indications, is the creation and execution of a detailed survey. A survey might present the reviewer with even more timely information regarding development tools and practices used in specific market segments. Researching success factors that are supraliminal to current thoughts on knowledge management issues and methodologies and extending the investigation to government and academia might provide additional valuable insight to the reader. Most organizations are unfit for the management and capitalization of intangible assets and counter-productive in terms of knowledge generation, however further study might discover ways to change this.

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