CLOSING THE MARKETING STRATEGY-TACTICS GAP: AN INSTITUTIONAL THEORY ANALYSIS OF PHARMACEUTICAL VALUE CHAIN

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Abstract

This chapter identifies a strategy-tactics gap in most previous studies of pharmaceutical marketing, and addresses it by systematically analyzing the marketing strategies used in practice with the help of a unique dataset of court discovery documents unsealed in a recent litigation. Adopting an institutional theory perspective, we examine the dominant logic that underlies pharmaceutical marketing strategies, and contrast it with the organizing logics of the value chain partners. Four distinct marketing strategies with carefully crafted interdependencies emerge from our analysis: (1) market penetration strategy involving a focus on segmentation and penetration, (2) evidence based strategy involving production of science, (3) medical education strategy involving development and dissemination of standards of care, and (4) surrogate selling strategy involving leverage of peer-to-peer influence among target physicians. Together, the strategies uncovered in our analysis provide coherence to the observed marketing tactics and show that they are largely consistent with the logic of consequences which conflicts with the logic of appropriateness guiding the actions of the value chain partners. Going beyond the strategy-tactics gap, the institutional theory analysis of the pharmaceutical value chain shows that: (1) conflicted logics of the value chain scarcely remain dormant, (2) but are amplified by pharmaceutical marketing strategies that, in turn, (3) invite regulatory intervention to constrain and restrict pharmaceutical marketing efforts. We propose an open systems framework that elaborates on value chain interdependencies and compare it with the economic framework that characterizes most current research. We close the chapter with an agenda for future research into the theory and practice of pharmaceutical marketing.

Scholarly research in pharmaceutical marketing has disproportionately focused on the *tactical* issues of optimizing the ROI of pharmaceutical promotion spend[1], paying scarce attention to the marketing *strategies* that underlie these tactics. In an integrative review of the literature, Manchanda and Chintagunta (2004, p.143) articulate marketing literature's emphasis well by observing that much research aims to identify "ways in which these [pharmaceutical] firms can increase the amount of prescriptions (i.e., increase revenues) or reduce the number of salesperson calls (i.e., lower costs) via a more efficient allocation of [promotion] effort." Enhancing the effectiveness and efficiency of pharmaceutical promotion tactics is the dominant theme in a diverse and rich body of marketing literature (Venkataraman and Stremersch 2007; Manchanda and Chintagunta 2004; Narayanan, Desiraju, and Chintagunta 2004; Mizik and Jacobson 2004; Oliver and Van Horn 2004; Wittink 2002; Gonul, Carter, Petrova, and Srinivasan 2001). By contrast, studies of the nature and scope of pharmaceutical marketing strategies are negligible. Strategy is a firm's organizing scheme for competitive advantage and provides coherence to a firm's diverse tactical choices. Moreover, strategy operationalizes the dominant logic of the firm's management for achieving its goals and objectives by blueprinting the underlying logic that gives meaning to organizational action (why are we doing this? why are we doing this way, and not some other way?) (Prahalad and Bettis 1986; Porac, Thomas, and Baden-Fuller 1989). In the integrative review cited above, mention, much less consideration, of strategy is remarkably absent while the diverse perspectives and findings related to detailing tactics and practices are thoroughly reviewed (Manchanda and Honka 2004). Without consideration of strategy, a tactical focus is as myopic as studying action without cognition, and analyzing *what* and *how* without understanding *why*.

[1] The promotion spend by the pharmaceutical industry in the United States is estimated to be between $27.7 and 57.5 billion (Gagnon and Lexchin 2008). Pharmaceutical promotion practices include detailing (where salespeople visit with physicians to update them on recent therapeutic advances and encourage them to write prescriptions that favor the firm's products), sampling (where samples of company's drugs are provided to encourage trial) and physician meetings (where educational meetings are convened to show efficacy evidence of company's drugs) among other related practices.

Curiously, inattention to pharmaceutical marketing strategy and the resultant strategy-tactics gap has persisted despite a growing drumbeat of surprisingly vigorous, and often unflattering, analysis of pharmaceutical marketing strategies among medical practitioners and public alike (DeAngelis 2006; Angell 2004; Brennan and Mello 2007; Heuvel 2007). For instance, medical scholars express uneasiness at the "[pharmaceutical industry's] sophisticated and wide-reaching marketing *strategies*," (Moncreif, Hopker, and Thomas 2005, p.84), and their ire appears focused on the "marketing *strategies* masquerading as evidence based medicine," (Eichacker, Natanson, and Danner 2006, p.1642). Concerned that "physicians have been the central target of marketing *strategies*" (Studdert, Mello, and Brennan 2004, p. 1891), several studies find this trend "at best very troubling" (Steinbrook 2008, p. 1062) and propose a "firewall between marketing and science" (Antonuccio, Danton, and McClanahan 2003, p.1028). Several books by medical practitioners claiming to unveil industry strategies paint a dark picture of an industry focused on maximizing profits at any cost (Petersen 2008; Angell 2005; Murray 2010). Swayed by this publicity, the pharmaceutical industry has seen its public standing fall from a 50% (1998) to less than 12% (2010) favorable rating in a *Harris survey of public trust*[2], with 46% favoring more governmental regulation, and its index of drug stocks decline by 25% over the last 5 years (Collis and Smith 2007). Angelmar (2005, p. 1) summarizes this trend by noting that the pharmaceutical industry's "business model has come undone."

Given such aversive value chain response, the strategy-tactics gap in the pharmaceutical marketing literature is inexplicable.[3] Lacking systematic studies of pharmaceutical marketing strategies lends an impression of uncontested validity to the mostly hostile studies reported in the medical literature; if considered valid, the medical practitioners' assessment of pharmaceutical marketing strategies undermines the legitimacy of the tactics employed. Thus,

[2] The *Harris Interactive* survey is a longitudinal study of public trust across a range of industries and asks the following question, "Do you think each of the following does a good or bad job of serving its customers?" The results reported here are from a report in the *Economist* titled, "Prescription for Change," published June 16, 2005.
[3] To some extent, this neglect is indicative of lack of access to data on pharmaceutical strategy making, much of which is proprietary. By contrast, data on promotion spend has been made relatively accessible by research agencies such as IMS, Wolters Kluver and Verispan.

the strategy-tactics gap warrants attention from researchers interested in pharmaceutical marketing. In particular, two questions are germane to our study:

1. What specific marketing strategies do pharmaceutical companies use to engage medical practitioners, and how do these strategies relate to particular tactics?
2. Under what conditions and why do pharmaceutical marketing strategies amplify (or diminish) the aversive (approving) response from its value chain partners?

This chapter aims to address the preceding questions by making three contributions. First, we aim to conduct a systematic analysis of a pharmaceutical company's marketing strategies and relating them to specific tactics deployed to engage medical practitioners. Our theoretical lens is institutional theory which is well suited for examining the organizing logics that underlie strategy, and in going beyond an organizational focus to understand its value chain implications (Oliver 1991; DiMaggio and Powell 1983; Scott 1987). Our premise is that understanding value chain implications of organizational strategy requires an explicit consideration of legitimacy, not just profitability, outcomes. No previous study has utilized institutional theory to examine pharmaceutical marketing strategies or to explore its value chain implications.

Second, this chapter empirically examines the dynamics of value chain's response to pharmaceutical marketing strategies using the concept of institutional logics. The institutional view conceives "logics" as socially constructed mental models that groups of individuals hold as shared cognitions of socialized routines for action that are "essential" to facilitate communication, order interactions, and promote learning among market actors (Denzau and North 1994, p. 4-5; March and Olsen 1998; Scott 2001). In this sense, logics provide mental maps for constructing market action (e.g., strategies) and interpreting it (e.g., by physicians), as well as guide subsequent response (e.g., physicians' response towards pharmaceutical marketing). In our conception, different market actors in the pharmaceutical value chain respond to disparate institutional logics and, when market action amplifies this disparity, conflict within the value chain increases. Specifically, our conceptualization develops three interrelated ideas: (1) pharmaceutical marketing strategies are rooted largely in the *logics of consequences*,

(2) physicians' interactions with their patients are rooted largely in the *logics of appropriateness*, and (3) a value chain with members rooted in disparate logics of consequences and appropriateness are inherently conflicted. Building on this conceptualization, we examine the ebbs and flows of the conflicted logics in the pharmaceutical value chain.

Third, using the empirical analyses as a foundation, we outline a conceptual framework grounded in an open systems view for future research on pharmaceutical marketing strategies. Our framework emphasizes an embedded analysis of pharmaceutical marketing, where studies of pharmaceutical marketing are incomplete and likely misleading without consideration of value chain dynamics. Specifically, we weave our framework around three key assertions: (1) systems (e.g., value chains) with disparate logics are prone to entropy due to inherent conflicts in their dominant logics, (2) managerial action focused on internal logics enhances value chain conflict and results in counterintuitive effects, and (3) a focus on organizational legitimacy can seed coordinated exchanges among value chain partners to potentially overcome system conflict. We show that our theorizing can explain current trends that are particularly averse to pharmaceutical marketing despite increasing knowledge of its efficiency and effectiveness. We close by outlining an agenda for future research on pharmaceutical marketing.

AN INSTITUTIONAL THEORY ANALYSIS OF PHARMACEUTICAL VALUE CHAIN

The institutional perspective provides an embedded view of market exchanges where regulatory institutions, public and private firms, and consumers are linked through market interactions (Oliver 1991; Dimaggio and Powell 1983; Scott 1987). Generally viewed as one of the leading perspectives for analysis of market action and evolution, institutional theory gives privileged status to the notion of logics and the institutions that create, maintain and disrupt them (Heugens and Lander 2009; Lawrence and Suddaby 2006; DiMaggio and Powell 1991; Grewal and Dharwadkar 2002; McFarland, Bloodgood, and Payan 2008). Neo-institutional scholars construe logics as socially constructed mental models that market actors hold as shared

cognitions for socialized routines of action. For instance, Scott (2001, p. 57) defines logics as collective "frames" and navigational guides for market decision making (Caronna 2004).

Collective frames for corporate decision making are conceptualized as a "dominant logic" in the strategy literature (Prahalad and Bettis 1986; Porac, Thomas, and Baden-Fuller 1989; Lampel and Shamsie 2000). Prahalad and Bettis (1986, p. 490) define dominant logic as "the way in which managers conceptualize the business and make critical resource allocation decisions." From an institutional lens, dominant logic provides a mental model of a common set of assumptions and beliefs about organizational purpose and goals that guide managerial decision making and strategic choices. Thus, pharmaceutical marketing strategies are located at the intersection of strategy and institutional theory literatures within the dominant logic framework of shared cognitions that underpin strategic choices by pharmaceutical managers.

We develop the dominant logic at this intersection for pharmaceutical marketing strategy next. Thereafter, we take this theorizing forward by conceptualizing the dominant logic underlying physician-patient exchanges. In the final section, we join these developments to highlight the conflicted action implications of disparate logics in the pharmaceutical value chain.

Pharmaceutical Marketing Strategy and Logics of Consequences

The dominant logic of pharmaceutical marketing conforms to the institutional theory conception of the logic of consequences (March 1996; March and Olsen 1998), which asserts that an orderly and stable system of market relationships arises as a result of exchanges among market actors pursuing self-interested gains. The logic of consequences is reminiscent of Adam Smith's merchant logic, manifested through assumptions of market mechanisms and goal of maximizing ROI. Heide and Wathne (2006) note that the logic of consequences is common to several theories of inter-firm relationships including transaction cost, agency, and game theories. For instance, in a supply chain, self interested manufacturers and distributors may coordinate their actions and trust each other because the long term payoffs from coordination and restrained opportunism exceed short term benefits from unilateral opportunism (Barney and Hansen 1994).

Past research provides evidence supporting the foundation of pharmaceutical marketing on the bedrock of the logic of consequences. In their review, Manchanda and Honka (2005) note that much pharmaceutical marketing effort is directed at physicians and consumers with the goal of facilitating market exchanges that optimize the company's return on marketing investments (Narayanan, Desiraju, and Chintagunta, 2004; Ahearne, Gruen and Jarvis 1999). Consider, for example, physician detailing, a wide spread practice of using sales representatives to reach physicians. Detailing efforts are guided by a consequential logic to deploy selling skills to slant physicians' "tastes" and "utility functions" in favor of the company's products (Narayanan et al. 2005). Consistent with this, research examines whether the amount of detailing is "optimal" from a ROI perspective (Narayanan, Desiraju, and Chintagunta 2004). Manchanda and Honka (2005, p. 785) note that it is an "important" goal of research to "establish that detailing [has] significant effect on physician prescription behavior" and to "improve the efficiency and effectiveness of detailing practices." Thus, a primary objective of detailing is to enhance ROI, a logic that is consistent with emphasis on consequential returns.

The logic of consequences is also evident in other pharmaceutical marketing practices. For instance, direct-to-consumer marketing is intended to enhance awareness and provide information about product benefits to indirectly stimulate demand by provoking consumers to consult their physicians for prescriptions. Although pharmaceutical companies assert the importance of patient welfare and product information, they openly acknowledge their motive to maximize return on shareholder investments. It is well known that return on investments of pharmaceutical companies (estimated at 15%) consistently exceed normal market returns and are one of the highest across a range of industries (Fagan 1998).

However, absent systematic studies of pharmaceutical marketing strategy, it is premature to unequivocally assert the logic of consequences as its underlying dominant logic. We recognize that such studies pose nontrivial challenges because significant aspects of strategy practice are "invisible" as they are either proprietary or hold competitive advantage only if they

remain obscure. As a result, most commercially available data on pharmaceutical marketing practices (e.g., IMS, Verispan/Scott-Levin) include instruments that illuminate only those aspects of the strategic practice that the organizations wish to make "visible." Nevertheless, we believe that it is critical to call for systematic and creative studies that shed light on the heretofore "invisible" practice of pharmaceutical marketing strategy to understand its dominant logic and address the strategy-tactic gap. Such studies need to consider pharmaceutical marketing strategy in the context of the logics of its value chain, which we develop next.

Physician-Patient Exchanges and Logic of Appropriateness

The logic of appropriateness provides a theoretical foundation for conceptualizing physician-patient exchanges that are governed by institutionalized norms of fiduciary responsibility and rule driven cooperative behaviors even when such behaviors may undermine individual pay-offs (March 1996). Patients rely on the professional expertise of physicians to obtain prescription regimens that help cure diseases and enhance well-being. From an economics perspective, such professional-mediated exchanges are problematic because of "hidden information"—not knowing how to distinguish credible professionals, and "hidden action"—not knowing whether the professional, once engaged, will shirk from acting to safeguard patient interest, among other agency problems (Arrow 1985).

Sociological studies of the medical profession in particular, and professionals in general (e.g., lawyers, auditors), show that institutionalizing the logics of appropriateness is a mechanism for solving the agency problems (Parsons 1968; Starr 1982; Freidson 2001). Shapiro (1987, 2005) formalizes these arguments by positing that professionals may be viewed as "agents" who are bound by fiduciary responsibility to serve the interests of "principals" (e.g., patients) such that there is an expectation that the agent will put the principal's interests above self-interest (Boatright 1992). Actors resolve choice dilemmas by following a set of prescribed rules paying less attention to the personal gains from their decisions (March and Olsen 1998).

Grayson, Johnson, and Chen (2008) note that in some industries (e.g., banking), professional organizations codify expectations for members' actions that foster a "climate of trust" to draw and reassure customers. Such rules are not instrumental, but essential to the evoked role identity. A banker is rule-bound to limit exposure of consumer deposits to risky investments, even though such practice may enhance payoffs, because doing so without consumer consent violates the norms of a "trusted banker" who upholds consumers' best interests *no matter what*. Here, the principle of trust is essential to the identity of the banker; without trust one cannot claim to be a credible banker.

Institutionalized norms of fiduciary responsibility commit professionals to follow codes of conduct or an oath of service (e.g., the Hippocratic Oath) that build trust and curb opportunism. Consequently, an effective and stable system of market relationships, here involving physicians and patients, emerges when market agents (i.e., physicians) behave in accord with institutionalized norms of fiduciary responsibility that are "socially constructed, publicly known, anticipated, and accepted" (March and Olsen 1998, p. 952).

Conflicted Logics in a Pharmaceutical Industry Value Chain

Our preceding analysis suggests that different market actors (i.e., pharmaceutical companies and physicians) in a pharmaceutical value chain are embedded in their own distinct logic. Collectively, industry-physician and physician-patient exchanges coexist as an interdependent market system. Viewing the logics of consequences and appropriateness as coexistent requires theorizing their potential conflict and its consequences for the value chain (March and Olsen 1998). This potential for inherent conflict is centered on physicians who are engaged in consequential logic-based exchanges with the pharmaceutical industry on one side of the value chain, and in appropriateness logic-based relationships with patients on the other side.

Coexistent logics need not *necessarily* lead to conflicted logics. Many physicians' actions that are guided by consequential logic, such as the pursuit of a reputation for conducting controversial and influential studies, earning a decent income, and quality of life commensurate

with their status, need not compromise physicians' fiduciary responsibility in patient relationships. Likewise, while it may be commonly understood that detail salespeople work for pharmaceutical organizations that primarily follow a consequential logic, they are not necessarily restrained from acting as a trustworthy source of unbiased information. Only when actions implied by a particular logic directly or indirectly constrain or suppress possible actions that are implied by the second logic does a problem of conflicted logics exist (Carson 2004).

The institutionalized frame of professionalized medicine holds that its members give priority to fiduciary responsibility and forgo self-interested gains. In other words, professions address conflict of logics problems by legislating norms that mandate the priority of the logic of appropriateness (e.g., American Medical Association's *Ethics Opinion* at assn.org/ama/pub/category/print/4001.html, and U.K. Medical Council's *Good Medical Practice* at gmc-uk.org/guidance/good_medical_practice). Thus, pharmaceutical marketing efforts directed at building close relationships with physicians may amplify the problem of conflicted logics. Moore et al (2006, p.11) note that "doctors are loath to admit" that conflict of logics "slant" their professional judgments even as they are "succumbing" to them and "*believe* that their biased advice is unbiased."

Insights are needed to map how the conflicted logics of the pharmaceutical value chain unfold over time, and what factors amplify or diminish the underlying conflict. Although the logics of pharmaceutical marketing and physician practice are *theoretically* conflicted, in *practice* the logics may coexist without posing impediments to collaborative relationships in the value chain. For instance, the pharmaceutical industry may pursue its consequential goals indirectly or passively while directly or actively focusing on value creation by emphasizing its products and therapies that serve appropriateness goals of the value chain. The nature and degree of conflict in practice will vary by pharmaceutical industry's choices of strategy content, and the dynamics they engender. Thus, to facilitate our theoretical development, we conduct a systematic and comprehensive examination of pharmaceutical promotion practices and

thereafter intersect the findings with the discourse in academic medicine to examine the nature and degree of conflict between the logics and its evolution over time.

STUDY DATA AND ANALYTICAL APPROACH

A particularly useful source for unadulterated view of the industry's strategies is publicly available court documents generated as part of discovery in a litigation involving industry marketing practices. The laws governing public access to court records provide detailed, authenticated, and otherwise proprietary data for review and analysis. Court records include internal memos, contractual arrangements, internal/consultant reports, strategy and tactics, financial/accounting analyses, and other related materials that are "discovered" during the process of case filing and research. Discovery materials do *not* inherently indicate illegal practices. Many materials represent business as usual, and are used to provide the background for developing the court's arguments and evidence.

A careful, comprehensive, and thorough analysis of these discovery documents can provide a unique insight into industry practices that are neither illegal nor unconventional and are otherwise not available for public scrutiny. Moreover, triangulating these insights with those available from the professional medicine and popular press literature is likely to bolster the confidence in the obtained insights and mitigate the risk that stems from analyzing a single case that may be idiosyncratic or atypical. Because they grant access to proprietary materials, recent research has increasingly used court documents to obtain insights into pharmaceutical marketing (Ross et al. 2008; Psaty and Kronmal 2008; Healy and Cattell 2003). Nevertheless, court cases are subject to biases of small (e.g., N = 1) and unrepresentative samples, and caution is warranted in generalizing from such analyses.

We analyzed over 5,827 pages of discovery documents from a recent court case that involved marketing practices related to Neurontin® (gabapentin). Details of the case, *United States of America ex. rel David Franklin vs. Pfizer Inc, and Parke-Davis, Division of Warner-Lambert Company* (Steinman, Bero, Chren, and Landefeld 2006) settled on May 13, 2004, and

our analytical procedures are in the Appendix. In order to keep the discussion focused, we elaborate on the nature and scope of strategies revealed in our analysis, and the underlying logics reflected in these strategies. We supplement our analysis with reviews of professional medicine and popular press literature. To the extent professional medicine and popular press are voices of the industry's downstream value-chain members, this supplementary review is of material significance in understanding conflicted logics of pharmaceutical value chain.

RESULTS

Our data analysis revealed (a) four distinct strategies used by the pharmaceutical company to communicate with physicians, and (b) systematic interdependencies among the four strategies that we categorize as either expertise- or promotion-based for the discussion that follows. Figure 1 displays both the strategies and their interdependencies. Table 1 summarizes each of the four strategies providing links to relevant documents that provide evidence of individual strategies. Included in Table 1 are marketing objectives and tactics established for each strategy as extracted from internal company documents (see columns, "Strategy" and "Marketing Tactics"). Verbatim comments are included from internal documents and sworn testimonies. In addition, Table 1 also includes references to additional popular sources to provide evidence of broader industry use of the identified strategy (see last column titled "External Validity"). We also supplement this source of external validity with discourse in academic medicine under each strategy. We use this evidence to mitigate the concern that the identified strategies are idiosyncratic to the pharmaceutical company involved in the focal court case. Below, we discuss each of our results and refer to actual court documents and verbatim notes (and quotes) to illustrate our findings.

(Insert Figure 1 and Table 1 about here)

Pharmaceutical Marketing Strategies and Associated Tactics

The four distinct strategies identified in our analysis to influence physician decision making include: (1) market penetration strategy involving a focus on segmentation and

penetration, (2) evidence based strategy involving production of science, (3) medical education strategy involving developing and disseminating standards of care, and (4) surrogate selling strategy involving promoting and leveraging peer-to-peer influence among target physicians. We discuss each in turn and the tactics associated with each strategy.

The *Market penetration strategy* involved (a) identifying and profiling high-potential physicians; (b) estimating each physician's market potential; and (c) establishing penetration goals for each segment to achieve maximal consequential impact (first row Table 1; Figure 1). High potential physicians were identified using data from health information companies (e.g., IMS Health, Verispan) providing records of each physician's prescription writing (identified by license number) which is linked to physician demographic profile obtained from the American Medical Association (Steinbrook 2006). This unique data allows segmenting the market to identify "high prescribers" and tracking their prescription writing over time. Market potential was calculated by categorizing prescription writing patterns into deciles—higher deciles indicate higher market potential (e.g., market potential of 10th decile physicians estimated at $309,517 (exhibit 35[4])). Using the decile information, Parke-Davis set penetration goals for sales people by emphasizing that it takes "17 decile 7 physicians to bring the same business as one decile 10 physician," (Exhibit 35). To enhance salespeople credibility with decile 10 physicians, Parke Davis implemented a Medical Liaison Program where highly qualified scientists (often with Ph.D.s) were partnered with salespeople to address scientific questions about efficacy of drugs in physician interactions. For instance, a Parke Davis territory manager explains the difficulty in gaining access to a decile 10 physician and the role of medical (clinical) liaisons to overcome it:

"Dr. X was decile 10 …. doesn't see anybody. And the door was opened by bringing the clinical liaison in … I think it's an ego trip for the physician," (Exhibit A).

Similar indication of market penetration strategy is evident as common industry practice in the secondary data we collected to examine the validity of our findings (last column of Table 1).

[4] Referred exhibits pertain to materials included in the court documents related to *United States ex rel. David Franklin vs. Parke-Davis, 147 F. Supp.2d 39* and available at http://dida.library.ucsf.edu.

Datamonitor (2001) reports that physician profiling through prescription tracking improves profit margins by as much as 3% and the initial uptake of innovative drugs by 30%. Research suggests that profiling dates back to 1940s when the American Medical Association collaborated with pharmaceutical companies to help assemble physician profiles (Greene 2007), and prescription writing data, and making both open to industry access which the latter used to increase pharmaceutical sales force effectiveness (Grande 2007).

The *Evidence-based strategy* involved a three pronged approach: (a) industry funding of clinical trials through research grants; (b) generating publications from clinical trials with a bias for positive results; and (c) contractual arrangements with commercial companies to write, process and orchestrate publications in referred journals without explicitly exposing their role; (second row Table 1; Figure 1). Internal documents noted that research grants to physicians were intended to encourage clinical trials that induce familiarity with higher doses of Neurontin (exhibit 39). The objective of the evidence-based strategy was to favor publishing articles with positive findings that "increase sales" (exhibit 21), and return on investment estimates were explicitly calculated to target disease indications with the greatest revenue potential. The company entered into formal contracts with commercial companies to develop a coordinated effort for executing publications by "life cycle planning" (exhibit 72) that involved a time-based program of sequentially publishing scientific articles in peer-reviewed journals (exhibit 57) in order to create a "drumbeat in the literature," (Exhibit 63; Table 1). Company managers routinely tracked the status of manuscripts processed for publication by contract companies to coordinate their promotional efforts, as they also reviewed problems in keeping the publications on track. For instance, AMM Adelphi, a commercial provider contracted for evidence based strategy, reported to a Parke Davis manager as follows:

"… these physicians [designated authors] are clinicians rather than academicians or researchers, making them less accessible than scientific authors. Thus, these papers require more time and management than is usual… We anticipate that by year's end, you will have several manuscripts submitted to journals as well as either a paper or poster accepted for the AAN," (Exhibit 64).

Parke-Davis internal documents reveal that the company contracted with Medical Education Systems Inc. to ghost write articles (e.g., failure to include an individual as author who has made substantial contributions to research or writing of the manuscript) for $13,375 to $18,000 per article and to include physicians as guest authors (e.g., include an individual as author who does not meet authorship criteria) for an honorarium of $1000 (Table 1).

Our secondary data reveals that several companies including Scientific Therapeutics Information and Health Sciences Communication openly advertise their commercial intent to contract for publishing scientific articles for the pharmaceutical industry. Moreover, in the recent VIOXX litigation, Psaty and Kronmal (2008) found evidence that the mortality rates reported by Merck to FDA indicated non-significant differences, while actual mortality rates from internal documents were highly significant (HR = 2.13, $p < .001$). Likewise, Turner et al. (2008) found that, while 97% of the 38 clinical trials for 12 antidepressant agents with positive findings were published, only 39% of the 36 trials with negative or questionable findings were published. Similarly, ghost writing and guest authorship in peer-reviewed journals remains a common practice (Ross et al. 2008). In a recent survey of six peer reviewed medical journals, ghost writing was demonstrated in 13% of research articles, 10% of review articles, 6% of editorials, and 11% of Cochrane reviews. Guest authorship was even more prevalent, and found in 16% of research articles, 26% of review articles, 21% of editorials, and 41% of Cochrane reviews (Flanagin et al. 1998; Mowatt et al. 2002).

The *Medical education strategy* involved: (a) shaping standards of care; (b) actively managing a Speakers' bureau; and (c) contracting with medical education companies providing continuing medical education (CME) to physicians (third row Table 1; Figure 1). Parke-Davis marketing efforts focused on influencing standards of care to position Neurontin as a first choice in treatment regimens. This goal was achieved through scheduling presentations by influential thought leaders who are favorable to Neurontin at various CME events. In some instances, Parke-Davis paid physicians to attend these events, act as part of the audience, and plant leading

questions intended to portray Neurontin in a positive light (exhibit 79). Parke Davis managed a Speakers Bureau, a data base of key influencers and thought leaders who were paid to present at educational symposia. Parke-Davis encouraged sales representatives to "identify and train strong Neurontin advocates and users to speak locally for Neurontin," (exhibit 19). Our review of Parke-Davis' documents suggests that the company granted unrestricted educational grants to medical education companies ostensibly for educational purposes; however, company managers provided input in shaping conference content, suggesting thought leaders as speakers, and in tracking participating physicians' pre- and post-seminar prescribing behavior. Territory managers evaluated unrestricted educational grant proposals as illustrated below:

"I am forwarding two budget proposals… One is the satellite symposium alone and one includes a highlights proceedings.. with the satellite. Please review.. so that we can move forward with the grant request through Dannemiller[commercial provider]," (Exhibit D).

Similar examples of industry efforts to leverage physician education efforts for consequential gains abound in medical literature (Table 1). For instance, studies show that industry sponsored CME programs "preferentially highlighted" the sponsors' drugs and positively affected physician prescription habits after attendance (Bowman and Pearle 1988; Wazana 2000; Relman 2001). Drug companies provided 65% of total revenue of CME programs organized by commercial providers, providing a financial incentive to create educational programs that cast a favorable light on the companies' products (Steinman and Baron 2007). Choudhry, Stelfox and Detsky (2002) found that 59% of authors responsible for updating or developing clinical practice guidelines had financial relationships with companies whose products they considered or included in the guidelines.

Finally, Parke-Davis used a *surrogate selling strategy* by (a) promoting contagion effects through "Neurontin® Champions," (b) recruiting thought leaders; and (c) managing disease based advisory boards (last row Table 1; Figure 1). Promotion of contagion effects involved a "pyramid of influence," where Neurontin® Champions, influential and favorably disposed epileptologists recruited from large teaching hospitals, reassured their peers about Neurontin's

efficacy. The company invited these champions to disease-based advisory boards for discussing diagnostic criteria and appropriate treatment plans for specific diseases (e.g., neuropathy, migraine) that promoted Neurontin as a first choice in standard treatment plans. The key goal of the surrogate selling strategy was to "increase Neurontin new prescriptions by convincing non-prescribers to begin prescribing and current prescribers to increase their prescription behavior" (exhibit 78, 79). Medical liaisons encouraged Neurontin champions to publicize their feelings:

"In fact, John had met with somebody... who had asked about restless leg... told her exactly what he's doing. And, she's using it like crazy now. That zip code that Dr. X is in like up to a fifteen percent curve on the market share," (Exhibit A).

The medical literature provides corroborating evidence on surrogate selling. For instance, Henry et al. (2005) report in their study involving Australian physicians that 23% of their sample was on industry advisory panels and 16% acted as expert speakers for specific pharmaceutical products. Surrogate selling influence has been examined in seeding trials where the pharmaceutical company awards drug-trial grants to physician investigators with the intent to encourage the physicians to advocate the drug to their colleagues. For instance, internal documents pertaining to Merck's ADVANTAGE (Assessment of Differences between Vioxx and Naproxen to Ascertain Gastrointestinal Tolerability and Effectiveness) seeding trial revealed that Merck designed the study with a quest to engage future prescribers with Vioxx (Hill et al. 2008). Additionally, the appropriateness of physician membership in speakers' bureau and advisory boards and their role in surrogate selling have been questioned by a number of medical researchers (Brennan et al. 2006; Angell 2008; Jampol et al. 2009; Insel 2010). In a national survey of department chairs in the 125 accredited medical schools and 15 largest independent teaching hospitals, Campbell et al (2007) found that 27% of department chairs surveyed had a consulting relationship with the industry and 14% served on the speakers' bureau.

Strategic Interdependencies

Our analysis indicates that Parke-Davis structured deliberate and systematic interdependencies among the four strategies outlined above, which we broadly classify as

expertise or *promotion* based interdependencies. The goal of these interdependencies was to link strategies so that they collectively exert a synergistic influence on a physician's decision to write prescriptions that favor the company's products. Expertise based interdependencies focus on leveraging knowledge (e.g., scientific evidence) and knowledgeable physicians (e.g., thought leaders) across strategies to support Parke Davis' objectives for Neurontin. Promotion based interdependencies focus on leveraging data (e.g., prescription writing) and networks (e.g., Neurontin champions) to bolster the sales efforts in direct interactions with targeted physicians. These interdependencies are shown in Figure 1 as direct or indirect linkages corresponding to promotion or expertise based interdependencies respectively. Promotion based interdependencies are direct linkages because they largely involve sales people employed by the company, while expertise based interdependencies mostly involve independent physicians. We discuss the findings related to expertise- and promotion based interdependences in order.

Expertise based interdependencies. Our analysis reveals that Parke Davis leveraged expertise in several forms of interdependencies. For instance, the expertise of lead investigators funded by Parke Davis as part of evidence based strategy was leveraged by inviting them to participate in CME initiatives as part of the education strategy. The CME initiatives by favorably pre-disposed physician scientists assured standards of care in favor of Neurontin since participants were unaware of financial ties between the physician-scientists and Parke Davis. A sworn testimony of an expert witness illustrates these interdependencies:

"A continuing medical education monograph ... was supported by an unrestricted educational grant from Parke-Davis… [to]the author of the monograph and narrator of the accompanying audio tape ... Dr. X [name withheld]*, President of the International Headache Society..."* (Exhibit N).

In another form of interdependency, the speaker's bureau constituted as part of the education strategy was systematically culled to solicit physician scientists favorable toward Neurontin for disease advisory boards (exhibit 69) and encouraged to disseminate the emergent knowledge from their recently "published" research as part of surrogate influence strategy

(exhibit 34). To broaden the reach of surrogate influence, teleconferences were used to connect Neurontin "champions" with over 1,000 physicians and facilitate the creation of 100 "Pain CME Case Study Groups" to promote education as part of Parke Davis efforts to increase Neurontin's off-label use for pain. In an expert testimony, this interdependence is noted as follows:

"Dr. X [name withheld] sponsored through an unrestricted educational grant discloses participation on the speakers bureau for Parke-Davis [among other affiliations], writes in a CME monograph that it is important not to under dose gabapentin when managing PHN," (Exhibit P).

Parke Davis structured interdependencies between evidence and surrogate selling strategies by routinely rewarding physicians who were Neurontin champions with privileged research grants. For instance, in a major phase IV trial, STEPS (**S**tudy of Neurontin: **T**itration to **E**ffectiveness and **P**rofile of **S**afety), recruited more than 700 physicians with payments of $300 for each patient enrolled, a strategy that resulted in a 20% increase in new patients and 3% increase in market share (exhibit 72). Although Parke Davis limited the number of patients that physicians could recruit for the study to 10, it allowed leading physicians at large teaching hospitals or centers of influence (who had potential to sway a large number of their colleagues) to recruit up to 50 patients each. Grants made to these thought leaders were to further Neurontin sales within the hospital and to use these physicians in surrogate selling programs (Exhibit 34). For instance, a request by Dr. X [name withheld] was approved because he was a "great Neurontin believer," (Exhibit 85) as noted in the following excerpt from an expert testimony:

"Parke-Davis considered Dr. X [name withheld] a "key influencer" at one of Boston's "centers of influence" with the potential not only to increase his own Neurontin prescriptions, but to influence his peers' Neurontin prescribing at New England Medical Center. Dr. X was offered money to conduct a study on Neurontin's use for restless leg. After the payment was made, Dr. X placed more than 160 patients (non-study patients) on Neurontin," (Exhibit 85).

Promotion based interdependencies. To structure these interdependencies, Parke Davis regularly analyzed and tracked market research data on physicians' prescription behaviors and patients' prescription filling to bolster the sales efforts in direct interactions with targeted physicians (Exhibit 132). For instance, Parke Davis used consultant and dinner meetings to wine

and dine high decile doctors to provide them with information about off-label uses of Neurontin. Internal documents revealed that the invitation to attend these meetings was based solely on high rates of prescribing (exhibit 17) and attendees were provided a "hard hitting message about Neurontin," (exhibit 69). One such meeting at the Jupiter Beach, Florida was set up to expose 100 physicians with the "greatest potential" to prescribe Neurontin," (Exhibit 49; 53). Area business managers were provided with trending work sheets to track the pre- and post-meeting prescription writing by participants (Exhibit 54). The Neurontin Marketing team monitored the attendance and provided attendee names to territory managers for follow-up. The following memo to area business managers illustrates the penetration-surrogate interdependencies.

"*Attached is the Trending Worksheet for the recent Neurontin Consultants Program in Jupiter Beach, Florida. The attendees from your district are listed. This tool is very valuable in tracking the value of participating in this program,"* (Exhibit 54).

In another form of promotion interdependence, Parke Davis targeted thought leaders from large teaching hospitals who have the greatest potential to write Neurontin prescriptions. Sales people were reminded that "the key influencers should be …kept aware of the availability of research opportunities in clinical trials," (exhibit 24). Territory managers and medical liaisons used published evidence garnered from such grants to persuade targeted physicians to write prescriptions favoring the company. A territory manager from Parke Davis explains thus:

"*Medical liaison A [name withheld] and I went to see Dr. X [name withheld] last July... and we brought Y's data with us on restless leg. We showed him that… right after we talked to him, he began to try Neurontin on patients that he just started on,*" (Exhibit A).

Internal documents also illuminate the interdependence between penetration and education strategies. For instance, exhibit 39 states that "medical education supports the Neurontin promotional campaign and supplements field sales efforts providing physicians with the opportunity to share their experiences and to learn from key thought leaders how to successfully use Neurontin in clinical practice." As noted above, Parke-Davis used commercial companies to monitor pre and post prescription behavior of attendants to Educational Teleconferences using a Promo Trak methodology (exhibit 79). This data was provided to sales

people to find new prospects as well as fine tune current market penetration efforts. An expert testimony describes how the penetration-education interdependencies were carried out:

" *An unrestricted educational grant for $303,740 was granted to Handbooks in Health Care Co. for the production of 75,000 copies of an epilepsy handbook. Approximately 96,000 high prescribers of anticonvulsant agents were identified as targets for this book and territory managers were instructed to introduce the book to high prescribers in their territory,"* (Exhibit B; Exhibit 90).

Marketing Strategies and Conflicted Logics in the Pharmaceutical Value Chain

Our analysis reveals that the marketing strategies and the deliberate structuring of interdependencies conflate the logics of appropriateness and consequences escalating the problem of conflicted logics within the value chain. As depicted in Figure 1, this conflation occurs because pharmaceutical marketing strategies and the systematic interdependencies built among them exploit the logic of appropriateness for consequential gains. For instance, our analyses reveals that the industry provides "unrestricted" funds to produce favorable "research" that is published in peer-reviewed journals through ghost writing. Upon publication, the "research" is disseminated using a "medical education" strategy involving "grants" for continuing education and "surrogate selling" strategy involving "contracted" thought leaders. Moreover, "thought leaders" identified through prescription tracking are awarded research grants for clinical trials, and subsequently invited to populate speakers' bureau and disease advisory boards to sway their peers through medical education and surrogate selling strategies.

As long as the industry's efforts to camouflage its conflation are successful, the strategy produces consequential results. Grants are considered a contribution to science not marketing, research is viewed with credibility not tainted by commercial intent, and thought leader's recommendations carry legitimate weight of an expert, not a contracted spokesperson. However, the industry's investments in strategic interdependencies are hard to justify internally without linking them to a continuous stream of consequential gains. However, these strategies undermine the very mechanisms (for example CME and Journal Publications) of interpersonal trust that are crucial to the legitimacy of the medical profession. As a result, the more successful the

pharmaceutical marketing strategies are in achieving their objectives, the more likely are they to amplify the conflicted logics of the value chain with one caveat; the growing conflict is latent and inert as long as the industry's deliberate conflation of logics remains undetected.

Once detected, however, the conflict stoked and amplified by the particular nature of pharmaceutical marketing strategies deployed by the industry rises to the surface and invites swift and strong response. For instance, the industry's evidence-based strategy prompted the *Journal of American Medical Association*, along with *International Committee of Medical Journal Editors* to require all authors to include an explicit disclosure of conflict of interests and, for industry sponsored research, ask authors to conduct independent statistical analysis as a condition for publication (DeAngelis 2006). Noting that "over 50% of articles" in top journals may be "ghost-written," the U.K. House of Commons (Health Committee 2005, p. 53) stressed that regulatory guidelines should "leave no room for ghost-writing." Additionally, the Accrediting Council for Continuing Medical Education has enforced strict policies against faculty recommendations and CME content reviews by commercial sponsors. The American Medical Association and the American Psychiatry Association have followed suit by restricting industry involvement in CME activities. In March 2009, the *Journal of the American Medical Association (JAMA)* called on all professional medical associations to end drug company relationships. Academic medical centers including Yale, Harvard, Duke, Stanford, University of Pennsylvania, Henry Ford Health System, and UCLA have banned physicians from receiving monetary or non-monetary gifts, however small, and prohibited drug samples and detailers from patient care areas (Croasdale 2006).

Rising public aversion to industry's deliberate conflation of logics in its marketing strategies has also invited regulatory intervention. The recent health care reform in U.S. includes the Physician Payment Sunshine Act, a mandate for transparency in the financial relationships between pharmaceutical industry and physicians. Additionally, prosecutors and professional agencies have imposed monitoring and oversight restraints on pharmaceutical industry-physician

interactions. Recently, ProPublica has provided open access to a searchable database called "dollars for docs" for public to uncover industry payments to local physicians.

OPEN SYSTEMS FRAMEWORK FOR PHARMACEUTICAL MARKETING STRATEGIES: NEW DIRECTIONS FOR FUTURE RESEARCH AND PRACTICE

Our comprehensive analysis of pharmaceutical marketing strategies and tactics unveils new insights and calls for new directions for research and practice. First, our analysis provides evidence that pharmaceutical marketing strategies are largely driven by an economic model to maximize ROI and maintain focus on consequential gains. More significantly, our analysis lays bare the intricate and carefully crafted interdependencies among a diverse set of tactical moves that pharmaceutical marketing managers construct as strategy to influence physician decision making. What makes these strategies aversive to physicians and public alike is not so much as they are driven by an economic imperative of "self-interest without guile" but the systematic and sustained effort to cloak the economic self-interest within a logic of appropriateness to appear as benevolence acts in the interest of enhancing physician knowledge and public health. By ignoring strategies that underlie pharmaceutical marketing tactics, most past research in marketing misses both the intricate interdependencies among tactics and willful effort to obscure these interdependencies from scrutiny by physicians and public. As a result, extant research in marketing is of limited use to anticipate or explain the increasingly unfavorable response to pharmaceutical marketing tactics, and regulatory effort to contain and constrain their reach. Thus, a new direction is needed to break free from the myopia of past research.

Second, our analysis indicates that an institutional theory perspective is well suited for studying pharmaceutical marketing strategies within a broader, value chain perspective. Our institutional theory-based development considers both the logics of consequences that govern pharmaceutical marketing efforts and the logics of appropriateness that frame physicians' medical decision making. Joint consideration of industry and physician logics allows us to explicitly analyze the conflict that actions rooted in these disparate logics entail. Our analysis

highlights that conflicted logics become institutionalized and rationalized as normative routines making the system less flexible and susceptible to market failure. More significantly, our analysis shows that this conflict is amplified over time, perhaps inadvertently, by self-centered actions of market actors who are narrowly focused on their own logics and unable to grasp a system view—in a way, *missing the forest for the trees*. Past studies have generally given scant attention to the disparate logics that characterize pharmaceutical industry-physician relationships, and hesitated in adopting a value chain perspective. New frameworks for studying pharmaceutical marketing strategies are needed that consider: (1) interdependencies among pharmaceutical value chain partners motivated by disparate logics, (2) embeddedness of market actors, and (3) temporal evolution of the nature and intensity of system conflict. Absent these considerations, we risk incomplete, if not misleading, understanding of pharmaceutical marketing strategies and its consequences.

We propose one such framework that draws from open system theories of organizational action (Stern and Barley 1996; Katz and Kahn 1966). Our proposed framework has several distinct aspects that together constitute a theoretically useful foundation including: (1) focus on a system of market relationships that characterize the pharmaceutical value chain, (2) emphasis on organizational and system legitimacy, and (3) linking *macro*-level system logics and *micro*-level actions of individual market actors as they negotiate an order from emergent contests of competing logics. Table 2 outlines the key elements of this proposed framework—referred to as "open systems framework"—and compares it with current economic framework that characterizes most studies of pharmaceutical marketing. Specifically, the nine elements in Table 2 are organized around three discussion points relating to foundations (what are the basic theoretical and conceptual building blocks?), premises (what are its assumptions and axioms?) and key questions and mechanisms (what are its proposed hypothesis and processes?). These elements are best viewed as building blocks of a theory rather than a fleshed out theory itself. We believe that outlining the elements of a theory with a focus on comparative analysis will

likely provoke debate and discourse essential to fine tuning and adding elements that will prove useful for guiding future theoretical efforts. We develop the elements in Table 2 in more detail below, and outline the key propositions resulting from it in Table 3 to guide future research.

(Insert Table 2 and Table 3 about here)

Foundational Elements

Whereas an economic framework directs managerial attention to the objective of maximizing ROI, the open systems framework directs managerial focus to organizational and system legitimacy. We assert that legitimacy is a stronger predictor of organizational effectiveness in value-chains characterized by conflicted logics, and where fiduciary obligations are relevant. Suchman (1995, p. 574) defines legitimacy as a "generalized perception that the actions of an entity are desirable, proper or appropriate within some socially constructed system of norms, beliefs and definitions."[5]. That is, legitimacy is not an abstract, monolithic or enduring evaluation; rather, it is socially constructed by an organization's value chain partners based on a multidimensional evaluation including (1) pragmatic legitimacy or the degree to which it delivers something that adds value to the system, (2) moral legitimacy or the degree to which it employs means and procedures that are trustworthy, and (3) cognitive legitimacy or the degree to which its activities are meaningful and desirable for the use and distribution of societal resources (Scott 1987; Suchman 1995). As such, a legitimacy objective draws attention not only to value creation but also on *how* (using trustworthy means?), *what* (using meaningful activities?) and *for whom* (fair allocation of benefits).

A particularly foundational element in the open systems framework is that interdependencies assume special importance in systems where value chain partners are embedded in institutionally disparate logics. Unlike an economic framework that achieves its coherence by its assertion of a unitary logic of consequences, an open systems framework

[5] Deephouse and Carter (2005) note that legitimacy claims are distinct from reputational claims. Organizational reputation is a qualitative assessment based on social comparison among a set of, possibly legitimate, firms. However, legitimacy is about social acceptance based on conforming to social norms.

problematizes coherence by consideration of dualistic logics. In our study, we have noted that the pharmaceutical value chain involves partners that are beholden to different logics. An open systems framework argues that pharmaceutical industry embrace the dualistic logics of the value chain in designing its strategies and tactics. Singular focus on its own logics ignores the interdependence of the value chain as a system. Consequently, while the economic framework focuses on the mechanisms of creating and extracting value, the open systems framework requires focus on mechanisms that balance the organizational need to extract value with the objective of gaining legitimacy (Table 2).

To balance value extraction with legitimacy gains does not necessarily imply accepting tradeoffs. Rather, an open systems framework suggests that organizational effectiveness is likely to be enhanced (compromised) when strategic actions in pursuit of consequential logics also bolster (undermine) the social codes and norms implied by the appropriateness logic of value chain partner. In studying hospital survival rates from 1945 to 1990, Ruef and Scott (1998) found that, after controlling for organizational and environmental factors, top-rated hospitals (with greater legitimacy) improved their survival rates by factors of 2 to 5 over average-rated hospitals (with lower legitimacy). Likewise, Arthur (2003) showed that Fortune 500 organizations that gained (moral) legitimacy by investing in work family initiatives during 1971 and 1996 posted "excess" shareholder returns to enhance firm's financial resources. Consistent with this, Rao, Chandy and Prabhu (2008) demonstrate that U. S. biotechnology firms derived greater stock market returns from innovations if they were perceived to possess greater legitimacy by their value-chain partners. Thus value extraction and legitimacy are not inherently incompatible goals.

Nevertheless, our position is not that an open systems framework is universally appropriate, and legitimacy objective necessarily relevant for all organizations. Value chains organized around a singular, coherent logic commonly shared by its members may be well described by an economic framework rendering an open systems framework less meaningful.

Consider, for instance, the oil industry value chain. One may be appalled by the windfall profits of oil companies at times of rising gas prices, but one accepts it as business practice. As such, while legitimacy is important (e.g., oil companies resist perceptions of price gouging), its role in organizational effectiveness is not overtly enhanced. The American Petroleum Institute's chief economist, John Felmy, recently provided details of industry costing to assert that industry "profits are not much higher than those of large industrial companies" and, in fact, some refiners are "losing money" (Esch 2008). The industry felt no compulsion to outline actions for *enhancing* its legitimacy such as increase supplies or production efficiency to reduce costs.

Our position is that open systems framework is more appropriate, and legitimacy risk more relevant for organizations that are embedded in value chains characterized by conflicted logics. In such value chains, market action motivated by singular economic objective of creating and extracting value is likely to exacerbate the conflict of logics, and diminish organizational legitimacy. For instance, in our study, we show that pharmaceutical marketing strategies escalate system conflict within the value chain because they exploit the very mechanisms that physicians have institutionalized to preserve impersonal trust necessary for the legitimacy of the medical profession (Mello and Messing 2008; Fugh-Berman 2008; Orentlicher 2010). For instance, the stated motivation for the AAMC task force for prescribing industry-profession interactions is "all real or perceived conflicts of interest" concerns that stem from "increasingly dependent" relationships between the physicians and pharmaceutical industry (AAMC 2008, p. iii.). Likewise, the American Medical Association responded to numerous complaints by physicians troubled by aggressive tactics of drug sales representatives to implement an "opt-out" program for physicians to remove their data from the Physician Master file used by the industry to target and track physicians' prescribing patterns (O'Reilly 2006). A Gallup survey of physicians who opted-out of the Masterfile program indicated that 60% would be willing to change their mind if they were assured that the prescribing data was used to support public good, not marketing practices (O'Reilly 2006). Thus, legitimacy risks can escalate with increasing

intensity of conflicted logics, and undermine long term gains usually flowing from collaborative relationships with value chain partners (Bansal and Clelland 2004).

From the standpoint of managerial practice, it is appropriate to question if legitimacy is resistant to direct managerial intervention because it is conceptually nebulous and pragmatically resilient to managerial control. After all, legitimacy, like reputation, is earned not manufactured or acquired. As such, the relevant organizational challenge is not how to manipulate legitimacy assessments of its value chain partners, but to understand how managerial action builds or depletes legitimacy assessments, and how to repair legitimacy breeches. For instance, Suchman (1995) notes that legitimacy response is a strategic issue and mending legitimacy breeches may require managers to decouple or disassociate from offending activities, institute credible monitoring controls, restructure market arrangements, or engage in aggressive damage control. Whether such managerial action mends or exacerbates legitimacy breeches within the value chain is an important line for theorizing and empirical work. The proposed open systems framework offers several lines of inquiry for exploring the preceding issues as noted in Table 3.

Premises

The economic and open systems frameworks differ in their underlying premises. Specifically, in contrast to economic framework's premise of autonomous managerial action (March 1996), the proposed open systems framework is premised on the notion of action-system interdependence. Rooted in the notion of a "rational man," the economic framework holds that individual managers largely hold agency for action, and their collective actions are the key to understanding how institutional systems are structured and shaped over time, and how these system dynamics, in turn, influence organizational outcomes. Indeed, the economic framework does not assert that institutional systems are swayed by any single manager. Rather, it posits that managers in an industry often share common schemas of their institutional environments and, as common patterns of managerial action emerge, their collective actions are powerful forces in influencing organizational, value chain, and institutional outcomes (George et al. 2006).

By contrast, the open systems framework adopts a constrained role for managerial agency while emphasizing the role of action-system interdependence. Sidestepping both the agency versus structure debate and paradox of embedded agency (Heugens and Lander 2009), an open systems perspective recognizes that managers hold agency in shaping institutional structures and processes; however, it does not accord agency the status of taken for granted as per the economic framework. Rather, an open system framework views managerial actions to be just as empowered as they are constrained by the institutional structures and processes that embed their actions. This open systems view of managerial action, empowered *and* constrained, is referred to as action-system interdependence. Dating back to action theory (Parsons 1956), action-system interdependence implies that individuals construct actions from repertoires available in the institutional system; yet, actions are interpreted or are effective in catalyzing change depends on processes of sense-making and response by other actors in the system.

The pharmaceutical value chain is a prototypical instance of such interdependence. Fiduciary responsibility requires subordinating self interest in the service of external constituencies (e.g., pubic, society), enlarging the scope of the system and exposing it to external scrutiny. Considerable evidence exists to suggest that market actors in such systems are often blind sighted by implications of action-system interdependence and fall prey to its counter-intuitive dynamics when they become overly focused on their internal logics. Notable instances of such blind sighting include Arthur Anderson in the auditing scandal, Student Loan Xpress in the student loan disaster, Lincoln Savings and Loan in the S&L crisis, and AIG insurance and Prudential in the insurance industry debacle.

The two frameworks also differ in their premise for the equilibrium state of the market (or lack thereof). Market equilibrium is a premise of the economic framework, such that market actors are assumed to exercise agency to move markets toward a stable, steady state. An equilibrium state is thought to be more likely when the value chain is aligned with a singular institutional logic by design, default or managerial agency. By contrast, an open system is

agnostic to market state and is inherently antithetical to stable, orderly and equilibrating processes of market evolution and shift. Consistent with its foundations in conflicted logics, an open systems framework is more compatible with the premise of disorderly movement where markets become arenas of contested logics that risk negative system spirals and are marked by increased conflict, aggressive retaliation, and eroding cooperation among value chain partners.

It is important to note that the open systems framework is not premised on inevitable negative spirals. Just that this *could* and *does* happen. The fundamental point is that system dynamics evolve in response to interactions among market actors, often resulting in emergence of new types of actors, relations, and networks (Katz and Kahn 1966). As per systems theory, order and structure emerge in a bottom-up, self organizing way from the micro-interactions among market actors making the process nonlinear, path dependent, and unpredictable. The emerging order and structure are not necessarily conducive for the survival and growth of individual market actors. Nevertheless, managerial intuition and instruments of "planning and strategic action" rooted in autonomous action may be problematic because they promote system run downs (Wilkinson and Young 2007, p. 372). For survival and growth, actors "must move to arrest the entropic process" by drawing energy (negative entropy) from its environments through interdependent action that recognizes system as the unit of analysis, co-learning and collaboration as key system processes, and legitimacy as the desired outcome (March 1996). These possibilities are captured in our research propositions presented in Table 3.

Key Questions and Mechanisms

The open systems and economic systems offer contrasting pathways for inquiry and practice. Representing the current state of the literature, the economic framework focuses research inquiry on understanding how, when and why do market-mix instruments influence physician decision making, and in developing models for optimizing the return on market-mix investments. Such inquiry is especially powerful when it can identify the unique and synergistic effects of clearly defined market mix instruments. Much past research has used this framework

to study effects of diverse instruments such as detailing, sampling and advertising. Consistent with its premises, the economic framework asserts that managers can use the evidence of market mix effects to make top-down decisions that set up incentives to structure market exchanges in way that is favorable to the organization.

The open systems framework shifts inquiry and practice attention away from ROI of market mix instruments and toward market action and its legitimacy implications. By using market action as the unit of analysis, the open systems approach places more emphasis on strategies that underlie market action, and in understanding how market action is interpreted to construct legitimacy judgments. Because market action is centered on the actor and legitimacy on the partners and observers who interact with or are exposed to the actor, the open systems adopts a more holistic view in understanding how, when and why market action is effective.

Moreover, the open systems approach offers novel concepts for understanding value chain system dynamics. For instance, consider the concepts of conflicted logics and market dilemmas. The notion of contested logics focuses on system mechanisms triggered by ongoing contests among market actors rooted in the conflicted logics of the value chain. In some decisions, the contests may favor a consequential logic while for others the logic of appropriateness may hold sway. Outcome patterns of such contests over time and decisions shape the ebb and flow of system dynamics. Patterns that are heavily weighed by consequential logic may erode moral legitimacy, just as patterns tilted heavily by logic of appropriateness may exact a price in terms of pragmatic legitimacy. Although speculative, the notion of conflicted logics as games of trust-value tradeoffs in micro-level managerial decisions provides a novel way of examining system dynamics. When tradeoffs persist as interactional routines that are reinforced over time, a market dilemma exists. Such dilemmas may require policy intervention to set new ground rules for market exchanges that favor resolution of conflicts through market self-regulation. Likewise, when actors are sensitive to market dilemmas, they may be motivated to overcome path dependencies to stem further legitimacy losses and avoid regulatory

intervention. The systems theory notions of equifinality—many different paths leading to the same outcomes, and entropy—progressive mechanization can be mitigated by arresting energy from the system, provide a foundation for understanding processes of contested logics and the resultant market dilemmas that open new windows for future research.

Most notably, an open systems framework rejects the orderly, linear and largely predictable trajectory of market interactions implied by the economic framework. Instead, it suggests that evolution of market dynamics occur as bottom-up processes that are resistant to predictable analytics. However, recent work in co-evolutionary game theory offers useful directions (Bergstrom and Lachmann 2003; Lewin and Volberda 1999). Drawing on biological principles of mutualistic interaction between two or more species that are embedded in a large milieu of a biological system, evolutionary game theorists examine questions such as what keeps the interaction from breaking down as individual species succumb to their own consequential logic, disorderly movement toward less differentiated structures and possible dissolution, how they allocate benefits of cooperation to avoid interaction breeches (e.g., market failure), why certain routines get replicated and reinforced and what makes certain species or systems to break away from their path dependencies to be more flexible and adaptable (Lewin and Volberda 1999). Future research can build on this stream of work to more fully articulate the co-evolutionary processes involved in an open systems theory of interdependence.

Viewing pharmaceutical value chain as an open system centers attention on the recursive relationships among market actors (DiMaggio 1997; Giddens 1990). For instance, Moore et al. (2006) discuss the implications of interdependencies within the context of accounting organizations. Faced with legitimacy threats from persistent conflicts between their auditing and consulting functions, accounting firms aggressively pursued "cosmetic changes" that improved the appearance of auditor independence and "skillfully masked rent seeking in the rhetoric of the public good," till the excesses of one organization (Enron) wrought a political and public backlash for a new institutional order (Moore et al. 2006, p. 20).

A particularly provocative insight from an open systems perspective is that the dominant coordinating logic at any given point is not necessarily conducive for preserving legitimacy. System theorists note that, akin to biological evolution, socio-economic systems move in the direction of more differentiated mechanisms that initially allow nuanced, flexible and contingent resolution of conflicted logics but later tend to be drawn into progressive mechanization as dominant market actors assert "fixed arrangements" to gain efficiency and reduce complexity in market interactions. However, progressive mechanization also tends to "gradually diminish and eventually abolish the equipotentiality" of the system as a whole thereby inhibiting its capacity to solve emergent problems rooted in system conflict (von Bertalanffy 1968; Katz and Kahn 1966). Thus, an open system perspective broadens current conceptualizations to include the dynamics of recursive relationships among market actors and opens several avenues for future research as outlined in Table 3.

CONCLUDING NOTES

This chapter is motivated by the strategy-tactics gap in the extant pharmaceutical marketing literature. Much previous research appears preoccupied by modeling the ROI of diverse marketing mix instruments while largely neglecting to study the strategies that underlie these tactics. Using the aversive discourse of pharmaceutical marketing strategies in the medical literature and public press as a point of departure, the chapter aims to systematically analyze the marketing strategies used in practice by pharmaceutical industry using a unique data involving court discovery documents unsealed in a recent litigation. Moreover, we adopt an institutional theory perspective to analyze the disparate logics that characterize the value chain of pharmaceutical markets. Lacking institutional and system perspectives, current approaches are hard pressed to anticipate, much less explain, the persistent and increasingly unfavorable assessments of pharmaceutical marketing by its value chain partners including professional medicine and consumers. Our analysis suggests that the pharmaceutical value chain evidences dynamics consistent with several aspects of institutional theory: (1) system conflict due to

coexistence of competing logics, (2) institutional failure in resolving conflict of logics that are amplified by pharmaceutical marketing practices, and (3) continued escalation of conflicts of logics that invite regulatory intervention which constrains and restricts marketing efforts.

Building on our insights, we develop an open systems view of the pharmaceutical value chain and contrast it with an economic framework that guides much current research. We do not propose that the current approaches are flawed and need to be abandoned. Current approaches have produced useful insights to guide managerial action. Our point is that these approaches miss a systems view that provides action guidelines that differ or counter those resulting from current approaches. Using current approaches and system view as two sides of the coin, and conjoining them when possible, can be effective.

Going forward, conceptualizing and operationalizing legitimacy dimensions require a shift in focus from organization-centric calculus to a system-centric orientation. For instance, instead of focusing on value *extracted* from its value chain (e.g., ROI), pragmatic legitimacy attends to value *added* to its value chain. This does not imply that value extraction is ignored. Rather, value added is given greater significance in pragmatic legitimacy considerations. Likewise, moral and cognitive legitimacy are system-centric, requiring focus on evaluations of value chain partners and downstream customers. However, value chain partners are usually dispersed and are not easily accessible, making legitimacy assessment less tractable than ROI calculations. Institutional theorists have provided useful conceptual and operational advances for assessing organizational legitimacy which can be leveraged for developing legitimacy constructs appropriate for marketing contexts (Suchman 1995). For instance, Tyler (2006) suggests that justice theory concepts of distributive, interactional, and procedural fairness may be bootstrapped to assess pragmatic, moral and cognitive dimensions of organizational legitimacy.

In closing, we note that our study holds broader relevance to other markets characterized by conflicted logics and market actors bound by fiduciary responsibility. Such markets abound in modern civil societies and tend to suffer legitimacy setbacks with alarming regularity,

incurring substantial societal, organizational, and human costs. We hope that our study highlights the dilemma of such markets and provides the guiding impetus for future research that provides insights for managerial action with foresight to navigate legitimacy dilemmas.

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1. Appendix I

Background Note on Analysis of Court Documents for Mapping PM Strategies

Data Background. Several key litigations involving pharmaceutical marketing practices have been processed in US and international courts including: (a) TAP Pharmaceuticals who settled its nationwide class action lawsuit by paying $885 million to consumers and insurers, (b) AstraZeneca who pled guilty and paid $335 million for promoting Zoladex, (c) Eli Lilly who was charged for marketing practices involving Evista and paid $36 million dollars to the US government, and (d) Schering-Plough Corporation who paid $435 million dollars as part of their plea agreement to settle charges for marketing drugs. In fact, 6 out of the top 10 pharmaceutical companies[6] in 2007 have faced recent or current litigation due to their marketing tactics.

The case we selected, *United States of America ex. rel David Franklin vs. Pfizer Inc, and Parke-Davis, Division of Warner-Lambert Company,* involved marketing practices related to Neurontin® (chemically known as gabapentin) which was marketed in over 100 countries, used by over 12 million patients and was generating revenue of over $2.7 billion. The FDA initially approved gabapentin in 1993 for adjunctive treatment of partial complex seizures in adults older than 12 years in age and for dosages not exceeding 1800mg/day. However, by the mid-nineties, gabapentin experienced its highest growth in off-label treatment of pain syndromes (e.g., neuropathic pain, migraine) and psychiatric disorders (e.g., social phobia, bipolar disorders). Parke-Davis admitted that it used marketing and promotion strategies for unapproved, off-label uses. Under current United States law, it is neither illegal nor unethical for physicians to prescribe a drug for purposes unrelated to its FDA approved uses. Physicians are privileged by law to prescribe a drug for treatments for which they believe there is sufficient evidence of efficacy based on scientific evidence in peer reviewed journals and expert recommendations. Pharmaceutical companies are legally restrained from directly marketing and promoting a drug for off-label uses. As such, the marketing practices used are not illegal *per se*. They are illegal only if they are used to directly promote off-label uses.

Data Characteristics and Analysis. The court documents were obtained directly from the attorneys, and supplemented with archived data from a website of all pertaining documents housed at the University of California, San Francisco (http://dida.library.ucsf.edu). The documents included internal correspondence, details of sponsored activities and programs, exchanges between drug companies and physicians, and sworn depositions from key individuals. In analyzing these documents, we adopted an inductive approach with multiple coders. Two teams, each involving a lead researcher and a student, were constituted. The first team initially combed the materials to extract the key strategies and associated networks that had a direct or indirect bearing on the company's relationships with physicians. The second team then independently extracted the key strategies and networks, and met with the first team to resolve differences and integrate extracted strategies. Further, to ensure that the inductively derived descriptive patterns are not idiosyncratic to the gabapentin case but reflect broader industry practices, we supplemented this analysis with review of secondary materials including: (1) media reports and articles (e.g., *Business Week*, *The Wall Street Journal, CBS News*), (2) industry (e.g., PhRMA) and association (e.g., AMA) reports and materials, (3) federal sources (e.g., FDA), and (4) scientific journal articles, books, and editorials. This supplementary evidence is also summarized in Table 1.

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[6] The top 10 pharmaceuticals based on revenues (http://www.contractpharma.com/articles/2007/07/2007-top-20-pharmaceutical-companies-report) are: Pfizer, GlaxoSmithKline, Sanofi-Aventis, AstraZeneca, Novartis, Merck, Johnson & Johnson, Roche, Wyeth, and Eli Lilly and Co. The companies that were taken to trial and successfully convicted are Pfizer, AstraZeneca, Merck, Johnson & Johnson, Wyeth, and Eli Lilly and Co.

Table 1
The Logic of Consequences and Pharmaceutical Marketing Practices

Strategy (%Budget)	*Marketing Tactics*	*External Validity*
Market Penetration Strategy (6.6%) Marketing Objectives: • increase the accessibility of the Parke-Davis portfolio to all major teaching institutions • An epilepsy and pain educational program that is targeted at (1) neurology specialists including general neurologists and neurosurgeons, and (2) primary care physicians whose practice includes a significant number of patients with epilepsy or chronic pain. (exhibit 51).	Target centers of influence based on (1) availability of neurology, geriatric, psychiatric, cardiology and internal medicine programs, (2) number of residencies and fellowships, and (3) out-patient visit volume (exhibit 34, phase I). PPS (Professional Postgraduate Services) developed a Home Study Program (HSP) supervised by Parke-Davis representatives to be distributed to about 10,000 target physicians in April 1996 (exhibit 51).	Neurometrix instituted a "customer referral program" in which physicians receive credits for steering other doctors to Neurometrix (Abelson 2006). Urorad Healthcare aggressively targets urologists for marketing IMRT (intensely modulated radiation therapy), a procedure for radiation therapy in patients with prostate cancer (Saul 2006).
Evidence-based Strategy (53.6%) Marketing Objectives: • "Execute publications, educational activities, and promotional plan to expand Neurontin® monotherapy usage." • ..to seed the idea in physicians' minds that Neurontin® can and should be used earlier in the treatment armamentarium." (verbatim from 1998 Situation Analysis Report; Exhibit 57). • To increase the titration level of Neurontin® dosage (1200mg/day to 1800mg/day) (exhibit 39).	Clinical trial program to financially support research studies and publish them sequentially in reputable journals to promote a "life cycle planning" of Neurontin® market performance (exhibit 72, 57). "MES (Medical Education Systems Inc.) will work with medical faculty (chosen at the discretion of Parke-Davis) to draft approximately twelve scientific articles on the topic of AED therapy" budgeted $160,500 in grant money for these articles. (exhibit 65, 66). Promotional campaign using detailing, direct mail, and journal advertising to promote the use of Neurontin® earlier and titration at higher doses (exhibit 39).	Sleeping pill manufacturers orchestrated publications to undermine a competing generic drug—Trazodone—which is considerably cheaper than manufacturer branded drugs such as Lunesta and Ambien (Carlat 2006). Mathews (2005) reports widespread practice of "ghost writing" research articles for publication in medical journals that are written by professional writers on behalf of physicians and funded by pharmaceutical companies at the cost of "$30,000 per article or more."
Medical Education Strategy (27.8%) Marketing Objectives: • To develop or support educational programs consistent with Parke-Davis's marketing • To increase Neurontin new prescriptions by educating non-prescribers to begin prescribing and current prescribers to increase prescription behavior.	"Unrestricted" educational grant to Medical education companies to prepare programs accredited by ACCME with Parke-Davis representatives shaping the content and following attendance counts to support a "growth opportunity" in off-label uses (1997 situation analysis). Educational seminars and teleconferences to increase Neurontin® new prescriptions (exhibit 79).	Cephalon funded doctors' participation in seminars at which paid speakers promoted off-label uses. (Carreyrou 2006).
"Surrogate Selling" Strategy (11.9%) Marketing Objectives: • "Maximize relationship with key epileptologists to expand Neurontin usage with residents/fellows, office based neurologists and selected PCPs." • Use peer influence to give non-users reassurance of Neurontin®'s efficacy and tolerability. • Gain 100% access for Neurontin®.	Recruit physicians qualified as high prescribers of AED's by providing incentives to entice participation. (exhibit 76). "Make influencers aware of availability of research opportunities in clinical trials." "Emerging thought leaders will be paired with existing thought leaders to meet others supportive of Parke-Davis and its products." (exhibit 45) Disease-based Advisory Boards (e.g., AIDS Neuropathy, Child Neurology, Migraine).	Dr. Gleason was arrested for promoting Xyrem for off label uses and acknowledged receiving more than $100,000 from Jazz Pharmaceuticals (Berenson 2006). AstraZeneca provided 400 physicians financial inducements as consultant's fees to prescribe Zoladex (Petersen 2003).

Table 2
Comparative Analysis of Frameworks Rooted in Consequential and Open Systems based view of Institutional Logics for Pharmaceutical Marketing

	Elements	Economic Framework	Open Systems Framework
Foundational Elements	Fundamental Objective	Return on Marketing Investments	System and Organizational (subsystem) Legitimacy Gains from Marketing Investments
	Focal Phenomenon	Consummation of Market Exchanges	Interdependence and Interconnectedness of Market Relationships
	Foundational Logics	Logics of Consequences	Logics of Consequences and Appropriateness
	Market Mechanisms	Creating and extracting value	Balancing value extraction and legitimacy gains
Premises	Agency	Managerial actions are sufficient to assert control to structure and shape market exchanges in the value chain	Managerial actions are insufficient to unilaterally structure market exchanges in the value chain; instead, outcomes of managerial actions are influenced by system interdependence.
	Market State	Orderly movement toward stability and equilibrium	Disorderly movement toward less differentiated structures and possible dissolution
Key Questions and Mechanisms	Guiding Questions	How, when and why do market-mix instruments influence value chain partners, and how to optimize return on these instruments	How, when and why do market actions enhance or diminish system and organizational legitimacy, and how to enhance the effectiveness of market actions
	Market Concepts	Detailing, sampling, advertising, and networks that are critical to extracting value from market exchanges	Contested logics, differentiation, progressive mechanization, market dilemmas, and equifinality that are critical to enhancing system and organizational legitimacy
	Market Order	Emerges through top-down processes supported by market-mix instruments that the market actors deploy to align market exchanges with their favored logics	Emerges in bottom-up, self organizing processes that characterize interactions among market actors guided by disparate and usually conflicted logics making the process nonlinear, path dependent, and unpredictable.

Table 3: Propositions for a Research Agenda of an Open Systems Study of Pharmaceutical Marketing

Foundational Elements

1. Market exchanges between value chain partners with disparate organizing logics are prone to conflict when fiduciary responsibility is central to one, but not both, of those logics.
2. Organizational legitimacy is a key mediator for the influence of marketing strategy on long term (a) sustainability, and (b) profitability.
3. Marketing strategies centered exclusively on a firm's own internal logics will (a) enhance value chain conflict and (b) lower organizational legitimacy.
4. An organization is likely to be perceived as more legitimate, the more it is perceived by its value chain partners and customers to (a) deliver something that adds value to exchange relationships in the system (pragmatic legitimacy), (b) be a trustworthy partner that can be relied upon to protect the best interests of its downstream customers and curb opportunism (moral legitimacy), and (c) engage in activities that are meaningful and desirable for society (cognitive legitimacy).
5. In the long term, marketing strategies centered exclusively on pragmatic legitimacy will undermine (a) moral legitimacy, and (b) cognitive legitimacy.
6. The higher the organization's legitimacy, the greater its effectiveness in (a) securing scarce societal resources, (b) long term sustainability, and (c) overcoming market threats (e.g., due to unfavorable information, shocks, crisis).
7. Greater the persistence of unresolved conflict among value chain partners, lower the organizational legitimacy for one or both partners.

Premises

8. Greater the marketing incentives to physicians with the objective of influencing their prescription writing (a) higher the system conflict and (b) lower the organizational legitimacy.
9. Greater the effectiveness and efficiency of marketing strategies rooted in consequential logic, (a) higher the system conflict and (b) lower the organizational legitimacy.
10. Greater the focus of value chain partners on the stability of their own internal dominant logic, greater the intensity of system conflict.

Key Questions and Mechanisms

11. The more a value chain is characterized by persistent system conflict, the more likely are retaliatory actions by value chain partner(s) to safeguard their own legitimacy.
12. Managerial actions with a strong (weak) focus on consequential logic will result in increasing (decreasing) unilateral actions by value chain partners to safeguard their legitimacy by (a) erecting firewalls and (b) maintaining arms length relationships..
13. Collaborative actions among value chain partners are likely to be more effective, the more they are organized as open, bottom-up, self organizing systems (rather than structured, top-down, regulated systems).
14. Over time, value chains will have an increasing tendency toward mechanisms that provide efficiency gains and reduce complexity (progressive mechanization).
15. Greater the system's success in progressive mechanization, lower its capacity to effectively resolve emergent system conflicts.

Figure 1
Strategic Interdependencies in Pharmaceutical Promotion Practices