

## Pharmacists, the Pharmaceutical Industry, and Ethics

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### ABSTRACT

Considerable ethics-related focus has been directed to the pharmaceutical industry's relationship with physicians, in part because physicians have the only profession able to prescribe much of what the industry manufactures. In Alberta, however, pharmacists have recently been permitted to modify physician prescriptions for a patient and even to prescribe without physician involvement. This paper will examine how this change in responsibilities could change pharmacists' relationships with the industry.

**Key words:** pharmacist, pharmaceutical industry, ethics, prescribing, conflicts of interest.

Ethical concerns about the pharmaceutical industry have prompted numerous media stories, academic articles, conference presentations, books and television storylines. However few people would applaud the demise of commercial pharmaceutical manufacturers -- whether of branded or generic products -- because many of their products help prevent or forestall death, restore diminished or lost functions and recover lives of meaning and connection. Since product development and manufacture occurs in an exceedingly competitive marketplace, many corporate activities can be ethically justified as per business ethics. But perfect competition requires many buyers and sellers, full and timely information, freedom of entry and exit and a uniform item. These qualities are absent or minimal within healthcare and so the marketplace alone cannot be relied on for quality, efficiency, fairness or met needs. Various pharmaceutical company activities seem not just questionable, but far beyond the pale of such business-related virtues as integrity, fair reciprocity and respect. Substantial suspicion about the industry is the result. Multimillion-dollar legal settlements for deceptive advertising, holding back negative research findings, and unfair business practices stoke such cynicism. Likewise for misleading patent extensions<sup>1</sup>, "ghost written"<sup>2</sup> academic articles, lavish professional conferences, and statistics correlating researcher and physician honorariums and grants with disproportionately favourable conclusions about their products.

Much attention, appropriately so, has been devoted to conflicts of interest among industry, physicians and university-college medical programs (Davar 2008, Streiffer 2006, Perlis et al 2005,

Wazana 2000, Bodenheimer 2000, Schwartz 1987). As fiduciaries, physicians must put patients' well being before all else and serve as their advocates. Universities and colleges' purposes are to develop and share knowledge and to promote open inquiry. As private health-related businesses, pharmaceutical companies are expected to "provide a societal benefit which helps generate... profit" (Schwartz, 83). These objectives often compete and clash with each other. This paper, however, will examine the ethical implications of pharmacists' relationships with the pharmaceutical industry. Impetus for this examination comes from a recent change in pharmacist responsibilities in Alberta. The province's *Health Profession Act* was amended to include the *Pharmacists Profession Regulation* in 2006. This amendment permits licensed pharmacists to alter physician-written prescriptions as well as to prescribe independently of physicians. This change is important because pharmacist responsibilities are becoming progressively similar to those of physicians. Moreover this is a substantive issue in mental health and addiction care because many therapies are pharmacological. Just as significant ethical worries about the relationships between physicians and the pharmaceutical industry have and continue to exist, what worries about pharmacist-industry relationship need analysis and resolution?

### Pharmacy's Evolution:

Around 1080 A.D., infirmaries built by the Knights Hospitallers to care for ailing pilgrims to the Holy Land included the first pharmacists qua chemists (Jonsen 2000). "Apothecary" appears in the English language around 1350 A.D. and *apotheca* is Latin for storehouse for such things as herbs and spices (Webster's 1983). Specialized knowledge about natural products and chemicals and mixing them into therapeutic compounds defined the pharmacist role into the 1900s. Large scale, assembly line manufacturing began to emerge in the 1950s in North America when immense research efforts produced substantive health benefits for many common illnesses and conditions. Yet knowledge of clinical diagnoses and prognoses as well as drug benefits, burdens and risks rested with physicians. Physician-written prescriptions were therefore a necessary condition for access to pharmacotherapies.

Although mixing and selling products from manufacturers remained primary responsibilities, pharmacists were recognized as health professionals in various provincial regulations during the 1960s. The concept of "clinical pharmacy" subsequently arose,

indicative of closer interactions with individual patients and with their healthcare practitioners. As Pearson notes, pharmacists' role in "the responsible provision of drug therapy for the purpose of achieving definitive outcomes that improve a patient's quality of life" helps explain why they are often considered important members of someone's in-hospital or community-based health team (2007, 1295).

Since 2000, provincial legislatures have gradually permitted pharmacists to provide emergency contraception without a physician's prescription (all other Schedule II drugs must be prescribed by a physician). Related to the aforementioned change to Alberta's professional legislation, Saskatchewan's College of Pharmacy has published a paper supportive of pharmacist prescribing (*Position Statement on Enhanced Authority 2007*). In 2006, Manitoba passed *Bill 41 Pharmacist Act*, which permits independent prescribing and administering of certain drugs plus independent ordering and interpreting certain diagnostic tests (the Bill has not been enacted yet; Pearson 2007). And British Columbia's Pharmacy Association has recently expressed support for independent prescribing (*Pharmacist Prescribing Position Statement 2007*).

Evolution of the pharmacist role mirrors the evolution of the physician's role. The Hippocratic Oath, written in the fourth or fifth century A.D., portrays physicians as a guild-like group who helped alleviate suffering and injury through non-surgical techniques and medicinal compounds. The reliability and effectiveness of medical interventions themselves -- as opposed to public health measures and comfort care -- became significant with the discovery of antibiotics in the early 1900s. The technological boom began in the 1950s when large public institutions (e.g., the U.S. National Institutes of Health, the Canadian Institutes of Health Research) and private corporations funded research studies and companies invested in patenting, production and distribution. In terms of mental health treatments, in the late 1950s and 1960s, psychotherapies and rehabilitative or protective institutionalization were augmented or replaced by the first generation antipsychotic medications (e.g., thiorazine, stelazine and haldol). Atypical or second-generation antipsychotic medications, such as olanzapine, quetiapine and risperidone, appeared in the 1990s. Sales of these drugs alone now total approximately 3% of the industry sales or \$20 billion (*Antipsychotics Market Insight & Analysis 2008*).

### Distress of Pharmacists:

Surveys of pharmacists who face ethical quandaries and feel moral distress are illuminating. Moral distress has been defined as "incoherence between... what one sincerely believes to be right, what one actually does, and what actually transpires" (Webster & Baylis 2000, 218). Sporrang et al describe it as "traditional negative stress symptoms that occur due to situations that involve ethical dimensions and where the health care provider feels she or he is not able to preserve all interests and values at stake" (2006, 418). Mott found that 70% of the pharmacists he studied admitted to being morally distressed in their work (Sporrong et al 2005). In 2006, Sporrang et al surveyed 259 staff working either in a pharmacy or a pharmacy department. While the departments' physicians and nurses experienced somewhat more distress than

the pharmacists (59% to 51%), their openness to ethical concerns was also higher (34% to 28%).

In a study of 377 pharmacists, 32% identified ethical conflicts with customers, 27% with gifts and kickbacks, 23% with pricing practices and 23% with honesty of business agreements (Vitell et al 1991). Moreover 38% of the respondents stated that ethical standards had declined over the past ten years. Latif (2000) compared 130 community pharmacists' ethical reasoning to that of first-year pharmacy students and other healthcare professionals. His finding: the pharmacists scored lower than the students and other professionals plus the length of practice inversely correlated with reasoning abilities. Smith et al (2006) examined the industry's impact on academic pharmacy programs. Respondents were asked to indicate whether a variety of ethically questionable and unacceptable practices in program planning had occurred. Incidence of eight ethically questionable practices ranged from 3 to 37% while incidence of six unacceptable practices ranged from 2 to 11%.

Worrisomely, several writers note that focused, sustained teaching of ethics in many pharmacy academic programs remains absent (Banks 2005, Resnik et al 2000, Latif 2000). An important rejoinder to this absence comes from Murawski (2007). A pharmacy professor himself, he finds that students usually hold unjustified, distorted viewpoints about the industry because instructors tend to teach from a "Zeitgeist<sup>3</sup> of the industry... [being] unrepentantly evil" (36). If a university's purpose includes facilitating open inquiry, reified and absolutist positions qualify as anathemas just as naïve and superficial positions so qualify.

### Hospital Pharmacists:

Many people living with a substance use and/or psychiatric problem include pharmaceuticals in their recovery and health regimens. The patient- or client-pharmacist relationship typically occurs in two settings: hospitals and in the community.

Hospital pharmacists work in a somewhat more insular environment compared to community pharmacists (Wilson 2007). Snead (2007) and Wilson both note that the industry has paid less attention to hospital-based pharmacists. Fewer financial incentives exist. Nonetheless Latif insightfully argues that "most workplace settings are strong settings... that exert significant influences on individual attitudes and behaviors" (344). And moral distress exists:

Hospital pharmacies find themselves in the uncomfortable position of having to choose between achieving cost savings for their cash-strapped institutions by accepting less than definitive data as the basis for P & T and bedside therapy decisions and making a more conservative data-based decision. (Wilson, 58).

When first developed, hospital drug formularies were simply lists of available products (Helling 2000). However as the variety and cost of drugs increased dramatically, "formulary decisions [came to be] decisions about rationing" (Haddad 2000, 857). Formularies have become focal points for competing professional, organizational and industry interests. For instance, as presented in Carroll's

description of pharmacy-industry evolution, during the 1950s the job description of the Director of Hospital Relations for the U.S. National Pharmaceutical Council included the goal to “slow up, if not stop, the trend of more hospitals adopting a compulsory formulary” (2007, 28). In terms of pharmacy associations, for many years pharmacists employed by pharmaceutical companies could not belong to the Society for Health-System Pharmacists in the United States because indefensible conflicts of interest were presumed inescapable. Only recently has the Society changed its position by requiring transparent, proactive management of such conflicts by every pharmacist, irrespective of his or her workplace (Frye & Witmer 2002). Pharmacy and Therapeutics (P & T) committees are commonplace in hospitals now, given the complexity and number of available pharmaceutical and mechanical products.

Drug formularies have been characterized as “an instrument of management” (Jonsen 2000, 485) and as a “safe haven... of sorts that minimizes organizational conflicts and the potential influences of individuals” (McAllister 2000, 860). Formularies are hoped-for outcomes of defensible compromises among patient needs and wants, clinicians’ preferences, pharmacists’ expertise and hospital budgets. Various writers however worry that hospitals’ bottom-line pressures erode quality care and patient health outcomes (Wilson, Wertheimer, Carroll, Snead, Maine, O’Brien, Peck, Haines & Dumo, all 2007; Lisi 1997). They recommend that pharmacists act as patient advocates in cost-effectiveness and budget discussions. Furthermore hospital pharmacists must understand the types and forms of messaging the industry directs to physicians qua prescribers and to patients qua customers. They can then counter incomplete and skewed information and interpretations. Helling holds that, in the end, pharmacists must stay focused on patients first and be “good fiscal stewards” (2000, 859). Stewardship involves such ethical values as fairness, dependability and duties to future as well as immediate patients.

## Community Pharmacists:

The major difference between hospital and community pharmacists is the latter works in a market place setting. According to sociologists Denzin and Mettlin, “retail pharmacists represent the most non-professional aspects of the profession” (Latif 2000, 346). Maine (2007) and Carroll (2007) characterize community pharmacists as a channel of distribution from manufacturer to patient. Not surprisingly, the goals of manufacturers and pharmacists differ: profits and control of prescribing and information flow versus provision of effective medicines and individualized information. Yet the history of the industry, community pharmacists, and state associations’ rift is revealing, as described by articles in a recent issue of the *Journal of Pharmaceutical Marketing and Management*. Carroll explains that in the 1950s, different brand manufacturers typically produced identical items, which meant increased pharmacy inventories. Pharmacists subsequently stocked only one brand of an item and/or stocked generic products. In response, the industry canvassed the Federal Drug Administration, initiated legal action against pharmacists, and lobbied state associations in order to ban generic substitutions. These efforts proved successful in that forty-four states had non-substitution legislation by the late 1950s. Yet by the 1970s, all such legislation had been repealed.

In 1984, the U.S. Congress passed the *Waxman-Hatch Health Act (or Drug Price Competition and Patent Term Restoration Act)*, which sanctioned generic prescribing and substitutions. The pharmaceutical industry, according to Carroll, then countered with inaccurate messages that generic drugs were of inferior quality, but these efforts were ultimately unsuccessful.

Because the pharmaceutical industry is a business and pharmacy is a profession, goals vary. However community pharmacists are often offered financial incentives to dispense branded medications or receive volume rebates. The American College of Clinical Pharmacists has tried to promote a collaborative drug therapy management approach to strengthen and regularize interactions between patients and pharmacists in hopes of achieving better health outcomes and improved access. As of 2002, thirty-eight U.S. states permit CDTM practices wherein pharmacists can adapt prescriptions to better fit a patient’s circumstances (Carroll).

Just as ethical concerns exist over industry’s marketing to physicians and medical schools, concerns exist over the dubious marketing tactics to pharmacists. Sales representatives try to have their branded drugs become pharmacist’s “default choice.” Moreover there are roughly 800,000 sales reps in the U.S., which translates into one full time rep for every ten physicians, according to Wright et al (2007). Not surprisingly, their marketing tactics have had to be creative and aggressive.

Yet to be fair, the reps themselves have worried about increasing pressures to achieve monthly sales targets. Because it is a “prescribers markets,” many reps came to feel they were “prostituting themselves or their products... or began to approach outright bribery to capture physician time and attention” (Wright et al. 49). As Maine aptly cautions, unfortunately “pharmacists and the industry both suffer if the buyer of medications simply thinks of a drug as a commodity to be acquired at the lowest possible price” (2007, 73).

## Conclusions:

“The best future for all concerned depends upon strong alignment between interests for pharmacy and pharma in transcending pills and adding capabilities to improve health” (Peck 2007, 92). As reflected by the *Journal of Pharmaceutical Marketing and Management’s* issue about the pharmacy-industry rift, various initiatives reflect increased collaboration that should help serve the public better. In 2002, the Pharmaceutical Research and Manufacturers Association (PhRMA) finally developed a policy for its members regarding gift giving. In 2003 a working document titled “Guiding Principles for a Pharmacy Benefit: A Call for Pharmacy Provider Services and Access to Pharmaceuticals” was developed by American state pharmacy associations and PhRMA to help counter mistrust, imbalance, and reduced patient outcomes (Snead 2007).

“Professional” has two connotations: someone whose work meets formal standard of social exchange or someone who belongs to a socially regulated profession. In the context of healthcare, nurses and physicians’ professional standards require that a patient’s welfare come before their own interests and serious conflicts of

interest must be avoided. These standards are especially high and unyielding because patients are so vulnerable and in need of others' specialized resources, skills and knowledge.

Business interests must come far after patient well being, regardless of whether a pharmacist's work is in a hospital or community drug store. Community pharmacists can choose one of two paths: one focused on the business of mixing and selling pharmaceuticals only and one that includes individual counselling and prescribing. The former is typified by the emergence of drive-through pharmacies, mail order pharmacies and mass merchandising chains that promise convenience and lower costs. These pharmacists' relationship with the pharmaceutical industry must be guided by principles and practices reflective of sound and thoroughgoing business ethics. On the other hand, the relationship between pharmacists who counsel and prescribe and the industry must be guided by robust business ethics and a thoroughgoing professional ethic akin to that of physicians and nurses. Without these ethical paradigms informing their work, pharmacists, their associations and their academic programs will be among those who harm, exploit and disrespect people who are living with a psychiatric and/or addiction problem and their families.

### Footnotes:

1. A patent extension is misleading if the reason for the extension is to financially benefit the manufacturer, but it is marketed as if the primary reason was to benefit patients in a meaningful way.
2. The classic example of ghost writing is a company employee researches and writes an article and it is subsequently reviewed by a healthcare professional. When published, though, the professional is listed as the only author or the professional is listed first, implying he or she is the primary contributor. Both options are inaccurate and misleading.
3. "Zeitgeist" is a German word meaning the spirit of an age or time. In other words, the overall moral, social, and intellectual outlook of a particular time period.

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