

Internal Medicine Prescribers' Knowledge of Medications and Effect of Lack of Access to
Pharmaceutical Representatives

by

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Abstract

Historically pharmaceutical companies have used sales representatives to directly promote and educate prescribers about their products. However, in the past decade there have been several policy changes within the health care community, such as by the Pharmaceutical Research and Manufacturers of American (PhRMA), the American Medical Association (AMA), and the Association of American Medical Colleges (AAMC), which limits the access of pharmaceutical representatives to prescribers and places specific limitations on what and how these interactions can take place. The purpose of this study was to determine if these policy changes, specifically lack of direct access to detailing, has had an impact on internal medicine prescribers' knowledge of new information regarding medications. A web-based, self-administered survey of 41 internal medicine prescribers at a large academic medical center was conducted. The survey targeted prescribers' current practice of obtaining information about new medications, their comfort level and familiarity with two recently approved medications, and if they practiced prior to 2007, if they had found the in-service education by pharmaceutical representatives helpful. The survey found that the most common methods prescribers' use to gain information regarding new medications is conferences, journals and word of mouth. Ninety percent of the participants were not at all familiar with one of the new medications and consequently not comfortable with prescribing; and approximately half of the prescribers were somewhat familiar with the other drug, and again, somewhat comfortable with prescribing. For those prescribers that practiced prior to 2007, 71.4% found the in-service education provided by pharmaceutical representatives very to somewhat helpful and 66.7% reported that drug representatives had "a little or no influence" on their prescribing practices. Overall, this study showed that limiting access to pharmaceutical representatives has had a negative impact on prescribers' knowledge of

medications. Further studies need to be conducted at a larger scale among all types of prescribers to determine the best avenue for getting valuable information to medical staff without concern for bias, coercion or fraudulent practices.

Table of Contents

Acknowledgement	ii
Abstract	iii
List of Tables	vi
Chapter 1: Introduction and Background.....	1
Chapter 4: Discussion	17
Chapter 5: Conclusions and Recommendations for Further Research and Action.....	20
References.....	22
Attachment A: Survey Questions	26
Attachment B: IRB Approval Letter.....	31
Attachment C: Permission to Access Email Lists	32

List of Tables

Table 1: Demographic Characteristics of Participants Included in the Analyses.....	12
Table 2: Frequency of Use of Modalities to Learn About New Medications.....	13
Table 3: Number and Percentage of Respondents who were Familiar and Comfortable with Prescribing Invokana™ and Suprax®.....	14
Table 4: Number and Percentage of Participants Practicing Prior to 2007 who Report Value of In-service Education and Influence on Patient Care.....	16

Chapter 1: Introduction and Background

Pharmaceutical marketing and detailing are quintessential to the success of medications. Historically sales representatives had direct access to prescribers to provide product information, samples, and product reminders, known as detailing. And while the pharmaceutical representative's primary goal of the interaction was promotion, a synergistic relationship was established where the prescriber could gain invaluable information about the latest drugs and their administration. This relationship, however beneficial, also presented the appearance of opportunity for undue influence in the prescribing habits of clinicians. Out of public and political concerns, the healthcare community, with support from the Office of the Inspector General of Health and Human Services, promoted several guidances to prevent potential abuse (Rothman & Chimonas, 2008). Consequently, the collaborative relationship between pharmaceutical representatives and healthcare providers has dwindled. The goal of this study is to evaluate the impact of these changes on the prescriber's knowledge of new medications.

Pharmaceutical sales date back to the 1800s as proprietors tried to sell their snake oils and other home-made remedies. Over time, medications became more sophisticated. The industrial and scientific discoveries of the late 1800 and early 1900s, accompanied by several wars, promulgated pharmaceuticals as a major commercial industry (Walsh, 2010). The 1930-1960s were known as the "golden age" of pharmaceuticals, as the number of medications brought to market exploded (Daemmrich & Bowden, 2005). The industry continued to grow during the 1980's as several blockbuster drugs, such as Tagamet, Prozac and the first statin were brought to market (Walsh, 2010). The pharmaceutical industry peaked in the 1990s. The cost of prescription medications in the United States, measured by National Health Expenditures was

\$2.7 billion in 1960, \$40.3 billion in 1990, and \$259.1 billion in 2010 (Centers for Medicare & Medicaid Services, 2012). The peak in the annual percent increase in expenditures from the previous year (12.8%) occurred in 1990 and has been slowly declining ever since (1.2%, 2010). Since 2005, pharmaceutical costs have remained fairly constant at approximately 10% of total health care expenditures (Centers for Medicare & Medicaid Services, 2012).

As medications became more abundant and sophisticated, and competition between pharmaceutical companies skyrocketed, the need for diverse marketing techniques increased. Consequently, the need for sophisticated sales representatives heightened. The increase in drug sales during the 1980's-2000 was in part due to the expanse of marketing directly to the prescriber. From 1996 to 2000 the cost of pharmaceutical advertising tripled when it reached \$2.5 billion annually, in which eighty percent of these costs were associated with promotional activities directed specifically towards physicians (Rosenthal, B., Donohue, Frank, & Epstein, 2002).

Prescription drug costs are currently 10% of the total health care spending in the U.S., totaling \$263 billion (NCSL, 2013). In an effort to control spending, several states have enacted laws which require drug companies to publicly disclose any monetary exchanges with healthcare providers. The intention was to discourage clinicians from accepting gifts from drug companies in return for prescribing brand name drugs and requesting these more costly drugs on formularies. Some have argued that the process of detailing and physicians prescribing brand named drugs instead of generics has increased the overall cost of health care in addition to costs for the consumer (Campbell, et al., 2010). Consequently, in February 2013, CMS announced its final ruling on the "Sunshine Rule," also known as the National Physician Payment Transparency Program. This requires manufacturers of drugs and devices which are covered

under any federal insurer (Medicare, Medicaid or CHIP) to report any transaction of value, monetary or otherwise, to both physicians and teaching hospitals.

In addition to concerns of raising health care costs from pharmaceutical detailing there was also growing concern regarding the ethics of undue influence on prescriber's prescription writing practices. A review of 29 empirical articles by Dr. Ashley Wazana, looked at physicians' interactions with the pharmaceutical industry and found the relationship typically began in medical school with drug company sponsored meals and continued to grow throughout their careers into research funding, honoraria, and conference travel (Wazana, 2000). Several studies have shown that receiving gifts, even small gifts, can influence people's behaviors. One study surveyed 467 residents and faculty at seven different academic institutions and found that a majority of the respondents believed that any gift greater than \$100 in value could potentially influence one's prescribing practices (McKinney, et al., 1990). Studies have also shown a direct correlation between prescriber and pharmaceutical representative interactions and increased prescribing and formulary requests, often regardless of cost of the medication (Wazana, 2000; Watkins, Moore, Harvey, Carthy, Robinson & Brawn, 2003; Spurling, et al., 2010). As the physician is responsible for the health and welfare of their patient, prescribing higher cost drugs without additional benefit presents ethical concerns. Others have argued that patients are not only directly bearing the brunt of increased costs of the prescriber-representative interaction and their medications, but for costs of continuing education for healthcare providers as well (Schetky, 2007). At one point, almost half of all continuing education was funded by the pharmaceutical industry (Brody, 2009).

Most healthcare providers do not feel that their behavior is influenced by detailing. In fact, one study found that "physicians have so many ways of justifying their relationships with

detailers that conflict-of-interest policies based on self-regulation are unlikely to succeed” (Chimonas B. T., 2007).

Lastly, several fraud cases by pharmaceutical companies were brought to the attention of federal and state prosecutors. From 2000 to 2004, there were 12 major cases of fraud by pharmaceutical companies with over \$4 billion in criminal and civil fines (Rothman & Chimonas, 2008). A few specific examples are: Novartis Pharmaceuticals for providing kickbacks to physicians and pharmacies that used their products (Department of Justice, 2013); Takeda and Abbott Labs for fraudulent billing to Medicare and kickbacks to healthcare providers for its drug Lupron (Sillup, Trombetta, & Klimberg, 2010); and lastly, GlaxoSmithKline was recently fined \$3million for improper marketing tactics, part of which, was for kickbacks to physicians in the form of expensive trips and entertainment (Thomas & Schmidt, 2012). Although fraud and abuse cases are not common, they often carry great weight in the media and have a tremendous impact on the public’s view of the pharmaceutical industry.

These issues of increasing costs, ethical concerns for practitioners, as well as actual fraud and abuse cases led to several policy changes. In 1992, the American Medical Association presented its policy, *Gifts to Physicians from Industry*, clearly outlining acceptable procedures for receiving gifts with the intention to provide consistent principles of medical ethics for physicians and other parties in the health care sector (AMA, 1998). A year later, the AMA followed this policy with another on Continuing Medical Education (CME), which discouraged physicians from accepting compensation for time or expenses for participating in any CME activity other than one sponsored by their employer. The FDA presented its *Guidance for Industry: Industry-Supported Scientific and Educational Activities* in 1997. This Guidance is intended to ensure that programs or activities sponsored by the pharmaceutical industry are not

promotional in nature by controlling the content and selection of material and requiring financial disclosure of involved parties (FDA, 1997). In 2002 (and revised 2009), the Pharmaceutical Research and Manufacturers of America (PhRMA) presented a code of actions for ethical interactions with healthcare professionals. The PhRMA code establishes a foundation for the prescribers' and drug representatives' relationship which is based on providing information that is accurate and not misleading, does not make unsubstantiated claims, clearly balances the risks and benefits of the product, and complies with all other FDA regulations (PhRMA, 2008). It also prevents any gifts and limits meals provided during any presentations, either promotional or educational, to being of modest value, not part of any entertainment or recreational event, and provided in a manner and environment appropriate for the communication (i.e. office or hospital setting). Lastly, the PhRMA Code prevents direct financial support for continuing education except through a third party company or sponsor of the event who independently decides on the material presented. Finally, The Office of the Inspector General in April 2003 presented *The Compliance Program Guidance for Pharmaceutical Manufacturers*. This Guidance contains suggestions for manufacturers to create internal controls to promote voluntary compliance with current state and federal statutes and regulations (OIG, 2003). According to Michael Labson (2003), an attorney who represents PhRMA and several research companies, the endorsement of the PhRMA Code by the OIG essentially establishes "the legal requirements that govern health care marketing, and ensures that it will be followed."

There have been multiple impacts from these policy changes. Most notably are restrictions placed on the pharmaceutical industry's marketing strategies. A survey of over 150 pharmaceutical executives in 2011 found that 69% felt the market was more restrictive to access and 69% found a decrease in their sales-force access to physicians. Additionally, 50% of

respondents plan on increasing their budget for marketing to social media sites, mobile technologies and electronic detailing (Booz & Company, 2012). Event planners for health care educational events are financially struggling and planning for a decrease in both sponsor and participant attendance (Collins, 2008).

Many academic healthcare centers followed the recommendations presented in the article *Health Industry Practices that Create Conflict of Interest: A Policy Proposal for Academic Medical Centers* (Brennan, et al., 2006) and formally closed their doors to pharmaceutical representatives (Sell, 2009). According to Rothman and Chimonas (2008) over 25 public and private medical centers and several large health care organizations, such as the Veterans Administration, Kaiser Permanente and Henry Ford Health Systems, have all adopted a strict limited access to drug company representatives. One study conducted in 2011 looked at the AccessMonitor database which tracks physician and sales representative interactions (Chressanthis, Khedkar, Jain, Poddar, & Seiders, 2012). They found access to be most challenging in New England, the Upper Midwest, parts of the Mountain West and the West Coast. The data also showed an increase in restriction from 2008 to 2011 (noted by a decrease in high access physicians from 74% to 55%). Additionally, those physicians who had greater restriction to sales representatives were correlated with restricted flow of medical information and consequently a reduction in their adoption of new drugs. Chressanthis et al. (2012) also found a significant difference between primary care physicians and specialists. Specialists embraced new medications sooner and more frequently than their primary care physicians (PCPs) counterparts, suggesting the need for additional information and education for PCPs.

Since these recent changes in the pharmaceutical industry, especially the changes in detailing practices, there has been very little data about the direct effect on health care

prescribers' practices and its direct and indirect effects on patients. Although the primary endpoints for the changes in regulations (ethical and financial implications of prescriber-representative interaction) can be measured, secondary endpoints are not as easily seen, specifically the effect of the regulations on prescribers' knowledge of new medications and updated information on existing products and the resultant clinical outcomes for their patients.

In light of these issues, a pilot survey was planned to better capture the current access and knowledge of healthcare prescribers to new medications. The purpose of the study was to determine if changes in direct access to detailing has had an impact on internal medicine prescribers' knowledge of new information regarding medications. Furthermore, this study planned to assess current avenues prescribers use for learning about new drugs, whether prescribers felt that they have sufficient, timely information to safely prescribe medications and lastly if the prescriber was practicing prior to 2007, to what extent did they feel that pharmaceutical representatives detailing aided in new medication instruction. It was predicted that prescribers in an academic medical center, who have extremely limited access to pharmaceutical representatives, would have limited knowledge of new medications.

Chapter 2: Research Design and Methodology

This study involved a web-based, self-administered survey of internal medicine prescribers at the University of Michigan Medical Center, which has a strict vendor policy and prohibits the promotion of any drugs or devices to its staff. A descriptive research designed was used. The survey was emailed to 84 internal medicine physicians, nurse practitioners, and physician assistants. The first page of the survey contained the informed consent which detailed the purpose of the study, what participation involved, and risks associated with the study (See Attachment A). To proceed to the survey, respondents had to indicate that they provide consent to participate. The survey contained questions pertaining to access of information on new drugs and/or significant drug updates. The survey took 5-10 minutes and no personally identifying information was collected.

IRB approval was obtained by Eastern Michigan University prior to distribution of the survey (See Attachment B). Permission was also obtained by the medical directors of the Adult Medical Observation Unit and Hospitalists program at University of Michigan (See Attachments C). Participants were notified that involvement was completely voluntary and they would have to actively connect to a link to access the survey after reading and agreeing to the informed consent. Data collected was anonymous and encrypted. Following the completion of the study and all analyses, all data will be destroyed.

The survey consisted of fourteen questions (see Attachment A). The first four questions were demographic in nature. These questions gained information about degree status, years in practice, prescribers' age and patient population they care for. One question was designed to obtain information about how prescribers' access new drug information (conferences, journals,

peers/word of mouth, Internet/web sites, phone applications, email alerts or other). Four questions were devoted to testing prescribers' knowledge of two medications and the prescriber's comfort level of prescribing with their current knowledge of the medication. The medications were chosen from the FDA website for medications approved from January-March 2013 (approximately one year prior to the study start). The medications were selected based upon a disease process that would be universally managed by an internal medicine physician. Based on these criteria, Invokana™ (canagliflozin) and Suprax® (cefixime) were selected. Invokana™ is an oral medication for the treatment of Type II diabetes that was approved by the FDA on March 29, 2013. Suprax® is a cephalosporin antibiotic approved for both adults and pediatric use on March 26, 2013. From 1980-2003 Suprax® was used for treating *Neisseria gonorrhoeae* (Center for Disease Control, 2008). It was removed from the market by Wyeth Pharmaceuticals once its patent expired due to its small volume of sales. Lupin Pharmaceuticals purchased the license and began marketing the drug as a branded generic (Golani, 2011). This drug was chosen to compare prescriber's knowledge and comfort level of the drug prior to 2003 (with detailing) and those practicing after (without detailing) to determine if there were any differences. The last four questions were devoted to those prescribers that were in practice prior to the institution of the PhRMA code. The first question was a yes/no. If the participant answers "no" the survey ended. If the participant answers "yes" an additional three questions were included with a Likert scale response. Options were provided ranging from 1-5. The first question concerned how helpful the prescriber found the in-service education by the pharmaceutical representative. This was followed by two additional questions of how the in-service education impacted their patient care decisions and if they found the in-service education helpful for their current practice. The last

question was open ended for comments. Univariate and bivariate analyses were conducted to analyze the data.

Chapter 3: Results

The survey was sent to 84 internal medicine prescribers from the Medical Faculty Hospitalist group and the Adult Medical Observation Units at the University of Michigan. The participants of the study included 41 subjects (See Table 1), which was a 48.8 % response rate. The majority (92.7%, n=38) were physicians while 7.3% (n=3) were physicians assistants. The majority of the participants were under the age of 40 (68.3%, n=28) and almost all were under the age of 50 (87.8%, n=36). More than half of the sample had been practicing for 10 years or less (65.8%, n=27). Most participants worked with an adult population (82.9%, n=34) or both adults and children (14.6%, n=6); only one participant worked solely with children (2.4%).

Frequencies were calculated to describe the avenues participants used to learn about new information about medications (See Table 2). The three most popular methods involved “traditional” information channels including conferences (82.9%, n=34), journals (80.5%, n=33), and word of mouth (85.4%, n=35). Newer electronic avenues were also used but less frequently; these included email (36.6%, n=15), Internet (70.7%, n=29), and mobile apps (22.0%, n=9). T-tests were conducted to determine whether participants who used each of the different modalities of information differed from those who did not use them in terms of age and years of practice; no significant differences between the groups were obtained. Furthermore, chi-square tests were conducted to determine whether participants who used the avenues differed from those who did not in terms of the degree of the participant (MD or NP vs. physician’s assistant) and patient population in which they practice (adult, pediatric or both). Physician assistants were less likely than physicians to obtain information by word of mouth (33.3% vs 86.6%, $\chi^2 = 6.2$, $p < .05$). However, there were only 3 physician assistants included in these analyses, and thus the findings should be taken with caution. No differences were found based on patient population.

Table 1

Demographic Characteristics of Participants Included in the Analyses

	Number	Percentage
Degree		
MD	38	92.7
NP	0	0
PA	3	7.3
Age		
28-40 years	28	68.3
41-50 years	8	19.5
50 years +	5	12.2
Years of Practice		
< 10 years	27	65.8
> 10 years	14	34.2
Patient Population		
Adults	34	82.9
Pediatrics	1	2.4
Both	6	14.6

Note: Total number of respondents is 41.

Table 2

Frequency of Use of Modalities to Learn About New Medications

Modality	Number	Percentage
Conferences	34	82.9
Journals	33	80.5
Word of Mouth	35	85.4
Email	15	36.6
Internet	29	70.7
Mobile Applications	9	22.0

Note: Percentages do not equal 100% as respondents could select all that apply.

Table 3 presents the results regarding participants' familiarity and comfort prescribing two recently approved prescription drugs, specifically Suprax® and Invokana™. Overall, participants were unfamiliar with the two medications. Nine out of 10 participants (90.2%, n=37) reported that they were "not at all familiar" with Invokana™ and a similarly high number (87.8%, n=36) reported being "not at all comfortable" prescribing the medication. Familiarity and comfort with Suprax® was higher than with Invokana™. Approximately half of participants (51.2%, n=21) reported being at best "somewhat familiar" with the medication and a similar number (48.8%, n=20) reported being at best "somewhat comfortable" with prescribing the medication. T-tests were performed to determine if participants' background in terms of age, years in practice, degree, and patient population were related to the familiarity and comfort in prescribing these medications, and no significant differences were shown.

Table 3

Number and Percentage of Respondents who were Familiar and Comfortable with Prescribing Invokana™ and Suprax®.

	Invokana™		Suprax®	
	Number	Percentage	Number	Percentage
Familiar with				
Not at all	37	90.2	8	19.5
A little	3	7.3	8	19.5
Somewhat	1	2.4	14	34.1
Moderately	0	0	6	14.6
Very much	0	0	5	12.2
Comfortable with				
Not at all	36	87.8	6	14.6
A little	3	7.3	5	12.2
Somewhat	2	4.9	9	22.0
Moderately	0	0	13	31.7
Very much	0	0	8	19.5

Analyses were also conducted to determine the participants' perceptions of whether in-service educational resources were needed and perceptions of drug representatives (if the participant had been practicing prior to 2007). When asked about whether pharmaceutical in-service education would be helpful, the 21 participants who had been practicing prior to 2007 were more likely than the 19 who had not to report that in services would be valuable (practicing

prior=2.57, not practicing prior=1.89, $t= 1.85$, $p<.10$); these results showed a trend towards significance, suggesting further research is warranted prior to drawing conclusions.

Examination of the ten open ended responses about drug representatives indicated that those who had been practicing prior to 2007 had a more nuanced perception, with 50% of those respondents reporting positive benefits. While both groups tended to note the possibility of drug representatives providing biased information, those who had actual experience with drug representatives noted some ways in which they were valuable. For example, the following were stated by physicians who had been practicing prior to 2007:

“In the past I found Drug Reps to be honest. They gained favor by just being more present. The bias for me was that the generic medications did not get represented.”

“Pharmaceutical reps come with bias of selling but do provide insight about the drug mechanisms of action, data on efficacy, precautions needed which are helpful. This is now missing, esp. when you read an app – you are sure re: most common side effects – as all get listed in no particular order”

In contrast, of the ten open ended responses the two participants who had not been practicing prior to 2007, and had no direct experience with pharmaceutical representatives, were more likely to have singularly negative views. For example,

“Drug reps might have useful theoretical info, but I don’t believe that they have much knowledge applicable to real life patient care. And if they’re pushing a med, it’s probably new and expensive and my patients can’t afford it.”

Examination of the follow-up questions about the experiences of those who had been practicing prior to 2007 provided additional information about how the presence of the drug representative was perceived by prescribers (See Table 4). Among this group, 38.1% (n=8)

found in services by drug representatives to be moderately or very helpful, 33.3% (n=7) found the services to be somewhat helpful, and 28.6% (n=6) found the services to be “not at all” or “a little” helpful. In terms of influencing care, 66.7% (n=14) reported that drug representatives had “no influence” or “a little.”

Table 4

Number and Percentage of Participants Practicing Prior to 2007 who Report Value of In-service Education and Influence on Patient Care.

	Number	Percentage
Value of Service		
Not at all	3	14.3
A little	3	14.3
Somewhat	7	33.3
Moderately	6	28.6
Very much	2	9.5
Influence on Patient Care		
Not at all	5	23.8
A little	9	42.9
Somewhat	6	28.6
Moderately	0	0
Very much	1	4.8

Note: The total number of participants who had been practicing prior to 2007 is 21.

Chapter 4: Discussion

The purpose of the study was to evaluate the impact of the lack of direct detailing on prescribers' knowledge of new medications. An online survey was conducted with internal medicine prescribers at a large academic medical center who has strict vendor policies. Findings from this study support the notion that prescribers do not feel they have adequate information regarding new medications to confidently prescribe. Methods for obtaining information on new medications varied among the respondents and had no correlation between the prescriber's age and years of practice. Moreover, there were mixed opinions about the value of the pharmaceutical representatives' direct in-service education.

Results from this study indicate that prescribers are using multiple avenues to learn about new drugs in 2014, seven years following the policy change. Information about new drugs was most commonly obtained from conferences, journals and word of mouth. Technological sources (email, Internet and mobile apps) were used less frequently; however, these sources appear to be gaining in popularity. The commonly used sources (conferences, journals and word of mouth) raise concerns about the quality and breadth of the knowledge gained. All of these methods require prescribers to be active participants in seeking information about new medications. Their scope is limited by personal selectivity, financial, and potentially geographical and political access. Even more concerning is one of the most common ways physicians gather information, word of mouth. Word of mouth can be inaccurate, bias, incomplete, and could potentially cause more harm. Regardless of the manner in which healthcare providers gain their information, it is imperative that the information be timely, accurate, and complete. It behooves the medical community to ensure that the sources of this data are able to meet these standards. It is with this intent that the changes in the PhRMA code were made, but unfortunately the changes appear to

have created an atmosphere of distrust rather than cooperation and sharing of invaluable information.

Additional support for the impact of these policy changes can be seen by the responses of the prescribers' and their current knowledge and comfort with prescribing two different medications. Nine out of 10 prescribers' were not at all familiar with a new diabetic medication (Invokana™), and half of the respondents were at best "somewhat familiar" with the new cephalosporin Suprax®. Their lack of knowledge was similarly reflected in their lack of comfort in prescribing and caring for a patient on these medications. There was no correlation noted between those physicians who were practicing prior to the removal of Suprax® in 2003 and the knowledge or comfort of the drug. This suggests that the limited knowledge the clinicians did have comes from a generalized knowledge of the drug class. The results from this study about these two drugs provide specific examples as to the lack of information available for health care prescribers' and the implications for their confidence to prescribe these medications. This also brings to light the need for pro-active education of healthcare providers. This study found that the majority of the healthcare providers were not familiar with these new medications, which were approved by the FDA a year prior. Learning about a new medication by a patient admitted under your care in the hospital is not the time or place to fully appreciate the associated drug interactions and precautions.

Lastly, a trend was found amongst those prescribers' that were practicing prior to 2007 and had experience with pharmaceutical detailing in favor of the in-service education. Although, most respondents stated they were aware of bias in the material provided by the pharmaceutical representative, two-thirds found the information to be somewhat to very helpful. For example, one participant emphasized that precautions were necessary, but the encounters did provide

information about the drug mechanisms, actions, and efficacy. Overall, these findings suggest that there are inadequate resources for prescribers' to obtain information about new drugs.

Chapter 5: Conclusions and Recommendations for Further Research and Action

The ability of healthcare providers to stay up to date with new technology, medications, health trends and information is imperative. The policy changes in the past decade limiting direct access to pharmaceutical representatives have made access to this information even more difficult for prescribers. Although there may be more avenues to gain information today than several decades ago, there is an increased burden upon the provider to actively pursue and obtain the information, with potentially less oversight of the content and validity of the source. In many ways the PhRMA code was designed to protect the integrity of the information, however, many institutions have taken the guidance to an extreme and completely denied access of pharmaceutical companies to their healthcare providers without a contingency plan to fill the void of information that was left. Although pharmaceutical companies are still allowed to present continuing education material through a third party vendor, the burden falls on the clinicians to seek out and arrange the interaction, which again places the burden upon the healthcare provider. This void in educational information needs to be addressed without placing further burden upon the provider to seek out quality information.

This study was limited by its small sample size; therefore, additional studies with larger sample sizes should be conducted. Specifically, larger samples from each prescriber group (MD, PA, and NP) as well as by clinical specialty should be examined for modes and access to new medication information, as tailoring education to different healthcare providers may be necessary. A comparative study of several different types of healthcare facilities (academic, private, inpatient, or outpatient) with varying ranges in access to detailing should be explored to better identify healthcare providers knowledge of new medications and amount and type of interaction with drug representatives.

Lastly, further exploration needs to address the growing technological applications for medical information to assess for validity, ease of use, as well as detailed marketing reports of the end users. This may have more of an impact on consumers, as most healthcare prescribers' have access to regulated Internet sites through the institution in which they work.

Overall, this study has identified an increased need to provide pro-active education to healthcare prescribers about new medications in a timely, accurate and non-bias manner. Direct detailing of the pharmaceutical representative to health care prescriber's has indeed been reduced by changes in the PhRMA Code and additional resulting polices. It appears the negative aspects of detailing overshadowed the positive, and the medical field has now swung the pendulum in the other direction and has become too restrictive. Detailing provided an invaluable exchange of information, which has now been lost to several institutions, especially academic medical centers that have a stricter "no vendor policy". This void was intended to be filled by an unbiased third party to provide education. Although, this study clearly shows the present system is not meeting the current needs of healthcare prescriber's. Perhaps, future studies need to address the ease of access, timeliness, and relevance of content by third party continuing education providers, especially at academic medical centers.

References

- AMA. (1998, June). E-8.061 Gifts to Physicians from Industry. Retrieved November 10, 2013, from American Medical Association: <https://ssl3.ama-assn.org>
- Booz & Company. (2012, February). Pharmaceutical Sales and Marketing Trends 2011. Retrieved December 10, 2013, from National Analysts Worldwide: <http://www.booz.com/media/file/BoozCo-Pharmaceutical-Sales-Marketing-Trends-National-Analysts-2011.pdf>
- Brennan, T., Rothman, D., Blank, L., Blumenthal, D., Chimonas, S., Cohen, J., . . . Smelser, N. (2006, January 25). Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers. Retrieved November 10, 2013, from JAMA: <http://www.jama.jamanetwork.com>
- Brody, H. (2009, August 28). Pharmaceutical Industry Financial Support for Medical Education: Benefit, or Undue Influence? Retrieved December 10, 2013, from The Journal of Law, Medicine & Ethics: <http://www.onlinelibrary.wiley.com>
- Campbell, E., Rao, S., DesRoches, C., Iezzoni, L., Vogeli, C., Bolcic-Janovik, D., & Miralles, P. (2010). Physician Professionalism and Changes in Physician-Industry Relationships From 2004-2009. *Archives of Internal Medicine*, 1820-1826. Retrieved from American Medical Association.
- Center for Disease Control. (2008, April 25). Availability of Cefixime 400mg Tablets---United States, April 2008. Retrieved from CDC MMWR: <http://www.cdc.gov>
- Centers for Medicare & Medicaid Services. (2012). National health expenditures, average annual percent change, and percent distribution, by type of expenditure: United States, selected years 1960-2010 . Retrieved December 8, 2013, from Centers for Disease Control and Provention: <http://www.cdc.gov/nchs/data/hs/2012/113.pdf>
- Chimonas, B. T. (2007, January 17). Physician and Drug Representatives: Exploring the Dynamics of the Relationship. Retrieved November 10, 2013, from JGIM: <http://www.ncbi.nlm.gov>
- Chimonas, S., & Rothman, D. (2005, July/August). New Federal Guidelines For Physician-Pharmaceutical Industry Relations: The Politics Of Policy Formation. Retrieved October 4, 2013, from Health Affaris: <http://www.healthaffairs.org>
- Chressanthis, G., Khedkar, P., Jain, N., Poddar, P., & Seiders, M. (2012, July). Can Access Limits on Sales Representatives to Physicians Affect Clinical Prescription Decisions? A Study of Recent Events With Diabetes and Lipid Drugs. Retrieved November 10, 2013, from The Journal of Clinical Hypertension: <http://www.onlinelibrary.wiley.com>

- Collins, M. (2008, September 1). New PhRMA Code: the Impact on Medical Meetings. Retrieved November 10, 2013, from Meetings Net: <http://meetingsnet.com>
- Daemmrich, A. A., & Bowden, M. (2005, June 20). Emergence of Pharmaceutical Science and Industry: 1870-1930. Retrieved December 10, 2013, from Chemical & Engineering News: <http://pubs.acs.org/cen/coverstory/83/8325/8325future.html>
- Dana, J., & Lowenstein, G. (2003, July 9). A Social Science Perspective on Gifts to Physicians From Industry. Retrieved December 8, 2013, from Journal of the American Medical Association: <http://www.jama.jamanetwork.com>
- Department of Justice. (2013, November 4). Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations. Retrieved December 10, 2013, from The United States Department of Justice: <http://www.justice.gov/opa/pr/2013/November/13-ag-1170.html>
- Department of Justice. (2013, April 26). United States Files Complaint Against Novartis Pharmaceuticals Corp. for Allegedly Paying Kickbacks to Doctors in Exchange for Prescribing Its Drugs. Retrieved December 10, 2013, from The United States Department of Justice: <http://www.justice.gov/opa/pr/2013/April/13-civ-481.html>
- FDA. (1997, November). Guidance for Industry: Industry-Supported Scientific and Educational Activities. Retrieved November 10, 2013, from Food and Drug Administration: <http://www.fda.gov>
- Golani, S. (2011). Corporate Divas. New Delhi: Penguin Books India.
- Grande, D. (2009, September 12). Limiting the Influence of Pharmaceutical Industry Gifts on Physicians: Self-Regulation or Government Intervention? Retrieved November 10, 2013, from JGIM: <http://www.ncbi.nlm.gov>
- Kornfield, R., Donohue, J., Berndt, E., & Alexander, G. (2013, March 4). Promotion of Prescription Drugs to Consumers and Providers, 2001-2010. Retrieved October 4, 2013, from PLOS Medicine: <http://www.ncbi.nih.gov>
- Labson, M. (2003, July). The PhRMA Code: A New Roadmap for Industry-Physician Interactions. Retrieved November 10, 2013, from American Medical Association: Virtual Mentor: <http://www.virtualmentor.ama-assn.org>
- McKinney, P., Schiedermayer, D., Lurie, N., Simpson, D., Goodman, J., & Rich, E. (1990, October 3). Attitudes of Internal Medicine Faculty and Residents Towards Professional Interaction with Pharmaceutical Sales Representatives. Retrieved December 8, 2013, from Journal of the American Medical Association: <http://jama.jamanetwork.com/>

- NCSL. (2013). Pharmaceutical Costs and Pricing. Retrieved December 10, 2013, from National Conference of State Legislatures:
<http://www.ncsl.org/research/health/pharmaceuticals.aspx>
- Nelson, J. (1990, August 8). A piece of my mind. A snorkel, a 5-iron, and a pen. Retrieved December 8, 2013, from PubMed: <http://www.ncbi.nlm.nih.gov/>
- OIG. (2003, May 5). OIG Compliance Program Guidance for Pharmaceutical Manufacturers. Retrieved December 10, 2013, from Federal Register: <http://www.federalregister.gov>
- Oldani, M. (2008, January 8). Thick Prescriptions: Toward an Interpretation of Pharmaceutical Sales Practices. Retrieved December 8, 2013, from Medical Anthropology Quarterly:
<http://www.onlinelibrary.wiley.com>
- PhRMA. (2008, July). Code on Interactions with Healthcare Professionals. Retrieved November 10, 2013, from Pharmaceutical Research and Manufacturers of America:
<http://www.phrma.org>
- Rosenthal, M., B., E. R., Donohue, J., Frank, R., & Epstein, A. (2002, February 14). Promotion of Prescription Drugs to Consumers. Retrieved December 8, 2013, from New England Journal of Medicine: <http://www.nejm.org>
- Rothman, D., & Chimonas, S. (2008, September 3). New Developments in Managing Physician-Industry Relationships. Retrieved from Journal of American Medical Association:
www.jama.jamanetwork.com
- Schetky, D. (2007). Conflicts of Interest Between Physicians and the Pharmaceutical Industry and Special Interest Groups. Retrieved November 10, 2013, from Elsevier Saunders:
<http://www.sciencedirect.com>
- Sell, L. (2009, August 28). Drug Reps Off Campus! Promoting Professional Purity by Suppressing Commercial Speech. Retrieved December 10, 2013, from Journal of Law, Medicine & Ethics: <http://www.onlinelibrary.wiley.com>
- Sillup, G., Trombetta, B., & Klimberg, R. (2010, November 6). The 2002 PhRMA Code and Pharmaceutical Marketing: Did Anybody Bother to Ask the Reps? Retrieved December 10, 2013, from Taylor & Francis Online: <http://www.tandfonline.com>
- Spurling, G., Mansfield, P., Montgomery, B., Lexchin, J., Doust, J., Othman, N., & Vitry, A. (2010, October 7). Information from Pharmaceutical Companies and the Quality, Quantity, and Cost of Physicians' Prescribing: A Systematic Review. Retrieved October 4, 2013, from PLOS Medicine: <http://www.ncbi.nlm.nih.gov>

- The PEW Charitable Trusts. (2013, November 11). Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients. Retrieved from The Pew Charitable Trusts: www.pewtrusts.org
- Thomas, K., & Schmidt, M. (2012, July 2). Glaxo Agrees to Pay \$3 Billion in Fraud Settlement. Retrieved from The New York Times: www.nytimes.com
- Tsougarakis, G., & Turk, J. (2008, August 18). The Impact of Revisions To The PhRMA Code. Retrieved November 10, 2013, from Law 360: <http://www.law360.com>
- Walsh, R. (2010, September 10). A history of: The pharmaceutical industry. Retrieved December 8, 2013, from PharmaPhorum: <http://www.pharmaphorum.com/articles/a-history-of-the-pharmaceutical-industry>
- Watkins, C., Moore, L., Harvey, I., Carthy, P., Robinson, E., & Brawn, R. (2003, May 31). Characteristics of general practitioners who frequently see drug industry representatives: national cross sectional study. Retrieved December 10, 2013, from British Medical Journal: <http://www.ncbi.nlm.nih.gov>
- Wazana, A. (2000, January 9). Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? Retrieved December 8, 2013, from Journal of the American Medical Association: <http://www.jamanetwork.com>

Attachment A: Survey Questions

Prescribers Knowledge of New Medications

INFORMED CONSENT

Project Title: Internal Medicine Prescribers' Knowledge of Medications and Effect of 2007 PhRMA Code

Investigator: Patricia J. Brink, Eastern Michigan University

Co-Investigator: Irvin G. Martin, PhD Chair

Purpose of the Study: I am a graduate student at Eastern Michigan University. This survey is part of a master's thesis and involves research. The purpose of this research study is to gain a better understanding of the relationships between health care providers who can write prescriptions (prescribers'), their knowledge of new medications and access to pharmaceutical sales representatives.

Procedure: This email has been sent to you for participation in a research study. The purpose of the study is to gain information about how prescribers acquire knowledge about new medications. Information is included on who to contact should you have additional questions. If you are in agreement with participation in this study, your consent will be noted by checking the appropriate box below. The survey contains 14 questions. One is open ended for your comments; all other questions are check boxes. You will be asked to complete questions about your demographic information, including your degree, age, and years of practice. Additional questions will be asked about where you obtain information about new medications and your opinions about in-services provided by pharmaceutical representatives.

The email will be sent out twice, two weeks apart. The survey only needs to be submitted once. Other than the two emails, this is a one-time interaction for completion and submission of the questionnaire. No follow up interactions will be performed. The approximate total time to complete the questionnaires should be about 5-10 minutes.

Confidentiality: All information collected is anonymous. At no time will your name be associated with your responses. Information will be encrypted prior to the investigators review. All related materials will be kept in locked file cabinets in the researcher's office and electronic data will be stored on a password-protected computer. All data will be destroyed once the study is complete.

Expected Risks: There are no foreseeable risks to you by completing this survey, as all results are anonymous and will be kept completely confidential.

Expected Benefits: There will be no direct personal benefit to you, but your participation will

contribute to our understanding of how prescribers' get information about new medications.

Voluntary Participation: Participation in this study is voluntary. You may choose not to participate. If you do decide to participate, you can change your mind at any time and withdraw from the study without negative consequences.

Use of Research Results: Results will be presented in aggregate form only. No names or individually identifying information will be revealed. Results may be presented at research meetings and conferences, in scientific publications, and as part of a master's thesis being conducted by the principal investigator.

Future Questions: If you have any questions concerning your participation in this study now or in the future, you can contact the Principle Investigator, Patricia Brink at pbrink1@emich.edu, or 734-255-3987.

This research protocol and informed consent document has been reviewed and approved by the Eastern Michigan University Human Subject Review Committee for use from March 1, 2014 to April 30, 2014. If you have any questions about the approval process, please contact CHHS-HSRC, Chair Dr. Jayne Yatzak, jyatzak@emich.edu, 734-487-0461.

Print this screen for future reference.

1. Consent to Participate: I have read or had read to me all of the above information about this research study, including the research procedures, possible risks, side effects, and the likelihood of any benefit to me. The content and meaning of this information has been explained and I understand. All my questions, at this time, have been answered. I hereby consent and do voluntarily offer to follow the study requirements and take part in the study.
 No, I choose not to participate in this research study
 Yes, I choose to participate in this research study
2. What is your degree?
 MD or DO
 PA
 NP
3. How many years have you been practicing?
 0-5
 5-10
 10-15
 15-20

- 20-25
- 25+

4. What is your age?

- 28-35
- 36-40
- 41-45
- 46-50
- 51-55
- 56-60
- 60+

5. What patient population do you work with?

- Adults*
- Pediatrics*
- Both*

6. How do you get information on new medications? Check all that apply.

- Conferences*
- Journals*
- Peers or word of mouth*
- Internet or web sites*
- Mobile phone applications*
- Email alerts*
- Other*

Please specify:



7. Are you familiar with Invokana™ canagliflozin?

- Not at all*

- A little*
 - Somewhat*
 - Moderately*
 - Very much*
8. Based on your current knowledge of Invokana™ canagliflozin, how comfortable would you be prescribing or caring for a patient on this medication?
- Not at all*
 - A little*
 - Somewhat*
 - Moderately*
 - Very much*
9. Are you familiar with Suprax® cefixime?
- Not at all*
 - A little*
 - Somewhat*
 - Moderately*
 - Very much*
10. Based on your current knowledge of Suprax® cefixime, how comfortable would you be prescribing or caring for a patient on this medication?
- Not at all*
 - A little*
 - Somewhat*
 - Moderately*
 - Very much*
11. Were you practicing when pharmaceutical representatives provided in-services on new medications?
- Yes*
 - No*
12. How helpful did you find the in-services for providing information about new medications?
- Not at all*

- A little*
- Somewhat*
- Moderately*
- Very much*

13. How much did the in-services impact your patient care decisions?

- Not at all*
- A little*
- Somewhat*
- Moderately*
- Very much*

14. Would you find in-services by drug representatives helpful in your current practice?

- Not at all*
- A little*
- Somewhat*
- Moderately*
- Very much*

15. Comments:

Attachment B: IRB Approval Letter

EASTERN
MICHIGAN UNIVERSITY
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COLLEGE of HEALTH & HUMAN SERVICES
www.emich.edu/chhs

March 13, 2014

Patricia Brink
c/o Irwin Martin
Eastern Michigan University
School of Health Sciences
313 Marshall
Ypsilanti, Michigan 48197

RE: CHHS-HSRC #1147

Dear Patricia Brink:

Congratulations! After careful review, your proposal "Internal Medicine Prescribers' Knowledge of Medications and Effect of 2007 PhRMA Code" has been accepted by the College of Health and Human Services Human Subjects committee. We stress that you do not stray from your proposed plan.

The current version of your submission is available here:

http://commons.emich.edu/cgi/preview.cgi?article=1147&context=chhs_hs

Good luck with your research effort.

Sincerely,



Jayne Yaczak, PhD, OTRL
Chair, CHHS-HSRC
Eastern Michigan University
Ypsilanti, Michigan 48197

Attachment C: Permission to Access Email Lists



The University of Michigan

Dr. Robert Chang
Medical Faculty Hospitalist Program
Taubman Center Floor 3 Rm 3119
1500 E Medical Center Dr Spc 5376
Ann Arbor, MI 48109-5376
March 10, 2014

Eastern Michigan University
Institutional Review Board
900 Oakwood St
Ypsilanti, MI 48197

Dear IRB Committee Members:

Please accept this letter as my consent to allow Patricia Brink access to the email lists of medical providers for the Medical Faculty Hospitalist team. I am aware that the purpose for the access is to administer a survey as part of the research study "Internal Medicine Prescribers' Knowledge of Medications and Effect of 2007 PhRMA Code", and provide my support for this project.

Sincerely,

A handwritten signature in blue ink, appearing to read "Robert Chang".

Dr. Robert Chang
Director Medical Faculty Hospitalists



**Department of
Emergency Medicine**
1500 E. Medical Center Dr., SPC 5303
Ann Arbor, Michigan 48109-5303
(734) 936-6020
FAX (734) 763-7228

**EMERGENCY
MEDICINE**

Robert W. Neumar, MD, PhD
Professor & Chair

March 4, 2014

Marie M. Lozon, MD
*Interim Associate Chair,
Clinical Operations*

Eastern Michigan University
Institutional Review Board
900 Oakwood St
Ypsilanti, MI 48197

Sally A. Santen, MD, PhD
Associate Chair- Education

John G. Younger, MD, MS
Associate Chair - Research

Dear IRB Committee Members:

Laura R. Hopson, MD
Residency Program Director

F. Michael Jaggi, DO
*Division Director
Hurley Medical Center*

Nicole Stroufe, MD
*Interim Division Director
and Service Chief
Children's Emergency Services*

Michele Carney, MD
*Director, Pediatric Emergency
Medicine Fellowship*

Steven L. Kronick, MD, MS
*Service Chief
Adult Emergency Department*

Jason J. Ham, MD
*Director, Adult Medical
Observation Unit*

Peter L. Forster
Department Administrator

Please accept this letter as my consent to allow Patricia Brink access to the email lists of medical providers for the Adult Medical Observation. I am aware the purpose of the access is to administer a survey as part of the research study "Internal Medicine Prescribers' Knowledge of Medications and Effect of 2007 PhRMA Code", and provide my support for this project.

Sincerely,

Jason Ham, MD
Director
Adult Medical Observation Unit

University of Michigan
500 E. Medical Center Dr., SPC 5303
Ann Arbor, Michigan 48109-5303

Children's Emergency Services
C.S. Mott Children's Hospital, Floor 2
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