The impact of pharmaceutical industry salesperson regulations, guidance statements, and laws on their sales behaviours

A taxonomy with managerial insights

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Abstract

Purpose – The purpose of this research is to develop a taxonomy of the impact of sales process regulations, guidance statements and laws (henceforth, referred to as "regulations") on sales behaviours within the pharmaceutical industry, particularly as it relates to those within the USA.

Design/methodology/approach – Given the large number of regulations, guidance statements and laws and sales behaviours that comprise the domain of this study, this research uses a "multicenter, parallel-arm clinical trial data gathering method". This approach aggregated or "stacked" the responses from three individual questionnaires; 7,493 total observations generated by 381 respondents were analyzed.

Findings – The analysis produced a six-cluster solution of regulations, guidance statements and laws indicating distinct taxonomic structures of items that affect selling activities.

Research limitations/implications – The research was conducted with a single firm in the USA. Therefore, results may not be applicable to other geographical areas, firms and industries.

Practical Implications – The knowledge of which behaviours are perceived by the salespeople to be impacted by what regulations, guidance statements and laws provides managers with a useful tool to sort their own companies' regulations on the basis of the classification scheme.

Originality/value – This paper provides a novel taxonomic approach to organize sales activities affected by regulations, guidance statements and laws which provides a look at the unintended consequences of the item not compliance. Additionally, it uses a research methodology relatively unknown to social science inquiry.

Keywords Taxonomy, Governmental regulations, Industry regulations, Pharmaceutical sales, Sales behaviours

Paper type Research paper

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Introduction

How do regulations, guidelines and laws affect the way salespeople do their jobs? This is an important and largely unexplored question which has not been adequately

addressed by previous researchers. Although considerable research has been devoted to regulation of business at the firm level, companies need to understand the impact of regulations on the selling environment to evaluate potential opportunities and threats during the decision process (Jones *et al.*, 2005). Regulations, guidelines and laws intended to control selling activities are in some cases not industry specific. Numerous selling activities are regulated in telecommunications, real estate, energy, tobacco, pharmaceuticals and financial services (Stremersch and Lemmens, 2009). For example, there have always been more general regulations prohibiting certain types of activities such as bait and switch or activities perceived as fraud, and many sales activities come under common law protection in legal jurisdictions where that is appropriate. The rationale for regulating various selling practices has been attributed to an increase in scrutiny by industry groups, federal regulators and consumer watchdogs on the practice of promotion and personal selling. This increased scrutiny has resulted in a labyrinth of new laws, the issuance of revised rules and the creation of specific agencies designed to enforce compliance (Danzon *et al.*, 2005).

In the USA, many companies are faced with growing numbers of regulations with which they must comply. In general, there are one or more government agencies that oversee virtually every part of a company's organizational chart. Regulations are particularly common in the areas of employment, health and safety, environmental protection and licensing of businesses: Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), Equal Employment Opportunity Commission (EEOC) and the Federal Trade Commission (FTC) are examples of agencies responsible for regulating such areas. Other parts of the world such as the European Union group of countries have similar regulatory authorities and in many cases even a higher degree of regulation.

Costs associated with regulatory compliance have been reported to cause a significant burden on companies (Becht *et al.*, 2008; Hahn and Tetlock, 2008; Laeven and Levine, 2009; Nicoletti and Pryor, 2006; Weidenbaum, 1998). The seemingly widespread growth of government regulations placed on businesses continues to generate noticeable concern in the USA. Carey (2014) has documented the rules as published in the federal register. While the publication of rules was the highest in the late 1970s and early 1980s, since 1985, between 3,500 and 5,000 rules' documents have been published annually in the federal register. And the rules' documents have gotten much more complex going from 12,500 pages published in 1976 to 26,417 in 2013 with a steady growth along the way.

Pharmaceutical firms in the USA have had increased regulatory pressure over the past 100 years. But prior to April 2003, selling efforts by life sciences firms such as medical device, pharmaceutical and biotechnology experienced no formal regulatory control over their selling activities. However, on May 5th, 2003, the Office of Inspector General (OIG) issued the Compliance Program Guidance for Pharmaceutical Manufacturers which changed the way many salespeople previously conducted selling activities. This program sparked the beginning of a sequence of newly outlined controls, procedures and regulations directed at selling activities and customer interactions of life sciences companies.

Most recently, additional guidelines have found their way into the selling and sales management business environment as demonstrated by the 2009 Code on Interactions with Healthcare Professionals published by the Pharmaceutical Research and

Manufacturers of America (PhRMA). The PhRMA Code is specific to the pharmaceutical industry and provides guidance related to interactions with health-care professionals regarding the marketing of products. It also provides direction on how pharmaceutical products and related pre-launch activities are to be conducted between company representatives and customers. Complying with these codes requires salespeople to change the ways in which they conduct selling activities and perform their jobs (Code on Interactions with Healthcare Professionals 2009). It should be noted that virtually all products and services worldwide face some sort of regulation (Mintzes *et al.*, 2013). However, in this case, pharmaceutical and life sciences in the USA face specific regulations and guidelines intended to guide their personal selling behaviours.

The purpose of this paper and its contribution is to report on a study within a single company in the pharmaceutical industry in the USA which sought to develop a taxonomy of the impact of regulations, guidelines and laws on sales behaviours as perceived by the sales force executing those behaviours. The contribution it makes is to provide the discovery, not justification, of the perceptions of salespeople on the impact of various controls on their behaviours in the sales process and to organize those perceptions in a taxonomy. Thus, the reader will be afforded with a view of how the impacts of regulations, guidelines and laws on behaviours cluster together.

It is important to note that this research is unique, in that it is the first to examine various controls and behavioural impacts at an individual employee level rather than looking at how the entire firm or industry copes with regulations with which they must abide. In addition, it does not focus on the intended effect of regulations that prohibit or otherwise control certain types of sales behaviours. Examples could include an alleged intended consequence of regulation to reduce health-care costs by removing actions which supposedly motivate physicians to prescribe a more expensive drug in response to promotional activities. Instead, this study focuses on unintended consequences of the regulation, guideline or law which has never been done before. Finally, it does not examine compliance, but instead examines how the various controls govern general selling behaviours.

The remainder of the paper will begin with a literature review of both sales behaviours and regulations, guidelines and laws affecting sales behaviours. Then the research design to develop the taxonomy will be outlined, results will be reported and both managerial insights and future research efforts will be suggested.

Literature review

The literature review consists of two distinct parts: a review of the regulations, guidelines and laws on pharmaceutical salespeople in the USA and a review of the concept of sales behaviours. It will be assumed that the reader is familiar with the concept of a taxonomy, and the unique research methodology will be discussed in that section.

Pharmaceutical sales regulation, guidelines and laws

As noted above, there was little or no overt "control" of the sales function in pharmaceuticals until 2003. At that point, the OIG issued a Compliance Program Guidance for Pharmaceutical Manufacturers which either prohibited or otherwise controlled and impacted sales behaviours that had been conducted previous to that legislation. In 2009, an industry trade group, the PhRMA published a code to be followed

by its members, including the company that provided the sample frame of sales representative and most other major pharmaceutical companies. In addition, California, Maine Massachusetts, Nevada, South Dakota, Vermont and the District of Columbia established regulations and laws on sales behaviour in their states. Finally, firms have also established additional self-regulations applicable to employees in their firms. In total, 94 regulations, guidance statements and laws (henceforth referred to as "regulations") can be identified, with the majority coming from OIG (36) and PhRMA (31).

In March 2010, a new law entitled the Physician Payment Sunshine Act, was adopted as part of the health-care reform bill. The so-called "Sunshine Act" required, for the first time, drug manufacturers, medical device companies and manufacturers of biologicals to report payments, and items of value provided to physicians and teaching hospitals (Centers for Medicare and Medicaid Services. 2015). Starting August 2013, under the Sunshine Act, pharmaceutical and medical device companies began reporting the name and address of any doctor who received any payments exceeding US$10 for items such as consulting fees, gifts or entertainment expenses. This Act put into law several items described in the PhRMA code which contributes to the direct impact on sales activities.

As might be imagined, these controls have a cost of compliance associated with them. While that has not been identified directly to these regulations of sales and marketing behaviours, estimates of cost include those of Crain and Hopkins (2010) who estimated the direct cost of all US Federal Regulations on business was $970bn or $8,086 per employee. This is only direct burden and would not consider indirect costs such as a reduction in the efficiency and effectiveness of salespeople in driving sales as a result of the regulations (McClaren, 2013).

These are the regulations that affect the salesperson; there are other non-regulatory entities such as the Food and Drug Law Institute which recommended disclosure legislation requiring life sciences companies (e.g. pharmaceutical, medical device and biotechnology) to report sales and marketing promotional expenses. This action is the basis for compliance professionals to ensure that sales organizations value the significance of their activities and maintain compliance. According to the Food and Drug Law Institute (Oroho *et al.*, 2011), employee training, updated policies and procedures, inspections and specific compliance strategies are necessary in today's highly regulated business environment.

As will be noted in the Methods, a process was undertaken that reduced these regulations ultimately to 59. These 59 regulations were then evaluated and applied to a series of selling behaviours.

Sales behaviours

The one fundamental trait that all salespeople have in common is the activity of selling. Regardless of the role or industry, salespeople engage in selling activities, and these activities can be identified readily. Common selling activities include: building trust with customers, sharing product information, overcoming objections, entertaining customers and gift giving (Moncreif *et al.*, 2006). Additionally, work by Reid *et al.* (1997) proposes a useful means of conceptualizing sales as an interpersonal communication process. The authors identify getting information, giving information and using information to reflect a communication orientation in selling behaviour.

Reid *et al.* (2002) operationalized and tested these measures of a salesperson's communication behaviours for different types of purchase situations. The authors reported among the six purchasing situations used in their research, namely, casual, routine low priority, simple modified re-buy, judgemental new task, complex modified rebuy and strategic new task (Bunn, 1993), differences were found in the persuasiveness of the salesperson (Reid *et al.*, 2002). This research suggests that a salesperson's selling behaviour is affected by external/environmental situations, and in this specific study, by purchase situations.

Much prior work on sales behaviours stems from the need to define salespeople and types of sales positions. Moncreif (1986), as well as a follow-up study by Moncreif *et al.* (2006), used taxonomic processes to follow-up on earlier work by McMurry (1961) and Newton (1973). This work not only derived a taxonomy of types of salespeople, but also identified over 100 different behaviours that salespeople can do. As will be noted in the Methods, these were ultimately reduced to 17 behaviours.

Within the context of pharmaceutical selling, there has been significant research on a broad variety of topics. However, little of it has focused on sales behaviours. Blackshear and Plank (1993) examined adaptive sales behaviours and their relation to sales performance, but did not provide any specificity. Ryerson (2008) examined the role of self-efficacy on sales behaviours and performance. She utilized the behaviours framework developed by Reid and Plank (1997) and found support, not only for the notion that self -efficacy is a better predictor when it is specific rather than general but also measure validation and confirmation of the usefulness of the behavioural paradigm.

The personal selling and sales management process continues to change in an attempt to adapt to the shifting demands of customers and various business conditions. The current salespeople rely on strategies such as technological advancements, consultative selling approaches and solution-selling tactics to adapt in the current competitive environment (Rapp *et al.*, 2008). Adaptive selling is defined as:

> […] engaging in planning to determine the suitability of sales behaviors and activities that will be undertaken, the capacity to engage in a wide range of selling behaviors and activities, and the alteration of sales behaviors and activities in keeping with situational considerations (Sujan *et al.*, 1994, p. 40).

Sales representatives in the pharmaceutical industry provide medical providers, physicians and pharmacists with important information related to specific prescribing facts and patient care data. Their customers depend on such information due to the widespread changes taking place in the field of medicine. Because of the volume, and intricate details related to the information shared with their customers, pharmaceutical salespeople's success is largely determined by the relationships they have made with physicians (Kara *et al.*, 2013).

Research methodology

The methodology used in this research follows that originally developed by Hickson *et al.* (1969), further developed by McKelvey (1975), and has been applied amongst the social sciences (Bunn, 1993; Homburg *et al.*, 2008; Moncreif *et al.*, 2006). The standard system used to develop empirical taxonomy contains four common steps: Step 1 identifies the variables to be used to form the categories. Variables are typically derived from several sources. For concepts not clearly specified in the literature, an iterative

process of interviews and focus groups is commonly used (Moncreif, 1986; Moncreif *et al.*, 2006). Step 2 – measure development – then produces feedback and an empirical foundation on which to specify the variables. In Steps 3 and 4, cluster analysis is applied to the data to assemble the objects based on the distinctiveness they possess. Step 5 "defines the clusters as the categories of the classification scheme – summarizing the similarities and differences across the categories" (Bunn, 1993). The goal of this research methodology is to classify the impact different regulations have on the sales process.

Defining regulations, guidelines and laws

The initial step in developing the taxonomy was to subject the entire list of 94 core regulations (OIG, PhRMA, State and firm) for thorough content analysis, remove replica items and ensure the list only includes unique controls that were relevant to the area of study and effectively represent the subject area. A panel of eight pharmaceutical industry experts (one Vice President of Sales, two Regional Sales Directors, four Critical Care Sales Representatives and one Human Resources Manager) was assembled to examine a combined list of 36 OIG, 31 PhRMA, 9 state, 2 District of Columbia and 16 firm regulations ($n = 94$). They were asked to identify duplicate items, validate only those controls that applied to the sales function and unanimously agree on a final list that accurately reflect their current industry landscape.

This iterative process of specification and comparison by eight pharmaceutical industry experts collectively identified 3 federal, 4 industry, 10 state, 2 District of Columbia and 16 firm regulations as either extensions or duplicates of existing federal and industry controls. These 35 items were therefore combined and eliminated from the finalized list which included the 10 state, 2 District of Columbia and 16 firm regulations. As a result, the final typology of combined items contains a complete parsimonious set of 59 unique controls (Appendix 1). A 60th control item which was known not to impact sales was added to the list as a validity check on the responses to the questionnaire.

Defining sales behaviours

The sales behaviours chosen for the current study were derived following the lead from several authors. The process began by using the 121 sales activities developed by Moncrief (1986) coupled with the model posited by Reid *et al.* (1997) that defined salesperson behaviours as those involved in "getting" information, "giving" information and "using" information. This view of sales behaviours is based on the observation that communication is fundamental to the selling process (Reid *et al.* 2002). Finally, the list was further refined from a series of personal interviews and focus group sessions with salespeople and sales managers representing banking (NAICS 521110), real estate (NAICS 531210), pharmaceutical (NAICS 325412) and automobile (NAICS 441110) industries because of their known high degree of regulation (García-Canal and Guillén 2008).

Initial personal interviews were conducted at a large pharmaceutical company's annual national sales meeting in central Florida. The firm's Vice President of Sales was asked to randomly select six to eight associates from his sales organization to participate in a focus group discussion regarding selling behaviours and activities. The discussion was conducted in a hotel boardroom with three pharmaceutical sales representatives, two district sales managers and one key account manager. Each of the participants was provided a list of Moncrief's (1986) 121 selling behaviours and

Reid *et al.* (1997) 31 sales behaviours. The participants were asked to "circle" the activities that they currently perform in their day-to-day job as a salesperson. Following this exercise, a "semi-structured interview" focus group was conducted that allowed the interviewer to probe and expand on the participant's responses regarding the relevance each of the activities has on their day-to-day job as a salesperson.

In addition to the focus group, a series of three phone interviews were conducted with the Vice President of a major US bank, an independent real estate agent and the owner of an automobile dealership. Consistent with the focus group procedure, the phone interviewees were asked to review the lists for relevance and application by "circling" the activities they currently perform in their daily job as a salesperson. The interviewer individually facilitated a "semi-structured interview" with each of the participants to explore and develop the participant's responses.

The results of this process and those of a pre-test of the questionnaire after its development were the creation of a final list of 17 behaviours which were classified into three groups. The following provides the listing of the sales behaviours and their origin:

Sales communication behaviors measures:

(1) Relationship building (Reid *et al.*, 1997):
- ability to ask probing questions;
- listened to the customer;
- ability to make a charismatic presentation;
- ability to work well with other people who are involved in the purchase (Adapted from industry interviews and focus groups); and
- follow-up with customer.

(2) Getting to buy (Reid *et al.*, 1997):
- gain participation and got customer involved in the sales presentation;
- ability to use analogies and similes in his/her presentation to help customer see how it relates to his/her situation;
- ability to link his/her product/service attributes to customer needs;
- could differentiate his/her product/service from the competition;
- ability to do "homework" on a customer; and
- ability to handle objections raised by customer.

(3) Planning (Moncrief *et al.*, 2006):
- search out new leads;
- pre-call planning/targeting;
- administrative activities/documentation (adapted from industry interviews and focus groups);
- conduct targeting activities;
- designing sales plan; and
- business planning.

Source: Adapted from Moncrief *et al.* (2006); Reid *et al.* (1997); industry interviews and focus groups)

Survey instrument

Once the sales activity list and the inventory of relevant regulations were created, the original survey was formulated to determine the relative significance of each known control item and its perceived effect on the identified selling activities based on pharmaceutical sales representative perceptions.

Using a seven-point Likert scale (−3 very negatively, −2, −1, 0 not at all and +1, +2, +3 very positively), respondents were asked to individually rate each regulation, guidance statement and law's effect on their ability to perform the 17 identified selling activities. A balanced (equal number of positive and negative response choices), bipolar (negative to positive: −3 to +3) scale was used due to the opposite attributes of the dimensions being studied (Schwarz, 1999). Because the notion being measured is not a range, with the low end of the scale representing the absence of the attribute, and instead uses two poles describing opposite attributes ("very negatively" and "very positively"), the bipolar numeric properties of the scale were chosen.

Because the questionnaire was developed for the purpose of this study, the instrument was pretested with pharmaceutical sales representatives. Representatives were asked to examine questions for completeness; in other words, the degree to which the list of items effectively encompassed selling activities within the categories of regulations presented. They were also invited to identify any doubt, oversight or other obscurity when answering each activity item, and also to offer ideas for survey improvement (De Vaus, 2002). To test for face and content validity, the preliminary survey containing the complete list of 60 regulations and 17 behaviours was appraised by 11 first-line sales managers and 26 sales representatives attending their company national sales meeting in northeastern USA.

In addition, one retired and four current senior-level pharmaceutical executives, who were not employees of the sample frame, appraised the survey from the perspective of specificity, readability, accuracy and internal and external validity. The final questionnaire was then approved by this group. It consisted of 59 regulations for all 17 behaviours with an additional control regulation as noted previously for validity purposes.

Randomized, multicenter, parallel-arm clinical research trial design

Given our research objective of empirically developing a taxonomy of 59 identified regulations that accurately reflect their effect on 17 recognized selling activities, the projected questionnaire would contain 1,020 items. Clearly, the issue of questionnaire length became a major concern. With such an extensive survey, "respondents might not answer properly at later stages of the questionnaire or may stop filling the questionnaire out" due to respondent fatigue and boredom (Berdie, 1989). Based on strong conceptual support predating the application of the technique, the primary investigator felt that the number of regulations and the number of selling activities could not be reduced (Hair *et al.*, 2010). Therefore, we propose a method used by medical researchers (Appel, 2006; Localio *et al.*, 2001), "randomized, multicenter, parallel-arm clinical research data gathering design", as an effective tool to reduce respondent burden without making trade-offs between the amount and quality of information obtained.

Medical researchers commonly use more than one medical centre or clinic to gather clinical trial data. This method is known as a "multicenter research trial" design. In addition, multiple treatment groups ("arms") are established to test at least two

medications (e.g. Treatment A and Treatment B). Study participants are randomly assigned to one of the respective treatments. This type of "parallel-arms" study design provides remarkable efficiency by testing multiple treatments in identical populations simultaneously (Appel, 2006). The sample size is typically similar across parallel arms such that there is no interaction linking treatments. Hence:

> […] if there is no interaction between therapies, then one can test the effect of treatment A by combining the results across groups, regardless of whether they receive treatment B. Likewise, one can test the effect of treatment B by combining the results across groups, regardless of whether they receive treatment A (Appel, 2006, p. 1360).

Due to the large number of required subjects, most large clinical trials are conducted at numerous clinical research centres.

A key requirement when conducting a multicenter, parallel-arm research trial is the establishment of patient or subject "inclusion criteria". Inclusion criteria are a method of establishing precision in your cohort. In medical research for example, the investigator might suspect that a new brand of hypertension medicine is more effective than an existing brand, but for some reason this seems to be true only for female patients who are over 60 years of age with a history of diabetes and smoking. Based on this information and the investigator's professional knowledge, he can establish specific inclusion criteria for his study. More specifically, inclusion criteria are the criteria or standards that specify which subjects are to be included in the study, lending to increased generalizability. In medical research trials, inclusion criteria may include demographic data, previous medical history, disease states being investigated and related medical conditions. "Inclusion criteria help identify suitable participants" (Agency for Healthcare Research and Quality AHRQ.gov). It is necessary that these criteria be objective and clearly defined, so that those involved in the study (or investigators trying to duplicate the study) can replicate participant inclusion decisions accurately.

In summary, randomized, multicentre, parallel-arm trials allow clinical investigators to include larger numbers of participants, longer data-gathering tools such as surveys, diverse geographic locations, inclusion of broader population groups and the ability to compare results among participants, all of which increase the generalizability of the study (Localio *et al.*, 2001). The current study is a randomized, three-arm parallel group, multicentre study assessing the effect of regulations on selling activities in pharmaceutical sales representatives. The current study mirrors randomized, multicenter, parallel-arm research trial design methodology with inclusion criteria standards in the following ways. This trial design permitted us to collect responses from three separate arms (surveys), and test and combine a large number of observations ($n = 7493$) as often gathered from multiple clinical trial sites, regardless of which survey the respondent received (Appel, 2006; Association of Clinical Research Professionals, 2012). This method is unknown in marketing research and is therefore a new alternative to the heuristic methods that are currently used when massive questionnaires are used.

Sample frame and primary data collection

Subsequently, the next phase in the process of taxonomy development is to gather data for the purpose of dividing the sample into meaningful groups. In keeping with the multicentre, parallel-arm clinical research trial methodology, a feasibility study was performed. A feasibility study is typically performed as part of the planning process

before the initiation of a new clinical study (Hagen *et al.*, 2011). One of the biggest challenges of initiating a new clinical research trial is the identification and recruitment of the appropriate patient population for the study. The feasibility sample frame for this study consisted of phone interviews with company officials from six respective pharmaceutical firms. The interviews were used to ascertain the level of response, company interest and ability to satisfy a pre-established set of participant inclusion criteria. A subject may be included in the study if all of the following criteria are met:

- currently employed by a pharmaceutical firm that is a member of the PhRMA;
- currently works as a salesperson, account representative, managed care representative or marketing manager;
- works in primary care, specialty, hospital or account management division; and
- successfully completed a training programme on "pharmaceutical promotional practices and guidelines.

All of these criteria ensure that the respondent has the interest and ability to answer the questions, both from experience and in line with their training received from the organization on obeying the regulations.

For construction of the taxonomic system described here, only pharmaceutical salespeople who met all of the above inclusion criteria were used. A sample of 489 pharmaceutical sales representatives was randomly drawn from a large US pharmaceutical firm that employs 1,162 salespeople. Each respondent was randomly assigned to one of three questionnaires. A total of 396 completed surveys were submitted via a website, generating an overall response rate of 80.9 per cent. After surveys, more than 5 per cent of missing data were removed (Little and Rubin, 1989; Acuna and Rodriguez, 2004). Thus, 381 usable surveys were left, producing an effective response rate of 77.9 per cent. The data from these 381 surveys were used to create the taxonomy. Respondent demographics are reported in Table I.

Validity and reliability of the responses

As noted above, a single control regulation was used to address the validity and reliability of the answers by respondents. The control regulation is that "speakers and their materials must clearly identify the company that is sponsoring the presentation". The focus group convened to examine the regulations agreed that this had no impact on field selling activities, but did have impact on staff marketing activities. This control regulation was linked to all 17 behaviours and asked the impact of the regulation on the various sales behaviours. All respondents (100 per cent) answered those questions as having no impact on sales activities, thus providing evidence that they also responded accurately to the other questions in the survey.

Factor analysis

To generate meaningful categories (in this study, regulations affecting selling activities), factor analysis using SPSS 17.0 was executed. An unweighted least squares model with an oblique rotation was specified to minimize further bias and allow correlation.

The scree plot indicated a three-factor model. The explained variance by the three factors was 82.6 per cent. A score of 0.4 was used as a cut-off to indicate inclusion in a

Demographic	All respondents	Questionnaire 1	Questionnaire 2	Questionnaire 3
Gender				
Female	189 (49.6%)	63 (51.2%)	65 (51.2%)	61 (46.7%)
Male	192 (50.4%)	60 (48.8%)	62 (48.8%)	70 (53.4%)
Age (years)				
18 to 25 years	90 (23.6%)	28 (22.8%)	26 (20.5%)	36 (27.5%)
26 to 35 years	100 (26.2%)	36 (29.2%)	36 (28.3%)	28 (21.4%)
36 to 45 years	86 (22.6%)	26 (21.1%)	30 (23.6%)	30 (22.9%)
46 and older	105 (27.6%)	33 (26.8%)	35 (27.6%)	37 (28.2%)
Education				
Associates degree	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Bachelor's degree	159 (41.7%)	54 (43.9%)	54 (42.5%)	51 (38.9%)
Master's degree	213 (55.9%)	65 (52.8%)	70 (55.1%)	78 (59.5%)
Doctoral degree	9 (2.4%)	4 (3.3%)	3 (2.4%)	2 (1.5%)
Education other				
MD	1	0	0	1
ARNP	5	2	2	1
RN	15	5	6	4
LPN	5	1	2	2
Paramedic (PMD)	3	1	1	1
EMT	3	1	1	1
Cath Lab Tech	1	0	0	1
Lab Tech	1	0	0	1
Selling experience				
Less than 1 year	31 (8.1%)	8 (6.5%)	11 (8.7%)	12 (9.2%)
1 to 5 years	114 (29.9%)	28 (22.8%)	25 (19.6%)	61 (46.6%)
6 to 10 years	86 (22.6%)	23 (18.7%)	35 (27.6%)	28 (21.4%)
11 to 15 years	56 (14.7%)	19 (15.4%)	26 (20.4%)	11 (8.4%)
16 to 20 years	56 (14.7%)	24 (19.5%)	20 (15.7%)	12 (9.2%)
More than 20 years	38 (9.9%)	21 (17.0%)	10 (7.9%)	7 (5.3%)
Industry experience				
Less than 1 year	51 (13.4%)	9 (7.3%)	16 (12.6%)	26 (19.8%)
1 to 5 years	114 (29.9%)	34 (27.6%)	33 (25.9%)	47 (35.9%)
6 to 10 years	96 (25.2%)	23 (18.7%)	37 (29.1%)	36 (27.4%)
11 to 15 years	53 (13.9%)	19 (18.7%)	20 (15.7%)	14 (10.7%)
16 to 20 years	47 (12.3%)	23 (18.7%)	17 (13.3%)	7 (5.3%)
More than 20 years	20 (5.2%)	15 (12.2%)	4 (3.1%)	1 (0.7%)
Company experience				
Less than 1 year	107 (28.1%)	24 (19.5%)	27 (21.3%)	56 (42.7%)
1 to 5 years	123 (32.2%)	45 (36.6%)	38 (29.9%)	40 (30.5%)
6 to 10 years	86 (22.6%)	25 (20.3%)	37 (29.1%)	24 (18.3%)
11 to 15 years	35 (9.2%)	16 (13.0%)	12 (9.4%)	7 (5.3%)
16 to 20 years	28 (7.3%)	11 (8.9%)	13 (10.2%)	4 (3.0%)
More than 20 years	2 (0.5%)	2 (1.6%)	0 (0.0%)	0 (0.0%)

(*continued*)

Table I.
Demographic profile

	All respondents	Questionnaire 1	Questionnaire 2	Questionnaire 3
Region				
Northeast	73 (19.2%)	24 (19.5%)	26 (20.5%)	23 (17.5%)
Southeast	99 (25.9%)	32 (26.0%)	33 (25.9%)	34 (26.0%)
Caribbean*	7 (1.8%)	3 (2.4%)	3 (2.4%)	1 (0.8%)
Central USA	29 (7.6%)	9 (7.3%)	9 (7.1%)	11 (8.4%)
North Central USA	64 (16.8%)	18 (14.6%)	19 (15.0%)	27 (20.6%)
Southwestern USA	40 (10.4%)	14 (11.3%)	14 (11.0%)	12 (9.2%)
Northwestern USA	56 (14.6%)	19 (15.4%)	19 (14.9%)	18 (13.7%)
Nationally (entire USA)	13 (3.4%)	4 (3.2%)	4 (3.1%)	5 (3.8%)
College major				
Marketing	137 (35.9%)	52 (42.3%)	42 (33.1%)	43 (32.8%)
Finance	35 (9.2%)	6 (4.9%)	13 (10.2%)	16 (12.2%)
Accounting	19 (5.0%)	8 (6.5%)	11 (8.7%)	15 (11.4%)
Sales	19 (4.9%)	0 (0.0%)	3 (2.4%)	1 (0.8%)
Education	11 (2.9%)	8 (6.5%)	2 (1.6%)	1 (0.8%)
Psychology	18 (4.7%)	4 (3.2%)	6 (4.7%)	8 (6.1%)
Health related	90 (23.6%)	24 (19.5%)	31 (24.4%)	35 (26.7%)
Computer science	4 (1.0%)	2 (1.6%)	2 (1.6%)	0 (0.0%)
Other	48 (12.6%)	19 (15.4%)	17 (13.3%)	12 (9.2%)

Table I.

Note: *For US FDA jurisdictions only

factor. As shown in Table II, 15 of the 17 indicators clearly loaded on one of the three factors. Variables v1, v2, v3, v4 and v16 highly loaded on factor one; variable two is characterized by variables v5, v6, v7, v8, v9 and v10; and factor three has four distinctive characteristics (v11, v12, v13 and v14). As shown, v15 and v17 have significant loadings on factors two and one, respectively. Because two variables are given on both of these factors, v15 and v17 were deleted from the analysis (Hair *et al.*, 2010). As noted in the table, the factor structure for the remaining 15 variables is now well defined, representing three distinct groups of variables that are consistent and theoretically supported for the purpose of later cluster analysis.

Description of the factors

Following the preliminary selling activity groupings, each group was examined and given a name that identifies it by the correlating nature of the selling activities (Hair *et al.*, 2010). The following three selling activity groups emerged from the factor analysis.

Factor 1. "Customer relationships through communication" (activities x1, x2, x3, x4 and x16). The five items that load onto Factor 1 relate to activities associated with building relationships with customers through relational communication skills such as asking questions, listening to the customer, ability to make a charismatic presentation and follow-up with the customer. Thus, this factor was labelled "customer relationships through communication". Building customer relationships through communication focuses on the "process" of communication (i.e. the how rather than the what), and is

Pattern Matrix Maximum Likelihood Analysis Oblimin Rotation Factor[a]	Customer relationships (Communication)	Core selling skills	Planning activities
Indicator			
Ability to ask probing questions (v1)	0.934		
Listened to Customer (v2)	0.942		
Ability to make a charismatic presentation (v3)	0.887		
Ability to work well with others involved in purchase (v4)	0.859		
Follow up with customer (v16)	0.900		
Gain participation and got customer involved (v5)		0.427	
Ability to use analogies and similes in presentation (v6)		0.628	
Ability to link product attributes to customer needs (v7)		0.565	
Could differentiate product/service from competition (v8)		0.587	
Ability to do "homework" on customer (v9)		0.592	
Ability to handle objections raised by customer (v10)		0.405	
Search out new leads (v11)			0.414
Pre-call planning/targeting (v12)			0.638
Conduct targeting activities (v13)			0.739
Designing sales plan (v14)			0.451
Business planning (v15)		*0.521*	*0.455*
Administrative activities/documentation (v17)	*0.462*	*0.505*	

Notes: Italic items represent cross-loadings and were therefore eliminated from the analysis; [a]loadings less than 0.40 are not shown and variables are sorted by highest loading

Table II. Exploratory factor analysis of sales behaviors

maximized by brief social encounters, as well as longer, ongoing interactions (Grissom *et al.*, 2003).

Factor 2. "Core selling skills" (activities x5, x6, x7, x8, x9 and x10). Factor 2 involves activities that lead prospects toward the purchase of a product or service by changing customer perceptions through reason or figurative means. This factor comprises six activities that represent foundational selling skills such as linking products to customer needs, differentiating products from the competition, having the ability to handle customer objections and the having the ability to use influential presentation skills to relate to customer needs. Factor 2 was therefore labelled "core selling skills". Salespeople make use of these "core selling skills" as a way of changing customer perceptions and influence customer decision-making.

Factor 3. "Planning" (activities x11, x12, x13 and x14). Items for Factor 3 identified selling activities that help salespeople prepare for customer interactions. The act of "planning" for a salesperson is much like "pre-game" activities for sports teams. These are the activities that build a structured understanding that salespeople use to become organized, mentally prepared and solve problems so that everything is "routine" when the salesperson is in front of a customer (game-time). Prospecting skills such as

searching out new leads, pre-call planning, conducting targeting activities and designing a sales plan are the selling activities that created Factor 3.

By factor analyzing selling activities from a regulatory impact point of view, we obtained three distinct groups (factors) which generated a novel way to organize selling activities (Appendix 2). While the three-factor solution reported here generated meaningful categories, it is important to note that the results are specific to the industry studied (pharmaceutical) and represent the interaction between identified regulations and selling activities. As such, our results do not represent generalizability and are subject to empirical validation using other industries with similar regulations.

Cluster analysis

The objective of the clustering stage was to group different regulations into descriptive classifications. Because of our large data set (7493 observations) and the need to vary large numbers of clusters, the two-step clustering approach, developed by Chiu *et al.* (2001), was chosen to develop the taxonomy. "Unlike hierarchical clustering which requires a matrix of distances between all pairs of cases, and the k-means algorithm that requires 'shuffling' objects to and from clusters" (Norusis, 2008), the SPSS two-step cluster analysis requires only a single pass of data, and can produce solutions for large data sets for varying numbers of clusters.

Within SPSS 17.0, the two-step cluster method relies on the "auto-clustering" procedure when shaping the number of clusters that represents the data sample. The calculation first measures the lowest Schwarz Bayesian Information Criterion (BIC), and then the algorithm adjusts the result by considering solutions with a large "Ratio of Distance Measure", thus generating the optimal number of clusters. Replication studies have shown that BIC and AIC in combination (two-step cluster) work better than BIC or AIC alone (SPSS, 2001). The analysis created six definite clusters which will be described and discussed in the following section.

When performing a two-step cluster analysis within SPSS 17.0, the investigator has the opportunity to supersede the "auto-clustering" default and perform any number of cluster iterations as a cross-validation procedure to corroborate the appropriate number of clusters for the final cluster solution. After five iterations, the procedure was terminated because none of the observations changed membership and the clusters were stable (Bunn, 1993).

Moreover, cross-tabulations were performed, crossing each regulation by selling activity, cluster and a number of demographic variables. The cross-tabulations added value when clarity was needed in interpreting the clusters. Group (cluster) association after this process was the final assignment of the observations to clusters. In the following results section, we list the major factors that play a part in defining each of the six clusters – either positively, negatively or no role at all.

Cluster analysis results

The results of this study offer a classification system based on three selling activity factors and six clusters or groups of regulations. The two-step cluster analysis produced a six-cluster solution, which will be described in this section. The clusters are reported in descending rank order based upon the total number of regulations comprised in each respective cluster.

The following cluster tables contain the specific regulation, guidance statement and law number assigned for this study, as well as a brief paraphrased description of the actual item. The actual item descriptions used for this study are provided in the Appendix I.

Cluster 1 (Table III)

The "highly restrictive regulations" group had the lowest negative scores among the clusters and contains the largest number of regulations from the overall sample. In total, 19 of the 59 regulations studied (31.7 per cent) were perceived as highly negative by salespeople in each of the selling activity categories. In this group, items impacting a salesperson's ability to perform "core selling skills" scored the lowest (−2.82) among all selling activity categories. "Customer relationships through communication" activities scored −2.81 followed by "planning" activities at −1.82. This cluster ranks last on each centroid and contains the largest number of observations ($n = 2224$) of the sample (Table III).

This finding indicates that the majority of respondents studied perceive a preponderance of regulations as negatively affecting (restricting) their ability to build relationships through communication (relationally communicate), use their core selling skills and plan. Demographically, respondents with less than 10 years of industry experience perceived Cluster 1 regulations the most restrictive; however, the results were not statistically significant. This is clearly not the intent of the regulations but is perceived by the respondents and can be considered unintended consequences.

Cluster 2 (Table IV)

The "no effect" cluster is the second largest group ($n = 2052$) of observations in the study, representing 27.4 per cent of the sample. Unlike the other five clusters, Cluster 2 contains regulations that salespeople perceive as having no effect on their selling activities. On a seven-point Likert scale, where −3 indicated "very negatively" and +3 indicated "very positively", this group reported 16 of the 59 regulations (27.6 per cent) to have little to no effect on selling activities. "Customer relationships through communication" was impacted the least (−0.05) followed closely by "core selling skills" (−0.07). The final factor, "planning" scored slightly higher (0.10), however not high enough to differentiate it from the grouping. Demographically, respondents with less than five years of selling experience perceived Cluster 2 items as having no effect; however, the results were not statistically significant. In other words, Cluster 2 contains regulations viewed as having a neutral impact on selling activities (Table IV).

Cluster 3 (Table V)

This group ranked third in overall negative impact (16.6 per cent) with 1,241 overall observations. Of the three centroids, "core selling skills" had the lowest negative score (−2.26), ranking it the fourth most negative category among all groups. "Customer relationships through communication" and "planning" scored slightly better; however, they were all perceived as negative. Cluster 3 is still relatively low on all measures and contains 8 of the 59 regulations (13 per cent) studied. This group was most similar to Cluster 2 with respect to overall negative impact (Table V).

Cluster 1: Highly restrictive regulations
Regulation 4 – Manufacturer is prohibited from coupling services that confer a benefit to provider
Regulation 5 – Sales and marketing functions are prohibited from providing grants
Regulation 11 – Relationships with customers should not influence decisions for referrals
Regulation 15 – Compensating physicians for services related to sales and marketing activities are prohibited
Regulation 16 – Compensating physicians for time spent listening to sales presentations are prohibited
Regulation 18 – Entertainment, recreation, and travel in association with sales activities are prohibited
Regulation 19 – Gifts, gratuities, and other business courtesies are prohibited
Regulation 25 – Meals offered by sales representatives must be limited to in-office or in-hospital settings
Regulation 26 – Inclusion of a heath-care professional's spouse or guest at a meal is prohibited
Regulation 28 – Companies are prohibited from providing any entertainment or recreational items
Regulation 32 – Financial support is prohibited for expenses of non-faculty heath-care professionals
Regulation 35 – Financial support is prohibited for heath-care professionals for professional meetings
Regulation 37 – Sponsoring companies are prohibited to influence conference content, venue or faculty
Regulation 38 – Financial support for the cost of personal expenses at conferences are prohibited
Regulation 46 – Companies are prohibited from providing recreation or entertainment at meetings
Regulation 47 – Honoraria and travel expense payments are prohibited at company sponsored meetings
Regulation 56 – Items intended for personal benefit (such as floral arrangements) is prohibited
Regulation 57 – Payments in cash or cash equivalents (such as gift certificates) are prohibited
Regulation 59 – Items designed for education of patients should only be offered on an occasional basis

Table III.
Cluster 1: Highly restrictive regulations (29.7 per cent of observations)

	Centroids					
	Customer relationships through communication		Core selling skills		Planning	
	Mean	SD	Mean	SD	Mean	SD
Cluster 1	−2.81	0.278	−2.82	0.230	−1.82	0.477

Cluster 4 (Table VI)
This category contains two factors that were slightly negative, and equally revealed minimal-factor centroid values and rankings: "core selling skills" (−0.59) and "customer relationships through communication" (−0.97). "Planning", the third factor, reported a much more negative score (−1.55), indicating that activities such as searching out new leads, pre-call planning, conducting targeting activities and designing sales plans were more negatively impacted by this group of regulations (Table VI).

Cluster 5 (Table VII)
Examination of the fifth group (636 observations) shows that "customer relationships through communication" and "core selling skills" were both negative (−2.29 and −1.81, respectively). "Planning", on the other hand, was positive at 1.14. Cluster 5 is unique compared to the other clusters such that no other clusters reported a mix between positive and negative means across centroids (Table VII).

Cluster 2: No effect regulations
Regulation 1 – Offer or payment of anything of value for patient referrals are prohibited
Regulation 2 – Remunerative relationships must be identified between company and customers/speakers/consultants
Regulation 3 – Information provided to decision-makers, patients, customers must be accurate and complete
Regulation 7 – Manufacturer must document grant making and educational presentations regularly
Regulation 8 – Any payments to cover the costs of "converting" from a competitor product is prohibited
Regulation 9 – Selective offers of remuneration is prohibited
Regulation 13 – "Switching" arrangements involving cash or other benefits are prohibited
Regulation 14 – Consulting and advisory payments must be at fair market value to bona fide consultants or advisors for their services
Regulation 29 – Giving of any subsidy directly to a heath-care professional by a company is prohibited
Regulation 39 – Consulting agreements are prohibited to serve as either inducements or rewards for prescribing or recommending a particular medicine or course of treatment
Regulation 41 – A legitimate need for the consulting services must be clearly identified in advance
Regulation 43 – The number of heath-care consultants retained must not exceed the number reasonably necessary to achieve the identified purpose
Regulation 50 – Companies must establish policies for the appropriate use of speakers and their training
Regulation 52 – Speaker programmes must be monitored for compliance with FDA requirements
Regulation 53 – Heath-care professionals serving as consultants, speakers, or advisors are required to disclose the existence and nature of his/her relationship with the company
Regulation 60 – Grants, scholarships, subsidies, support, gifts, etc. are prohibited as exchange for prescribing products or for a commitment to continue prescribing products

	Centroids					
	Customer relationships through communication		Core selling skills		Planning	
	Mean	SD	Mean	SD	Mean	SD
Cluster 2	−0.05	0.258	−0.07	0.315	0.10	0.388

Table IV.
Cluster 2: No effect regulations (27.4 per cent of observations)

This group scored the highest with respect to regulations that are perceived by salespeople as "helpful" when performing selling activities. On a scale of −3 to +3, this group had the highest mean score on "customer relationships through communication" (2.55), "core selling skills" (2.39) and "planning" (2.54). This category includes the approval of activities such as providing meals to customers and staff, initiation of contracts with customers to enforce agreed-upon services and requirements of firms to substantiate product claims. Each of these regulations were perceived by salespeople to facilitate communication with prospects, assist their interpersonal influencing efforts and support planning efforts. Thus, this cluster was labelled "helpful", indicating that the majority of sales-people perceived regulations 20, 22, 24 and 40 as useful. "Helpful Regulations" is the smallest cluster representing just 6.7 per cent of 7,493 total observations. In total, 4 of the 59 items included in this study reside in Cluster 6. This finding indicates that less than 7 per cent of the regulations examined are perceived as "helpful" by salespeople (Table VIII).

Cluster 3: Somewhat restrictive regulations
Regulation 6 – Manufacturer is prohibited from having control over speaker or speaker content
Regulation 10 – Relationships with formulary committee members prohibited to influence decisions
Regulation 21 – Promotional materials must be consistent with approved FDA requirements and cannot be altered, highlighted, etc.
Regulation 31 – The company is prohibited to provide any advice or guidance to CME providers
Regulation 33 – Funding is prohibited to compensate for time spent for participating in CME events
Regulation 42 – Criteria for selecting consultants must be directly related to the identified purpose
Regulation 45 – Venue and circumstances of any meeting with consultants are conducive to consulting services and activities related to purpose of meeting; resorts are not appropriate venues
Regulation 48 – The selection or retention of speakers must be based on defined criteria

Table V.
Cluster 3: Somewhat restrictive regulations (16.6 per cent of observations)

	Centroids					
	Customer relationships through communication		Core selling skills		Planning	
	Mean	SD	Mean	SD	Mean	SD
Cluster 3	−1.55	0.646	−2.26	0.443	−1.08	0.527

Cluster 4: Restrictive in office regulations
Regulation 12 – Good or services provided to eliminate an expense that the physician would have otherwise incurred is prohibited
Regulation 17 – Payments for time spent accessing web sites to view or listen to marketing information or to perform research is prohibited
Regulation 27 – Offering "take-out" meals or meals to be eaten without a company representative present is prohibited
Regulation 44 – The retaining company must maintain records for consulting services provided
Regulation 49 – Companies are required to "cap" the total amount of speaker compensation it will pay annually
Regulation 55 – Promotional items such as; pens, note pads, mugs and similar "reminder" items with company logos or product names are prohibited
Regulation 58 – Items designed for education of patients must be $100 or less in value

Table VI.
Cluster 4: Restrictive in office regulations (11.2 per cent of observations)

	Centroids					
	Customer relationships through communication		Core selling skills		Planning	
	Mean	SD	Mean	SD	Mean	SD
Cluster 4	−0.97	0.558	−0.59	0.527	−1.55	0.494

Discussion

The results of this study offer a classification system based on three selling activity factors and six clusters or groups of regulations. Table IX gives the mean ratings for each taxonomic group across group descriptors. The discussion provided in the following section is based on the results supplied by this table as well as analysis of individual items.

The results are interesting and instructive for a number of reasons. First, six clusters of regulations were revealed which provide a foundation for understanding the interaction between these items and selling activities in the form of an empirical

Cluster 5: Bad with customer/Good in office regulations
Regulation 23 – Occasional meals may be offered, so long as the presentation provides scientific value
Regulation 30 – Financial support must be given to the CME provider directly
Regulation 34 – It is prohibited to provide meals directly at CME events, except that the CME provider may apply the financial support from the company to provide meals for all participants
Regulation 36 – Financial support for conference registration fees must be given directly to the conference sponsor and not to participants
Regulation 54 – Financial assistance for scholarships or other educational funds to support medical students, residents, or fellows may not be offered directly, but may be offered to the institution

	Centroids					
	Customer relationships through communication		Core selling skills		Planning	
	Mean	SD	Mean	SD	Mean	SD
Cluster 5	−2.29	0.387	−1.81	0.373	1.14	0.402

Table VII.
Cluster 5: Bad with customer/good in office (8.5 per cent of observations)

Cluster 6: Helpful regulations
Regulation 20 – Promotional material claims must be fair and balanced
Regulation 22 – Meals may be offered to customers and staff as long as they are modest in value
Regulation 24 – Occasional meals must be accompanied by educational or scientific presentations
Regulation 40 – Written contracts must specify the nature of consulting services to be provided

	Centroids					
	Customer relationships through communication		Core selling skills		Planning	
	Mean	SD	Mean	SD	Mean	SD
Cluster 6	2.55	0.500	2.39	0.711	2.54	0.439

Table VIII.
Cluster 6: Helpful regulations (6.7 per cent of observations)

	Centroids					
	Customer relationships through communication		Core selling skills		Planning	
	Mean	SD	Mean	SD	Mean	SD
Cluster						
1	−2.81	0.278	−2.82	0.230	−1.82	0.477
2	−0.05	0.258	−0.07	0.315	0.10	0.388
3	−1.55	0.646	−2.26	0.443	−1.08	0.527
4	−0.97	0.558	−0.59	0.527	−1.55	0.494
5	−2.29	0.387	−1.81	0.373	1.14	0.402
6	2.55	0.500	2.39	0.711	2.54	0.439
Combined	−1.24	1.539	−1.29	1.545	−0.60	1.357

Table IX.
Centroids for the six clusters

taxonomy. This study revealed that salespeople perceive most regulations as either highly restrictive (Cluster 1) or have no effect at all (Cluster 2) on their selling activities. Very few items (only 4 out of 59) were perceived as helpful. Analysis of respondent demographic backgrounds revealed slight, yet non-statistical differences across all six clusters.

"Highly Restrictive" Regulations (Cluster 1)
When we examine the regulations within this group, we find that salespeople are prohibited from using gifts and entertainment and other kinds of business courtesies that not only are they used to using, but that are used in many other industries. It also limits the time with customers. This suggests that the majority of items enforced by the OIG and PhRMA prevent customer relationship opportunities, which by default restrict a salesperson's ability to execute core selling skills and planning.

"No effect" regulations (Cluster 2)
When we examine regulations linked with "no effect", we can observe that these mainly control firm-level behaviour, enforce laws such as anti-kickback legislation and other regulations regarding forms of remuneration. These were simply not perceived as positive or negative with respect to the ability of the salesperson to perform selling activities. This is an interesting finding in two respects. First, this suggests that a large portion of regulations may not be necessary considering they are viewed to have no impact on selling activities. Second, as federal, state and local agencies continue to generate more regulations targeted toward sales forces, and with over 27 per cent of existing regulations having no effect on selling activities, a thorough needs' analysis should be conducted prior to implementation of the regulation.

"Somewhat restrictive" regulations (Cluster 3)
Cluster 3, it should be noted, is different because each of the eight regulations comprising this group are largely related to third-party entities which limit or eliminate the ability of a salesperson to interact directly with their customers. Item 10 is a good example; "relationships with formulary committee members should not include any remuneration from a manufacturer or its agents, nor to influence formulary decisions […] " A formulary is a list of medicines that specify which products are approved or available for physicians to prescribe in a hospital and is akin to an approved supplier list in generic business to business marketing (Plank and Kijewski, 1991). It is not surprising that sales representatives view these items as somewhat restrictive, as they prohibit key selling activities that can influence customer buying decisions.

In addition, many pharmaceutical firms use third-party vendors to conduct promotional speaking events, educational symposia and physician speaker events. However, rules like item number six specifically state, "the manufacturer should have no control over the speaker or content of an educational presentation". This form of control prohibits the salesperson from speaking directly with a customer who they have sponsored to speak. All content must go through a third-party entity. Thus, the salesperson is unable to build customer relationships, use his/her core selling skills and plan. This finding indicates that salespeople perceive certain regulations as somewhat restrictive when dealing with entities other than their direct prospects.

"Restrictive in office" regulations (Cluster 4)
Overall, the regulations grouped in the "restrictive in office" cluster ($n = 7$) are all perceived to have at least a somewhat negative impact on selling activities. Unlike the "no effect" cluster which was highly negative in all categories, this cluster was slightly negative in customer relationships through communication, and core selling skills. On the other hand, planning was perceived as highly negative. Inspection of the seven items in this cluster suggests that planning activities are perhaps more strategic and therefore

experience a greater negative impact than other more direct customer activities such as relationship building and core selling skills.

Historically, giving inexpensive "reminder" promotional items (pens, note pads, mugs, etc. with company logos or product names) to potential and existing customers was a common selling activity for pharmaceutical representatives. This practice was believed to enhance a salesperson's ability to "gain access" to new customers, search out new leads and conduct other types of targeting activities. For example, experienced salespeople would use a pen or similar item that contained their product name and logo as a way to get a customer's attention and to initiate product or service discussions.

Item 55, is an example of this restriction, as it prohibits the practice of *providing items for healthcare professionals' use that do not advance disease or treatment education*. We suggest that the salesperson perceives this item as "highly restrictive" when conducting planning activities such as pre-call planning and searching out new leads. But, it was perceived to have minimal negative effect on activities such as listening to customers or handling customer objections. This specific example demonstrates how a regulation, guidance statement or law can have different effects depending on the specific selling activity being conducted.

"Bad with customer/Good in office" regulations (Cluster 5)

This cluster suggests this group of regulations has an opposite effect on selling activities conducted in front of customers ("customer relationships through communication" and "core selling skills", −2.29 and −1.81, respectively) versus those conducted away from customers ("planning", 1.14). Examining these five items in this cluster reveals that four of the regulations (Items 30, 34, 36 and 54) limit and/or prohibit providing meals, financial support or other business courtesies *unless* they are facilitated through a third party. This is much like in Cluster 3 where many of the regulations mandated in some way the use of a third party. In addition, Item 23 states:

> […] occasional meals may be offered as a business courtesy to healthcare professionals (including members of their staff) attending sales/marketing presentations *as long as* the presentations provide scientific or educational value.

Each of the regulations in "bad with customer/good in office" contain a "condition" statement (i.e. as long as, only if or except that) that appears to separate selling activities conducted in the customer's presence ("customer relationships through communication" and "core selling skills") from those conducted away from customers ("planning"). This condition's statement appears to have opposite effects on face-to-face selling activities versus those conducted outside the presence of a customer. This finding, the fact that certain regulations can have both positive and negative effects on selling activities, further supports the value of a classification system such as that mentioned to examine the impacts of, in this case, controls on sales behaviours which can be mixed.

"Helpful" regulations (Cluster 6)

After examining the four regulations ($n = 4$) found within the "helpful" group, we observed that each of the items supported activities such as providing customers with occasional meals, the ability to include staff members in the activity and the requirement that customers must sign a contract describing the nature of their commitment and services to be provided. If a regulation, guidance statements or law makes it easy to gain access to a customer and facilitates relationship building such as providing a meal, it is

not surprising that sales representatives would find these items as "helpful". What this suggests is that sales organizations may benefit by providing their salespeople with regulations, guidance statements or laws describing what they "can" do rather than what they "cannot" do. Each of the four items within this group specifically states examples of promotional activities that are allowed. Of note, these are the only four items that describe what is allowed versus what is prohibited. The usefulness of these regulations was viewed as positive by all respondents, indicating a wide acceptance among the entire sales force.

Based on our initial findings reported within this research, further analysis is required to determine specific areas where the regulatory bodies at the federal, state and firm levels can advance levels of compliance within the spirit of law. Preliminary findings, not reported in this study, have revealed some promising areas for further investigation, one being whether the "wording" of a regulation, guideline or law impacts the degree of unintended consequence with respect to compliance and adherence. Initial analyses suggest regulations that are worded in a manner that describes what the salesperson "can do" trends toward significance versus regulations that state what is "prohibited".

Managerial implications

In terms of practical application, the taxonomy developed is this study could help a manager develop their own companies' approach to regulations and ascertain the impact different items have on their sales force activities. Furthermore, the value in our taxonomy lies in its potential to provide managerial insight and direction by isolating groups of regulations with predictive significance regardless of industry.

Sales managers whose industries are exploring the idea of tighter regulatory controls, or whose firms have not considered the impact regulations might have on their sales and marketing activities, can use this taxonomy to develop alternative selling strategies to enhance customer impact. For example, by identifying whether salespeople perceive a regulation, guidance statement or law as "highly restrictive", "helpful" or having "no effect" on their day-to-day activities, a manager can tailor training and education for his/her sales force to provide the skills necessary to better serve their customers as well as comply with the item(s).

From a sales and marketing perspective, using the six known clusters of regulations, sales managers and salespeople can compare specific tactics they are using (or plan to use) such as the use of certain promotional materials and selling activities with those that are depicted within the six clusters. Based on the cluster, practitioners would then have the necessary information to choose whether they want to produce particular resources and supplies, or develop different strategies to accommodate the needs of their customers, as well as their selling strategies. In other words, are there certain strategies and tactics that allow them to overcome issues related to the regulations categorized within the respective clusters?

For the sales manager, this study may be useful in the identification of skills and behaviours associated with highly effective sales representatives in a highly regulated and controlled environment. For example, a successful pharmaceutical representative that relies heavily on building customer relationships through communication as their primary selling skill may find the control item that *permits occasional meals at meetings, so long as the presentation provides scientific value*, as highly restrictive. From their

perspective, they prefer to have lunch with a customer to build relationships and rapport and believe that conducting a scientific presentation would negatively impact their interaction. Therefore, they may decide to not provide occasional meals at all and exclude customers who will only meet over lunch. On the other hand, another successful pharmaceutical representative has found that conducting scientific presentations at lunch meetings is an effective way to search out new leads, target customers and design their sales plan. For those reasons, the second representative routinely meets new customers over lunch meetings while sharing scientific product information. This example implies the need for further training among affected sales representatives and managers based upon identified best practices.

Finally, from the taxonomy developed in this study, managers can sort their own companies' regulations on the basis of the classification scheme presented. From the taxonomy, they can determine new ways to approach customers and develop alternative selling strategies. The detailed yet simplistic descriptions of the taxonomical categories represent an important forward step for the field.

Limitations and future research opportunities

Before future research opportunities are noted, several limitations should be raised. First, the sample in this study included sales representatives from one firm within the pharmaceutical industry. Although pharmaceuticals are known to be one of the most regulated industries today, industries such as banking, real estate, telecommunications and tobacco would also be appealing and meaningful for other investigators to test our taxonomical methodology. We acknowledge this as a "limitation"; however, this was a mindful strategic choice in designing the research.

An inherent limitation of the taxonomic process includes several subjective and sequential decisions related to data analysis. We recognize that strong conceptual support is necessary to deal with issues such as what variables to include, why groups exist in the first place and determining the number of clusters in the final solution. Additionally, an analysis of this type of data required several different analytical approaches; however, the present study relies heavily on the use of exploratory factor analysis (EFA) and two-step cluster analysis. Although each step of the analysis was carefully specified and reviewed by two additional researchers, applying a different sequence of analytical steps might deduce the data in a slightly different way. We recognize that problems are inherent in both methods which are acknowledged.

Future research directions are several. Marketing and sales scholars can play an important role in the growing area of regulations and selling. To date, key decisions about how to effectively sell in an ever-increasing regulated environment have been guided by "reaction" and "intuition" rather than by marketing/sales experts and scholars. Research in the area of sales strategy development is needed to guide these decisions which often have huge financial consequences. Building upon an initial taxonomical scheme, as described here, can help develop theoretical strategy frameworks for future research in the areas of relational communication, and interpersonal influencing in the context of selling. Moreover, further research could explore which regulations impact customer commitment and trust (Morgan and Hunt, 1994).

There is a pressing need for better understanding of the costs associated with regulations placed on sales organizations. Many companies are unaware of the costs to

monitor, enforce and implement regulations within their organizations and how those costs impact overall firm performance. It would be interesting to extend this regulatory taxonomy to include demographic data, longitudinal performance outcomes and cost measures. With large quantities of complex and vague regulations with which salespeople must comply, our research underscores the need to execute fiscal analyses on the major clusters of regulations to examine whether a regulation's intended benefits surpass its costs. The research presented here provide a timely context for further research on the interaction between regulations and selling behaviours, which seem to be central to the advancement in research selling and sales management.

Finally an interesting issue is that of how regulations are written to ensure compliance with them versus how they are perceived and what kinds of unintended consequences there might be. From the regulators point of view, the key is to write a regulation that will gain compliance and thus solve a problem they perceive to be worthy of the regulation. Yet, there is neither any known literature where compliance versus other consequences are examined nor any normative literature instructing regulators on how to actually write regulations to maximize compliance and minimize other impacts. What this research has discovered is that the salespeople perceive many of these regulations to inhibit the successful accomplishment of their job duties.

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Appendix 1

Item no.	Description of regulation, guidance statement or law
1	The manufacturer, sales representatives, or other agents of the company, may not offer payment or anything of value for patient referrals or in return for purchasing (prescriptions)
2	Manufacturer should identify any remunerative relationship between itself (and its representatives) and persons or entities in a position to generate federal health care business for the manufacturer directly or indirectly
3	When providing information to decision-makers, prescribers, or patients, the information must be complete, accurate and not misleading
4	Manufacturer is prohibited from coupling a service that has no independent value in tandem with another service or programme that confers a benefit on a referring provider
5	Sales and marketing functions are prohibited from providing grants, nor can it be involved in any aspect of grant making
6	Manufacturer should have no control over the speaker or content of the educational presentation
7	Manufacturer must document grant making and educational presentation procedures and regularly monitor
8	Any payments to cover the costs of "converting" from a competitor's product is prohibited
9	Selective offers of remuneration (i.e., offers made to some but not all purchasers) are prohibited
10	Relationships with formulary committee members should not include any remuneration from a manufacturer or its agents, nor to influence formulary decisions which are exclusive or restricted status
11	Relationships with physicians and other persons and entities in a position to make or influence referrals should not influence the referral, ordering, or prescribing of the manufacturers products
12	If goods or services provided by the manufacturers eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement is prohibited
13	"Switching" arrangements involve pharmaceutical manufacturers offering physicians or others cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product, is prohibited
14	Consulting and advisory payments whereby pharmaceutical manufacturers frequently engage physicians and other health care professionals to furnish personal services as consultants or advisers to the manufactures must be at fair market value to small numbers of physicians for bona fide consulting or advisory services
15	Compensating physicians for services directly or indirectly related to sales and marketing activities such as speaking, certain research, or preceptor or "shadowing" services is prohibited
16	Payments for detailing (i.e., compensating physicians for time spent listening to sales representatives market pharmaceutical products), is prohibited
17	Payments for time spent accessing web sites to view or listen to marketing information or perform "research" is prohibited

(*continued*)

Table AI.
Table of regulations, guidance statements, and laws (In ascending order by number)

Item no.	Description of regulation, guidance statement or law
18	Entertainment, recreation, travel and meals in association with information or marketing/sales presentations are prohibited
19	Gifts, gratuities, and other business courtesies are prohibited
20	Promotional materials provided to heath-care professionals by or on behalf of a company should make properly substantiated claims and reflect the balance between risks and benefits
21	Promotional materials provided to heath-care professionals by or on behalf of a company should be consistent with all other Food and Drug Administration (FDA) requirements governing such communications
22	Occasional meals may be offered as a business courtesy to heath-care professionals (including members of their staff) attending sales/marketing presentations provided the meal is modest as judged by local standards
23	Occasional meals may be offered as a business courtesy to heath-care professionals (including members of their staff) attending sales/marketing presentations as long as the meeting is not part of an entertainment or recreational event
24	Occasional meals may be offered as a business courtesy to heath-care professionals (including members of their staff) attending sales/marketing presentations so long as the presentations provide scientific or educational value
25	Meals offered in connection with informational presentations made by field sales representatives or their immediate managers should also be limited to in-office or in-hospital settings
26	Inclusion of a heath-care professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is prohibited
27	Offering "take-out" meals or meals to be eaten without a company representative being present is prohibited
28	Companies are prohibited from providing any entertainment or recreational items including tickets to theatre or sporting events, sporting equipment, or leisure and vacation trips
29	Giving of any subsidy directly to a heath-care professional by a company is prohibited
30	Any financial support should be given to the CME provider, which, in turn, can use the money to reduce the overall CME registration fee for all participants
31	The company is prohibited to provide any advice or guidance to the CME provider, even if asked by the provider, regarding the content or faculty for a particularly CME programme funded by the company
32	Financial support is prohibited for the costs of travel, lodging, or other personal expenses of non-faculty heath-care professionals attending CME
33	Funding should not be offered to compensate for the time spent by heath-care professionals participating in the CME event
34	A company should not provide meals directly at CME events, except that a CME provider at its own discretion may apply the financial support provided by a company for CME event to provide meals for all participants
35	Any subsidy or financial support for professional meetings may not be provided to a heath-care professional
36	Financial support for professional meetings should be given directly to the conference's sponsor, which, in turn, can use the money to reduce the overall conference registration fee for all attendees

Table AI. (*continued*)

Item no.	Description of regulation, guidance statement or law
37	When companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conference and may not be influence by the sponsoring company
38	Financial support for the costs of travel, lodging, or other personal expenses are prohibited
39	Consulting agreements are prohibited to serve as either inducements or rewards for prescribing or recommending a particular medicine or course of treatment
40	A written contract must specify the nature of the consulting services to be provided and the basis for payment of those services
41	A legitimate need for the consulting services must be clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants
42	The criteria for selecting consultants must be directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular heath-care professionals meet those criteria
43	It is required that the number of heath-care professionals retained is not greater than the number reasonably necessary to achieve the identified purpose
44	The retaining company must maintain records concerning and makes appropriate use of the services provided by consultants
45	The venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting; specifically, resorts are not appropriate venues
46	Companies are prohibited to provide recreational or entertainment events in conjunction with consultant/educational meetings
47	It is prohibited to pay honoraria or travel or lodging expenses to non-faculty and non-consultant health-care professional attendees at company-sponsored meetings, including attendees who participate in interactive sessions
48	Company decisions regarding the selection or retention of heath-care professionals as speakers should be made based on defined criteria such as general medical expertise and reputation
49	Each company should cap the total amount of annual compensation it will pay to an individual health-care professional in connection with all speaking arrangements
50	Each company should develop policies addressing the appropriate use of speakers, including utilization of speakers after training and the appropriate number of engagements for any particular speaker over time
51	Speakers and their materials must clearly identify the company that is sponsoring the presentation
52	Companies must monitor speaker programmes for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines
53	Companies must require any heath-care professional who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the existence and nature of his or her relationship with the company
54	Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other heath-care professionals in training to attend educational conferences may only be offered by the academic or training institution

(*continued*)

Table AI.

Item no.	Description of regulation, guidance statement or law
55	Providing items for heath-care professionals' use that do not advance disease or treatment education is prohibited. Examples include but are not limited to: pens, note pads, mugs and similar "reminder" items with company or product logos
56	Items intended for personal benefit of heath-care professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) are prohibited
57	Payments in cash or cash equivalents (such as gift certificates) are prohibited
58	Items designed primarily for education of patients or heath-care professionals must be $100 or less in value
59	Items designed primarily for the education of patients or heath-care professionals should not be offered on more than an occasional basis
60	No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a heath-care professional in exchange for prescribing products or for a commitment to continue prescribing products

Table AI.

Appendix 2

1. Relationship Building building (Reid *et al.*, 1997):
   - x1: Ability to ask probing questions.
   - x2: Listened to customer.
   - x3: Ability to make a charismatic presentation.
   - x4: Ability to work well with other people who are involved in the purchase (Adapted from industry interviews and focus groups).
   - x16: Follow up with customer.
2. Getting to Buy buy (Reid *et al.*, 1997):
   - x5: Gain participation and got customer involved in the sales presentation.
   - x6: Ability to use analogies and similes in his/her presentation to help customer see how it relates to his/her situation.
   - x7: Ability to link his/her product/service attributes to customer needs.
   - x8: Could differentiate his/her product/service from the competition.
   - x9: Ability to do ""homework"" on customer.
   - x10: Ability to handle objections raised by customer.
3. Planning (Moncreif *et al.*, 2006):
   - x11: Search out new leads.
   - x12: Pre-call planning/ targeting.
   - x17: Administrative activities/ documentation (Adapted from industry interviews and focus groups).
   - x13: Conduct targeting activities.
   - x14: Designing sales plan.
   - x15: Business planning.

About the authors

John F. Riggs, DBA, Kennesaw State University, has over 25 years of significant sales and marketing experience in the pharmaceutical industry prior to joining academia. His research interests are in understanding the impact of regulations on business and specifically marketing and sales in the industries that are highly regulated. John F. Riggs is the corresponding author and can be contacted at: john.riggs@nova.edu

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