RESEARCH

An Elective Course for Student Pharmacists on Pharmaceutical Industry Practice

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Objective. To design and implement an elective course on pharmaceutical industry practice and assess its impact on student pharmacists' knowledge and perceptions.

Methods. This was a two-credit hour, elective course offered to second- and third-year student pharmacists during the 2015 and 2016 spring semesters. The goal of this course was to provide instruction regarding skills and competencies for pharmaceutical industry practice. Curricular content included didactic instruction, assigned readings, weekly quizzes, classroom discussion of industry-based functions and responsibilities, and three application projects. A 65-item survey instrument was developed to assess changes in student pharmacists' perceptions and understanding of pharmaceutical industry practice.

Results. Forty-four students enrolled in the elective course over the two offerings. The average rating on the course evaluation was 4.7 out of 5. Average scores on graded quizzes were 90%, and grades on the application projects ranged from 92% to 99%. There was an increase in the number of students who perceived that they understood various functions and roles in the pharmaceutical industry, and who rated themselves confident in completing unique tasks associated with pharmaceutical industry practice. Furthermore, there was an increase in the number of students who reported improved perceptions regarding the trustworthiness of the pharmaceutical industry, costs of prescription medications, and promotional advertising for branded prescription medication.

Conclusion. Student pharmacists' perceptions of the course were positive, and overall perceptions and understanding of the pharmaceutical industry improved. Active collaboration between colleges and pharmaceutical companies can lead to positive educational opportunities for students interested in pharmaceutical industry careers.

Keywords: pharmaceutical industry, perception, student pharmacist

INTRODUCTION

The pharmaceutical industry positively contributes to patient welfare by developing prescription medications that are used to treat a myriad of disease states and medical conditions. Pharmacists are employed extensively throughout the pharmaceutical industry with diverse functions and responsibilities that include roles in medical affairs, regulatory affairs, drug development, outcomes research, pharmacovigilance, and commercial marketing. Required components of the pharmacy curriculum provide training in skills related to clinical knowledge, literature evaluation, leadership, and communication, which can position student pharmacists well to pursue postgraduate training and career

opportunities in the pharmaceutical industry.¹ There are relatively limited curricular content devoted to the many pharmacist roles that are unique to the pharmaceutical industry setting. Elective courses can provide exposure to these functions and may assist student pharmacists who desire to positively differentiate themselves in a competitive job market.²

Several studies have evaluated medical students' perceptions of the pharmaceutical industry; however, pharmacy pedagogical literature on the pharmaceutical industry is limited.³⁻⁷ Hartman and colleagues described the design and implementation of two separate pharmaceutical industry elective courses and assessed the impact of these courses on student pharmacists' selection of advanced pharmacy practice experiences (APPEs) and pursuit of pharmaceutical industry fellowships.⁸ This study found that 31% of students who took a pharmaceutical industry-based APPE had previously taken one of the

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elective courses; 18% of graduating students who took one of the elective courses pursued a postgraduate pharmaceutical industry-based fellowship program compared to only 5% of graduating students who had not taken these elective courses. Mihm described the design of an elective course that placed student pharmacists in marketing teams overseeing a hypothetical new product launch.⁹ Groups were tasked with preparing an abbreviated marketing plan and developing a Food and Drug Administration (FDA) compliant direct-to-consumer (DTC) advertisement. Neither of these studies evaluated students' perceptions of the pharmaceutical industry or their perceived confidence to perform tasks associated with industry practice.

The objective of this study was to describe the design and implementation of an elective course for student pharmacists on a broad range of roles and functions unique to pharmaceutical industry practice. Furthermore, the study evaluated changes in student pharmacists' perceptions regarding the pharmaceutical industry, familiarity with roles and responsibilities of pharmacists within the pharmaceutical industry, and confidence in performing specific tasks associated with pharmaceutical industry practice.

METHODS

This course was a two-credit hour, weekly elective offered during the 2015 and 2016 spring semesters to second- and third-year student pharmacists. All students had previously participated in a dedicated class session on the pharmaceutical industry during a required first-year introductory course which included discussions related to the prescription drug development process and career opportunities in the pharmaceutical industry. The elective course was developed and coordinated by a faculty member who had prior work experience in the medical affairs organization of a US-based pharmaceutical company. Electronic and live announcements regarding the course were made to all second- and third-year students and those with an explicit interest in pursuing careers in the pharmaceutical industry were strongly encouraged to enroll in the course.

The course was designed to introduce student pharmacists to foundational knowledge, skills, and competencies required for selected entry-level and advanced practice roles in the pharmaceutical industry. The course topics and learning objectives are shown in Appendix 1 and Appendix 2. The course coordinator was present for all class sessions to take roll, administer quizzes, and introduce guest speakers. Attendance was required for all the sessions to facilitate didactic instruction and interaction with the pharmaceutical industry-based speakers. Speakers were identified by the course coordinator from pharmaceutical companies around the United States and served as content experts on various course topics. Four-

teen external pharmaceutical industry-based speakers from nine separate companies comprised the course faculty. Over a period of 12 months the course coordinator developed the course structure and identified appropriate topics and speakers. In addition, the course coordinator provided four hours of didactic instruction and classroom facilitation. Guest faculty members reported allocating two to 10 hours for initial lecture preparation depending on the course topic and one to three hours in updating the lecture content for the subsequent year. In addition, faculty members provided their time for the two-hour class sessions as well as for any travel to campus, which often included arrangements for out of state travel. Didactic lectures were delivered primarily using PowerPoint presentations, which were made available to the students on the day prior to class.

The elective course was divided into three focus areas: medical affairs, drug development, and interfacing with internal and external customers. Course work consisted of didactic lectures, assigned readings, weekly quizzes, and application projects. Classroom sessions were constructed with an expectation that students would increase foundational knowledge by actively engaging in discussions facilitated by pharmaceutical industry-based speakers. Most class sessions began with the course coordinator administering a short quiz (one to five questions), which evaluated students' understanding of either the previous week's content or assigned pre-class readings. Assigned pre-class readings, obtained from the primary literature or FDA guidance documents, were related to the topic for classroom discussion. In addition, students used lecture notes and assigned readings to complete application projects. The projects provided students with the opportunity to apply concepts related to specific functions that are common entry-level roles for pharmacists in the pharmaceutical industry. Application projects were evaluated by the course coordinator and included two individual projects and one group presentation. Students' grading assessment consisted of weekly quizzes (20%) and application projects including the promotional advertisement review exercise (20%), medical information response letter (20%), and group managed care presentation (40%).

The promotional advertisement review exercise required students to evaluate the appropriateness of an assigned DTC television advertisement for a branded prescription product (Table 1). Televised advertisements were identified by the course coordinator from YouTube and assigned to individual students via email. Second-year student pharmacists received advertisements pertaining to products in psychiatry, neurology, or cardiovascular disease as these were the only therapeutic topics to be completed during the second professional year of the required

Table 1. Grading Rubric for Individual Application Projects Completed by Student Pharmacists Enrolled in an Elective Course on Pharmaceutical Industry Practice

Category	Description	Points
Promotional Advertisement Review Exercise ^a		
FDA indication	List the specific FDA indication that is being marketed by the assigned DTC advertisement.	10
Pivotal clinical trial(s)	Provide a brief summary of the pivotal trial(s) that is being used to support the FDA indication that is being marketed by the assigned DTC advertisement.	20
Claims evaluation	Provide a thorough evaluation of each individual efficacy and safety claim addressing whether the claim is accurate or misleading, and if it is supported by substantial evidence. Be sure to consider each specific verbal, graphic, visual, and audio claim.	40
Overall evaluation	Address whether you consider the advertisement as a whole is fair and balanced.	20
Regulatory violations	Address if there are any regulatory violations in the advertisement including omission of risk information, unsubstantiated claims, promotion of unapproved uses, or overstatement of efficacy.	10
Medical Information Response Letter ^b		
Cover letter	Address the response to a physician and re-state the question that was asked. In addition, include any relevant disclaimer statements regarding the response.	10
Summary page	Provide a one-page summary of the response in bullet points that addresses efficacy and safety information related to the question from the product's package insert and relevant published trials	20
Body	The body should include a more detailed, scientifically written overview of all relevant efficacy and safety information regarding the question that includes data from the product's package insert and published primary literature.	60
Reference list	The last page should be a listing of references used in their order of appearance using the American Medical Association style for citations.	10

Abbreviations: DTC=direct to consumer, FDA=Food and Drug Administration

^a Students were assigned a direct-to-consumer television advertisement for a branded prescription medication and were required to individually submit a written evaluation using concepts covered during class. The course coordinator evaluated all submissions and assigned a grade out of 100 points based on the grading rubric. The grade for this assignment comprised 20% of the total course grade

^b Students were assigned a drug information question for a branded prescription medication and were required to individually develop and submit a written medical information response letter using the concepts on pharmaceutical industry-based drug information covered during class. The course coordinator evaluated all submissions and assigned a grade out of 100 points based on a grading rubric. The grade for this assignment comprised 20% of the total course grade

curriculum at the study institution. Third-year student pharmacists could be assigned televised advertisements for branded products in a broader range of therapeutic areas. Prior to the class session on Principles of Promotional Review, students were asked to view their assigned DTC televised advertisement and read the branded product's package insert. Furthermore, prior to class, students were required to read the FDA guidance document, "Presentation of Risk Information in Prescription Drug and Medical Device Promotion."¹⁰ During class, students reviewed various concepts related to the medical review

of promotional advertising, including the importance of fair balance, on-label versus off-label information, false and misleading claims, unsubstantiated claims, and omission of risk information. In addition, the course coordinator oriented the students to the Office of Prescription Drug Promotion (OPDP) within the FDA and the corresponding website for warning letters to pharmaceutical companies. Students reviewed warning letters from the previous calendar year and discussed their findings with fellow students before completing the individual application project on their own.

The second individual application project required students to develop a written medical information response letter for an assigned drug information question on a branded prescription product (Table 1). The students had to write the letter from the perspective of the pharmaceutical industry and the content had to be in compliance with regulatory guidelines. Prior to the class session on Medical Communications, students were required to read the Drug Information Association (DIA) Core Curriculum on Medical Communications, which provides an overview of best practices related to the provision of written drug information responses by individuals in the pharmaceutical industry.¹¹ The course coordinator developed a specific drug information question related to a branded prescription drug that students would also be learning about in their separate required therapeutic modules: a cardiovascular module for second-year students and an infectious disease module for third-year students. During the class session on Medical Communications, the course coordinator reviewed principles of good pharmaceutical industry-based drug information practice, including understanding solicited versus unsolicited requests for information, scientific balance, strength and quality of evidence, and use of disclaimers. Students were asked to address their medical information response letter as if the question came from a practicing physician. The medical information response letter had to be five to six pages

in length, appropriately incorporate principles of industry-based drug information practice discussed in class, and non-promotional in nature. Students using any form of plagiarism received zero points for the assignment and were subject to disciplinary action.

Finally, students were required to work in groups to complete a managed care presentation that served as a capstone project, incorporating learnings from class sessions on medical communications, drug development, clinical development, pharmacovigilance, health economics and outcomes research, and market access (Table 2). This application project was also designed to provide students with an opportunity to appreciate the role of field-based medical affairs personnel in dealing with external customers like pharmacy and therapeutics committees. Second-year student pharmacist groups were assigned the specific anticoagulant or antiplatelet agent that was the focus of their medical information response letter. Third-year student pharmacist groups were assigned a specific antibiotic. Along with their presentation slides, students were required to submit an evidence table that included information on study design, patient population, interventional arms, efficacy, and safety results from pivotal clinical trials for their assigned product. Students groups were also encouraged to consult with the Academy of Managed Care Pharmacy (AMCP) Format on Formulary Submissions for additional guidance on the presentation.¹²

Table 2. Grading Rubric for Group Managed Care Presentations by Student Pharmacists Enrolled in an Elective Course on Pharmaceutical Industry Practice^a

Category	Description	Points
Disease state overview	Using an appropriate published clinical practice guideline, provide a brief summary of the disease state(s) where the product is FDA indicated.	10
Product information	Highlight relevant information from the product package insert including indications, contraindications, warnings, precautions, dosing, administration, and any other items that are deemed pertinent for consideration of the branded product.	10
Supporting clinical evidence	Summarize relevant efficacy and safety information from clinical trials that were used to support the FDA indications. Optionally, students may include information on off-label clinical studies that groups feel would be important for consideration.	30
Economic value and modeling	Provide a summary of any health economic studies that are directly relevant to the product. If this information is not available, groups may include health economic studies related to the disease state(s) in question.	20
Executive summary	This is the bottom line – justify the value of the product based on the clinical and health economic studies including discussion of efficacy, safety, costs, and perceived medical need.	30

Abbreviations: FDA=Food and Drug Administration

^a Students were placed into groups that were assigned a branded prescription medication. For a capstone project, student groups were required to develop a presentation for a mock Pharmacy and Therapeutics Committee using concepts covered throughout the course. The course coordinator evaluated all submissions and assigned a grade out of 100 points based on the grading rubric. The grade for this assignment comprised 40% of the total course grade

Course evaluations were administered at the end of each semester and included a five-item Likert scale (5=excellent, 4=more than adequate, 3=adequate, 2=less than adequate, and 1=poor). Specific areas for students to evaluate included organization of the course, coordination of team teaching, value of required materials in promoting learning, effectiveness of technology use in the course, value of active-learning activities in promoting learning, and appropriateness of evaluation methods in reflecting course content. The course also incorporated a survey evaluation of changes in student pharmacists' perceptions of the pharmaceutical industry, familiarity with various roles and responsibilities for pharmacists in the pharmaceutical industry, and confidence in performing selected pharmaceutical industry-based tasks. The original concept for this evaluation came in part from a publicly available survey developed by the Kaiser Family Foundation and Harvard University School of Public Health that assessed the general public's perceptions regarding prescription drugs and the pharmaceutical industry.¹³ Several questions from the survey were modified and additional questions were developed to form a new 65-item survey instrument which was in a 5-point, Likert-scale format with responses ranging from strongly agree to strongly disagree. The modified survey instrument was tested with first-year student pharmacists at the study institution, and feedback was incorporated into the version used in the elective course. Positively and negatively worded statements were included in the survey to minimize the risk for acquiescent response bias (tendency to agree with statements regardless of the content). Questions were categorized as those pertaining to student pharmacists' perceptions of the favorability and trustworthiness of the pharmaceutical industry, safety and costs associated with prescription drugs, promotional advertising for prescription drugs, and governmental regulation of the drug development process. Furthermore, questions were included related to students' perceived familiarity with different types of drug information communicated from the pharmaceutical industry, familiarity with roles and responsibilities for pharmacists within the pharmaceutical industry, and self-reported confidence in delivering specific types of drug information from the perspective of the pharmaceutical industry. The survey also included questions on demographics, work history, and future career plans related to the pharmaceutical industry.

The survey was offered to students enrolled in the pharmaceutical industry elective at the beginning (pre-course survey) and end of the spring semesters (post-course survey) in 2015 and 2016. The survey was prepared using Qualtrics (Qualtrics Lab, Provo, UT), a data collection and analysis software program. Students received an electronic link to the survey and were given 30 minutes on the first

and last day of class to complete the survey. Participation in the study was voluntary, and informed consent was obtained from all participants. Institutional review board approval was obtained from the study institution. Demographics of the student respondents were summarized. For ease of presentation and interpretation, the 5-point Likert scale was collapsed into a 2-point Likert scale on which agree or strongly agree responses were grouped together (agreed with the statement) and the rest of the responses were classified as disagreed with the statement. Results are presented as the percentage of students who agreed or strongly agreed with various statements related to the pharmaceutical industry during the pre-course survey and the post-course survey. Differences between the pre-course survey and post-course survey responses were analyzed using the signed ranked test. SAS, version 9.3 (SAS Institute Inc, Cary, NC) was used for statistical analyses.

RESULTS

Forty-four student pharmacists enrolled in the elective course during the 2015 and 2016 spring semesters. Nineteen students completed the course evaluations (43% response rate), and the average rating on all items was 4.7 out of 5.0. Students' impressions were positive regarding organization of the course (4.7), value of required material in promoting learning (4.7), value of active-learning activities in promoting learning (4.7), and appropriateness of evaluation methods (4.9). The average grade for quiz assessments was 90%. Average grades for the application projects were as follows: promotional review exercise (92%), medical information response letter (98%), and group managed care presentation (99%). Eleven students (25%) who enrolled in the course were able to complete a pharmaceutical industry-based APPE during the fourth year of the professional program.

Forty-two student pharmacists completed the pre-course survey and 44 student pharmacists completed the post-course survey. Forty-one student pharmacists completed both surveys (93% response rate). Participating students were mostly in the second-year of the program (84%) and only three students (7%) had prior work experience in the pharmaceutical industry. Students reported a favorable view of the pharmaceutical industry throughout the course (88% of students on the pre-course survey and 90% of students on the post-course survey). By the end of the course, greater than 95% of student pharmacists believed that the pharmaceutical industry offered pharmacists the opportunity to make valuable contributions to patient care (98%), apply skills and competencies learned during pharmacy school (98%), and pursue various career pathways (98%). Approximately 75% of students

reported that they planned on pursuing a career in the pharmaceutical industry at some point after graduation.

During the course, there was an increase in the number of students who felt confident in their understanding of the pharmaceutical industry (18% to 98%, $p < .001$). Specifically, there was an increase in the number of students who reported being confident in their ability to write a medical information response letter from a pharmaceutical industry perspective (8% to 85%, $p < .001$), discuss differences in drug information practice in the pharmaceutical industry compared to other pharmacy practice settings (23% to 95%, $p < .001$), provide medical review for a promotional advertisement (10% to 83%, $p < .001$), and develop a managed care presentation based on criteria in the AMCP Formulary Dossier Format (20% to 60%, $p < .001$). Furthermore, there were increased numbers of students who reported improved understanding of roles in regulatory affairs, legal affairs, publications, clinical study monitoring, pharmacovigilance, health economics and outcomes research, market access, and commercial marketing.

Student pharmacists' perceptions of the pharmaceutical industry appear to have improved in general during the course and are noted in Table 3. There was an increase in the number of students who believed the pharmaceutical industry makes a comparatively greater contribution to society's welfare than other industries (54% to 80%, $p = .007$). Furthermore, there was an increase in the number of students who believed the pharmaceutical industry was reliable in providing drug information about product efficacy (39% to 78%, $p < .001$) and adverse events and safety concerns (41% to 78%, $p < .001$), and in informing the public quickly of newly discovered safety concerns (51% to 73%, $p = .02$). There were increases in the number of student pharmacists who believed that the benefits of prescription drugs justify the price society must pay for them (32% to 56%, $p = .03$) and that prescription drugs reduce long-term, overall health care costs (73% to 93%, $p = .04$). However, by the end of the semester, only 46% of students felt that prescription drug costs in the United States were reasonable.

As shown in Table 4, the number of students who considered DTC advertising to be good for patients and society doubled (22% to 44%, $p = .02$), and those who believed that additional government regulation was needed to ensure that advertising was truthful and accurate declined (46% to 22%, $p = .04$). Despite this, there was not much change in the percentage of student pharmacists who believed that pharmaceutical companies should not be allowed to market their products directly to consumers (34% to 37%).

DISCUSSION

The elective course for student pharmacists described here covers a broad range of pharmacist roles that

are unique to pharmaceutical industry practice. This study adds to the pedagogical literature on elective courses by being the first to evaluate changes in student pharmacists' perceptions regarding the pharmaceutical industry, familiarity with roles and responsibilities of pharmacists within the pharmaceutical industry, and self-perceived confidence in performing specific tasks uniquely associated with pharmaceutical industry practice. Student response to the course was positive. There were increases in the number of students who reported improved familiarity with a diverse range of functions in the pharmaceutical industry and improved confidence in performing specific tasks uniquely associated with pharmaceutical industry practice. In addition, positive changes were noted in student pharmacists' perceptions regarding the trustworthiness of the pharmaceutical industry, prescription drug costs, and promotional advertising.

Pedagogical studies related to pharmacy education and the pharmaceutical industry are limited and have focused mainly on student pharmacists' perceptions of pharmaceutical industry-based promotional marketing practices.^{14,15} Prior studies on elective courses for student pharmacists have focused on promotional activities and medical communications.^{8,9} Pharmacists have the opportunity to pursue a broad range of functions that extend beyond these traditional roles within the pharmaceutical industry. This course expands on previous pedagogical studies by including discussions regarding the legal and regulatory oversight of the pharmaceutical industry, phase 3 and 4 clinical development, pharmacovigilance, health economics, outcomes research, market access, publication strategy, and business leadership. Furthermore, unlike previous studies, this course incorporated three application projects that were designed to simulate scenarios where students had to apply concepts from the perspective of a pharmacist performing common entry-level functions. The course coordinator relied on previous work experience and contacts within the pharmaceutical industry to identify a broad range of topics that would provide students with a holistic view of pharmacist roles within pharmaceutical industry practice. One important approach in achieving this objective was to identify and incorporate speakers who currently worked in the pharmaceutical industry so that students would receive information on current standards of practice. The course coordinator spoke with each speaker prior to the start of the course to discuss the overall goals of the course. It was important to allow speakers to have the flexibility to create individual didactic content, associated learning objectives, and active-learning classroom exercises based on their own experience and judgement. The course coordinator maintained contact with guest speakers in order to

Table 3. Student Pharmacists' Perceptions of the Pharmaceutical Industry and Prescription Drugs Before and After Completing an Elective Course on Pharmaceutical Industry Practice (N=41)^a

Statement	Pre-course, (%)	Post-course, (%)	p Value ^b
I have a favorable view of the pharmaceutical industry	88	90	>.99
Prescription drugs developed over the past 20 years have had a positive effect on society in the United States	93	98	.63
The impact of prescription drugs on our society is negligible	10	10	>.99
Pharmaceutical companies that research and develop new drugs make a greater contribution to society's welfare compared to companies in other industries	54	80	.007
Pharmaceutical companies are an example of bad business and health care practice in our society	2	10	.38
Pharmaceutical companies are trustworthy in offering reliable information about the efficacy of their products	39	78	<.001
Pharmaceutical companies are trustworthy in offering reliable information about safety concerns and adverse side effects related to their products	41	78	<.001
Pharmaceutical companies are trustworthy to develop new and effective prescription drugs	76	90	.11
Pharmaceutical companies are trustworthy to price their products fairly	24	46	.04
Pharmaceutical companies are trustworthy to inform the public quickly when they learn of a safety concern with one of their products [‡]	51	73	.02
I am confident that prescription drugs sold in the United States are safe	71	88	.07
Pharmaceutical companies do not do enough to ensure the safety of prescription drugs	12	12	>.99
There should be more government regulation to ensure the safety of prescription drugs	24	15	.39
The cost of prescription drugs in the United States is reasonable	20	46	.001
Insurance companies should only pay for prescription drugs that have been proven to be more effective or safer than existing available treatments	41	49	.61
The government should only approve prescription drugs that have been proven to be more effective or safer than existing available treatments	49	39	.39
The benefits of prescription drugs justify the price society must pay for them	32	56	.03
Prescription drugs do not reduce the need for expensive medical procedures and hospitalizations	12	15	>.99
In the long run, prescription drugs reduce health care costs	73	93	.04
There should be more government regulation on pricing of prescription drugs	46	37	.34
Pharmaceutical companies do not do enough to help people who cannot afford their medication	24	20	.73

^a Students were asked to read the statements and indicate their level of agreement or disagreement (1=strongly agree, 2=agree, 3=neither agree or disagree, 4=disagree, 5=strongly disagree). For ease of presentation and interpretation, the 5-point Likert scale was collapsed into a 2-point Likert scale where agreed or strongly agreed responses were grouped together (agreed with the statement) and the rest were classified as did not agree with the statement. The table indicates the percentage of students who agreed or strongly agreed during the pre-course survey compared to the post-course survey

^b Statistical analysis was performed using the Signed Rank test to determine the significance, defined as $p < .05$, of differences between the pre-course survey and post-course survey

ensure continuity from week to week and to avoid unnecessary overlap. In addition to didactic instruction, application projects were specifically designed to reinforce didactic concepts and to allow for practical application of concepts from a pharmaceutical industry perspective. These assignments centered on roles common for medical affairs personnel but required students to use understanding

of critical literature evaluation, regulatory oversight, health economics, drug development, writing, and verbal communication. The layout of the course and associated application activities allows for implementation by a faculty member within other colleges and schools of pharmacy.

Another unique aspect of this study was the incorporation of a survey to evaluate changes in student

Table 4. Student Pharmacists' Perceptions of Prescription Drug Direct to Consumer Advertising Before and After Completing an Elective Course on Pharmaceutical Industry Practice (N=41)^a

Statement	Pre-Course, %	Post-Course, %	p Value ^b
Direct to consumer advertising on the television and the Internet is good for patients and society	22	44	.02
Pharmaceutical companies should not be allowed to market their products directly to consumers	34	37	>.99
There is not enough government regulation to ensure that prescription drug advertising is truthful and accurate	46	22	.04
Prescription drug advertising does a good job of describing potential benefits of products	56	73	.09
Prescription drug advertising does a good job of describing potential adverse side effects and safety considerations for products	32	71	<.001
Prescription drug advertising does a good job of describing conditions or disease states that prescription drugs are used to treat	59	56	>.99
Prescription drug advertising is usually inaccurate and misleading	17	15	>.99
Promotional advertising costs do not contribute to making prescription drugs too expensive	7	15	.25
Advertising for prescription drugs encourages people to make medications they don't need	73	54	.06
Prescription drug advertising educates people about valuable treatments and encourages them to seek medical attention for conditions they might not be aware of	56	61	.77
Pharmaceutical companies spend too much money on prescription drug advertising	54	46	.55

^a Students were asked to read the statements and indicate their level of agreement or disagreement (1=strongly agree; 2=agree; 3=neither agree or disagree; 4=disagree; 5=strongly disagree). For ease of presentation and interpretation, the 5-point Likert scale was collapsed into a 2-point Likert scale where agreed or strongly agreed responses were grouped together (agreed with the statement) and the rest were classified as did not agree with the statement. The table indicates the percentage of students who agreed or strongly agreed during the pre-course survey compared to the post-course survey

^b Statistical analysis was performed using the Signed Rank test to determine the significance, defined as $p < .05$, of differences between the pre-course survey and post-course survey

pharmacists' perceptions regarding the pharmaceutical industry, familiarity with roles and responsibilities of pharmacists within the pharmaceutical industry, and self-perceived confidence in performing specific tasks associated with practice in the pharmaceutical industry. Students' views of the pharmaceutical industry can be shaped by many factors and can often include misconceptions that arise out of lack of knowledge regarding pharmaceutical industry practices. Even though students came into the course with a positive view of the pharmaceutical industry, there was an increase in the number of students that perceived the pharmaceutical industry to make a comparatively greater contribution to society than other industries. In addition, there was an increase in the number of students that positively viewed the reliability of drug information from the pharmaceutical industry related to efficacy and safety of products. There were also increases in the number of students who had positive impressions of promotional advertising and cost implications associated with use of prescription drugs. The incorporation of active-learning exercises may provide

some explanation for these observed changes. The course emphasized the need for students to understand usual practices within the industry and the federal regulations that governed these practices. Furthermore, the course incorporated several application projects that allowed students to experience the complexity of functions by requiring them to perform various tasks from the perspective of a pharmacist who would be working at a pharmaceutical company. Active-learning exercises may allow students to gain an appreciation for the specific processes associated with various tasks and the complexity of these functions.

Several challenges exist for colleges that seek to implement similar elective courses for their students. Primarily, faculty members with an interest in pharmaceutical industry practice must be identified. Furthermore, collaborative relationships must be developed with practitioners in the pharmaceutical industry who can represent a broad range of industry-based functions and responsibilities, and who have interest and skills for didactic instruction. Another challenge for the academy to consider is the need for developing experiential education opportunities that

provide a good next step for students who have gained a foundation of knowledge through elective courses. In this study, 75% of the students who took the elective course reported wanting to pursue a career in the pharmaceutical industry; however, only one quarter of enrolled students took a pharmaceutical industry-based APPE. This relatively low percentage most likely reflects the limited number of experiential opportunities that the pharmaceutical industry makes available to students through colleges. This effect can be complicated in that geographic distribution of pharmaceutical companies is not uniform around the country. Hartman and colleagues similarly found a very low percentage of students that were able to pursue experiential opportunities in the pharmaceutical industry.⁸ The opportunity exists for productive collaboration between colleges and pharmaceutical companies to address this challenge and develop experiential and postgraduate opportunities that meet student interest and demand.

There are several limitations to this study including likely selection bias as students in this course represented those who were most motivated to learn about the pharmaceutical industry. Despite this, student responses reflected an improvement in confidence with a variety of pharmaceutical industry specific tasks. Another limitation is that student perceptions of the pharmaceutical industry would be expected to improve as they were mostly exposed to instructors who currently worked in the pharmaceutical industry. Furthermore, the survey used to evaluate students' perceptions did not include a validated knowledge assessment, which would have enhanced the ability to objectively measure changes in student learning. Future work should focus on the development of a validated knowledge assessment that can be used to properly evaluate changes in student knowledge regarding pharmaceutical industry practice.

CONCLUSION

This study demonstrates the feasibility of successfully implementing an elective course for student pharmacists that provides instruction and application opportunities regarding a broad range of pharmacist roles that are unique to the pharmaceutical industry setting. Collaboration between colleges of pharmacy and pharmaceutical manufacturers can lead to an increased number of curricular offerings. Furthermore, these courses can assist students as they seek to expand familiarity and knowledge regarding prescription drug development, commercialization, and the role of the pharmaceutical industry in modern health care delivery.

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Appendix 1. Weekly Topics Covered in an Elective Course on Pharmaceutical Industry Practice

Sections	Topics
Medical Affairs	Legal and regulatory oversight of the pharmaceutical industry Introduction to medical affairs Principles of promotional review Medical communications from a pharmaceutical industry perspective
Drug Development	Drug development overview Translational medicine Clinical development Regulatory affairs Health economics and outcomes research
Customer Interface	Market access Field based medical affairs Scientific publication strategies Commercial marketing Leadership in business

Appendix 2. Learning Objectives for an Elective Course on Pharmaceutical Industry Practice

Explain the major federal laws and regulations that govern the pharmaceutical industry in the United States
Discuss the application of the following regulatory terms during the review of promotional advertising: on-label, off-label, claim, false and misleading, material facts, substantial evidence, fair balance, and materiality
Evaluate a direct to consumer prescription drug advertisement using principles of promotional review
Discuss the following regulatory violations related to promotional advertising: omission of risk information, minimization of risk, misleading claims, unsubstantiated claims, broadening of indication, and lack of adequate directions
Describe the position of medical affairs organizations within a pharmaceutical industry and discuss gaps in knowledge that create the need for these organizations
Demonstrate the ability to provide a written response to a drug information inquiry from an industry perspective using appropriate, critically evaluated primary medical literature
Discuss the following terms as it relates to good drug information practices: scientific balance, unsolicited requests for information, disclaimers
Discuss the pre-clinical, Phase 1, Phase 2, Phase 3, and Phase 4 stages of prescription drug development and the corresponding regulatory filing and agency interaction milestones in the United States
Describe the different types of clinical studies that can be used during the drug development process and discuss the contribution toward determining causation when evaluating clinical studies
Discuss the rationale supporting the importance of health economic and outcomes-based research for prescription drugs
Apply knowledge regarding types of health economic and outcomes research studies to recommend a strategy to define the value of a prescription drug product
Discuss the strategic value of field based medical affairs functions for the pharmaceutical industry
Describe the scientific publication landscape including authorship best practices