Direct-to-Consumer Sale of Prescription Drugs by Pharmaceutical Companies: An Assessment of the Patient Experience?

Journal of Pharmacy Technology
2016, Vol. 32(3) 98–103
© The Author(s) 2016
Reprints and permissions:
sagepub.com/journalsPermissions.nav
DOI: 10.1177/8755122515627361
pharmatech.sagepub.com

David Seal, PharmD¹, Sylvia Jackson, PharmD¹, Jeffrey Brooks¹,
Kiydra Harris¹, April Haskell¹, and Rodney Ransom¹

Abstract

Background. Direct-to-consumer sale of prescription medications by pharmaceutical companies has emerged as a novel delivery method. It is important to ensure that patients who choose this method are receiving adequate pharmaceutical care that meets established practice standards. **Objective.** The objective of this study was to assess consultation for patients who are receiving medications via direct-to-consumer sales of prescription drugs from pharmaceutical companies. **Methods.** We conducted a blinded telephone survey using 10 mock prescriptions for simulated patients (secret shoppers) by contacting the 2 companies currently offering prescription medications for sale directly to consumers. **Results.** Simulated patients in this pilot study only had a pharmacist initiate consultation for 20% of the calls. Multiple pharmacy technicians offered consultation and this behavior does not follow state statutes. In addition, technicians also failed to forward calls to the pharmacist-on-duty, instead suggesting the patients contact their physicians. On a further direct request to speak to a pharmacist, a consultation did occur for 90% of the calls. However, the consultation failed to achieve practice standards set by Omnibus Budget Reconciliation Act of 1990 and the state statutes for the majority of the encounters. **Conclusion.** These results warrant a larger scale study of consultation for direct-to-consumer prescription sales. In addition, they highlight areas for training needed for all pharmacy personnel who work in this venue.

Keywords

direct-to-consumer sales, Internet pharmacy, pharmacist consultation, simulated patient, mail-order pharmacy

Background

Direct-to-consumer (DTC) medication sales have quietly emerged as a novel way for consumers to receive prescription drugs. Recently, several medications have become readily available from their manufacturers and are sold directly to patients via prescriptions that are sent to drug companies rather than traditional pharmacies, bypassing wholesalers. Company-sponsored medication assistance programs have offered branded prescription medications directly to patients in the United States with limited incomes for years; however, this practice involves the actual sale of prescription product to a patient by a pharmaceutical company.

Direct-to-consumer advertising for prescription drugs has been a controversial practice for well over a decade. The practice is limited primarily to the United States and New Zealand. Previous studies have demonstrated that DTC marketing increases both sales for manufacturers and physician prescribing habits and also may improve patient health outcomes.¹ The controversy continues as a ban in Europe demonstrates opposition to this practice, arguing it is merely in the interest of profit. In contrast, DTC sales

may not provide patients with adequate or pertinent drug information pertaining to their medications.^{2,3} Studies that examine this novel practice of sales are lacking.

Research has demonstrated that Internet medication sales often fail to provide patients with the actual medication they are seeking. Study findings presented in 2012 demonstrated that 77% of Viagra sold through 22 different sites was fake.⁴ More important, the NABP (National Association of Boards of Pharmacy) Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators found that approximately 97% of the more than 10 500 websites selling prescription medications do not operate in compliance with pharmacy laws and practice standards, a genuine public health concern.⁵ In 2013, after the results detailing the counterfeit Internet sale of Viagra tablets were released, Pfizer

¹Florida A&M University Jacksonville Instructional Site, Jacksonville, FL, USA

Corresponding Author:

Sylvia Jackson, Florida A&M University Jacksonville Instructional Site,
2050 Art Museum Drive, Jacksonville, FL 33324, USA.
Email: Sylvia.jackson@famuedu

announced an Internet campaign to sell its branded drug directly to consumers who have prescriptions.⁶ Pfizer named this process “Viagra Home Delivery.” Pfizer’s site states that consumers can order their Viagra from the comfort of their homes and that their prescriptions are handled by trusting pharmacists. In addition, AstraZeneca launched Nexium Direct in 2014, whereby patients can receive brand Nexium directly from the manufacturer.⁷ This move preceded the release of the over-the-counter (OTC) product and generic versions of the prescription product. The Food and Drug Administration continues to oversee DTC advertising, but there is not yet an established standard for DTC sales of prescription medication. Both the aforementioned products are essentially being offered directly to consumers via mail-order pharmacies not owned by the pharmaceutical companies. Eagle Pharmacy partnered with AstraZeneca for Nexium (esomeprazole), and CVS partnered with Pfizer for Viagra (sildenafil citrate) in these DTC ventures.

The published literature was examined and there are limited studies evaluating mail-order pharmacies and none that address DTC medication sales. In a study published in 2003, it was found that 8.7% of the nearly 300 000 mail-order prescriptions examined required clarification from a prescriber.⁸ The study determined that fax and mail prescriptions required clarification at a higher rate than directly phoned or electronic prescriptions. The results of a 2005 Medco-sponsored study published in *Pharmacotherapy* suggested that mail-service pharmacy was far more accurate than retail pharmacy, reporting dispensing error rates less than 1 error per 1000 prescriptions.⁹ Next, Express Scripts sponsored a study in 2010 that reported increased adherence and decreased health care costs for diabetic patients who switched to mail-order pharmacy.¹⁰ The controversy that abounds with any mention of “mandated mail-order pharmacy” along with the quiet emersion of “direct-to-consumer” prescription sales prompted this research.

Objective

The aim of this study is to assess the consultation practice of this innovative trend allowing patients to bypass conventional pharmacies and receive medications directly from pharmaceutical companies. The intent is to determine how pharmaceutical care is provided to patients who choose to utilize such companies for their prescription medications. The study will evaluate if the quality of information provided to consumers is achieving the standards of pharmaceutical care set forth by Omnibus Budget Reconciliation Act (OBRA) of 1990 and state law.¹¹

Methods

A 2-page telephone survey (see the appendix) was created to evaluate if patients receiving their medications through

DTC sales are afforded pharmaceutical care that meets practice standards. Pharmacy interns designed the survey in their final year of pharmacy school as part of a research methods course. Two ambulatory care pharmacy practice faculty guided them in the design of the survey. It was designed to meet the criteria established by (Florida) state statutes that govern prospective drug review. The survey did not ask the pharmacy personnel for any personal information. The types of pharmacy personnel were documented as pharmacists, pharmacy technicians, operators, or customer service representatives. In addition, the survey evaluated the counseling content covered by the pharmacy personnel and included the medication indication, the route of administration, adverse effects, drug-drug interactions, drug-food interactions, and drug-disease interactions and interventions, all of which are the essential components of a prospective drug utilization review.

Ten mock patient prescriptions for Viagra and Nexium were provided by physicians who consented to participate in the study. The simulated patient participants used to evaluate the counseling practice were fourth-year PharmD candidates. The simulated patient (ie, secret shopper) has been validated in pharmacy research.¹²⁻¹⁵ This method of assessment has been validated outside of the United States and is now used to routinely evaluate counseling. In addition, it was also used by Auburn University, Alabama, to evaluate pharmacist counseling in the retail setting, again proving its utility.¹⁶

Two male students acted as the patients seeking Viagra. The 2 female students acted as the patients seeking Nexium. All encounters followed the same script in an attempt to minimize researcher bias and ensure validity. Documentation was made immediately during the phone survey to prevent recall bias. The phone calls were not recorded but all students were required to make detailed notes for each call. The prescriptions (for Viagra or Nexium) were sent directly to their respective DTC sales fax numbers as required and detailed at each company website. The 2 pharmacy companies and the personnel that manage the DTC sales and counseling of the aforementioned medications were blinded to ensure that the assessments were evaluating normal daily operational practices. The mock patient prescriptions were solely used to evaluate consultation practice and were not dispensed. Based on a literature search and product information for each branded product, mock profiles were established to include BiDil (isosorbide dinitrate/hydralazine) for those simulated patients seeking Viagra, setting up a scenario for a commonly cited nitrate interaction. Last, the simulated patients seeking Nexium had profiles to include Plavix, setting the scenario for the commonly cited interaction between proton pump inhibitors and Plavix. These scenarios appear in the aforementioned script (see the appendix). Florida A&M University’s Institutional Review Board (IRB)—Division of Research Office—approved the study.

Table 1. Telephone Survey Results.

Initial Approach	Results
The telephone number was readily available on the website	Yes: 10/10; no: 0/10
How long did it take the patient to receive service?	Average of ~6 minutes/call
On calling, who offered information regarding the product?	Pharmacist: 2; pharmacy technician: 6; customer service representative: 2
Did the individual providing counseling services seem distracted?	Yes: 4/10; no: 6/10
The individual asked open-ended questions to gauge initial understanding of the drug?	Yes: 4/10; no: 6/10

Study Results

There were 5 categories used to evaluate the services rendered to the mock patients. Table 1 shows the specifics evaluated in the 5 categories. This study demonstrated that patients who utilize DTC sales wait approximately 6 minutes before receiving service from any pharmacy personnel when contacting the listed telephone numbers. Ten telephone surveys were completed with the pharmacists offering initial product information to the mock patients only 20% of the time. Moreover, it was observed that of the pharmacy personnel who provided drug information, 40% of them seemed distracted. Last, open-ended questions were observed for only 40% of the calls.

The counseling content addressed was the secondary objective of the evaluation, and shortcomings were observed. When the mock patients specifically requested a pharmacist, the consultation content provided beyond the medication indication failed to meet established pharmacy practice standards. Table 2 exhibits the apparent deficit in consultation when patients actually request it. Notably, all mock patients used in this study were scripted to be concurrently taking either BiDil (if mock prescription was starting Viagra) or Plavix (if mock prescription was starting Nexium). The results found that 40% of pharmacy personnel made an intervention based on these interactions.

Discussion

Overall, this study suggested a lack of adequate pharmacist-to-patient interaction within the DTC medication sales market. It is noteworthy that pharmacy technicians in some instances offered drug information to the mock patients. According to the Board of Pharmacy Florida Statute (465.014), pharmacy technicians are not allowed to provide such consultations. Technicians can offer a pharmacist

Table 2. Counseling Assessment Results.

Counseling Content Addressed With the Mock Patient	Results
Medication indication/benefits of action	Yes: 9/10; no: 1/10
Medication administration	Yes: 6/10; no: 4/10
What to expect when taking this medication	Yes: 4/10; no: 6/10
The patient was asked about concurrent medications ^a	Yes: 4/10; no: 6/10
An intervention was made based on the mock patient's severe drug interactions	Yes: 4/10; no: 6/10
In general, the patient was counseled on drug-drug, drug-food, drug-disease interactions	Yes: 1/10; no: 9/10

^aConcurrent medications for Viagra mock patients included the following: Coreg, BiDil, and Lisinopril. Concurrent medications for Nexium mock patient included the following: Aspirin, Chlorthalidone, and Plavix.

consultation, but under Florida law they cannot provide consultation to patients. The patients who use this venue will obviously be filling a prescription for a single drug leaving the pharmacist with an incomplete profile. The pharmacist is working for a mail-order pharmacy that likely has more complete profiles for many other patients who are not part of this special cohort. The automated safeguards—alerts—will be lacking for this group. Therefore, more clarification from the patient or provider would be necessary to a complete a prospective drug review.

The sample size was small for this pilot study, but the results merit further investigation, and a larger scale trial is warranted. During data collection, pharmacists were deemed “busy” and unable to answer drug-related questions when called by the simulated patients. Several technicians advised patients to speak with their primary care physicians about medication issues rather than forwarding them to the pharmacist-on-duty for assessment and/or consultation. However, after specifically requesting the pharmacist, he/she was made available and in most cases provided counseling. These actions underscore another opportunity for proper staff training. Another aspect of pharmacy practice is prospective drug utilization review, and such reviews were not conducted by all, thus resulting in the failure to identify drug-drug interactions. Completion of this study demonstrated the vital importance of pharmacist-to-patient interaction in the pharmacy practice setting.

Limitations

Viagra and Nexium are the only medications being offered for sale directly to the consumer. Nexium is currently

available as an OTC product in the United States and may have been deemed as low risk, which may be less likely to trigger a consultation. The researchers suggested that had all the medications been in patient profiles, an automated alert for the staged interactions likely would have prompted the pharmacists to action. The reality is that many patients use multiple pharmacies for cost savings, which places the burden on pharmacists to verify the profiles without the benefit of automated alerts. This is especially vital for patients requesting OTC products that may interact with current prescription products or in situations like the ones discussed in this report wherein patients opt for DTC sales. A limited sample size makes it difficult to draw statistically significant conclusions but the pilot has clinical significance.

The study methodology attempted to follow a mock scenario that represented a typical patient experience when filling via a DTC mail-order pharmacy. Actual prescriptions were faxed and ample time was given to allow for the prescriptions to be filled. This would, in theory, afford pharmacists an opportunity to review prescriptions and glean necessary information for a prospective drug review. The prescriptions were filled but not dispensed. Because we were contacting mail-order pharmacies at their listed phone numbers, we felt the pharmacists would provide complete consultation since the prescriptions had been filled and completed, except for the mailing out of the prescription. However, it is possible that these pharmacists may have altered their consultation on realizing the medication had not been dispensed. Future trials may avoid this potential confounder by ensuring the medications have been mailed out.

Conclusion

Our results suggest a system flaw in the medication use process. We identified a lack of appropriate counseling being provided to patients receiving their medication directly from manufacturers through mail-order pharmacies. This details opportunities for CQI (continuous quality improvement) programs that enhance training and optimize outcomes. Continuing education that targets best consultation practices for pharmacists and technicians who work in this venue is warranted. As suggested in the discussion we call for additional research that evaluates this practice, in particular mail-order consultation. Also, we feel it prudent to examine rules that govern this practice to assure appropriate oversight. Finally, the results identify the risks of polypharmacy, highlighting the need for complete medication profiles. Ultimately, consultation for these patients is just as important as it is for patients who use traditional pharmacies. The future is certain to bring increased Internet sales resulting in more mail-order prescriptions.

This pilot study revealed that pharmacy personnel employed by the manufacturers of the DTC prescription drugs did not provide adequate drug information as suggested by OBRA'90 and the state statutes. It was concluded that the majority of pharmacists of the aforementioned companies failed to meet these requirements. A primary question we set out to answer was, "What actually happens when you call the '800' number listed on a direct-to-consumer prescription?" Assessments of the patient experience—our results—emphasize areas where mail-order consultation may need to improve. Technological advances and a truly universal electronic medical record are tools to aid in the provision of optimal pharmaceutical care to ensure patient safety. As the profession evolves and moves toward provider status, it is imperative we maintain and embrace the core functions of pharmacy practice.

Appendix

Direct-to-Patient Drugs: Script for Phone Survey

1. Viagra
 - a. Phone: 1-888-702-1981
2. Nexium
 - a. Phone: 1-800-4-NEXIUM

Opening Statement (What the "Patient" Asks the Representative on Calling the Above Companies)

Hello, my doctor just prescribed me this medication called _____; she/he didn't cover anything about the medication and how it would help me with my condition. Can you give me some advice?

Initial Approach

Was the telephone number readily available on the website?

Yes No

How long did it take the patient to receive service? (*Minutes*)

1-3 3-5 5-7 7-10 10-15 >15

Had to call back/leave message

Upon calling, who offered information regarding the product?

Pharmacist service	Technician representative	Operator	Customer
--------------------	---------------------------	----------	----------

Did the individual providing counseling services seem distracted?

Yes No

The individual asked you (the patient) open-ended questions to gauge my initial understanding of the drug.

Yes No

Counseling Content

Information the Pharmacist covered during the counseling session with the “patient”:

1. Medication indication/Benefits of action

That is, What the medication is used for. Does it decrease symptoms, slow disease progression, or prevent a disease from occurring?

Yes No

2. Medication administration

That is, Route of the medication. Specific time the medication should be administered? Should the medication be taken w/ or w/o food or water? Counselor on how to take the medication?

Yes No

3. What to expect when taking this medication

(Potential common and serious adverse effects)

Yes No

4. If the pharmacist asked about other medications you were taking

	YES	NO
Rx		
OTC		

If you chose “YES” for the above question, your mock patient profile will consist of one of the following categories:

1. If your mock prescription is for Viagra your additional medications will be Coreg (carvedilol), BiDil (isosorbide dinitrate/hydralazine), and Lisinopril.
2. If your mock prescription is for Nexium your additional medications will be low-dose Aspirin, Chlorthalidone, and Plavix (clopidogrel)

5. If yes, was an intervention made?

That is, Rph recommended against taking the medication, instructed you to call your physician, or offered to contact your physician.

Yes No

6. In general, were you counseled on potential drug-drug, drug-food, or drug-disease interactions?

Yes No

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

References

1. Calfe JE. What do we know about direct-to-consumer advertising of prescription drugs? *Health Aff (Millwood)*. 2003;Suppl Web Exclusives:W3-116-9.
2. Schwartz LM, Woloshin S. The drug facts box: improving the communication of prescription drug information. *Proc Natl Acad Sci U S A*. 2013;110:14069-14074.
3. Ventola CL. Direct-to-consumer pharmaceutical advertising: therapeutic or toxic? *P T*. 2011;36:669-684.
4. Veronin MA, Nutan MT, Dodla UK. Quantification of active pharmaceutical ingredient and impurities in sildenafil citrate obtained from the Internet. *Ther Adv Drug Saf*. 2014;5:180-189.
5. National Association of Boards of Pharmacy. NABP Internet drug outlet identification program. https://awarerx.s3.amazonaws.com/system/redactor_assets/documents/237/NABP_Internet_Drug_Outlet_Report_July2013.pdf. Accessed January 7, 2016.
6. Thomas K. Facing black market, Pfizer is looking online to sell Viagra. *The New York Times*. <http://www.nytimes.com/2013/05/07/business/pfizer-begins-selling-viagra-online.html>. Published May 6, 2013. Accessed January 7, 2016.
7. AstraZeneca. Delivering our brands directly to you. <http://www.astrazeneca-us.com/medicines/astrazeneca-direct>. Accessed January 7, 2016.
8. Feifer RA, Nevins LM, McGuigan KA, Paul L, Lee J. Mail-order prescriptions requiring clarification contact with the prescriber: prevalence, reasons, and implications. *J Manag Care Pharm*. 2003;9:346-352.
9. Teagarden JR, Nagle B, Aubert RE, Wasdyke C, Courtney P, Epstein RS. Dispensing error rate in a highly automated mail-service pharmacy practice. *Pharmacotherapy*. 2005;25:1629-1635.
10. Devine S, Vlahiotis A, Sundar H. A comparison of diabetes medication adherence and healthcare costs in patients using mail order and retail pharmacy. *J Med Econ*. 2010;13:203-211.
11. Vivian JC, Fink J. OBRA '90 at sweet sixteen: a retrospective review. http://www.uspharmacist.com/content/d/featured_articles/c/10126/. Published March 20, 2008. Accessed January 7, 2016.
12. Alte D, Weitschies W, Ritter CA. Evaluation of consultation in community pharmacies with mystery shopper. *Ann Pharmacother*. 2007;41:1023-1030.

13. Weiss MC, Booth A, Jones B, Ramjeet S, Wong E. Use of simulated patients to assess the clinical and communication skills of community pharmacist. *Pharm World Sci.* 2010;32:353-361.
14. Benrimoj SI, Werner JB, Raffaele C, Roberts AS. A system for monitoring quality standards in the provision of non-prescription medicines from Australian community pharmacies. *Pharm World Sci.* 2008;30:147-153.
15. Norris PT. Purchasing restricted medicines in New Zealand pharmacies: results from a "mystery shopper" study. *Pharm World Sci.* 2002;24:149-153.
16. Flynn EA, Barker KN, Berger BA, Lloyd KB, Brackett PD. Dispensing errors and counseling quality 100 pharmacies. *J Am Pharm Assoc (2003).* 2009;49:171-180. doi:10.1331/JAPhA.2009.08130.