The Wonderful World of Drug Samples

By Sandra Zori

The relationship between the drug industry and healthcare professionals has always been one filled with controversy and ethical debate. One of the largest areas for potential conflict is the fine line between the need for an improvement in drug therapy outcomes and the fiscal interest of the pharmaceutical industry. It is a widely established opinion that clinical decision making should take precedence over profit motives.\(^1\) The drug industry is an influential and powerful force able to motivate prescribers in the direction it favors. While many physicians believe that they are unlikely to be influenced by drug representatives, incentives or promotional material, numerous studies have demonstrated that this is clearly not the case.

The role the medication representatives have is an influential and expensive one. More than $11 billion is spent annually by pharmaceutical companies in marketing and promotional strategies. Of that $11 billion, almost half is used to pay for sales representatives since they always come bearing gifts. It is estimated that up to $13,000 is spent on one physician per year.\(^2\) Of all the marketing strategies used to push a product forward from physicians and into the hands of patients, the use of a drug representative has some of the most promising results. Up to 40% of the pharmaceutical industry’s revenue is invested into promotional efforts. Marketing by way of sales representatives may be the most expensive method, but it is also the most widely applied because of its expansive success.\(^3\)
Of course the utilization of a drug representative will be more costly due to the fact that meals and travel have to be accounted for by the drug company, as well as the salary of the drug representative, and also all the incentives used to lure a physician into meeting with a representative. It is a fact that many physicians will not even meet with a drug representative if they did not have drug samples, gifts or a meal with them. While physicians do not believe the use of promotional gifts and incentives would affect their prescribing patterns, many disagreed with the statement: “I would have the same degree of contact with pharmaceutical representatives whether or not promotional gifts were distributed.”

Physicians are more likely than pharmacists to be satisfied with the marketing and promotional practices of drug representatives. This is probably due to the fact that physicians have a more clinical role with the patient, while the pharmacist is much more likely to evaluate and analyze scientific data.

A study published in 2002 found that over 10% of new chemical entities approved from 1975 to 1999 received a black box warning leading to a number of withdrawals. Almost 8% of all the chemical entities required a second black box warning. The authors of the study blamed the high incidence of adverse effects leading to withdrawals and black box warnings on the aggressive marketing by pharmaceutical companies and their representatives. It is advised that “clinicians should avoid using new drugs when older, similarly efficacious agents are available.” In another study from 1996, medical residents were surveyed after presentations for Lyme disease were given by pharmaceutical representatives. It found that attendees were more likely than non-attendees to name the speaker’s drug as first line even when it was not indicated.

Still, one must wonder what the true role of the drug representative is. It is obviously clear that they are there to make physicians aware of new medications, dosage forms, doses,
routes of administration, and statistics to name a few. However, the underlying rationale for this education may not be as clear. The Canadian Medical Association assumes that the primary goal of the industry is to show profit and one must always remember that a drug representative is part of the pharmaceutical industry, not the healthcare field. While it can be argued that drug representatives are there to enlighten physicians with new and upcoming information, a more cynical response would be to say that they are only there to push a product out, regardless of its safety, efficacy or cost as compared to a drug already out on the market. It would be safe to assume that if a drug truly was innovative and a product of higher quality than what is already available, then it would not need to be marketed for it would probably sell itself.

On the other hand, if that drug representative was not there to actively promote a new product or offer samples, what motivation does a physician have to prescribe it? If it was not for a drug representative and company to give a physician incentives to attend presentations about their product or even travel to association meetings or symposiums, would there be a reduced amount of overall attendance at these events? It is safe to assume that without the constant motivation and reminders that medication representatives give, there would be a much less diversified and more rational prescribing technique.

The knowledge of a drug representative may seem unreliable. Entry level positions are offered to people with no healthcare background and no sales experience. These entry-level positions are also called primary care or mass-market representatives. The target group is primary care physicians and the drugs marketed are usually antihypertensives or allergy medications – drugs that most patients are on. To specialize, it is preferred that the drug representative has a more scientific background, such as a college degree with classes in
biochemistry, pharmacology, as well as marketing, statistics and public speaking. The more professional the demeanor, the better an image the drug representative presents.\(^9\)

With all this knowledge about basic pharmacology of drugs, many pharmaceutical representatives cannot compare to practicing pharmacists, yet the representatives are considered expert enough to give presentations on certain medications. However, they still do not know much about drugs outside their area of expertise. Furthermore, much of what they know about a drug is information their company has trained them to say, making their presentations even more biased and unreliable.\(^8\)

On the National Association for Pharmaceutical Sales Representatives website, much of the information for drug representatives is about mastering the craft of selling, while becoming leaders in the sales field. Many of the topics for advancement include information on winning the sale and prospecting. Another highlight is the figures for the average salary for the most recent years. Depending on their commission, which could be highly lucrative, a sales representative is expected to make just over $90,000 annually.\(^10\)

While pharmaceutical representatives are responsible for more than just making certain the physician has all the information regarding a new drug, many of them will also give drug samples to the physician to hand out to patients. A drug sample is defined in the United States Code Service as “a unit of drug… which is not intended to be sold and is intended to promote the sale of the drug.”\(^11\) In other words, the purpose of a drug sample is not to make a quick profit, but to eventually create revenue somewhere down the line. This calls in to question the word “intend” – who is deciding what the purpose of this drug is? And how is it decided whether a drug is to be sold or given out promotionally? It seems that by this vague definition that the
intent of the drug is decided by the manufacturers, because it is too easy to say that a pharmacist may intend to sell the drug and therefore making it a legally acceptable action.

Secondly, the distribution of this drug sample is only authorized by the manufacturer or authorized distributor, in response to a written request so that all samples are accounted for. Once this request is inputted, the sample may only be distributed to licensed practitioners and to their associated pharmacies in hospitals or health care entities.

There are two fundamental purposes for the distribution of drug samples: first, it is to make available to patients medications that they could not otherwise afford and second, to “test” a drug for a trial period to assess side effects and interactions before a patient commits to it. Upon polling physicians in a New York hospital, only 13% of physicians had received a formal education on drug costs to patients, even though 88% felt that medication costs is an important consideration when prescribing and assessing compliance. Almost three quarters were willing to sacrifice efficacy to make drugs more affordable to patients.

One way to make medications more affordable is to give patients samples of the medications for as long as they need them. More pharmacists than physicians find it unethical to distribute no-cost medication samples to patients. This is probably due to the fact that pharmacists are less likely to be as heavily involved as the physician with the patient’s therapy and clinical decision-making. Yet, with the face of pharmacy changing and becoming more clinical, the opinions of pharmacists might eventually favor the use of medication samples in the near future.

However, due to the infusion of money into the promotion of medications, the new role of a medication sample is to serve as brand and company recognition, thereby promoting the manufacturing companies. This promotion is usually accompanied by the distribution of
incentives and promotional gifts to physicians. This is clearly stated in the definition of a drug sample in the United States Code Service.

These incentives and gifts range from the very small, such as pens and notepads, to the largely explicit, such as airfare and board to a conference held at a tropical destination. The appropriateness of these gifts is subjected to the opinions of those in the profession. While many physicians feel small gifts or meals are appropriate, most agree that larger incentives such as paying for registration at a medical conference is inappropriate and unethical. Between 48 and 75% of physicians surveyed stated that conference travel is inappropriate, and those that had accepted funding to a symposium were found to have additional formulary requests for the sponsor’s drug.²

On the other hand, 33-60% of physicians said that the distribution of samples is inappropriate, and almost 50% said it is influential on their prescribing habits.² In a study of Canadian physicians, 86% said that samples should be offered in order to better practice medicine and assist the patient.¹³ There is no real consensus on the attitudes regarding the role that samples should play in the healthcare setting. With regards to the physicians that do utilize samples or at least consider them, three main considerations were at the top of the list: side effects to the drugs, the cost to patients, and compliance with dosage.³ It is interesting to note that while physicians are open to samples and feel that drug representatives have a certain amount of knowledge, a large number of physicians agreed with the statement, “Pharmaceutical representatives should be banned from presentations where I practice.”³

Upon surveying patients and physicians, Gibbons et al found that patients were more likely to think gifts were less appropriate and more influential than the physicians. The belief is that gifts will influence prescribing. However, most physicians believe that a gift would not
influence their prescribing decisions,\textsuperscript{14} even if it was an all-inclusive trip to a luxurious destination for purpose for a symposium.\textsuperscript{15} These physicians also believe that they would not simply prescribe the drug as thanks to the drug company, but their prescribing decisions would be based on scientific knowledge, clinical experience and the needs of the patient.\textsuperscript{15} There is a significant and dramatic increase in the utility of a drug following the physicians’ luxury trip to a sunny destination, even if the new drugs were not completely replacing the older ones, but there was an increase in excessive use of the new drug. This only further proves that the use of drug representatives in combo with incentives is the most influential and best way to increase profits for the industry.

The American College of Physicians position paper on the physicians and the pharmaceutical industry states:

Gifts, hospitality, or subsidies offered to physicians by the pharmaceutical industry ought not to be accepted if acceptance might influence or appear to others to influence the objectivity of clinical judgment. A useful criterion in determining acceptable activities and relationships is: Would you be willing to have these arrangements generally known?\textsuperscript{4}

The American Medical Association has ethical guidelines regarding gifts to physicians from the industry. If specifies that small gifts under $100 may be accepted if they relate to the profession by either benefiting the patient or serving a genuine educational function. Cash payments at any value are unacceptable and are frowned upon, as are payments towards any costs of medical conferences or meetings. Upon surveying physicians, it was found that only 62\% were aware of at least one guideline on accepting gifts.\textsuperscript{14}

An interesting marketing strategy is one a new American company employs: if a consultation is secured with a doctor, the drug manufacturer will pay $105 to the company. Of this, $50 goes to the physician and $5 to a charity of the doctor’s choice. The company pockets
the remaining $50. Some physicians are keen on this new method as it lets them control when and how often these consultations occur.\textsuperscript{16} Although the guidelines explicitly state that cash payments of any value are unethical, these physicians feel that there is no ethical problem and that the fee does not even cover the cost of their time. This is clearly the utilitarian perspective towards the acceptance of gifts from the drug industry.

On the other hand, the deontological perspective is echoed in the words of Dr Frank Riddick, chairman of the American Medical Association’s council on ethical and judicial affairs: “If the purpose of the contact is to educate the physician, then there is no need to pay the physician.”\textsuperscript{16}

The guidelines also address the use of drug samples. Physicians may use drug samples for their personal use only if it does not interfere with patients’ access to these samples. However, a patient can only access samples at the written discretion of a prescriber. Unless a patient requests the prescriber order some samples, the only way for the patient to access the samples is then by the physician offering them. In this case, why would a physician feel a patient of no relation be of more importance than a patient that is a family member? It is unreasonable to ask a physician to sanction out sample medications to a patient when that physician knowingly has a patient of need that is a relative as well.

Furthermore, the American Medical Association ethical council only permits family use of samples in one of three situations: a) emergencies requiring immediate attention, b) trial basis, c) acute conditions.\textsuperscript{17} If these parameters are not met (ie. the drug is to be used for a chronic condition), then the use of these free pharmaceuticals is deemed unacceptable. One could argue that a physician’s access to drug samples, especially to be able to provide therapy for his or her
own family, is a perk of the profession and is deserved after having gone through many years of education as well as continuing to have a relationship with pharmaceutical representatives.

Upon surveying numerous residents and faculty, Zipkin et al found that most residents considered the distribution and promotion of medication samples to be appropriate. One half to three quarters of the respondents felt like the use of samples influenced prescribing. Although there is a wide range of opinions on the ethics of this matter, one study found that there was a statistically significant association between use of a medication within 12 weeks of a company’s visit and the drug sales of that company.¹⁸

To get a better idea of what members of the community know or assume with regards to drug samples and their distribution, the author polled numerous people using the following survey:

**Part One**

1. Please describe your demographics
   a. Prescriber (MD, DO, etc)
   b. Dispenser (RPh, PharmD, student pharmacist, etc)
   c. Other healthcare professional (RN, drug representative etc)
   d. Not affiliated with the healthcare profession

2. Have you ever used a drug sample?
   a. Yes
   b. No

3. If yes, did you request the drug sample or did the doctor give it to you?
   a. I requested the drug sample
   b. The doctor offered it to me
   c. Do not remember

4. Who do you think pays for drug samples?
   a. The drug manufacturer
   b. The prescriber
   c. The patient
   d. Other/Do not know

5. Which drug sample do you think is safer?
a. Prescription medications  
b. Over-The-Counter medications  
c. Do not know/Equal

6. When pharmaceutical drug representatives meet with prescribers, do you think that the prescriber is influenced by their presentation and are more inclined to give out and write prescriptions for the drug being promoted?  
   a. Yes, very much so  
   b. Maybe, to an extent  
   c. Do not know

Part Two

1. If you found a wallet on the sidewalk, what would you do?  
   a. Return it to its rightful owner, nothing removed  
   b. Return it to its rightful owner after helping yourself to a few dollars  
   c. Not return it  
   Briefly explain your decision:

2. Imagine you are a pharmacist working in close proximity with a number of physicians. The physicians have numerous prescription drug samples but do not actively distribute them to their patients. The physician instead hands you these samples and allows you to do whatever you want with them. What is your course of action?  
   a. You do not take the samples and want nothing to do with them  
   b. You take the samples, and distribute them to patients you think need them  
   c. You take the samples and incorporate them with your inventory, and use them to fill prescriptions which you charge for  
   d. Other:

3. Imagine the same scenario as above, but the drug samples are Over-The-Counter medications. What is your course of action?  
   a. You do not take the samples and want nothing to do with them  
   b. You take the samples, and distribute them to patients you think need them  
   c. You take the samples and incorporate them with your inventory, and use them to fill prescriptions which you charge for  
   d. Other:

In total, 72 people responded to the survey, predominantly through e-mail. The majority of the respondents were people from the “dispenser” category (46 respondents), primarily student pharmacists. The second largest group was anyone not affiliated with the health care profession (12 respondents), followed by the group of health care professionals that are not doctors or pharmacists, or “other healthcare professionals” (9 respondents). The smallest group
polled was the physician, or “prescriber,” group (5 respondents), simply for the reason that they are harder to get a hold of in the community.

Of the 46 pharmacists, only 34 have used a drug sample (74%). The author had assumed that since they are in such close proximity to medications and are more likely to work in close relation with other doctors that the number would be higher, closer to 100%. Of those 34, only six (18%) had asked the doctor for the specific sample. Again, this was surprising to the author since pharmacists are the medication experts and would be more proactive about the medications they are getting, whether or not those medications were samples. Most pharmacists (39 of the 46, or 85%) were correct when answering who pays for the drug samples: the drug manufacturer. Only a few (n=5, 11%) thought that the patient pays for the sample. Although this is not accurate, there could be the possibility that they thought the patient pays for the sample indirectly, through other spiraling healthcare costs and taxes. Dr Douglas Waud of University of Massachusetts confirms this belief that the money for samples and other gifts to physicians “obviously… comes out of the pockets of patients. It may come indirectly from their insurance premiums or even more indirectly from the insurance offered as a fringe benefit in association with their jobs.”

When asked which medication sample is safer, 21 of 46 (46%) pharmacist respondents chose prescription medications, while 16 (35%) said the non-prescription medications are safer. Nine of the respondents (20%) think that the safety of the medications is of equal caliber, or they do not know. This is again interesting to note since the pharmacist is the person responsible for knowing the pharmacology and therapeutic benefits of the medication better than anyone else.

The final question in part one asked whether the prescriber is influenced by the drug representative. Twenty-four of the 46 respondents (52%) said that physicians are definitely
influenced, while 22 (48%) said that they may be influenced. This question shows that pharmacists think that physicians are very easily influenced by the drug representative.

The second part of the survey was situational and only comprised of three questions. The first question about the lost wallet was strategically placed to determine how ethical or moral the respondents felt they were. Almost all of the respondents said they would return the wallet fully intact, without removing even a penny. Only one person out of the 46 pharmacists (2%) said they would not return it, but would leave it at the site, and one other respondent said they would take some money before returning the wallet to its owner. This means that the remaining 96% believe in some way or another that they are moral and ethical beings. Interestingly, when asked to explain their answer, the majority of respondents mentioned “karma” which is defined as “the force generated by a person's actions held in Hinduism and Buddhism to perpetuate transmigration and in its ethical consequences to determine the nature of the person's next existence”\(^{20}\). In other words, karma is a belief that an action will produce an equal and opposite reaction, meaning if one was to take the wallet, then on another day, that person would lose his/her wallet and not have it returned. Ironically, while most people said they would return the lost wallet, it is not returned for the sake of the person that lost it, but for the sake of the finder not having the same ill luck in the future. Again, while it is guised as a deontological outcome, in reality, the majority of respondents that stated that karma was their reason to return the wallet are of a utilitarian mindset.

In the second question regarding prescription samples, 21 of the 46 respondents (46%) said they would not want anything to do with the drug samples, while 41% (n=19) said they would distribute the samples to patients they thought would need them. Only one pharmacist
(2%) said they would incorporate the prescription samples with the inventory and sell it as if it were a purchased drug.

Legally, the distribution of prescription samples may only be administered by a physician. The pharmacist is not permitted under federal law to distribute samples, whether by selling them or giving them out. Furthermore, the question asks about distributing the samples to patient the respondent *thinks* needs the medication. The majority of pharmacists are not in a position to diagnose a condition and treat it using a prescription medication. Since most people enter the healthcare profession to better humankind, most people probably selected the “distribute to patients” answer in an effort to help their patients and it is interesting to see just how far outside the scope of practice they are willing to go to assist others. The majority of responses regarding this scenario more accurately reflect the deontological perspective, since the pharmacist is doing what is best overall for all involved. Should the majority of respondents have chosen to incorporate the samples with their inventory, then the stance of these healthcare providers is clearly utilitarian.

The final question in the survey was similar to the second question, except in this scenario the medication samples were non-prescription. In response to this question, 31 of the 46 pharmacists (67%) were more inclined to distribute the medications to needy patients, while 11 respondents (24%) wanted nothing to do with the medications. Recall that 35% of pharmacists thought that non-prescription medication samples are safer than prescription samples, yet almost double that number feel more comfortable distributing the samples to their patients.

Of the prescribers that responded, four out of five have tried a drug sample, and 75% of them had requested the medication from their doctor. This is quite the opposite of the
pharmacist group, yet is expected of the physician group. Conversely, 66% of the respondents from the other healthcare group admitted to having used a drug sample, and 66% of them had been offered the sample from their physician. Of the group that was not affiliated with the healthcare profession, 75% had used a drug sample, and none of them had requested the sample from their physician.

In all three remaining groups, the majority of the respondents (80% in the physician group, 89% of the other healthcare group, and 83% of the non-healthcare group) answered that the drug manufacturer is the entity responsible for the cost of the drug sample. These groups also responded similarly to the question regarding the safety of the samples: 60% of the physicians, 67% of the healthcare professionals, and 50% of the non-healthcare group answered that non-prescription medication samples are safer than prescription medication samples.

When asked if the prescriber is influenced by the drug representative, 100% of physicians responded by selecting, “Maybe, to an extent.” Interestingly, in numerous surveys of medical residents, less than one half believed that they would be influenced by interactions with a drug representative, yet over 80% believe that their colleagues would be more likely to be influence by those same interactions.6 One flaw of this survey was the lack of inclusion of an option that stated, “No, not at all.” One can imagine how different the responses might have been. In the healthcare group and non-healthcare group, 45% and 42% respectively answered that a physician is definitely influenced by the drug representative.

In the second part of the survey, 100% of respondents across the remaining three groups stated they would return the wallet to its rightful owner. In response to the scenario with the prescription medication samples, the majority of respondents would not want anything to do with the drug samples. Two respondents of the non-healthcare group selected that they would
incorporate the medications in with their inventory. This could be due to the fact that persons that are not up to date on current legislative issues in the medical field may not know that the sale of medication samples is illegal. In the scenario with the non-prescription medication samples, the majority of the respondents answered that they would distribute the medications to patients they think need them.

Of the 72 total respondents, only 70 completed the second part of the survey. This is probably due to the fact that it was on a second sheet of paper, and two people failed to notice it. Regardless, of the remaining 70 respondents, 97% claimed they would return the lost wallet.

Regarding the scenario with the prescription medication samples, 50% of all respondents wanted nothing to do with the samples, while 9% selected other reasons listed below:

- Donate them to an underserved clinic
- Distribute samples to poor patients based on need and consultation with physician
- I would take them and give them to the first patients who come with prescriptions for these drugs and do not have drug coverage, this way it’s legal and nice.
- As far as I know, it is illegal for a pharmacy to distribute free samples of medication – I would try to donate them to a charity
- At the clinic I worked at before we would give them to people who were going to third world countries so they could give them to the infirmaries.
- I would give them back to the physician and insist he gives them out to patients, who perhaps do not have insurance to cover prescription drugs.

While 26% of respondents to the scenario with the non-prescription medication samples stated they wanted nothing to do with the samples, 66% answered that they would distribute the samples to patients they decided were in need of the drug. Only 6% had other suggestions for the use of the samples:

- Donate them to an underserved clinic such as Community Care Clinic.
- Take the samples, do not sell them or give them out to patients, but keep them in the pharmacy for staff use.
- As far as I know, it is illegal for a pharmacy to distribute free samples of medication – I would try to donate them to a charity
I would distribute to patients, since legally as a pharmacist I can give out over-the-counter meds.

Despite the fact that the distribution of medication samples is illegal for persons other than physicians, the law specifies that this regulation is only regarding prescription samples. As noted above, one of the respondents assumed that distribution of all samples is illegal, when that is not the case. Perhaps that presumption plays a role in determining whether a pharmacist would like to have samples that can be shared with patients.

While there is no consensus on whether the interactions that physicians and pharmacists have with pharmaceutical representatives is ethical or not, it clearly remains one of the most debated issues in this field. Also, there is a wide range of opinions regarding what actions are more ethical than others. While today the American Medical Association claims it is ethical to receive small gifts that promote education or help the patient, no one can say how those guidelines with change in the future and what they will change to encompass. As the pharmaceutical market continues to expand and become more dominant, it is reasonable to believe that there will be an even heavier influence on prescribing patterns. Although pharmacists may not play an active role in drug marketing and promotions, perhaps it is a good area for them to venture towards since they are more qualified in determining the safety and efficacy of medications than pharmaceutical representatives.

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