Sample Medication Dispensing in a Residency Practice

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Background. The distribution of sample medications to physicians by pharmaceutical manufacturers has been regulated by Congress and extensively critiqued in the medical literature. Manufacturers distributed 2.4 billion samples in 1988, yet there are no published reports on the clinical use of sample medications.

Methods. A 4-week descriptive study was conducted that catalogued the contents of a sample medication collection in a family practice residency model office, calculated the value of the sample collection (average wholesale price [AWP]), and monitored dispensing of medication samples.

Results. The collection initially contained 5546 samples with an AWP of $19,273. A total of 1012 samples worth $4154 was withdrawn from the collection during the study period. Patients received 548 of the sample packages in 105 dispensements ($2583), physicians or their families received 169 samples in 44 dispensements ($603), others received 26 samples in 6 dispensements ($152), and the destination of 269 samples ($816) was unknown. When a prescription was written at the time that a sample was dispensed, it was almost always for the same brand-name medication.

Conclusions. Although a majority of medications dispensed were given to patients, approximately one third of the value of the medications withdrawn either went to physicians and their families or had an unknown destination. The high association of sample dispensing and simultaneous prescribing of the same brand-name drug supports the contention that sampling influences physician-prescribing habits. Further research should define how the availability of free sample medications affects physician-prescribing practices.

Key words. Drug industry; legislation, drug; prescriptions, drug. *J Fam Pract 1992; 34:42-48.*

In each of the last two decades the matter of sample medication dispensing has been vigorously debated in congressional committees.[1] In 1985 Congress considered legislation that sought to substitute a pharmacy coupon redemption system for the direct distribution of free sample medications to physicians by pharmaceutical representatives. The American Medical Association and the Pharmaceutical Manufacturers Association argued against such a restriction. The root of congressional concern was the knowledge that sample medications were diverted in a fraudulent fashion for resale. Legislation considered in the 1978 congressional session sought to eliminate the distribution of sample medications altogether.

At a hearing before the Senate Committee on Labor and Human Resources in December 1990,[2] Gerald Mossinghoff, president of the Pharmaceutical Manufacturers Association (which represents over 100 research-based pharmaceutical companies), testified that sample drugs

> . . . allow physicians to initiate therapy immediately in their office, which is important for urgent and painful conditions. In addition the physician can evaluate the effect of the drug, detect any early side effects in the patient, and adjust the prescribed dosage before a full prescription is paid for by the patient. The physician can also try one drug therapy for a short time and if necessary switch to another without cost to the patient. Samples thus provide a convenient mechanism to achieve the best available therapy without forcing the patient to incur costs for a drug that may not work for him or her.

Additional arguments in favor of sample medications are that they are useful for demonstration purposes and they may be a source of medication for indigent patients.[1]

Storrs[3] suggests, however, that physicians may be influenced to prescribe "sampled" medications over less expensive but equally effective alternatives. Samples have the potential to be diverted for resale or to be otherwise used inappropriately.[1,4–6] In addition, sample dispensing has been criticized as an ineffective method for dealing with the needs of indigent patients.[1] Storrs estimated that manufacturers of dermatological preparations spent

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more than $20 million in 1978 for sample medications, using funds that could have been directed toward research.

Sample dispensing furnishes pharmaceutical representatives with a reason to visit physicians' offices, and samples may also be an inducement for physicians to permit representatives to visit. Contact with pharmaceutical representatives has been shown to be a consistent predictor of physicians prescribing new medications.[7]

The distribution of free samples also raises the issue of gift giving.[8] The extent to which physicians will feel an obligation as a result of receiving a sample drug is not known. Gifts are known to be used in industry to cultivate social relationships and to promote grateful conduct and reciprocation.[9] The Code of Pharmaceutical Marketing Practices[10] states: "Samples may be supplied to the medical and allied professions to familiarize them with the products or to enable them to gain experience with the product in their practice. The requirements of the Prescription Drug Marketing Act of 1987 should be observed." An opinion issued by the Council on Ethical and Judicial Affairs of the American Medical Association[11] states: "No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician's prescribing practice."

Data collected from the pharmaceutical industry (self-report) for the hearing conducted by the Senate Committee on Labor and Human Resources[2] showed that 2,408,290,164 samples were distributed in 1988. The cost of these samples was not tabulated. Rawlins[12] noted that "no company gives away its shareholders money in an act of disinterested generosity." Although samples (also referred to as "starters" by pharmaceutical sales representatives) are only distributed after obtaining a signed request from a physician, the effect of their availability on the prescribing habits of physicians has not been studied. Mossinghoff[2] stated at the Senate hearing, "The experience with new pharmaceutical products is the key to its acceptance by the physician." In an industry where 24% ($5 billion) of sales revenue is spent on promotion and 13% is spent on research and development,[2] the use of medication samples to encourage physicians to try new drugs and thereby to promote sales seems likely.

Although sample medication collections are found in ambulatory clinics, there is no published information about the content of these collections or the distribution of sample medications from these collections. The purpose of this study was to learn which medications were in the office sample collection and what their value was, which types of samples physicians chose and why, whether samples were properly labeled, whether patients requested samples, whether the medical record documented their use, whether prescriptions were written in association with sample dispensing, and whether there were destinations for the samples other than patients.

Methods

The study was conducted at a suburban family practice center where there are 15,800 annual patient visits, 18 family medicine residents in training (5 first-year, 5 second-year, and 8 third-year residents), and 5 family physician faculty in part-time practice. The program permitted pharmaceutical representatives to sponsor lunch conferences for resident and faculty physicians and office staff and to deliver noncontrolled sample medications. There were no guidelines or restrictions on the dispensing of drug samples. The sample medications were stored in a closet that was adjacent to the department's library and conference room. The sample medication closet was unlocked each morning by one of the nursing staff and locked each night by the last nurse or physician to leave the office. This was a previously established routine and was not modified for the study. Some faculty and staff had key access, but residents did not. A separate medication storage cabinet for stock pharmaceuticals and controlled medications remained locked; access was available only through the head nurse.

Data collection proceeded in four phases: (1) an initial inventory was conducted on day 1; (2) samples added to and dispensed from the inventory were recorded from day 1 through day 28; (3) a final inventory was conducted at the end of day 28; and (4) a chart review was conducted following the monitoring period. A complete inventory of the six cabinets and the available shelf space (68.5 sq ft) in the sample medication closet was taken on the first day of the study. A medical student or one of the authors monitored the sample closet during each of the 49 clinic sessions (3 to 4 hours each) throughout the 4-week study period. The monitors were present whenever patients were in the office. There were intervals during lunch hours and at the end of the day when neither the monitor nor patients were in the office. Faculty, resident physicians, and nursing staff had unrestricted access to the sample collection during these periods, as is usually the case in the office. As is also typical, all deliveries of samples were monitored and accepted by the nursing staff, and pharmaceutical representatives did not have access to the medication sample closet unless accompanied by a nurse. All new sample deliveries during the study period were documented.

The unit of measurement for the study was the "sample." This was defined as the smallest medication

sample unit that could be dispensed without opening a bottle (if liquid), blisterpack (if tablets), or container. The quantity and dosage per sample varied considerably (eg, birth control pills in various strengths in 21- or 28-pill, 1-month packs, heterocyclic antidepressants in packages of 4 to 21 pills representing likely initial graduated doses for 2 to 10 days, bronchodilators in various strengths in tablet, liquid, and inhaler forms). Only items distributed by the manufacturers' representatives and stored in the sample medication closet were included in this study. A "dispensement" refers to the total amount of a specific sample medication removed on one occasion.

The physicians were told that a study of sample medication dispensing was in progress. They were not told that the medical record would be audited when a sample was dispensed. Each time that a physician sought a sample from the storage closet, the monitor interviewed the physician. The monitor was instructed to do this in a nonjudgmental manner, placing no restrictions on access to samples. The monitor recorded the names of the physician dispensing and the patient receiving the sample, the medication and the amount dispensed, the diagnosis, physician rationale for using a sample, whether the patient requested a sample, whether the sample was a new prescription for the patient, whether a prescription was written for the sample, whether the sample was labeled, and whether the patient received any written educational information about the sample medication dispensed. As was customary, self-stick labels (as required by state regulation) were readily available in the sample closet, preprinted with the family medicine center name, address, telephone number, and prompts for the patient's name, address, drug name, instructions for dosage, physician's name, and date.

When the physician was unable to find the medication sought, only the diagnosis, rationale, and whether a prescription was written were recorded. When the sample was dispensed to someone other than a patient, only the name of the dispensing physician and the type of person receiving the sample (eg, self, family member, staff, other) were noted.

At the end of the survey period, a chart audit was performed on each patient to whom a sample was dispensed to determine the patient's demographic and insurance status, diagnosis, whether subsequent prescriptions were written, and whether documentation of sample dispensing had been made.

Sample medications were coded into major therapeutic classes using the American Hospital Formulary Service classification directory.[13] The average wholesale price (AWP) of each sample was identified in the *Red Book Drug Topics Annual Pharmacists Reference,*[14] and the initial and final value of the sample collection, as well as the value of sample medications dispensed, was calculated. To determine the amount of samples that were removed from the sample closet during times when the monitor and patients were not present in the office, the final inventory was subtracted from the sum of the initial inventory and deliveries during the study period. The difference between the two inventories was the number of samples removed. After accounting for the recorded dispensements, the remaining number was the amount removed during the unmonitored periods.

Results

At the initial inventory there were 5546 samples in the sample collection with a total AWP of $19,273 (Figure 1). As determined at final inventory, 1012 samples with an AWP value of $4154 left the sample collection during the 4-week study period. Of this total, 269 samples worth $816 (20% of the value of the sample medications withdrawn) could not be traced. The majority of the samples went to patients (548 samples worth $2583), with 169 samples (AWP $603) documented as going to physicians and their families, and 26 samples (AWP $152) to colleagues and others (Table 1).

In the 4-week study period, there were 1244 patient visits at the family practice center; 416 patients (33%) were seen by faculty physicians, and the remainder were seen by residents. There were 105 occasions where a physician dispensed a sample medication to a patient. The mean age of the patients receiving samples was 37.4 years, and 72% of the patients were female. The physicians gave a primarily economic rationale (eg, cost of medication, no prescription insurance) for 39% of the occasions, which represented 62% of the AWP value of the samples dispensed. A primarily therapeutic rationale (eg, drug trial, need for urgent therapy) explained 53% of the occasions in which samples were dispensed and accounted for 33% of the AWP value of the medications dispensed. Other rationales were cited in 5% of the dispensements (4% of AWP) and no rationale was given for 3% of the occasions (1% of AWP). While patients requested the sample on 37 of these occasions, only once did a physician report that this was the primary reason for providing a sample.

Hormones (oral contraceptives) were the most common samples removed (17% of dispensements), closely followed by anti-infective (14%), cardiovascular (13%), ear, eye, nose and throat (EENT) (10%), and central nervous system medications (10%) (Table 2). By AWP, the hormone class accounted for 40% of the medications removed, followed by anti-infective and EENT (13%), and cardiovascular (10%).

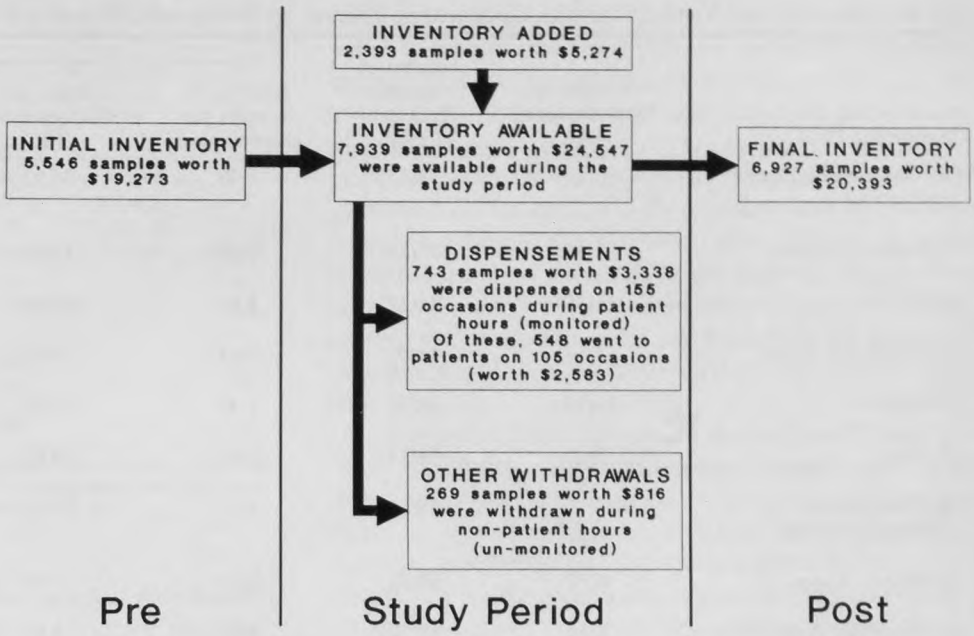

Figure 1. Tracking of sample medications inventory and their value in family practice residency office during 28-day study.

Of the 105 patients who received samples, 96 (91%) had medical insurance. Because of the variety of prescription benefit plans for each insurance type recorded, it was not possible to reliably determine whether patients had insurance coverage for prescription medications.

The progress note specifically mentioned that a sample was dispensed to a patient in 41% of the records. In 82% of progress notes the brand name was recorded, and in 3% of charts only the generic name of the sample medication was used. In 15% of charts there was no mention of any medication given or prescribed. The specific dosage had been documented in 78% of the notes, and the quantity dispensed had been documented in 32% of the notes. Records of the brand or generic name, medication dose, and quantity of medication dispensed were found in 29% of the progress notes. Neither the lot number nor the expiration date of the medication was ever recorded.

Faculty physicians accounted for 43 dispensements over 416 visits (ratio, .1034), while residents accounted for 62 dispensements over 828 visits (ratio, .0749). The finding that faculty provided more sample dispensements per visit was significant ($P < .001$). Age and sex of patients receiving samples did not differ significantly between faculty and residents. Faculty more frequently labeled the samples and provided patient education materials, with the latter trend being significant ($P < .005$). Overall, the sample was labeled with the patient's name in 20 of the 105 dispensements (19%), and written

Table 1. Quantity and Value of Samples Withdrawn During 4-Week Study Period

Sample Destination	Number of Dispensements	Number of Sample Packages	Number of Samples per Dispensement	AWP per Dispensement ($)	AWP per Package ($)	Total AWP ($)
Monitored dispensements						
Patient	105	548	5.22	24.60	4.71	2582.91
Self	28	87	3.11	13.41	4.32	375.55
Own family	16	82	5.13	14.24	2.78	227.90
Colleague	1	4	4.00	10.76	2.69	10.76
Other	5	22	4.40	28.20	6.41	141.02
Total dispensed	155	743	4.79	21.54	4.49	3338.14
Unmonitored withdrawals	N/A	269		N/A	3.03	815.65
Total	155	1012		N/A	4.10	4153.79

NOTE: "Sample" is defined as the smallest medication sample unit that could be dispensed without opening a bottle, blisterpack, or container. "Dispensement" refers to the total amount of a specific sample medication removed at one occasion; this could not be determined for unmonitored withdrawals. AWP denotes average wholesale price as determined by the Red Book Drug Topics Annual Pharmacists Reference.

Table 2. Quantity and Value of Samples Dispensed to Patients, by Therapeutic Class of the Sample Medication

Therapeutic Class	Number of Dispensements (%)	Number of Sample Packages (%)	Number of Samples per Dispensement	AWP per Dispensement ($)	AWP per Package ($)	Total AWP ($)	% of Total AWP
Hormones and synthetic substitutes	18(17)	73(13)	4.06	56.91	14.03	1024.33	40
Anti-infective agents	15(14)	108(20)	7.20	23.05	3.20	345.74	13
EENT	11(10)	94(17)	8.55	30.35	3.55	333.90	13
Cardiovascular drugs	14(13)	48(9)	3.43	19.16	5.59	268.22	10
CNS agents	11(10)	48(9)	4.36	21.62	4.95	237.82	9
GI drugs	9(9)	69(13)	7.67	19.92	2.60	179.26	7
Skin and mucous membrane agents	7(7)	25(5)	3.57	10.77	3.02	75.41	3
Autonomic drugs	6(6)	16(3)	2.67	7.92	2.97	47.50	2
Antihistamine drugs	8(8)	53(10)	6.63	5.84	0.88	46.73	2
Unclassified therapeutic agent	2(2)	2(0)	1.00	6.39	6.39	12.78	0
Antitussive, expectorant, mucolytic agents	2(2)	7(1)	3.50	3.18	0.91	6.36	0
Nutritional agents	1(1)	2(0)	2.00	2.82	1.41	2.82	0
Electrolytic, caloric, water balance agents	1(1)	3(1)	3.00	2.04	0.68	2.04	0
Total	105(100)	548(100)	5.22	24.60	4.71	2582.91	100

NOTE: Major therapeutic classes were determined according to the American Hospital Formulary Service classification directory.
AWP denotes average wholesale price.

patient education material (or the package insert) was provided 62 times (59%). Residents generally provided more complete documentation in the medical record, especially in recording of dosage ($P < .05$). Faculty were more likely to cite an economic rationale. In contrast, residents cited a therapeutic rationale twice as often as an economic rationale (the 2×3 χ^2 was nonsignificant, but the 2×2 χ^2, which examined only economic and therapeutic rationales, was significant, $P < .05$).

On 20 occasions physicians were unable to locate the sample medication they sought. Prescriptions were written after 16 of these searches. Seventeen (85%) of these unsuccessful searches were for a specific *brand* of medication (resulting in 13 prescriptions); the other three were for any brand of a specific medication (resulting in 3 prescriptions).

Slightly over one half of the sample dispensements to patients were for acute or self-limited problems (n = 58, 55%) (Table 3). Seventy-five of the dispensements represented new medications for that patient (71%), while only 30 were continuing medications. A prescription was written in 41 of the 105 times (39%) that a sample medication was given to a patient. However, when a sample medication was dispensed as a new medication for a chronic problem (n = 29), it was accompanied with a prescription 48% of the time; in every case, the prescription was written for the same brand name as the sample. Overall, prescriptions were written for medications in the same class as the sample in 41 of the occasions in which samples were dispensed. For 40 of the 41, the prescription was written for the same brand-name medication as the sample.

Conclusions

Only 54% of the samples withdrawn were documented as having been dispensed directly to patients. This rep-

Table 3. Prescriptions with Sample Dispensement, by Problem Chronicity

Problem Type	Is the Sample a New Medication for This Patient?	Prescription Written with Sample Dispensement: None	For Same Brand as Sample	For Generic in Same Class as Sample	Total
Acute	Not new	11	1		12
	New	30	15	1	46
Chronic	Not new	8	10		18
	New	15	14		29
Total		64	40	1	105

NOTE: The "Acute Not New" category represents dispensements to patients who had previously received that particular medication (for either a previous episode of the same problem or a different problem), but the current problem was acute.

resented 62% of the value of the samples withdrawn. Patients were not the most likely recipients for the 20% of the inventory (AWP) that was withdrawn during unmonitored nonpatient hours. Thus, nearly one half of the samples, or approximately one third of the value of the sample medications leaving the sample collection, were dispensed to persons (eg, physicians, their families, staff) other than patients. This may be a low estimate of samples going to nonpatients, as the study scrutiny may have discouraged some amount of this, and many of the pharmaceutical representatives routinely told these physicians that they preferred to arrange delivery of samples that were intended for the physicians' personal use directly to their homes.

Almost every prescription written in association with the dispensing of a sample medication was for the same brand-name medication as the sample. However, as this study did not assess steps in the medical decision-making process, it cannot be determined whether physicians decided on a brand, then sought a matching sample, or selected from any of the samples, then wrote a matching prescription. Whether sample availability affects physician prescription choice is an issue with extensive financial and ethical implications.[9] There is already a significant effort on the part of manufacturers to "educate" physicians. Pharmaceutical manufacturers spent approximately $5000 per physician in 1988 on promotional activities[4] and one third of their promotional budget is allocated to "detailing."[15] In 1989, 30 million sales calls were made on the 340,000 office-based physicians in the United States.[2] Since several medications are available for common chronic conditions, an effect on physician-prescribing behavior may have a significant impact on drug sales.

Although patients requested samples in 37 of the 105 patient dispensements, the physicians reported that patient requests were not a primary reason for dispensing sample medications. Physicians in this practice may be aware of the financial circumstances of their patients and dispense sample medications regardless of patient request, or they may be responding to other stimuli. The physicians indicated that their primary rationale for distributing a sample was economic only 39% of the time, yet this accounted for 62% of the value of the medications dispensed to patients. Dispensements for economic reasons were thus more valuable than those for therapeutic reasons, which is supportive of the physician's rationale.

Many physicians mentioned that the availability of a "free" medication was instrumental in their decision to dispense a sample medication. Although these medications are provided without a charge to the physician, there are production and distribution costs that appear to be ignored by the dispensing physician. If these findings are generalizable to other family practice residency programs (N = 384), it is estimated that approximately $7.4 million in sample medication inventories exist in these residencies alone. Faculty physicians should consider the implications of residents viewing these samples as "free." If the current finding that the average wholesale price ($4.10) per package of the samples leaving the formulary is representative, then the national wholesale cost of samples in 1988 was approximately $9.8 billion.

Patients received $2583 worth of samples, and $1571 worth of samples were withdrawn for physicians, their families, the staff, or others. On an annual basis, that would amount to $20,423 worth of samples diverted to nonpatients. This is not an insignificant sum and would violate the American Medical Association's opinion[11] regarding gifts accepted by physicians: "Any gifts accepted by physicians should primarily entail a benefit to patients and should not be of substantial value."

The notion that physicians use samples as gifts in therapeutic relationships is intriguing and deserves further study.[8,9] The financial benefit to physicians, staff, or their families, the promotional benefits to manufacturers, and the gift-giving behaviors may in combination explain the reluctance to change the distribution system. If sample use can be explained as gift-giving behavior beyond an economic rationale, physician support for modification of the distribution system will be limited.

Many of the samples were given for "trial" purposes. Since scientific trials require blinding of physicians and patients and randomization to reduce placebo effects and confounding, the trials as described would only detect patients who experienced immediate therapeutic or short-term adverse effects.

Documentation of sample-medication dispensing in the medical record was incomplete. Even a minimal record of the medication, dose, and quantity dispensed were absent in over 70% of the records. This would become a problem in the event of medication recalls, and is a serious lapse of record-keeping with other liabilities.

The interpretation and generalizability of these results are limited by several factors, particularly demand characteristics, monitoring only of the sample collection, and a single study site. The scrutiny of monitoring sample use may have altered physician behavior, resulting in decreased dispensements, particularly to nonpatients.

This initial study was conducted at a single training site. Training sites may differ from other family practice offices in factors such as patient population, record-keeping, solicitation by pharmaceutical representatives, and degree of long-term continuity of care, thus limiting the generalizability of this study. Certain results may have been site-specific factors, which vary widely among offices.

Tighter security of the sample closet with no unmonitored sample withdrawal would have allowed appraisal of all rationales and destinations. But this intense scrutiny would likely have decreased sample withdrawal. The study was designed to assess the sample traffic with minimal intervention in an office that has no policy or restrictions regarding sample medication use.

The effect of pharmaceutical manufacturers' distribution of sample medications in modifying physician prescription selection has not been adequately addressed in the research literature. Future studies should examine the influence of sample availability on the decision-making process in selecting prescription medications, the degree to which samples satisfy the stated industry rationale in other practice locations and arrangements, and the degree to which they satisfy the needs of physicians, their families, and others in both open and restrictive environments.

The availability of sample medications and their effect on physician medication choice are issues that deserve further investigation, as this study has shown an association between sample medication choice and subsequent identical brand name medication prescription. Should this finding subsequently be shown to be a causal relationship, physicians would need to add sample medications to the list of influences that can affect decisions regarding drug choice. On a national scale, there may be millions of dollars of pharmaceuticals stocked in physicians offices and hospital clinics. The investment in these drugs could be redirected to research or to a better method of distribution to indigent patients.

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