
THE CLINICAL ROLE OF THE COMMUNITY PHARMACIST

CASE STUDIES

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INTRODUCTION

This is a companion report to the January 1990 Office of the Inspector General report entitled, "The Clinical Role of the Community Pharmacist." That report describes the current level of clinical services available in community pharmacy settings, discusses the barriers that limit the availability of such services, and suggests actions that can be taken to improve pharmaceutical care for ambulatory patients.

This report provides an analysis and summary of the case studies that are referenced in the above report. These studies focus on six community pharmacists who provide a broad range of clinical services to their patients. Clinical services are those patient-oriented functions that identify, resolve, and prevent drug-related problems.

Our purpose in conducting the case studies was twofold: (1) to determine the extent and type of clinical services offered by the pharmacists, and (2) to identify methods they use to overcome barriers to clinical care. These barriers, which are discussed at length in the companion report, include:

- Economic: product-based reimbursement structure and uneven use of supportive personnel.
- Interprofessional: lack of collaboration between physician and pharmacist.
- Informational: incomplete patient profile information.
- Training: inadequate training in clinical pharmacy skills.
- Patient demand: uneven demand by patients for clinical pharmacy services.

In this context, it is important to note that our case-study pharmacists are not representative of community pharmacists as a whole. They were selected, in fact, because of the atypical nature of their practices. In each case, we observed their daily activities, interviewed patients served, and spoke with physicians with whom they collaborate. Based on these observations and interviews, we documented the range of services offered in each of the four components of clinical pharmacy services: collection of patient information, drug utilization review (DUR), patient counseling, and physician consultation. Measuring their performance against the mean level of clinical services offered in community pharmacy settings as documented in research literature, we can safely say that all provided an exceptional mix of clinical care to their patients. (See appendix 1 for a description of the case study methodology.)

In the first part of this report, we present an analysis of how the four case-study pharmacists who practice in traditional community settings were able to overcome the barriers to clinical practice. These pharmacists are: Calvin Knowlton, owner of Amherst Pharmacy in Lumberton, New Jersey; Howard Juni, co-owner of Capitol Drug in White Bear Lake, Minnesota; Linda Garrelts, co-owner of Jones Pharmacy in Spokane, Washington; and Nancy Culberson, owner of Lexington Family Practice Pharmacy in Lexington, South Carolina.

In the second part of the report, we offer a detailed summary of the practices of each of the above pharmacists and of the two others who do not practice in traditional community settings: Julee Alexander of Lifesource, Inc. in Larkspur, California, and Madeline Feinberg of Accredited Surgical Company in Columbia, Maryland.

ANALYSIS OF CASE STUDIES

Our analysis of how the case-study pharmacists have overcome barriers to clinical practice indicates that the methods used are typically a function of individual skills and personal commitment. We note that the flexibility inherent in managing one's own independent pharmacy is one condition in which these skills can be applied; nevertheless, as discussed in the companion report, the independent pharmacy setting does not, in itself, guarantee that a full range of clinical services will be provided.

There were no unusual environmental or market conditions that allowed the case-study pharmacists to develop clinical practices. All operate in highly competitive markets and compete for customers with chains, discount pharmacies and mail service pharmacies (MSPs). Populations served by the pharmacists are quite diverse, ranging from working class urban patients to more affluent suburban patients. In sum, these pharmacists enjoy no external advantage over their colleagues. Instead, a combination of skills in clinical pharmacy, business management and communications, coupled with an unusually strong professional commitment appear to be the ingredients for a successful clinical pharmacy practice.

Our conclusion from the case study analysis is that this formula cannot be duplicated easily either through reimbursement incentives or regulatory requirements. The conditions that obtain in these four cases where barriers to clinical pharmacy have been overcome are largely idiosyncratic and do not suggest an immediate or generalizable solution to the current gap in clinical pharmacy services for ambulatory patients.

Below is a summary description of how the case study pharmacists manage the barriers to providing clinical patient care as described in this report:

The Economic Barrier: All of the case study pharmacists have developed financially successful practices that include a broad range of clinical services, despite the constraints of a transaction-based reimbursement system. Their ability to do so is the result of two factors. The first is an aggressive, entrepreneurial approach to the business management aspect of their practice. As independent pharmacists, they are able to control all aspects of their practice and each has a history of experimenting with new products, services and marketing techniques. Several have expanded their traditional prescription drug services to home health care products; one has experimented with marketing his practice as a specialized geriatric service. Several offer blood pressure and cholesterol testing services for their patients. The development of new markets and services such as these appears to loosen the economic constraints and subsidize the clinical service aspect of the practice. One may conclude that the view of the pharmacist as a businessperson, traditionally associated with the view of the pharmacist as a non-professional, seems quite compatible with a clinically-oriented, professional role.

The second factor that reduces economic barriers is the use of technicians. Each of the case-study pharmacists uses technicians to count and pour pills and to perform other technical and supportive activities. Economically efficient allocation of personnel allows these pharmacists to spend their time interacting with patients, analyzing clinical problems and consulting with physicians.

The Interprofessional Barrier: Each of our study pharmacists appears to have a strong sense of his/her own professionalism. In day-to-day activities of their practice, they are not hesitant to initiate contact with physicians and each is aggressive in doing so when a question arises on patient care. Several are co-located with medical practices and are able to consult with physicians regularly on a face-to-face basis. One pharmacist who is co-located with a family practice has an arrangement with the physicians whereby she reviews each patient's chart every time a physician prescribes a drug. In no case did we sense that the pharmacists consider themselves inferior to the physicians with whom they dealt; rather, they see themselves as one part of a primary health care team.

In addition to collaborating closely with individual physicians, the study pharmacists also are quite active in professional associations, and some use those affiliations to educate local groups of physicians about the clinical services pharmacists can offer. One of our study pharmacists is involved in a project with her local pharmacy association in which pharmacists appear at local medical association meetings to present continuing education modules on drug therapy and the role of clinical pharmacy in the community setting. A physician who is involved in the project reported to us that he believes this education effort has encouraged his colleagues to collaborate more effectively with local pharmacists. Some other pharmacists we visited also lecture to groups of physicians in less formal settings. In sum, the case-study pharmacists have managed to improve interprofessional relationships through both individual and group efforts in the context of promoting their profession.

The Informational Barrier: All of the pharmacists we visited place strong emphasis on gathering patient information, including prescription and over-the-counter medications, allergies and diseases/conditions. The information is then automated (all use computerized screening tools) and updated when there is a change in status. As mentioned previously, some of the pharmacists also provide monthly blood pressure screening and all routinely request lab data information from physicians or patients when they suspect a dosage level problem. The most elaborate information review occurs in the case of the pharmacist who is co-located with a family practice and is able to review complete medical files for each patient.

The Training Barrier: All of the pharmacists we visited graduated in the past 20 years from colleges of pharmacy with curricula in clinical services. Several also have other undergraduate or graduate degrees and one has a Pharm.D. degree. Additionally, all are affiliated in some way with nearby academic institutions. All allow their pharmacies to be used as clerkship or internship sites by local colleges of pharmacy and some teach part time in these colleges.

These contacts with academic institutions help to keep the pharmacists in touch not only with trends in pharmacy education, but also more generally with the latest thought concerning their profession. In particular, ideas concerning clinical pharmacy, although they may be widely discussed and endorsed, are not so firmly entrenched in the mainstream of professional practice as they are in colleges of pharmacy. Thus, continued contact with these learning centers helps to reinforce pharmacists' commitment to clinical pharmacy practice.

The Patient Demand Barrier: This barrier is reduced in a number of ways by the pharmacists we visited. All provide some written information to their patients and discuss basic medication issues with each new prescription, whenever there is a status change in the patient's profile, and in cases that are deemed as high risk by the pharmacist. (They also make themselves available by phone when the pharmacies are closed.) The pharmacists believe that this information sharing and counseling both encourage patients to raise questions and create expectations among patients that affect demand.

Each pharmacist is also sensitive to issues of privacy and every pharmacy we visited had some semi-private space for patient counseling. One pharmacist who operates an apothecary has designed the physical setting so that the waiting area is separated from the space in which he counsels patients.

Several pharmacists publish newsletters on health care and drug topics that are available for their patients in the waiting area. This technique, they believe, also encourages patients to be more aggressive in requesting additional information. Most of the pharmacists also attend brown-bag sessions with elderly patients to discuss their drug regimens and educate them about clinical pharmacy services.

CASE STUDIES

CASE STUDY No. 1:

Calvin Knowlton and Amherst Pharmacy

GENERAL BACKGROUND

Amherst Pharmacy is located in Lumberton, New Jersey. Amherst was purchased by its current owner, Calvin Knowlton, in 1975 at which time it was a full-scale drugstore that included both pharmacy and non-pharmacy items. Over the next three years, Mr. Knowlton transformed the operation into an apothecary, which offers only pharmacy products. (At Amherst, the stock of non-prescription drug items is quite limited and represents only a small percentage of the overall pharmacy transactions.) In addition to drug products, Amherst also sells and leases durable medical equipment.

Lumberton is a suburb of Philadelphia and Amherst's client base is a mix of middle and working class patients. Approximately 11 percent of prescriptions are Medicaid-reimbursed, 45 percent are paid for by private third party insurers and the remainder are paid for in cash. Amherst services two nursing homes and one hospice as a provider of prescription drugs, but does not act as a consultant in those facilities. (Although pharmacies in New Jersey are permitted to provide both consulting and dispensing services to a nursing home, such arrangements are highly unusual.) Amherst competes with seven other pharmacies within a two-mile radius.

Approximately 1650 prescriptions are filled at Amherst on a weekly basis. Eight hundred twenty five or 50 percent are for nursing home and hospice patients and the remainder are for ambulatory patients.

PHARMACIST'S BACKGROUND

The pharmacy is owned and managed by Calvin Knowlton, who received his B.S. degree in 1972 from the Temple University School of Pharmacy. Mr. Knowlton is currently in the process of completing a doctorate degree in Pharmacy Administration and Health Policy at the University of Maryland.

For the past eight years, Mr. Knowlton has taught at several universities, including Temple, Rutgers and the Philadelphia College of Pharmacy (PCP), where he is currently a Clinical Associate Professor. He has also been continually involved in national and local pharmacy and health care organizations, and participates regularly in seminars and conferences that focus on health care issues.

From the onset of his practice, Mr. Knowlton has emphasized clinical pharmacy services and his transformation of Amherst from a full-service drug store to an apothecary reflects his commitment to confine his own practice of pharmacy to patient care. Although he has no formal training in business administration, he is a highly successful entrepreneur and a strong proponent of building business skill training into pharmacy school curricula.

Mr. Knowlton is currently in the process of developing an executive management program at PCP that will focus on preparing recent pharmacy school graduates to purchase their own pharmacy. It is Mr. Knowlton's belief that pharmacists would be more likely to purchase and manage their own businesses, if they had an opportunity to develop fundamental business skills. He feels that owner-pharmacists control the policies and procedures of the pharmacy much more than employee pharmacists, and that the most expedient way to implement clinical or patient-oriented policies in community pharmacies is first to empower pharmacists with the authority to set such policies.

STAFF

Consistent with his philosophy about efficient business practice, Mr. Knowlton's staff includes a high proportion of pharmacy technicians. Amherst employs four full-time pharmacists, seven full-time technicians and three part-time technicians. Technicians conduct routine counting and pouring activities, data entry on the pharmacy's information system, and stock management. Mr. Knowlton believes that liberal use of technicians is the most critical requisite to providing clinical patient care. Additionally, Amherst serves as an internship site for pharmacy students from PCP who are actively involved in all operational aspects of the pharmacy.

PHYSICAL SETTING

The patient waiting area at Amherst is similar in design to that of a physician's office with a seating area that is separated from the section where patients meet with the pharmacists. The waiting area is equipped with magazines as well as newsletters on health topics and is adjacent to a small section of non-prescription drug items. Beyond the waiting area and separated from it by a four-foot room divider is a counter section where patient consultation occurs. This arrangement allows for a great deal of privacy; conversations with patients are held outside the hearing range of other staff and patients. Next to the counseling area is a private room which is used for closed-door consultations as well as blood pressure monitoring.

CLINICAL ACTIVITIES

a) Data Collected

Each new patient at Amherst completes a patient information form which includes name, age, allergies, chronic conditions and current drug regimen. (In New Jersey, pharmacists are required to maintain patient profiles.) Mr. Knowlton reports that patients are quite cooperative in supplying this information; he has never encountered any serious resistance from his patients on this account. All of the patient profile information is maintained on the pharmacy computer system.

Unavailable Patient Data

Mr. Knowlton believes that the pharmacist's ability to monitor patient care would be enhanced considerably if he had access to lab information. Lab data would enable him to conduct more thorough drug utilization review and to identify adverse drug reactions (ADRs) on a more timely basis. At Amherst, blood pressure screenings are routinely offered to patients who are being treated for hypertension; however, New Jersey prohibits pharmacists from performing other standard tests that can be conducted through fingerstick procedures.

b) DUR/Patient Counseling

Each patient is interviewed by the pharmacist prior to receiving a drug, and a computer screening and pharmacist review is conducted each time a drug is dispensed. In addition to providing the patient profile information, each patient is asked why the drug is being prescribed and what over-the-counter (OTC) drugs the patient is using. After reviewing the patient's drug regimen, pharmacists then provide each patient with information on the name of the drug, its purpose, strength of dosage, how it should be taken and potential interactions and side effects. For new prescriptions and at the time of a first refill, this interview process is most extensive. Mr. Knowlton feels that the first refill is a critical time for pharmacist intervention with the patient; he places strong emphasis on the monitoring aspect of patient counseling and asks very specific questions at first refill time to assess the patient's reactions to the drug and to reinforce instructions on proper administration, side effects and interactions. Additionally, for patients who are deemed at high risk (e.g., have complex drug regimens or multiple conditions), or patients who are taking drugs that are particularly sensitive, more elaborate interviews are held throughout the course of treatment. One technique that Mr. Knowlton uses to monitor drug therapy is that of providing starter doses to patients who are at high risk and are starting a new prescription. (In some cases, he extends this policy on drugs that are particularly costly.) This allows for timely follow up by the pharmacist; once the patient, pharmacist and physician have ascertained that the drug can be tolerated, the length of fill is extended.

c) **Physician Consultation**

Approximately 50 percent of the prescriptions filled at Amherst are called in by a physician or staff of a physician's office. Other than orders placed by phone, most pharmacist/physician contact is initiated by the pharmacist when he has a question or concern about the physician's orders. Mr. Knowlton reports that over time he has developed good working relationships with the physicians who treat his patients and, in general, has found most of them open to discussing the specifics of their drug therapy decisions. Occasionally, some physicians contact Mr. Knowlton and consult with him prior to making a drug selection for a patient.

One issue that frequently arises in his daily practice is that of prescribing high cost "me-too" drugs. During our site visit, Mr. Knowlton identified a number of newly marketed and very expensive drugs that are not therapeutically different from alternative, lower-cost medications. When one of these higher-cost drugs is prescribed, Mr. Knowlton often contacts the physician to discuss the cost issue; in many cases, he reports, the physician is totally unaware of the retail cost and, when told, is willing to substitute a lower-cost alternative. Mr. Knowlton believes that patterns of high-cost drug prescribing are a direct result of marketing blitzes by manufacturer representatives, referred to as detailers. During our site visits, a drug detailer visited Mr. Knowlton and we were permitted to observe their conversation. In the course of the visit, Mr. Knowlton asked the detailer if she routinely discussed drug costs with physicians and she responded that she did not unless specifically asked by the physician. Mr. Knowlton believes an important component of his own clinical role is that of educating physicians about lower-cost therapies, notwithstanding the issue of who is paying for the drug.

EDUCATIONAL AND ASSOCIATION ACTIVITIES

Mr. Knowlton is actively involved in a number of local and national professional organizations. He currently chairs the American Pharmaceutical Association's section on Pharmacy Practice and Management in Ambulatory and Home Health Care and is Vice President of the American College of Apothecaries. He is a member of the Professional Affairs Committee of the American Association of Colleges of Pharmacy and Chairman of the Community Pharmacy Credentials Committee of the American College of Apothecaries. As mentioned previously, Mr. Knowlton is on the faculty of the PCP, and Amherst Pharmacy serves as an internship site for pharmacy students at that school.

Mr. Knowlton publishes a newsletter on health care issues which is distributed at the local level, and Amherst pharmacy staff conduct meetings on a regular basis with elderly patients in the Lumberton area and with nursing staff of his contracted nursing homes and hospice on issues associated with drug therapy.

CASE STUDY No. 2:
Howard Juni and Capitol Drug

GENERAL BACKGROUND

Capitol Drug's primary location is in White Bear Lake, Minnesota, a suburb of St. Paul with a population of approximately 23,000. There are two other locations: one in Minneapolis and one in Apple Valley, a suburb of the twin cities. Capitol Drug was established in 1908 and is now co-owned by Norman Carlson, Steven Carlson and Howard Juni, Pharm.D.

Originally located at a single site across the street from the state capitol in St. Paul, Capitol was a traditional drug store until 1967 when the owner, Norman Carlson, decided to convert the operation to an apothecary. Currently, Capitol is a community pharmacy which offers prescription and IV services to ambulatory and institutionalized patients. Capitol provides both pharmacy and consulting services to 18 long term care facilities and ten group homes, representing over 2000 beds. Capitol's staff are particularly proud of their accomplishments in the area of nursing home consulting. (As an example, the percentage of patients given sedative/hypnotic medications in one facility they serve has been reduced from 50 percent to 10 percent as a result of their clinical monitoring activities.) Additionally, Capitol sells, rents and services medical equipment, including durable medical equipment, colostomy and ostomy supplies, urologicals and oxygen.

Approximately 75 percent of Capitol's drug transactions are covered by third party reimbursement; the remainder are cash transactions. Among its three locations, Capitol dispenses 400-500 prescriptions per day, 20 percent of which are for walk-in patients.

Capitol's primary site competes with four other pharmacies within a one-mile radius, several of which are discount pharmacies. Capitol markets itself as a specialist in geriatric care, but its ambulatory patients are of a wide age range. The primary site is located in an office building which also houses a physician who specializes in family practice and Capitol services a number of his patients on a routine basis. Capitol has a reputation for innovation; within the State, it was the first pharmacy to use patient profiles to monitor therapy for its nursing home patients, the first community pharmacy to employ a Pharm.D., and the second pharmacy to use computers in its practice.

PHARMACIST'S BACKGROUND

Dr. Howard Juni graduated from the University of Minnesota College of Pharmacy in 1974 after which he was employed by Capitol Drug for four years. From 1978 to 1982 he served as Assistant Pharmacy Director in charge of clinical services at a St. Paul hospital, returning to Capitol in 1982 where he has remained. In 1986 he became a co-owner of the business. Dr. Juni works directly with ambulatory patients at Capitol, in addition to supervising four other pharmacists and directing the consulting service for institutionalized patients.

Dr. Juni is a preceptor for the University of Minnesota College of Pharmacy and instituted at Capitol one of only six post graduate community residency programs recognized by the American Pharmaceutical Association. Throughout his career, he has been associated with a variety of national and local pharmacy and health care organizations.

Dr. Juni's practice philosophy is centered on expanding clinical pharmacy care from teaching hospitals into community settings. He and his partners have used aggressive marketing strategies and experimented with new products and services to build an economic base that enables them to provide a broad range of clinical services for their patients. He believes that the combination of good communication and business skills along with a physical environment that is conducive to effective patient counseling are the primary ingredients for a successful clinical practice. Although he recognizes the constraints of a product-based reimbursement structure and supports the notion of compensating pharmacists for their professional services, he also believes that the issue of service fees is often an excuse rather than a reason for pharmacists' inability to offer clinical care in community settings.

STAFF

At its primary site, Capitol employs eight pharmacists and three full-time technicians in addition to the pharmacy students who rotate through the facility. Four pharmacist work years are devoted to nursing home consulting; however, all of the pharmacists staff the walk-in component of the business to varying degrees. This staffing pattern is designed to keep the pharmacists who are primarily involved in consulting in touch with patient counseling activities.

Although four of the pharmacists on staff have Pharm D. degrees, provision of clinical services is not limited to that group. Dr. Juni believes that pharmacists with bachelor of science degrees can be as effective in providing clinical services as those with more advanced degrees. From his perspective, the most important prerequisites for providing clinical patient care are staying current in the field and concentrating on good communication with patients.

Capitol makes liberal use of its technicians who perform routine tasks of counting and pouring as well as data input and stock management. The organization enjoys a stable staffing pattern; of its 25 employees across three sites, the average length of tenure is seven years.

PHYSICAL SETTING

As mentioned previously, Capitol stocks only pharmacy items and medical equipment. At its White Bear Lake facility non-prescription drugs are stocked in the front of the pharmacy with the equipment and supply section immediately behind. Adjacent to the display area is the pharmacy section with a front counter where pharmacists and other staff interact with patients

at eye level. Although there is no section isolated for patient counseling, Capitol is sufficiently spacious to create a sense of separation from sections of the store where customers may be browsing through displays. There is also a small waiting area where patients can sit while prescriptions are being filled. The general environment is quiet and, from our observations, patients feel comfortable engaging in conversation about their drug regimens with the pharmacists even though there is no physical separation from the rest of the facility.

CLINICAL ACTIVITIES

a) Data Collected

Each ambulatory patient completes a profile sheet which includes name, age, allergies, chronic conditions and current drug regimen. Capitol uses an automated information system to maintain patient profiles and patient information is entered into that system at the onset of treatment. Dr. Juni reports that he encounters no resistance from patients in gathering basic profile information as well as any other information the pharmacist may solicit in an interview. In fact, Dr. Juni reports that his patients appear to enjoy that aspect of clinical service.

Unavailable Patient Data

Dr. Juni believes that diagnostic information and lab data would significantly improve his ability to provide clinical services, particularly for the large proportion of geriatric patients he serves. His experience in providing consulting services to nursing home patients for whom this information is available has convinced him that services for ambulatory patients would be enhanced by the level of therapeutic drug monitoring made possible with more complete patient data. Dr. Juni notes that some lab information could be collected by finger stick tests, and, in fact, he is currently participating in a project (funded by Syntex) in which community pharmacists use finger stick tests to monitor drug therapy.

b) DUR/Patient Counseling

Each patient is interviewed by a pharmacist prior to receiving a new prescription and a computer screening and pharmacist review is conducted each time a drug is dispensed. After reviewing the drug regimen, pharmacists provide all patients receiving a new drug with information on the name of the drug, its purpose, strength of dosage, how it should be taken and potential interactions and side effects. Capitol's computer system is able to print these instructions on hard copy, which is given to patients with each new prescription. Follow-up counseling is provided by the pharmacist whenever a patient requests it and in cases when the pharmacist feels the patient or drug warrant

close monitoring. Dr. Juni believes that, ideally, patients should be counseled by a pharmacist each time a drug is dispensed.

c) **Physician Consultation**

Beyond occasions when physicians phone pharmacists to order a prescription, the most frequent contact with physicians occurs when a Capitol pharmacist calls a physician with a question or concern about a particular prescription. Dr. Juni places a strong emphasis on the importance of cultivating successful collaborative relationships with the physicians who treat his patients and reports that, in most cases, physicians are open to questions or suggestions he raises. On some occasions, physicians call Dr. Juni before prescribing to seek his advice on a particular drug. As mentioned previously, Capitol is located adjacent to a family practice office and, in cases when common patients are being treated, the physician and pharmacist have an opportunity to consult with one another in person. In managing the clinical staff at Capitol, Dr. Juni also emphasizes the importance of pharmacists keeping abreast of the most current scientific information on drug therapy; he believes that physicians' knowledge of such expertise among his staff encourages them to use pharmacists in an advisory capacity.

EDUCATIONAL AND ASSOCIATION ACTIVITIES

Dr. Juni is the immediate past president of the Minnesota State Pharmaceutical Association and is a member of the American Pharmaceutical Association. In his capacity as officer of the State Association, Dr. Juni spearheaded a number of community education efforts geared to increasing patient demand for clinical pharmacy services. He is a strong proponent of educating patients about the benefits and risks of drug therapy and encouraging them to seek consultation services from their pharmacists.

His long association with the University of Minnesota has enabled Capitol to serve as a site for internships, externships and residencies. Dr. Juni believes that this constant stream of students has been highly beneficial for Capitol's clinical staff; students bring new questions and perspectives with them that encourage the clinical staff to continually improve their own skills and knowledge.

CASE STUDY No. 3:

Linda Garrelts and Jones Pharmacy

GENERAL BACKGROUND

Jones Pharmacy is located in Spokane, WA. It is a full-scale drugstore, with a walk-in pharmacy and a large shopping area that includes both over-the-counter (OTC) drugs and numerous non-pharmacy items, located in the same building. The pharmacy and non-pharmacy sections of the business are not separated by a wall or by any other structure. However, the two parts of the business are managed separately.

The client base is of mixed social and economic status. Approximately 25 percent of prescriptions are Medicaid-reimbursed, and the percentage is growing. Another 10 percent are paid for by private third party insurers; most of these prescriptions are for nursing home patients. The remaining 65 percent of prescriptions are paid for in cash. Jones Pharmacy competes with approximately ten other pharmacies within a one-mile radius.

The pharmacy has three main components: the walk-in pharmacy for ambulatory patients; nursing home drug provider and consultant; and durable medical supply sales, which are usually made to home-bound patients. In addition, Jones Pharmacy serves as the provider to the county jail. The pharmacy fills approximately 900 prescriptions per week: approximately 75 percent of these prescriptions are for walk-in patients, and 17 percent are for nursing home patients. The pharmacy provides drugs for 105 nursing home beds. Additionally, Jones also provides cholesterol screening tests on a regular basis for ambulatory patients.

Jones Pharmacy has a branch pharmacy 30 miles away in Deer Park, a smaller, more rural community. The Deer Park pharmacy fills prescriptions almost exclusively for walk-in patients.

PHARMACIST'S BACKGROUND

The pharmacy is managed by Linda Garrelts. She graduated from the Washington State University College of Pharmacy in 1978, and immediately went to work at Jones Pharmacy. Soon thereafter she became a partner in the business. For the last ten years, she has increasingly emphasized clinical services in her pharmacy. She also has been continually involved in national and local pharmacy and health care organizations, including the Red Cross, but especially the American Pharmaceutical Association (APhA). She lectures and organizes community education sessions for these groups, and is a past president of APhA's practice management section. Through these activities, Garrelts has established a nationwide reputation in the pharmacy community as a practitioner and exponent of clinical pharmacy in the community setting.

STAFF

The pharmacy staff includes four full-time pharmacists working at the main store, and one full-time pharmacist and one half-time pharmacist working at the other store. In addition, one "Class A" pharmacy technician works full-time at the main store. A Class A technician has gone through a training program accredited by the Washington State Board of Pharmacy, and has passed tests devised by the Board of Pharmacy. She can fill prescriptions and take orders for prescriptions over the phone. Jones Pharmacy also serves as an internship site for Washington State University College of Pharmacy.

PHYSICAL SETTING

There is no space maintained especially for communication between the pharmacist and the patient. This communication occurs at the single window in the pharmacy section of the facility. According to Garrelts, this arrangement generally allows enough privacy for the patient to convey whatever information she/he needs to; in her view, the proper attitude on the pharmacist's part will make the patient feel comfortable discussing her/his drug therapy in such a conventional physical setting.

CLINICAL ACTIVITIES

a) Data Collected

When a new patient first has a prescription filled at Jones Pharmacy, the pharmacist obtains some basic information concerning the patient's drug regimen that will form the basis of a patient profile, to be used as a guide for appropriate drug therapy in the future. Washington State law requires the pharmacist to collect such information on all patients.

Jones Pharmacy asks patients for the names of all prescription drugs taken currently and in the past, and for the patient's allergies. (Jones Pharmacy typically does not keep information on OTC drug use on file.) This data is not kept on paper; the pharmacist simply receives the information orally from the patient and types it immediately into the pharmacy's computer system.

Unavailable Patient Data

Garrelts said that diagnostic information and data from lab tests concerning patients would be useful for her performance of clinical pharmacy services. This data would enable her to do more thorough drug utilization review (DUR) at the time a drug is dispensed, allowing her to identify more potential ADRs and other potential problems.

None of this data is currently available to her for her ambulatory patients, or to community pharmacists in general.

Consultant pharmacists typically have this data available to them when performing DUR for nursing homes. Garrelts acts as a consultant pharmacist for some nursing homes, and in that capacity, diagnostic and lab information are available to her. In that setting, she said that her increased access to data enables her to do a more thorough DUR.

Garrelts said that pharmacists could perform some of the standard lab tests themselves, through a fingerstick procedure, and could thus obtain some of the lab data. However, she said, any attempt to empower pharmacists to perform such tests would likely encounter strong opposition from physicians.

b) DUR/Patient Counseling

Garrelts reviews a patient's drug profile in order to consider the appropriateness of her/his prescribed drug therapy before the drug has been dispensed. She looks for duplicate prescriptions (more than one drug prescribed to treat one condition; this is the most common problem she discovers), potential drug interactions, and inappropriate dosages. If she discovers any of these problems, she contacts the prescriber immediately. Aside from those times when new prescriptions are presented, Garrelts will conduct individualized DUR only when she observes a negative reaction of some kind in the patient to her/his drug therapy.

Jones Pharmacy will soon have a new computer system installed that will facilitate DUR by displaying a patient's last several prescriptions on the screen automatically, when the patient's name is entered. The attending pharmacist will not need to access this information separately.

Pharmacists at Jones Pharmacy do most of their counseling of patients at the initial point of sale (POS), that is, for new prescriptions rather than for refills. The amount of counseling that a patient receives varies considerably. Patients who are receiving maintenance drugs receive less counseling than those who are being treated for acute conditions.

Information typically given to patients includes: the name of the drug they are receiving; the strength of the prescribed dosage; how to take the drug (method of intake, when to take it, with or without food); and potential interactions and side effects of the drug.

c) **Physician Consultation**

The initial contact between the pharmacist and the prescriber, in the case of a given patient, usually is made by the prescriber. She/he does this when she/he phones the prescription in to the pharmacist, which is most often the case with new prescriptions at Jones Pharmacy; this is done for the patient's convenience. At this time, the pharmacist has the opportunity to ask the physician questions concerning the patient's condition and therapy, and also to give the physician relevant information concerning the patient's clinical history, if the patient has been a patron of the pharmacy in the past. Physicians will occasionally consult with the pharmacist prior to prescribing a new drug for a patient. In these cases the physician may wish to consult with the pharmacist concerning allergic reactions or other kinds of ADRs that the patient has experienced in the past, and may wish to seek the pharmacist's opinion concerning the most appropriate drug therapy for the patient. In these cases, though they are infrequent, the physician displays great confidence in the pharmacist's clinical expertise, and in the closeness of the pharmacist's relationships with her/his patients.

The pharmacist at Jones Pharmacy usually will contact the physician in order to discuss the appropriateness of a prescription. This can be a delicate matter, and requires the pharmacist to exercise a great deal of judgment concerning the physician's personality. Garrelts said that she is familiar with most of her patients' physicians, and she knows which physicians will be amenable to taking advice from a pharmacist and which ones will not be. She will not contact those who seem to guard their professional functions, such as prescribing, jealously. Most, however, are cooperative and will discuss prescriptions seriously with her, she said, and are willing to change their prescriptions on her advice. The most frequent reason for Garrelts to contact a physician is that she recognizes an ADR in a patient. Patients who are reacting negatively to their medications often seek advice from her, rather than from the prescriber. Additionally, she may call the physician because she notices a potential ADR, from her review of the patient's profile, before filling the prescription. A situation such as this usually arises about once a day. Garrelts may also call a physician concerning the appropriateness of a prescription with the respect to the cost of the drug. Some prescription drugs are prohibitively priced, for many patients, and some of these drugs have much lower-priced alternatives. However, Garrelts usually does this only for patients who pay the full cash retail price of a drug, and not for those who are covered by a third party insurer, and who therefore pay the same copayment for every drug.

Significantly, Garrelts can change a prescription or a dosage level without consulting the physician, in some cases. Under Washington State law, a pharmacist can establish "prescriptive authority" with an individual prescriber. The pharmacist and the physician together develop a protocol for the pharmacist to follow, with clear parameters for her/his power to change prescriptions. Within those parameters, the pharmacist may alter the prescriptions of the given prescriber's patients, as she/he sees fit. Clearly, this possibility indicates the confidence that State law places in the ability

of pharmacists to conduct clinical analysis and to arrive at prognoses, and the existence of such an arrangement indicates similar confidence on the part of the prescriber involved.

In order to gain a physician's perspective on pharmacist-patient interaction, we talked with a Spokane physician who practices in the community setting, who is well acquainted with Jones Pharmacy, and who is active in the local medical society. He said that pharmacists most often initiate this interaction, usually to clarify a prescription or to suggest a change in prescription. Pharmacists usually contact physicians concerning clinical issues surrounding prescriptions, he said, but occasionally they call with respect to the cost of a prescribed drug.

This physician also told us that physicians sometimes initiate communication with pharmacists. In these cases, he said, physicians are often seeking information concerning a new drug that they may not receive from drug companies' salespersons, such as potential side effects and cost of the drug. In these cases, physicians clearly display respect for the pharmacological expertise of pharmacists.

However, this physician said, physicians more often are unaware of the level of pharmacological training and knowledge possessed by pharmacists—usually far more than a physician possesses. He felt that this situation could be alleviated through education of physicians concerning pharmacists' training, and he felt that local medical societies and pharmacy societies were well situated to perform this education. In fact, at the time we spoke with him, he sat on a County Committee for Pharmacist-Physician Communication.

EDUCATIONAL AND ASSOCIATION ACTIVITIES

Garrelts is unusually active in group-oriented education around drug issues, both with patients in the surrounding community and with other health professionals. As noted above, she is a former president of the APhA practice management section, and she still gives speeches for APhA to other pharmacists on how to manage a pharmacy.

She participates in community education primarily through the use of three programs developed by APhA, in association with Lederle Laboratories. These programs, designed to improve patient understanding of and compliance with drug therapy, are entitled "National Medication Awareness Test," "Self-Awareness Test," and "Managing Medication Wisely." These presentations combine cassettes, slides and oral presentation. They feature quizzes on the topics discussed, with individual answer sheets for all those attending, which are eventually graded.

Garrelts is involved with the local Red Cross, with the local Ostomy Board, and with the local Diabetes Board, on which she currently sits. She helps to get speakers for these organizations.

Her involvement with these organizations has helped her to become known to other health professionals, and to become respected by them as a health professional herself.

ECONOMIC ISSUES

Like most community pharmacies, Jones Pharmacy is not reimbursed directly for the clinical services the staff provide to their patients, such as patient counseling. The cost of providing these services—most of which is entailed in the time that must be taken to perform them—must be added to the pharmacy's drug prices. Jones staff must rely on the quality of these services to maintain the loyalty of their patients, in the face of the intense price competition Jones faces from nearby independent, chain and deep-discount pharmacies. Jones Pharmacy has managed to stay afloat financially, despite this competition; but its profit margin is far from comfortable, reflecting the difficulties encountered by even exemplary pharmacists in the community setting who make a concerted effort to provide clinical services to their patients.

HOME HEALTH CARE

Jones Pharmacy is involved with home health care through its sale and leasing of durable medical equipment. The clientele for this equipment are mostly recent discharges from hospitals, and the equipment is mostly of the kind one would find in hospitals or nursing homes: wheelchairs, leg supports, hospital beds, trapeze bars, siderails, and seatlift chairs, for example. Most of Jones's home health patients are geriatric. Jones has almost 1,000 home health patients.

Patients hear of Jones's medical equipment services mostly through referrals by physicians and discharge personnel in hospitals. Jones Pharmacy employs one staff member to work on home health care full-time, and he details hospitals, informing them of Jones's home health services. The pharmacy also runs monthly advertisements concerning their equipment sales on local cable television. The pharmacy's management thought TV ads would be an effective way of reaching the potential clientele for this equipment, since many of them are home-bound; they report that the ads have brought in a noticeable amount of new business. In addition, the pharmacy's home health supervisor currently plans to go to local retirement communities to give talks on the services he provides.

He interacts both with patients and with their caregivers, giving instruction to both in the proper means of using the medical equipment, though he is neither a pharmacist nor a nurse. He also makes follow-up visits to patients' homes to make sure that the equipment is being used properly. If patients have questions about the equipment, they can call him directly.

Virtually none of Jones Pharmacy's home health patients have the resources to pay for this equipment themselves. Approximately 70 percent receive some assistance from Medicare in paying for the equipment, and approximately 30 percent receive assistance from Medicaid. However, Jones's home health supervisor told us that Medicare reimbursement for home health equipment is quite incomplete and seems arbitrary. For example, Medicare covers equipment used to treat renal conditions, but does not cover equipment used to treat liver ailments; and Medicare does not cover bathroom items, which form an essential part of home health care. Overall, it does not seem that Medicare has yet recognized home health care as a distinct sector of health care, and has not yet developed any systematic method of reimbursing home health care costs. Thus, reimbursement gained for these costs is generally incomplete and piecemeal.

CASE STUDY No. 4:

Nancy Culberson and Lexington Family Practice Pharmacy

GENERAL BACKGROUND

Nancy Culberson is the owner and chief pharmacist of Lexington Family Practice Pharmacy, in Lexington, South Carolina. This is an independent, walk-in community pharmacy that is located in the same building with five physicians' offices, which make up Lexington Family Practice. All of the physicians' patients who receive prescriptions receive drug counseling at this pharmacy, but they have the choice of having these prescriptions filled there or elsewhere. The pharmacy and the family practice are, however, separate businesses with entirely separate finances.

Lexington is a suburban/exurban area, about ten miles outside Columbia. Ms. Culberson's pharmacy competes with six other pharmacies within a three-mile radius, two of which are chain pharmacies. Despite this competition, the pharmacy does a healthy business: approximately 18,000 families are on file as patients; the pharmacy sees approximately 120 patients per day, and fills between 140 and 200 prescriptions a day. Approximately 80 percent of those patients who come to the pharmacy from the physicians' offices have their prescriptions filled there.

Since it was founded, Lexington Family Practice Pharmacy has emphasized clinical services. Robert Davis, the pharmacy's founder, had gone through school with the physicians who started the family practice. They all worked together as residents in the Medical University of South Carolina (MUSC) teaching hospital, as a clinical team. This experience inspired them to set up their practices together, so that they could replicate some of the collaboration between physicians and pharmacists that appears in hospitals more often than in a non-institutionalized setting. This kind of collaboration is a basic component of clinical pharmacy practice; thus the atmosphere at Lexington Family Practice was probably conducive to clinical pharmacy practice when Ms. Culberson arrived there.

PHARMACIST'S BACKGROUND

Ms. Culberson received her B.S. in Pharmacy from MUSC in 1976. After completing a 3-month unpaid internship at Lexington Family Pharmacy, she was hired as a full-time staff pharmacist. She has been at the pharmacy since, and bought the pharmacy three years ago when the pharmacy's founder, Robert Davis, left the practice to pursue other interests. She and the physicians in the family practice have recently purchased and moved into a new, bigger building for their practices.

Ms. Culberson told us that she received little training in clinical pharmacy in school. She got such training on the job. She had a family member who was a community pharmacist when

she was growing up; perhaps it was this exposure that left her with the idea that, as she told us, emphasizing clinical services is simply the way that pharmacy should be practiced.

STAFF

Ms. Culberson herself is the only full-time pharmacist on staff; in addition, two part-time pharmacists and two full-time pharmacy technicians are employed in the pharmacy. (Under South Carolina State law, technicians can dispense drugs under the supervision of a pharmacist, and a ratio of one technician: one pharmacist must be maintained.)

Lexington Family Practice serves as an externship site for MUSC and typically has two pharmacy students on staff at one time. In addition, Lexington is a placement site for students enrolled in a local college pharmacy technician program.

There are four physicians practicing in the building, with plans for two more; and one nurse practitioner practices there as well.

PHYSICAL SETTING

The pharmacy seems designed to convey the sense of a health professional's offices, similar to a physician's offices in many ways. A waiting area, with chairs and reading material, is located in front of the broad pharmacy counter (this waiting area is centrally located among the physicians' offices and the pharmacy).

The pharmacy is technically an apothecary: nothing besides drugs is for sale. There is not even an open over-the-counter (OTC) drug section; a small OTC section is located behind the pharmacy counter, and a pharmacist will sell the patient something from this section if it is recommended by a physician, or if the patient asks for it.

Two private counseling rooms are located on either side of the dispensing area. The pharmacist will use one of these rooms to counsel a patient if privacy is desired, or to meet with a physician or drug detailer.

A drive-through window is a new feature of the recently constructed Lexington Family Practice building. A patient can call ahead for a prescription—usually a refill—and pick it up here. One of the two computer terminals in the pharmacy is located next to this window, so that the pharmacist can call up the patient's computer profile and screen for potential problems during a drive-through pick-up.

CLINICAL ACTIVITIES

a) Data Gathered

The pharmacy generally has extremely complete data on patients, because of the easy information flow from the physicians' offices. When a patient comes to the pharmacy from one of the physician's offices, the pharmacist gets the physician's file on the patient. (The carrier of the file varies.) This file, on paper, contains: allergies; medical history; drug history; vital signs; a list of the patient's chief complaints; reports of physical examinations; diagnoses; basic lab test results; and insurance information. This information from the physician's office generally goes back only to the point when the patient first visited that physician.

The patient also brings an "encounter form" with her or him to the pharmacy, from the physician's office. This is a sort of "superbill," telling the pharmacist what treatment the patient has received, and for what condition, and also allowing for easy tabulation of the costs of a patient's visits to all the health care professionals she or he sees in one trip. This encounter form also includes a special pharmacy section containing the most important few pieces of information for the pharmacist, concerning the patient's current physician's visit: namely, the drugs prescribed and the reasons why.

When a new patient comes to the pharmacy, if the physician's file is far less extensive than those of old patients, the pharmacist will ask the patient for some basic drug-related information, such as allergies and past adverse drug reactions.

b) DUR/Patient Counseling

The pharmacy's computer system accommodates basic information on patients such as: name of physician; drug history, including refill directions and dosage information on current prescriptions; insurance information; and allergies. (Allergy information generally is not kept on the computer files, since it is included in the physician's file on the patient, which is reviewed when a new prescription is made, and which can be consulted readily at other times when needed.) This information is reviewed whenever a prescription is filled, and each new prescription or refill that is dispensed is entered. When a patient receives a new prescription, the pharmacist gives the patient information including: the name of the drug; the purpose of the prescription; dosage information, including the exact meaning and the importance of following these instructions; the length of the fill; how to coordinate the drug therapy with eating habits and what foods to avoid; exactly when and how to take the drug; how to store the drug; the potential side effects of the drug, and how to spot them; and when the patient can expect relief. The pharmacist also gives the patient information on how the prescription can be refilled. Lexington Family Practice Pharmacy provides a two-page summary of its services to patients (attached) that informs the patient that when

receiving medication—from anyone—she or he should receive all the information listed here.

More extensive counseling sessions are deemed necessary by the pharmacist if the drug therapy prescribed is especially complex, if it carries unusual potential dangers, or if the patient requires special attention. In these cases, such a consultation will take place, either over the pharmacy counter or in one of the private counseling rooms, revolving around the issues enumerated above, and involving more extensive questions and answers between the pharmacist and the patient than is usual. Such a consultation will usually last between five and ten minutes. There is an additional charge for this consultation, which varies with the time spent by the pharmacist. (Sometimes this charge is waived; for more on this fee, see the *Economic Issues* section, below.)

A great deal of written material is available to patients at the pharmacy, in addition to all the verbal information. Culberson maintains a library of pamphlets and leaflets from pharmaceutical companies, the United States Pharmacopoeial Convention (USP), and other health organizations, on specific drugs and on different health conditions or risks. In addition, she prepares her own pamphlets on certain particularly serious drugs, such as coumadin, and prednisone, that are not available from any outside source. She regularly gives this information to patients, though not every patient receives this kind of written information.

When patients come in for refills, they receive basic counseling. The pharmacist asks the patient whether any problems have arisen since starting the drug treatment. If the pharmacist can detect no problems, the refill is dispensed and the transaction is recorded on the patient's computer file.

c) **Physician Consultation**

The ease and extent of physician-pharmacist interaction in Lexington Family Practice Pharmacy is perhaps, more than anything else, what sets this pharmacy apart from most community pharmacies. Almost all of the pharmacy's patients are referred there by the physicians on the premises. With the co-location of the pharmacy and the medical practices, the inter-professional collaboration usually confined to an institutionalized setting can be, to a great extent, replicated. We have already seen how this arrangement provides for ease and completeness of information flow from the physicians to the pharmacist. Occasionally a physician in the practice will contact Culberson prior to prescribing, to ask her about a patient's past reactions to drugs, or to ask about a drug's effects generally. Usually, however, discussion between Culberson and the physicians in the practice occurs after the physician has prescribed a drug. The procedures for such discussion seem very informal and flexible: discussion can occur either after a patient has left the premises, or while the patient is still there, if the

pharmacist thinks this is necessary; the physicians and pharmacists do not schedule regular patient care conferences.

In addition to discussing patients, the pharmacists and physicians are able to discuss other matters, such as the merits of new drugs being detailed or of various health insurance plans, very easily in this setting. Drug detailers usually meet with Culberson and with the physicians on the same visit, although not with all of them at the same time.

Under South Carolina law, a pharmacist may not substitute one drug for another that a physician has prescribed, at all, and may not change the dosage of a prescription, without the express permission of the physician. However, the proximity of Culberson's pharmacy to most of the prescribers with whom she deals, and the collegiality that has developed between her and these physicians, keep this legal restriction from functioning as a very substantial barrier to substitution. The physicians at the practice with whom we spoke told us that they generally allow the substitutions that Culberson suggests. Generic substitution for a brand-name prescription does not occur very frequently, simply because the physicians try to prescribe generics in the first place whenever they can.

EDUCATIONAL AND ASSOCIATION ACTIVITIES

Ms. Culberson is a member of the APhA, the National Association of Retail Druggists, the South Carolina Pharmacy Association and the Local 5th District Pharmacy Association. She has been a speaker at national pharmacy association conferences and is an instructor in clinical pharmacy at MUSC. Ms Culberson also serves on the Pharmacy and Therapeutics Committee of a local health maintenance organization.

ECONOMIC ISSUES

Only 30% of the pharmacy's patients are covered by third-party insurers, and approximately 70% are cash patients. Approximately 5 percent of patients are Medicaid patients, and 15 percent are geriatric patients, many of whom receive Medicare benefits.

Culberson charges a fee for some of her patient counseling services, in addition to the price of the drug. She does this rather than add the cost of the time she spends counseling patients onto the drug charges. The fee varies, from \$1 to \$5, according to the time spent in consultation. She charges this fee only if unusually extensive counseling is required. This fee is not reimbursed by any third-party insurers. For this reason, Culberson sometimes waives the fee; she is more likely to do so if the patient has the prescription filled at her pharmacy.

-----The pharmacy requests that cash patients pay for the drugs and services they receive at the time service is rendered. Insurance cards are presented to the pharmacist before the prescription is filled.

CASE STUDY No. 5:

Julee Alexander and Lifesource, Inc.

GENERAL BACKGROUND

Lifesource is a home infusion pharmacy in Larkspur, CA, just north of San Francisco. It prepares medications for use by home-bound patients; almost all of these medications are IV preparations. Lifesource delivers all its products to its patients; this service, Lifesource personnel told us, is driven by patient demand. It is a licensed retail pharmacy, but it has no walk-in facilities.

PHARMACIST'S BACKGROUND

Julee Alexander is the manager of Lifesource's main office (it has two other, smaller branches). She graduated from the University of California at San Francisco (UCSF) College of Pharmacy in 1981. UCSF was an early center of the clinical pharmacy movement: in 1966, the "ninth floor project" at the university's hospital brought pharmacists and physicians together in clinical care teams, and helped launch the hospital pharmacy movement that spread throughout colleges of pharmacy in the early 1970s. A graduate from the UCSF College of Pharmacy would likely be trained to emphasize the clinical aspects of pharmacy practice, and this education would, in part, explain Alexander's emphasis on clinical pharmacy in her own practice. She worked in hospital pharmacy for two to three years after graduating from school. Then she left hospital pharmacy to work for a different home infusion pharmacy for five years, before coming to Lifesource.

CLIENT BASE

This branch of Lifesource (which will be the subject of this case study) has approximately 100 patients at any one time. Approximately one-third of these patients are geriatric.

Approximately 50 percent of Lifesource's patients are AIDS patients. This preponderance of AIDS patients is not, Alexander said, typical of home infusion pharmacies. However, it is not so untypical for such pharmacies to specialize somehow in the kind of patient condition they treat, in response to the competitiveness of the market.

Lifesource also treats some children, delivering neonatal care to patients at Oakland Children's Hospital.

A key to Lifesource's viability is the general affluence of its clientele. The treatment they furnish is costly, and often is protracted, since many of the patients treated are terminally ill. Medicare and Medicaid provide little reimbursement for the products and services involved in

home infusion therapy (see below), and provide scant coverage for long-term care. This means that reimbursement must come either from private third party insurers—who are providing a growing share of Lifesource's revenues—or from the private resources of the patients. Lifesource screens prospective patients before agreeing to treat them, to determine whether reimbursement will be available through some means. Without this screening process, under the present public health system, it seems unlikely that a home infusion pharmacy like Lifesource could remain economically viable.

STAFF

This office has four full-time pharmacists on staff, one on three-fifths time, and all five are on call. In addition, two supervisory pharmacists are on staff. Lifesource also employs one dietician, one full-time warehouse worker, three part-time drivers, and one full-time accountant who handles billing and reimbursement. Lifesource employs no pharmacy technicians.

Lifesource coordinates the overall health care of its patients, and this includes arranging for nursing services. Unlike some other home infusion pharmacies, Lifesource does not have staff nurses. Healthsource is the name of the nursing agency that contracts with Lifesource to perform most of the direct care of those patients who require in-home supervision. Lifesource originally owned Healthsource, but the two businesses separated when that arrangement became unprofitable. Still, however, Lifesource brings its nursing business to Healthsource before any other nursing agency. Thus the relationships and the communication between the nurses at Healthsource and the pharmacists at Lifesource are well-established.

BASIC SERVICES

Lifesource provides some special services that are worth discussing at some length, in order to explain the kind of pharmacy Lifesource is:

(1) Patient Care Conferences:

Each Friday morning, most of the Lifesource staff—including all the pharmacists—gather to discuss the treatments of all current patients. Everyone present at the meeting has a patient chart, containing lists of every patient's name, address, physician, prescribed therapy, and insurer. Dennis Honda, a pharmacist who coordinates all of Lifesource's operations, facilitates the seminar-type discussion. The staff discusses the prescribed therapies, the attending physicians, and the reimbursement schemes of all patients. The pharmacist who is handling each case gives an update on the patient's progress, and suggestions are made concerning treatment.

(2) Nutritionist Services:

Lifesource employs a full-time dietician who services most, but not all, of the business's clients. She analyzes their diets, their medical conditions and their prescribed drug therapies; then she makes recommendations concerning the diets that, in her judgment, would best facilitate the distribution and effectiveness of the medications the patients are taking. These recommendations usually do not take the form of a strict dietary regimen, but rather, broad dietary guidelines. This dietician emphasizes personal contact with the patients she treats. She goes to many patients' homes, in order to develop a better idea of their dietary needs than she would otherwise possess, and in order to develop a general rapport with them. She also performs follow-up monitoring after making dietary recommendations, to check the compliance of patients with these recommendations, and to check their effectiveness.

Some patients are not able to ingest food orally, so they are placed on a therapy known as Total Parenteral Nutrition (TPN). This therapy involves the intravenous ingestion of all necessary nutrients. The staff dietician monitors patients on TPN, checking their progress weekly. If their health progresses far enough, she and the rest of the Lifesource staff try to replace the TPN with oral ingestion.

(3) Enteral Therapy:

Enteral therapy is instrumental administered by Lifesource to about 75 nursing home patients distributed throughout 20 different Skilled Nursing Facilities (SNFs). This therapy requires a wide range of paraphernalia and equipment used to administer these solutions. This sector of Lifesource's business is kept separate from the home health sector, to which a much greater share of the business's resources are devoted.

CLINICAL ACTIVITIES

(a) Data gathered

Lifesource has extensive information on all its patients. Virtually no clinical data is missing from its patient profiles and charts. This indicates the attentive and close nature of the relationship between Lifesource and its clients, as well as Lifesource's close professional collaboration with the physicians who treat these patients.

Lifesource's clinical data base on its patients includes: medication history (OTC as well as prescription), including dates, dosages, duration of therapy, purpose of treatments, and potential adverse reactions to each drug; history of smoking and alcohol intake; allergies; data from laboratory tests; general medical history; and summary of most recent hospitalization. Clinical information specifically concerning

the present treatment includes: age, weight and height; diagnosis; type of therapy; whether the patient is receiving IV treatment; whether the patient is diabetic; whether the attending physician has given standard anaphylaxis orders; duration of current therapy; and whether patient has taken the first dose of medication without incident.

Not only is Lifesource's background information on its patients very complete, given the close attention Lifesource gives to patients, and given the closed environment of these patients, it is highly unlikely that any new clinical information will escape the pharmacists. In this respect, a home infusion pharmacy like Lifesource is similar to a hospital or nursing home pharmacy.

b) DUR/Patient Counseling

Lifesource performs prospective DUR for all its patients. The pharmacists there examine patients' basic clinical data, in order to determine the appropriateness of a drug therapy that has been tentatively prescribed. They look for potential side effects, drug interactions and drug-allergy interactions. As noted above, the data base at Lifesource is very extensive, including information on OTC drugs and home remedies.

Most contact between Lifesource pharmacists and patients occurs over the phone. This occurs when pharmacists call patients to check their compliance and their general condition—which they do on a regular basis—and when patients call their attending pharmacists with questions or problems.

A fair amount of face-to-face contact is, nonetheless, an integral part of any patient's treatment. The attending pharmacist makes the initial visit to a patient's home, with a nurse. Sometimes, but not always, the pharmacist shows the patient how to use the medical equipment necessary for the patient's treatment.

Perhaps the most distinctive aspect of patient-pharmacist interaction at Lifesource is the frequency and quality of the follow-up contact. Pharmacists check on patients at least once a week if they are on infusion therapy, and in some cases more than once a week. The individualized care plans that the Lifesource staff plan and coordinate for patients are executed with individualized attention.

As a result, Alexander told us, the relationship between pharmacists and their patients are generally very positive, despite the emotionally depressed state in which many home-bound patients find themselves. The staff at Lifesource are generally very young, and are imbued with the communications training that has been emphasized in pharmacy school in recent years; furthermore, most of the staff pharmacists were trained at UCSF, which, as noted above, is a center of clinical pharmacy training. Staff, including drivers, are given further communications training on the job, through

“minicourses” designed to increase sensitivity to the needs and circumstances of patients; these minicourses focus particularly on AIDS patients.

c) Physician Consultation

The professional relations between Lifesource pharmacists and most of the physicians attending Lifesource’s patients are quite close, and long-standing. The character of Lifesource’s client population is, in fact, shaped to a great extent by these professional relationships. Several of the physicians with which the pharmacy has close relations specialize in AIDS patients, for example, and many patients come to Lifesource through referrals from physicians.

The Lifesource pharmacist is the coordinator for a patient’s overall treatment. The pharmacist may be able to give more individualized attention to the patient than a physician can. In any case, the pharmacist heads the clinical team that cares for the patient.

One issue that has become controversial in California is that of physician ownership of pharmacies. Under state law, physicians may own only less than 10 percent of a pharmacy. Lifesource personnel told us that physicians sometimes, through holding companies, own more than this 10 percent limit. No physician has any financial interest in Lifesource.

ECONOMIC ISSUES

Third-party reimbursement for Lifesource’s services and products comes mainly from private insurers, whether HMOs or other entities. Medi-Cal (the California Medicaid agency) provides some coverage for less than 25 percent of Lifesource’s clients (Medi-Cal does not cover AIDS treatment). Third-party insurers do not reimburse the cost of the clinical services that Lifesource provides. Most of the costs of these services must be added to the price of the products provided.

Medicare pays a small share of the cost of therapy known as “pain management,” usually given to terminal patients: Medicare pays for the pump used in IV treatment in these cases, and for a small portion of the morphine required. Pain management is becoming increasingly expensive, and may soon become costly beyond any available means of payment.

Another economic issue that looms large in Lifesource’s sights is drug pricing. Hospitals, and sometimes other pharmacies, may buy drugs at preferential prices from drug manufacturers, if this brings enough business to the manufacturer. Lifesource’s owners have just helped organize their own “buying group” of pharmacies (the Parenteral Alimentation Providers’

Association) that will negotiate collectively with the manufacturers, Lifesource hopes, for a competitive "contract price." This, of course, would be a stabilizing factor in the fees that Lifesource charges its patients.

The use of generic drugs reduces Lifesource's costs, as it does for any pharmacy. Lifesource uses generics whenever possible. Pharmacists in California can substitute generics for brand-name drugs without the prescriber's express permission. (However, they cannot use therapeutic substitutes, or change dosages, without such permission.)

LEGISLATIVE ISSUES

At least two legislative issues concerning pharmacy are currently under discussion in California. One bill pending in the state legislature is a patient counseling requirement for pharmacists. California currently has no such legal requirement.

Another bill would allow much wider use of pharmacy technicians than is now permitted. Currently, technicians may only work in hospital pharmacies. Under the proposed law, technicians could work in community pharmacies in a variety of capacities, so long as a ratio of 1:1:1, among pharmacists, technicians and clerks was maintained in a given pharmacy.

This is the bill that has engendered the most serious opposition from pharmacy groups, though only some pharmacy groups have lobbied against it. The national Association of Retail Druggists, for example, has lobbied against it, Lifesource personnel told us. Such a position may seem irrational, for the judicious use of technicians could free pharmacists to perform the clinical services in which technicians are not trained, and that pharmacists now often have no time to perform. However, Alexander told us, such opposition may make sense to those pharmacists who in fact do little more than a skilled technician could, and who envision themselves doing little more if given the opportunity.

CASE STUDY No. 6:
Madeline Feinberg and Accredited Surgical Company

GENERAL BACKGROUND

Accredited Surgical Company (ASCO) is one of the country's largest compliance packaging providers, as well as nursing home pharmacy provider and medical equipment company. The nursing home and medical equipment components of ASCO have been in existence since 1954. The home care component, specializing in the provision of compliance packaging for the non-institutionalized patient, has been in existence for only three years; this component is the subject of this case study.

ASCO personnel refer to their home care service as "residential care services" or "assisted living services." This seems apt since this component of ASCO does not service patients who are confined to their individual homes. Rather, it services group homes, and domiciliary care settings whose residents require supervision and some assistance with the Independent Activities of Daily Living (IADLs). Most residents are able to perform their own Activities of Daily Living (ADLs), except perhaps for bathing. In other words, although these residents can no longer live independently, they are not and need not be institutionalized. ASCO packages and delivers prescribed medications for these patients using its compliance packaging system.

ASCO fills approximately 1,800 prescriptions per month (both prescription and nonprescription drugs) in its assisted living component; this amounts to 8-9 percent of its total of 40,000 prescriptions per month, or 2,000 per day. In its assisted living component, ASCO services approximately 550 beds in 13 homes, the smallest of which contains six beds, and the largest of which contains 174 beds. ASCO's assisted living patients receive an average of 5.7 drugs each.

PHARMACIST'S BACKGROUND

Madeline Feinberg is the pharmacist in charge of ASCO's assisted living program. She received her B.S. from the University of Maryland School of Pharmacy in 1979, at which time she began seven years of work in a small community pharmacy located in an affluent suburb of Washington D.C.

Also in 1979, Professor Peter Lamy, then Chairman of the Pharmacy Practice Department, U. M. School of Pharmacy, approached her with an invitation to help develop a community drug education program for elderly focusing on the appropriate use of medications, self care, and wellness issues. This program, initially funded by the Administration on Aging, is now entirely funded by pharmaceutical industry, notably the Parke-Davis Company. As part of her effort in working with elderly and the aging provider network for the past 10 years, Feinberg

has recognized the need to develop packaging systems for elderly at high risk to medication mismanagement. She focused on the assisted living sector, which services the frail elderly, and whose providers are medically untrained.

Feinberg told us she enjoyed the interaction with her patients while working in the community pharmacy, but overall felt that more needs to be done for those elderly who are at risk of to making serious medication errors. Moreover, she had been asked by several county agencies to assist in developing a system to assure appropriate medication administration in group homes.

The alternative care site, or assisted living program, grew out of these efforts. Three years ago, Feinberg approached Milton Moskowitz, President of ASCO, with the idea of branching into this emerging marketplace. She convinced Moskowitz to hire her to develop such a component to the business and has been there ever since.

STAFF

ASCO employs more than 100 people in its entire operation. Only a small group, however, work exclusively in the assisted living component. Feinberg, who heads this section, works half-time for ASCO, while continuing her directorship of the Elder-Health Program at the University of Maryland School of Pharmacy. She has the exclusive use of two full time pharmacy technicians who fill all the medication orders for the assisted living residents. This packaging system is more complicated and intricate to use when compared to the standard nursing home blister card or unit dose systems. It requires special skills and concentration, as each card is customized for each patient, and must contain exactly the correct doses in the appropriate blister. More important, it requires special communication skills in dealing with residential care staff, who are medically unsophisticated, and often need help in sorting out the regimen as prescribed by the physician. Both pharmacist and technicians devote a considerable portion of time to talking with providers, and in addition, visit the homes for in-service education on the system periodically. (See section on compliance packaging under "basic services" below).

PATIENT POPULATION

As remarked above, the assisted living population, in terms of self-sufficiency and need for supervision, lies somewhere between the nursing home population and the unassisted population living in the community. The most important and most uniform characteristic of this population is its advanced age. Chronic illnesses are common among this group, as are polymedicine and multiple prescribers. Many, though by no means all, members of this population also suffer from mild cognitive impairment. Thus, an easy-to-use method of drug self-administration is highly necessary in this setting.

BASIC SERVICES

ASCO is an institutional pharmacy with no retail services, except for their medical equipment store which is located 15 miles from the pharmacy. The bulk of the pharmacy operation is devoted to taking medication orders from nursing homes, and other institutions which they service, including jails, intermediate care facilities for the mentally retarded, homes for the emotionally impaired, a psychiatric hospital, and assisted living homes. Drugs are prepared for their patients using a variety of systems as noted previously, including the compliance package.

(1) Compliance Packaging System

The compliance packaging system is one aspect of ASCO's service. It is intended to allow patients to self-administer medications according to a prescribed daily regimen. In many of the homes, staff take the responsibility to help the resident with this task, since most states do not permit unlicensed personnel to administer medication. The compliance package facilitates assistance and assures that the untrained staff person will readily identify the correct blister for the patient.

This package involves a small, hand-held board with clear plastic bubbles, inside of which tablets or capsules are enclosed. Each bubble represents the doses to be taken on that day. Each card is labeled with the time of day, e.g. "morning", "evening", or a special time, and contains the month's supply of medication for that time. The blisters on each board come in several sizes to accommodate several pills, as well as to accommodate very large pills. The bubbles may be labeled by day of the week, if requested by the administrator of the home. The board always contains one month's supply of medications. As needed medications are packaged separately, per card, and must be reordered when running low. Likewise, eye drops, ointments, liquids and other preparations are refilled as needed. But the compliance package containing the month's supply of medications is automatically refilled each month, thus assuring that a medication will not run out or be forgotten. The medication orders are updated by the physicians, and at the time of medication changes, the card may be re-packaged and sent to the home within a matter of hours.

This packaging system facilitates review of the patient's ability to self-medicate by the caregiver who may not be giving close supervision to a particular resident. The caregiver need only glance at the card to determine if the medication is being taken correctly.

Feinberg told us that these systems force pharmacists to communicate with their patients, or in this case, with their caregivers, i.e., those who manage the group homes. It provides an opportunity to talk about the therapeutic use of the drug, its side effects, and its proper administration. Feinberg particularly emphasizes the monitoring

component of the caregiver's duties, and insists that observed changes be reported to the physician.

(2) **Patient Education**

Although the pharmacists at ASCO do not counsel individual patients as a rule, they do conduct in-service staff education in nursing homes and in the assisted living sites that they service. Some of the topics on which Feinberg speaks are "Depression in the Elderly - Medications Used for Treatment," "Psychiatric Side Effects of Commonly Used Medications," "Drug Interactions" and others. ASCO consultant pharmacists offer talks on Parkinson's Disease, antianxiety drugs, dilantin dosing, constipation, gastrointestinal disease and treatment, AIDS, arthritis, OTC cough and cold remedies and other topics on request.

CLINICAL ACTIVITIES

(1) **Data Collected**

ASCO collects extensive data on its patients, which it can use in performing DUR, since the care sites where these patients are living have very complete data. ASCO collects data concerning prescription drug use, allergies, diseases and conditions, as well as diagnostic data on patients. In addition, ASCO collects complete information on OTC drug use.

(2) **DUR**

ASCO performs prospective DUR when filling new prescriptions, but only through the use of an automated computer program. ASCO's computers screen for allergic reactions and only for the most severe drug interaction. (They are currently in the process of acquiring a new computer which will permit a more comprehensive screen for drug/drug interactions.)

ASCO presently does not perform retrospective DUR in its assisted living sites. However, Feinberg told us, substantial therapeutic value could be gained through this type of DUR; she thinks it would serve to protect a population at risk from potential misutilization of prescribed medications. This kind of DUR, unfortunately, is rarely reimbursable in this setting. However, some states have considered the need for pharmacist conducted reviews in domiciliary care, and have mandated this service, for example, in North Carolina. Florida recently passed legislation requiring consultant pharmacy service when the home is inspected and found to be deficient with regard to medication management. In therapeutic terms, such a requirement is a step forward.

NATIONAL ISSUES

We discussed the policy context of our study with Feinberg and Moskowitz, and in response, they offered ideas concerning some national issue areas.

(1) Definition of Patient Counseling

Feinberg and Moskowitz are of the opinion that a wide range of counseling practices exist, reflecting great variations in quality of patient care, and that these variations should be recognized in government policy. They questioned whether contact over the telephone—which is central to the counseling activities of, for example, mail-service pharmacies—can provide adequate patient counseling. Furthermore, Feinberg raised the issue of follow-up counseling activities, saying that these are crucial to the effectiveness of counseling.

(2) Demonstration Projects

Feinberg had some ideas for general topics on which it would be informative for the Department to fund demonstration projects. One idea was a project involving compliance packaging, to determine whether the use of such a drug delivery system tends to increase the level of patient counseling and physician consulting that pharmacists conduct.

Another suggested project would involve consumer demand for clinical pharmacy services, and possible ways to stimulate such demand. Feinberg believes strongly that educated consumers, who demand such services, are more likely than anyone else to ensure that such services are provided. Thus determining how to stimulate consumer demand is essential, in her view, to any effective program design to stimulate clinical pharmacy practice.

APPENDIX I

CASE STUDY METHODOLOGY

The purpose of conducting the case study was two-fold:

- to observe and document activities that comprise clinical pharmacy practice; and
- to identify (in the case of clinical pharmacists who practice in traditional community settings) the barriers they face in providing pharmaceutical care to their patients and to determine the methods they use to overcome those barriers.

Given that objective, we made a purposive selection of pharmacists who were identified by members of professional and research organizations as practitioners who provide an unusually broad range of clinical services to their patients. A number of organizations and individuals were helpful to us in identifying a candidate pool, including the American Pharmaceutical Association, the American Association of Colleges of Pharmacy, the University of Florida College of Pharmacy, and the University of Maryland College of Pharmacy. We made selections from an initial pool of 35 candidates based on telephone interviews during which we solicited information about the nature of the pharmacist's practice, the population served, the pharmacist's therapeutic specialty, and her/his willingness to participate in the case study. Our final selection was based in part on geographical diversity; urban, rural and suburban practices are represented. Although we sought candidates who practice in chain, independent and apothecary settings, only the latter two are represented. None of the candidates nominated practice in chain pharmacies.

The pharmacists selected for our study are listed below:

Julee Alexander
Lifesource, Inc.
900 Larkspur Landing Circle, Suite 250
Larkspur, CA 94939

Nancy Culberson
Lexington Family Practice Pharmacy
P.O. Box 460
Lexington, SC 29072

Madeline Feinberg
Accredited Surgical Company
9515 Gerwig Lane, Suite 131
Columbia, MD 21046

Linda Garrelts
Jones Pharmacy
S. 906 Monroe
Spokane, WA 99204

Howard Juni
Capitol Drug Center
2007 E. County Rd. E
White Bear Lake, MN 55110

Calvin Knowlton
Amherst Pharmacy
332 Lumberton Rd.
P.O. Box 56
Lumberton, NJ 08048

In each case, we made site visits to observe the pharmacist's practice over a 2- to 3-day period. In the case of the four pharmacists who practice in traditional community settings (Knowlton, Juni, Garrelts, and Culberson), we conducted extensive interviews with the pharmacist and other staff on site, physicians who were familiar with the pharmacist's practice, and patients served by the pharmacist. We also observed the pharmacist in practice and reviewed the information systems they use to support clinical activities.

