



Introduction to Specialty Pharmacy

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Continuing Education Reading Course
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Introduction to Specialty Pharmacy

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Financial interests

- No relevant financial relationships

Learning Objectives

1. Explain what exactly is a specialty medications and how does it differ from traditional medications
2. Review the current state of the industry of specialty medications at its current impact on traditional community pharmacy
3. Describe exactly what clinical pharmacy services are and how these services could be implemented in a community pharmacy setting
4. Review the key steps in evaluating and preparing a community pharmacy to develop a specialty pharmacy niche

One (1) contact hour of credit (0.10 CEU)



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Introduction

Over the last few years, several factors have added to the financial challenges faced by community pharmacies, forcing the industry to more widely explore the clinical services side of the pharmacy model. These factors include: growth of generics, the aging of America, the slowdown in development of traditional, single-entity, oral medications, the slashing of reimbursement on pharmaceuticals by prescription drug providers, and the uncertainty of the new pricing structure of AMP (Average Manufacture Price). With the hope of Medication Therapy Management Services as outlined in the Medicare Modernization Act of 2003, community pharmacy can re-examine the traditional product-based model and consider evolving other streams of non-product revenues. One avenue that may play a role in this transition to a more clinically-focused model is that of specialty pharmaceuticals. Specialty pharmaceuticals still depend on the traditional pharmacy delivery and dispensing model, but also require clinical services that go along with these medications.

Specialty Pharmaceuticals have emerged as effective tools in treating a wide variety of chronic or rare diseases. These agents, although a small market in terms of number of medications available, are the fastest growing sectors in the prescription drug market over the last 8 years. According to the report PHRMA 2006 Report Medicine in Development BioTech there were about 125 biotechnology medications already approved with at least 400 to 600 in development for approval. Expenditures on these agents are projected to increase from approximately \$54 billion today to more than \$99 billion in 2010. It is estimated that specialty pharmaceuticals currently account for approximately 24% of total drug expenditures, but spending on these agents is rising about twice as fast as that for conventional drugs; a trend that is expected to continue for the next 20 years. In fact, this impact on cost has recently prompted the current Presidential administration and Congress to propose regulation changes on biotech patents to make generic medications more readily available in the biotech sector. For example, one of the proposed bills would give biotech medications just five years of market exclusivity and up to three more years for modifications³. This modification significantly would decrease the years for marketing compared to the usual standard of 17 years for a U.S. drug patent which after about 8 to 12 years of drug development leads to an average 10 years of market exclusivity.

So, what exactly represents specialty medications, and how can community pharmacy help control these growing costs, and perhaps find a new business opportunity? This continued education article will explore exactly what Specialty Pharmacy is, discuss how community pharma-

cy can play a role in this industry, and finally, identify the necessary skills needed to get started in this sector of pharmacy.

What exactly is Specialty Pharmacy?

What differentiates specialty pharmacy medications from conventional medications?

Specialty Pharmaceuticals for the most part target a small patient population which focuses on disease states such as anemia, cancer, growth hormone deficiency, hepatitis, immune-deficiency, and multiple sclerosis. Listed in Table 1 is an overview of examples of common disease states treated by specialty pharmaceuticals.

Specialty pharmacy agents are typically administered by injection or infusion processes that are more complicated and expensive than simply taking an oral dosage form. Additionally, there are some oral agents that require the "high-touch" aspect that only the community pharmacist is equipped to provide. Because of the complexities of administration, preparation, and storage requirements, some type of in home educational services (e.g. partner with a home health agency) may be required to support in home injection training or ongoing infusion.

In the past, because of the different means of administration (whether injected, infused or inhaled), these drugs were reimbursed under the private payer's medical benefit or Medicare Part B rather than the pharmaceutical budget.

These medications also have storage and handling concerns that are more complicated than traditional medications. Many specialty pharmaceuticals require refrigeration, or have special mixing and/or compounding instructions associated with them. This may not always be best suited for a pharmacy that must deliver from a far distance through a mail order service. Specialty medications typically, for maximizing efficacy or prevention of high risk adverse drug events, require more vigilant monitoring in terms of lab work, dosing and compliance. Characteristics of specialty pharmaceuticals include more frequent dosing adjustments than traditional medications, often due to a narrow therapeutic range. Additionally, due to the high-risk nature of these agents, more intensive patient education is required which differs from your traditional pharmacy patient counseling requirements. Often these patient education programs not only target the patient themselves, but also the health care professionals involved in caring for these specific disease states.

Specialty pharmaceuticals typically can be put in to three types of categories: (1.) Self-administered medications (orally ingested and/or injected) used for diabetes management, rheumatoid arthritis, and fertility, (2.) pharmaceuticals injected in a clinic, pharmacy, or office setting which can include vaccines, treatments of various immune disorders, and asthma, and (3.) office-only administered chemotherapeutic agents.

Ways to implement risk minimization measure with specialty medications include appropriate labeling to ensure safe and effective use of product, implementation of formal data collection requirements to help manufactures in post-marketing surveillance

In summary, the key differences of a specialty pharmaceutical compared to traditional pharmaceuticals include the following: higher level of patient training and education required associated with proper usage; handling and avoidance of adverse effects; more frequent and in-depth patient interaction requirements beyond the initial dispensing process; medications with a higher frequency of side effects that are very severe in terms of morbidity and mortality; complex dosage administration; extreme storage requirements; and patient non-compliance, having potential for significant impact on clinical outcome and obviously impact on costs. A classic example of this maybe comparing hydrochlorothiazide used for hypertension and the use of a protease inhibitor for treatment of HIV. Both have a high incidence of non-compliance which can lead to negative outcomes in terms of disease therapy; however, HIV medication non-compliance can lead to resistance and the need for additional HIV regimens, which can be ten times more costly than the addition of a generic anti-hypertensive.

How can community pharmacy help with these growing costs and perhaps find a new business opportunity?

Cost is a major factor associated with specialty pharmaceuticals. While only 1 percent to 3 percent of a typical health plan population takes specialty medications, those members are responsible for at least 25 percent of a health plan's costs and, if projections are correct, could eventually account for as much as 50 percent².

Because of these specialty pharmaceuticals were expensive, it was cost-prohibitive for most community pharmacies to maintain and manage an appropriate inventory of these agents. As such, over the last fifteen years, the industry saw the advent and growth of specialty pharmacies. Specialty pharmacy is a field that was created to handle the unique needs of specialty pharmaceuticals and the patients that are treated with these agents, and provide a mechanism to manage costs of these agents for the patient and the benefit sponsor. Services provid-

ed includes: dispensing, storage and distribution, patient/provider education, clinical documentation, reimbursement advocacy, and disease management associated with the use of these medications. Specialty pharmacy focuses on services that facilitate an understanding of the complexity of the rare diseases and the medications used in their treatment in order to provide detailed, patient specific education programs; develop standardized processes for distribution, to maintain product integrity and assist patients in navigating through the confusion of getting a specialty medication covered.

With the emergence of specialty pharmacy, benefit sponsors identified the opportunity to "carve out" these products from standard formularies and treat them as stand-alone product lines, and manage them outside of the "normal" pharmacy benefit. The model impacts the community pharmacy by reducing their ability to dispense certain medications and interrupting a patient's continuity of care. For example, a patient may receive a home infusion chemotherapy agent from their specialty pharmacy, but did not realize the importance and use of traditional medications such as antiemetic (e.g. ondansetron) to help with adjunct therapy for the specialty medications overall success. In another example, a patient being treated for multiple sclerosis also needs to understand the importance of concurrent use of medications such as antidepressants, antispasmodics, and analgesic medications.³ So, if community pharmacy does not take the opportunity to get involved in specialty pharmacy, these agents may also be carved out to the many specialty pharmacies that deliver their medications via mail order.

Recently, the specialty pharmacy arena has seen consolidation due to market share issues, scope of services concerns, complexity of services and access to patients; therefore, the playing field of competition for the community pharmacy has shrunk, but the threat of these services being excluded for community pharmacy has not. Also, with the consolidation of key players, the delivery of product has been fragmented and the large specialty pharmacies are experiencing service issues which are alarming to payers.

Many payers are re-examining the current specialty pharmacy model, as they identify a potential inherent conflict of interest. The current model has its interests caught between the manufacturers of these 'biotech medications' and the payers looking for clinical services to ensure a maximum positive clinical outcome and overall control of costs.³ The specialty pharmacies assist the pharma/biotech company by serving as a valuable, consistent distribution channel, facilitating quality control and volume/utilization forecasting. Furthermore, payers are

questioning whether or not they are getting the maximum benefit from the additional clinical services provided. For example, the average cost savings is about 3% on specialty medications with specialty pharmacies, and although the percentage seems low, the percent saving on a medication cost on average of at least \$1,500-\$2,000 per medication can have a significant impact³.

What are payers looking for with the future of specialty pharmacy? Better tools to measure value in terms of adherence and clinical outcomes, which is often a tough task for a specialty pharmacy working for a large payer that covers a large geographical area (Northeast United States).

And finally, with consolidation, the quality of service has decreased for several specialty pharmacies. With the increased patient census and layered complexity, many "remote" specialty pharmacies are not able to meet the payers' and /or patients' needs. For example, patients on Friday afternoon are not able to get their drug because the customer service line isn't open, a particular contact person isn't available, or the doctor couldn't be contacted because there wasn't a local community pharmacy option. Someone in Pittsburgh, dealing with a patient that lives in Iowa³ is a difficult process!

The current trend is on improved customer service and more accurate ways to measure real dollars in terms of positive clinical outcomes and adherence. The local community pharmacy has this opportunity now knocking at its door, but there are some operational challenges that will need to be evaluated and addressed before one considers entering this market, which the remainder of this paper will address.

What are the necessary skills needed to get started in this sector of pharmacy?

Before beginning a discussion regarding the necessary skills to get started, let's look at exactly what is clinical pharmacy and disease management. Together, they play an important role in the delivery of services for specialty pharmaceuticals.

Clinical Pharmacy is a commonly used term in pharmacy practice and in pharmacy literature. It is a health specialty, which describes the activities and services of the clinical pharmacist associated with the development and promotion of the rational and appropriate use of medicinal products and devices for an individual patient.

In the past, the term "clinical" implied an activity implemented in a hospital as this was the setting where we saw the first pharmacy clinicians and services evolve.

During the growth of clinical pharmacy in the hospital setting, we saw pharmacist focusing on medications that had some common characteristics. These agents usually were intravenous medications, high cost, had a narrow therapeutic index for efficacy and toxicity, and intense monitoring was required for success. Examples of those medications include antibiotics such as amino glycosides, anti-epileptic medications (carbamazepine, phenytoin) and anticoagulants such as warfarin, and heparin. Today, these medications are considered traditional medications. But in the early days of clinical pharmacy, where we focused on skills of dosing and monitoring due to the pharmacokinetics and narrow index range of these medications, these agents were specialty medications. Specialty drugs are the new narrow therapeutic drugs of today and the future, and, the majority of specialty pharmaceuticals are done as an outpatient setting. Now is the opportunity to make the community pharmacy the new setting for clinical pharmacy.

In the late 1970's, the first cost-benefit analysis of clinical pharmacy services was published. Since then, numerous research articles have shown these services to be effective for the medical profession, third party payers, and consumers. In the last 35 years, the profession of clinical pharmacy has been established in the hospital sector and managed care sector as a value added service. In the years since the 1970's, the great need has been to take these types of clinical services and bring them to the community setting. A community pharmacist can perform clinical activities as well as a hospital practitioner. The discipline of pharmacy embraces the knowledge of synthesis, chemistry and preparation of medications, whereas clinical pharmacy is more oriented to the analysis of population needs with regards to medicines, routes of administration, patterns of use, and drug effects on the patient.

These services promote maximizing clinical efficacy of the medication and minimizing the risk of adverse drug events. Both are achieved by having systems for monitoring the course of therapy, with follow up patient counseling by healthcare professionals. This, hopefully, ensures a patient's compliance with therapy. This should be accomplished with the control of health care costs for the pharmacological treatment by the patient, the pharmacy drug provider (PDP) and the responsible entity for medication coverage costs (e.g. Employer). The development of these skills and implementation of these skills is not impossible for the community pharmacy, but will take some preparation work to achieve this goal.

With recent opportunities emerging out of the Medicare Modernization Act (MMA) in regards to medication therapy management (MTM) services, it provides an excellent model for community pharmacies to provide highly spe-

cialized clinical services geared towards specialty pharmaceuticals. Additionally, the current MMA law states that Medicare Part D plans may not restrict access to Part D drugs by limiting distribution through a subset of network pharmacies. This stipulation may allow the opportunities for greater access to specialty pharmaceuticals by community pharmacies.⁴

In order for community pharmacy to get involved in specialty pharmaceuticals there are several key operational challenges that need to be addressed. Those challenges include the ability to bill these pharmaceuticals through current online billing methods, as you would traditional medications. Marketing to payers that specialty pharmaceuticals need to be a part of the pharmacy benefit (rather than be “carved out”) in order for billing to be seamless, thus cutting cost, and, effectively lowering costs of clinical services.

Another operational challenge is that community pharmacy needs to create a business plan on how clinical services are going to be performed. For example, who and how will disease state therapy management be conducted, what is your materials or modes of delivering patient counseling and physician education. Does your pharmacy offer 24 hour seven day week clinical support? What software package will be used for patient tracking and clinical reporting? There are numerous clinical software packages available for patient tracking (e.g. Rxpertise®, Medication PathFinder®) that can be incorporated as part of a clinical services offering. Also the American College of Clinical Pharmacy has a good resource text titled How to Develop a Business Plan for Pharmacy Services.

When considering the specialty pharmacy arena, one important step is to determine the “right” specialty products with which to build your program. If you are just one pharmacy, or one region of pharmacies, we recommend going “local.” Evaluate what current disease states you experience within your current patient population, which might warrant specialty pharmaceuticals. What categories of specialty medications have key growth potential? Diseases such as Crohn’s Disease, Infertility, Rheumatoid Arthritis and Cancer have an estimated growth potential greater than 20%.

Continuity of care is a key advantage that community pharmacy possesses over a remote, national specialty pharmacy provider. Community Pharmacy is positioned with a greater ability to provide continuity of care with the various other disease states that may interfere or medications that interact with the specialty pharmaceuticals. Also, from a business model, these disease states are going to require at least 2 to 4 additional traditional medications to support therapy. The importance of

patients understanding how all of these medications fit in their treatment regimen is a must for good clinical success.

Another way to start local is to identify physicians in your area that already treat diseases that require specialty pharmaceuticals. Talk with them and discuss the barriers they encounter when trying to start or continue their patients on specialty medications. Identify what pharmacy-related clinical services would the physicians value.

After identifying key specialty pharmaceuticals that you may be able to provide, take a good look at your infrastructure. Performing an analysis of your current workflow and capabilities is an exercise you might have already addressed in your business, as you begin to offer Medication Therapy Management Services (MTMS).

- Key components to consider; do we have enough storage (e.g. refrigeration space) for keeping the specialty pharmaceuticals on site?
- What type of pricing can I get from my wholesaler or manufacturer?
- What is the lead-time in obtaining these medications which will determine what type of inventory I must maintain?
- Does my staff have appropriate clinical experience, or would we need to recruit someone?
- Do I hire a new PharmD?
- Can I find a PharmD. to hire that has residency training or has worked in the specialty pharmacy market?
- What types of continuing education material or lectures are available for the various disease states for which I am interested in providing services for and who should I send for training?
- What support staff do I dedicate for this service in terms of preparation of product for delivery, coordinating the data capturing and reporting feed, medical claims billing, and coordination of prior authorization approval process?
- Can my pharmacy offer a 24/7 on-call service?
- How do I analyze my workflow to allow my current staff to provide the necessary time and the level of pharmaceutical care necessary for patient education and counseling?
- Does my current pharmacy software have the ability to capture the data that manufacturers are requiring: who is the prescriber, where is the medication being administered, what is the compliance rate of the medication, and what are the reported adverse events associated with this medication?
- The final overall thought to consider - Pharma manufacturers need accurate data to satisfy the FDA in terms of post marketing surveillance, in order to avoid a drug being completely pulled off the market or obtain a black box warning. A classic example of this is

the inappropriate use of erythropoietin. Over the years, the misuse of this agent has led to tighter restrictions on the use and monitoring of this medication due to case reports to the FDA in regards to thrombotic events. Manufacturers re-detailing of medication by the FDA is a costly endeavor. These issues on adverse events speak even more strongly of why enhanced patient education detail and monitoring is necessary to facilitate patient safety and promote positive outcomes.

All of the above questions require time to be set aside to analyze your current business structure and develop a strong business plan. One suggestion in developing a business plan is to conduct a 'S.W.O.T.' analysis, where you look at your internal strengths, internal weaknesses, external opportunities, and external threats, related to your business in the specialty pharmaceutical market.

When you identify the key specialty pharmaceuticals you wish to provide, begin to consider what complimentary medications, supplies, and/or ancillary services may be associated with the treatment of these particular disease states. What are the key components that my business needs to insure a strong disease management program? Please refer to the Disease Management Association of America for the critical key components of a disease management program. The website link is the following: www.dmaa.org.

Developing a strong business and marketing plan will enable community pharmacy to actively promote its capabilities to contract with benefit sponsors to be included as a viable specialty pharmacy provider.

One way to begin the development of your clinical tools would be to attend or enroll in some of the numerous on-line or live Medication Therapy Management Services training modules offered through various pharmacy associations (e.g. APhA, NCPA).

In conclusion, community pharmacy has a strong advantage in comparison to the large, consolidated specialty pharmacies. It serves as the key access point for the patient and the physician. Community pharmacies represent the broadest, most accessible outlets for reaching patients who might benefit from these therapies, often located in geographical rural-challenged areas. Face-to-face contact is still the best way to deliver good clinical pharmacy services. It makes sense to make these treatments available, if community pharmacies can develop quality services that capture and track the data needed by the manufacturers. Why wouldn't community pharmacies be able to partner with payers by helping their beneficiaries and, at the same time, control costs? With the advent of Medication Therapy Management Services, community pharmacy is poised to become more clinically oriented, and, consequently, more conducive and

accessible to providing the necessary services associated with Specialty Pharmaceutical agents

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4. Steiber D, Erhardt D. Specialty Pharmacy in Community Pharmacy NACDS Pharmacy Industry Council Supply Chain Committee November 2006
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Table 1

Drug Name:	Manufacturer:	Associated Disease State(s)
Aralast	Baxter Bio	Alpha 1-Proteinase Inhibitor Deficiency with Emphysema
Avastin	Genetech	Glioblastoma, Non-Squamous Non-Small Cell Lung Cancer
Avonex	Biogen	Multiple Sclerosis
Betaseron	Bayer	Multiple Sclerosis
Caverject	Pfizer	Erectile Dysfunction
Ceredase	Genzyme	Type 1 Gaucher's Disease
Cerezyme	Genzyme	Gaucher's Disease
Copaxone	Aventis / Teva	Multiple Sclerosis
Cubicin	Cubist	Complicated Skin & Skin Structure Infections (CSSSI's) Staph. Aureus Blood Stream Infections
Cytovene	Roche	CMV Retinitis Treatment /Prevention
DepoDur	EKR Therapeutics	Moderate / Severe Pain relief
Edex	Schwaz	Erectile Dysfunction
Eligard	Sanofi Aventis	Advanced Prostatic Cancer; Endometriosis
Enbrel	Amgen	Rheumatoid Arthritis, Psoriasis
Fabrazyme	Genzyme	Fabry Disease
Gleevec	Novartis	Chronic Myeloid Leukemia, Acute Lymphoblastic Leukemia
Humira	Abbott	Rheumatoid Arthritis, Psoriasis, Crohn's Disease
Hyalgan	Aventis	Osteoarthritis Symptoms
IVIG	Various	Immune Deficiency Syndrome
Iressa	Astra-Zeneca	Non-Small Cell Lung Cancer
Kineret	Amgen	Rheumatoid Arthritis
Leuprolide	Various	Advanced Prostatic Cancer; Endometriosis
Lupron	TAP	Advanced Prostatic Cancer; Endometriosis
Methotrexate	Hospira	Rheumatoid Arthritis, Psoriasis, Antineoplastic Chemotherapy
Muse	Vivus	Erectile Dysfunction
Myozyme	Genzyme	Pompe Disease
Orencia	Bristol-Myers Squibb	Adult Rheumatoid Arthritis, Juvenile Idiopathic Arthritis
Orthoclone OKT-3 DOM	Ortho Biotech	Immunosuppressive Therapy
Orthovisc-Hyaluron	DePuy Mitek Inc.	Osteoarthritis Symptoms
Prolastin	Talecris	Alpha 1-Proteinase Inhibitor Deficiency with Emphysema
Raptiva	Genetech	Psoriasis
Rebif	EMD Serono	Multiple Sclerosis
Reclast Inj	Novartis	Osteoporosis, Paget's Disease
Remicade	Centocor	Rheumatoid Arthritis, Crohn's Disease, Ulcerative Colitis
Rituxan	Genetech / Idec	Rheumatoid Arthritis, Non-Hodgkins Lymphoma
Sandostatin	Novartis	Acromegaly, Carcinoid Tumors, Vasoactive Intestinal Peptide Tumors
Sensipar	Amgen	Hypercalcemia in Parathyroid Carcinoma, Secondary Hyperparathyroidism
Stimate	CSL / Behring	Hemophilia A, von Willebrand's Disease (Type I), Central Diabetes Insipidus
Sutent	Pfizer	Advanced Renal Cell Carcinoma, Gastrointestinal Stromal Tumors
Synagis	Medimmune	Respiratory Syncytial Virus (RSV)
Synvisc	Genzyme	Osteoarthritis Symptoms
Tysabri	Elan	Multiple Sclerosis
Varivax	Merck	Varicella Vaccination
Vivitrol	Cephalon	Alcohol Dependence
Xolair	Genetech	Asthma
Zemaira	CSL / Behring	Alpha 1-Proteinase Inhibitor Deficiency with Emphysema

Self-Assessment Questions:

1. Which of the following characteristics does not necessarily define specialty pharmaceuticals

- a. High cost medications
- b. Must be an injectable medication
- c. Narrow therapeutic index with higher increase risk of adverse effects.
- d. Problem with patient access to these medications

2. The need for clinical services for specialty medications is needed for which entity.

- a. The patient
- b. The provider (e.g. employer, PBM)
- c. The Manufacturer
- d. All the above

3. Cost control of specialty medications can be done by which of the following:

- a. Educational on proper use of the product to both the patient and healthcare professional.
- b. Review and documentation of appropriate dosing
- c. Adherence/Compliance programs to prevent therapeutic failure
- d. All of the above

4. Pharmacist-Physician collaboration agreements may help with specialty pharmaceuticals clinical services by which of the following:

- a. Ensuring there is continuity of care between different health disciplines
- b. Allow the pharmacist to aid the physician by the ordering of labs for monitoring
- c. The development of dosage adjustment protocols which would allow the pharmacist to make appropriate dosage adjustment upon evaluation of the patient and any additional clinical findings.
- d. All of the above.

5. The end result for clinical pharmacy services wanted by manufacturers for specialty pharmaceuticals is which of the following:

- a. Promote the correct and appropriate dose of the medication
- b. Consolidate the industry to selected pharmacies to control inventory
- c. Clinical service programs that measure real dollars in regards to positive clinical outcomes
- d. A and C

6. Which of the following statements are incorrect?

- a. Pharma manufacturers need accurate data to satisfy the FDA in terms of post marketing surveillance, in order to avoid a drug being completely pulled off the market or obtain a black box warning.
- b. Patient education detail and monitoring has not shown to help to facilitate patient safety and promote positive outcomes
- c. Medicare Modernization Act in regards to medication therapy management (MTM) services, an excellent model for community pharmacies to provide specialty pharmaceuticals services
- d. All of the Above

CONTINUING EDUCATION

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ANSWER FORM

1. a. b. c. d. 2. a. b. c. d. 3. a. b. c. d. 4. a. b. c. d.
5. a. b. c. d. 6. a. b. c. d.

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After reading the home study monograph, please answer the following questions. Return the evaluation form, self assessment questions, and registration form (with payment) to:

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1. How long did it take to read this monograph? _____
2. Were the stated objectives met? _____yes _____no
3. Is the monograph pertinent to contemporary pharmacy practice? _____yes _____no
4. Are the illustrations and graphics clear and understandable? _____yes _____no
5. How would you rate the level of difficulty (low, moderate, high)? _____
6. Is the article written with assurance of non-commercialism? _____yes _____no
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10. Would you recommend the monograph to others? _____yes _____no
11. What changes would you suggest, if any?

12. Additional comments

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