Submitter : **Ms. Mary Ellen Kleliman** **Date: 12/05/2007**

Organization : **National Association of Chain Drug Stores**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

The National Association of Chain Drug Stores (NACDS) submits the attached November 13, 2007 report by Stephen W. Schondelmeyer, Pharm.D., Ph.D., FAPHA (with exhibits) regarding Average Manufacturer Price and Federal Upper Limits for agency consideration. Due to its size, it will be submitted in 2 separate submissions of 2 PDF files each. See the first 2 Attachments.

CMS-2238-FC3-6-Attach-1.PDF

CMS-2238-FC3-6-Attach-2.PDF

#6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF CHAIN DRUG STORES 413 North Lee Street Alexandria, VA 22314, and **NATIONAL COMMUNITY PHARMACISTS ASSOCIATION** 100 Daingerfield Rd. Alexandria, VA 22314, Plaintiffs, v. **UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES** 200 Independence Ave., SW Washington, DC 20201, and **MICHAEL O. LEAVITT, SECRETARY OF HEALTH AND HUMAN SERVICES,** solely in his official capacity 200 Independence Ave., SW Washington, DC 20201, and **CENTERS FOR MEDICARE AND MEDICAID SERVICES** 200 Independence Ave., SW Washington, DC 20201, and **KERRY WEEMS, ACTING ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES**, solely in his official capacity 200 Independence Ave., SW Washington, DC 20201, Defendants.	)	Case: 1:07-cv-02017 Assigned to: Lamberth. Royce C. Assign. Date: 11/7/2007 Description: TRO/PI

EXPERT REPORT OF
STEPHEN W. SCHONDELMEYER, PHARM.D., PH.D.

I. QUALIFICATIONS AND BACKGROUND

1. I make this statement as an independent expert in pharmacy, pharmaceutical economics, and public policy. I hold the following positions and titles in the College of Pharmacy at the University of Minnesota: Head, Department of Pharmaceutical Care & Health Systems; Century Mortar Club Endowed Chair in Pharmaceutical Management and Economics; Professor of Pharmaceutical Management and Economics; and Director of the PRIME Institute. I hold a Bachelor of Science in Pharmacy (1974, University of Missouri-Kansas City), a Doctor of Pharmacy and Residency Certificate (1977, University of Kentucky), a Master of Arts in Public Administration (1979, Ohio State University) and a Doctor of Philosophy in Administrative and Social Sciences in Pharmacy (1984, Ohio State University). A list of my professional memberships, professional activities, research activities, publications and other scholarly activities, citation of work in public media, offices held in professional and scientific organizations, university administrative and service positions, honors and awards, and civic and community activities is contained in a copy of my most recent curriculum vitae, which is attached hereto as Exhibit "1."

2. My experience related to pharmaceutical economics and public policy research spans more than 30 years. I am currently the director of the PRIME Institute at the University of Minnesota, which was established in 1991 to conduct research related to the management and economics of the pharmaceutical marketplace. Prior to accepting a position at the University of Minnesota, I directed the Pharmaceutical Economics Research Center (PERC) at Purdue University from the time the Center was established in 1986 to 1991. PERC also engaged in research related to the economics of the pharmaceutical marketplace.

3. In 1988, I was appointed by the United States Congress to the Prescription Drug Payment Review Commission, an 11-member independent Congressional commission that served as an advisory body to the U.S. Congress with respect to the outpatient drug program established by the Medicare Catastrophic Coverage Act of 1988.

4. I provided professional staff analysis for the Kentucky Drug Formulary Council, Department for Human Resources, Commonwealth of Kentucky from 1975 to 1977. The Kentucky Drug Formulary Council was the nation's first governmental body to establish a generic equivalence standard for determining whether or not brand and generic drug products could be considered as generic equivalents and, therefore, could be substituted for one another. This generic equivalence formulary preceded the FDA's Orange Book.[1]

[1] The publication commonly referred to as the "FDA Orange Book" is formally known as "Approved Drug Products with Therapeutic Equivalence Evaluations" (now in its 27th edition) which is published by the FDA annually with quarterly updates. The FDA Orange Book serves multiple purposes and one of the primary functions is to list approved drug products and the therapeutic equivalence ratings for

5. As an academic researcher, my principal areas of research have included trends in the pharmaceutical marketplace at all levels, the structure and performance of pharmaceutical markets, competition between and among brand name and generic drugs, and the impact of generic competition, including generic entry into brand drug markets. I have also conducted research on medication use and expenditures by the elderly, drug coverage under health insurance plans and access and affordability of pharmaceutical products, in addition to pharmacoeconomic research and policy analysis related to all aspects of the pharmaceutical marketplace.

6. I have performed pharmacoeconomic research for many organizations, including, among others, the U.S. Centers for Medicare and Medicaid Services (CMS, formerly known as the Health Care Financing Administration (HCFA)), the U.S. Government Accountability Office (GAO, formerly known as the U.S. General Accounting Office), the U.S. Food & Drug Administration (FDA), the U.S. Congress' Office of Technology Assessment (OTA), pharmaceutical firms, professional societies, and various state governments and agencies. I have also led pharmaceutical research and policy projects at the international level for governments including Thailand, Singapore, Spain, Canada, Argentina, Venezuela, South Africa, South Korea, and Taiwan.

7. Based upon on my experience in professional consulting and academic research, I have particular expertise in economic and public policy issues in the pharmaceutical marketplace. One of the major focuses of my research and work relates to the impact and role of generic drugs and generic competition. In this context, I am well versed in assessing the economic impact of generic competition on all levels of the pharmaceutical marketplace, including on the various channels of distribution and upon consumers, the behavior of brand manufacturers faced with generic competition, and the mechanisms by which generic competition is fostered and, by contrast, impeded. I also have experience examining the impact of 'class of trade' on pricing behavior in the pharmaceutical market. Another of the major foci of my research and work relates to the reimbursement for prescription drugs under private and public insurance programs including Medicaid and Medicare. In this context, I am well versed in assessing the economic impact of reimbursement policies on all levels of the pharmaceutical market including providers, patients, and payers.

8. My research projects directly relate to general issues in the pharmaceutical market, such as drug prices, competition, generic entry, market penetration, channels of distribution and 'classes of trade,' the effects of generic competition on the market for originator drug products, and other economic and marketing issues, which also are listed in my curriculum vitae. (*See* Exhibit 1).

9. My experience includes conduct of several studies specifically for the Centers for Medicare and Medicaid Services (CMS)—the federal agency that oversees both Medicare

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brand and generic drug products. The current version of this publication can be found on the FDA website at: http://www.fda.gov/cder/orange/obannual.pdf.

and Medicaid. Among the studies conducted for CMS (formerly HCFA) are the following:

a. *Report to Congress on Manufacturers' Prices and Pharmacists' Charges for Outpatient Drugs Covered by Medicare* (U.S. Department of Health and Human Services, June 27, 1989, Stephen W. Schondelmeyer and Joseph Thomas);

b. *Impact of the Medicaid Drug Rebate Program on Expenditures, Utilization, and Access: Final Report* (U.S. Health Care Financing Administration, Contract # 500-92-0022, DO #3, April 1995, Stephen W. Schondelmeyer, Judy A. Johnson, Dong Churl Suh, George Wright, Ann Cherlow, Andrew Asher, Angela Schmitt, Portia DeFilippes, Jon B. Christianson, John Kralewski);

c. *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* (CMS Contract # 500-00-0049, Task Order 1, August 30, 2004, Stephen W. Schondelmeyer and Marian V. Wrobel);

d. *Sales of Drugs and Biologicals to Large Volume Purchasers: Final Report* (CMS Contract #500-00-0049, Task Order 1, September 19, 2005, Marian V. Wrobel, Stephen W. Schondelmeyer, Susan Jureidini, Shuchita Agarwal, Rachel Sayko, A.C. Doyle);

e. *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report* (CMS Contract # 500-00-049, Task Order 1, September 26, 2005, Marian V. Wrobel, Stephen W. Schondelmeyer, Shuchita Agarwal, and Janice Cooper); and

f. *Evaluation of Pharmaceutical Pricing Under Medicare Drug Card: Final Report* (U.S. Dept. of Health & Human Services, Assistant Secretary for Planning and Evaluation, Task Order Contract #100-03-0106, November 16, 2006, Stephen W. Schondelmeyer, Margaret Artz, Shriram Parashuram, Lois Olinger, and Sarah Shoemaker).

10. A list of other cases in which I have testified as an expert at trial or by deposition is attached as Appendix B to my curriculum vitae. (*See* Exhibit 1).

11. I am being compensated for my time spent working on this case at the rate of $600.00 per hour for time spent testifying, or preparing for testimony, and $400.00 per hour for all other time.

II. SCOPE OF REPORT

12. I understand that this action was initiated by the plaintiffs, the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), on behalf of their member pharmacies.

13. I have reviewed the "Complaint" filed against the United States Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), Michael O. Leavitt, Secretary of HHS, and Kerry Weems, Acting Administrator of CMS,

the defendants. The plaintiffs allege, among other things, that the final rule on AMP published on July 17, 2007 does not follow the statutory language of the Social Security Act and that the implementation of these rules would have a substantial negative impact on pharmacies throughout the United States.

14. I have reviewed numerous documents, including the relevant sections of the Social Security Act, Deficit Reduction Act of 2005, the Conference Report for the Deficit Reduction Act of 2005 (U.S. House of Representatives, 109th Congress, 1st Session, Report 109-362, December 19, 2005), the proposed rule and the preamble to the proposed rule (Federal Register, Vol. 71, No. 246, December 22, 2006, pp. 77174-77200, "42 CFR Part 447, Medicaid Program: Prescription Drugs; Proposed Rule"), the public comments related to the proposed rule, and the final rule and preamble (Federal Register, Vol. 72, No. 136, July 17, 2007, pp. 39142-39245, "42 CFR Part 447, Medicaid Program: Prescription Drugs; Final Rule"). Also, I have reviewed various reports by the U.S. Government Accountability Office and the U.S. Department of Health and Human Services, Office of the Inspector General that addressed specific aspects of the Deficit Reduction Act of 2005, the prices of drug products including AMP, ASP, and other prices. I have reviewed the literature in the field of pharmaceutical economics and other related publicly available documents and sources. In addition to those sources specifically referred to in this Report, the documents I considered, received, relied upon, or created in connection with this Expert Report are listed in an attachment. (*See* Exhibit 2).

15. I have been asked to testify about the following subject matters: an overview of the pharmaceutical market including classes of trade; an overview of pharmaceutical pricing; a description of the Medicaid drug program and the Medicaid drug rebate program; and other topics related to pharmaceutical pricing and reimbursement.

16. Specifically, I have been asked to render an opinion regarding the final rule to implement AMP-based FUL pricing under the DRA of 2005 (Federal Register, Vol. 72, No. 136, July 17, 2007, pp. 39142-39245, "42 CFR Part 447, Medicaid Program: Prescription Drugs; Final Rule"). I have also been asked to render an opinion regarding industry understanding and definition of various entities such as manufacturers, wholesalers, the retail pharmacy class of trade, and other providers. In addition, I have been asked to render an opinion regarding the impact of this final rule on pharmacies and access to, and provision of, prescription medications to Medicaid recipients.

17. My opinions contained herein are based upon my review of the above-described documents, as well as upon my qualifications and 30 years of experience described above. I understand that discovery may take place in this case and an administrative record will be produced, and as always with an expert report, I reserve the right to amend and update my opinions based upon additional information that may be provided to me, or that may become known to me by other appropriate means in the future.

III. SUMMARY OF FINDINGS

18. This case involves implementation of a final rule for AMP based on statutory language from the Social Security Act and CMS' promulgation of a final rule that is substantially inconsistent with the original statutory language, other federal and state statutory and regulatory language, the plain meaning or common usage of key terms, and the use of these key terms within the pharmaceutical industry.

19. The general substance of my opinions is briefly summarized here. The remainder of the report provides more detailed opinions and the bases for my opinions.

20. The bases for my opinions include documents and reports related to the final rule that I have reviewed, my education and experience as reflected in my curriculum vitae, my accumulated knowledge and understanding of the pharmaceutical industry, pharmacoeconomics, government health care policy, pharmaceutical reimbursement policies and practices, and other documents and resources broadly related to the areas of interest in this case.

21. An overview of the pharmaceutical market including classes of trade reveals that pharmacies and other providers are grouped by each manufacturer into various classes of trade based on the structure of the pharmaceutical market (e.g., independent pharmacies, chain pharmacies, mail order pharmacies, long term care pharmacies, hospitals, physicians, etc.) and the average price paid to the manufacturer usually varies across classes of trade.

22. An examination of pharmaceutical pricing found that class of trade pricing operates based on structural criteria in the market and not necessarily economic efficiency-based criteria. Contrary to widely held perceptions, prices in the pharmaceutical market are based more on structural position than on market efficiency. The structural nature of the pharmaceutical market is due to monopoly status for single source drugs, statutorily prohibited arbitrage (i.e., as provided under the Prescription Drug Marketing Act (the PDMA)), and discriminatory pricing across structural classes of trade. Consequently, a retail pharmacy (independent, chain, mass merchandise, or food & drug store pharmacy) can not purchase at the lower prices of other classes of trade and can not obtain those lower prices through market behavior or arbitrage.

23. The AMP final rule published on July 17, 2007 (Federal Register, Vol. 72, No. 136, July 17, 2007, pp. 39142-39245) promulgated definitions for key terms used in the statutory definition of AMP including "average price paid to manufacturer," "wholesaler," and "retail pharmacy class of trade." As defined in the final AMP rule, these key terms are not consistent with the original statutory language of the DRA, the Social Security Act, numerous other federal and state statutes and regulations, the plain meaning and common usage of the terms, or the use of the terms in the pharmaceutical market context.

24. The terms "class of trade" and "retail pharmacy class of trade" have a specific meaning in the context of the pharmaceutical market. The CMS final rule definition of "retail pharmacy class of trade" is in conflict with the use of this term in the pharmaceutical market.

25. CMS has re-defined the term "retail pharmacy class of trade" to encompass virtually all pharmacies and providers who dispense or administer drugs to the end consumer. This re-definition stands in stark contrast to the use of the term "retail pharmacy class of trade" in the pharmaceutical market.

26. The inclusion of different classes of trade with pricing based on different structural positions in the market will result in some pharmacies (especially traditional retail pharmacies, that is independent, chain, mass merchandise, and food & drug store pharmacies) being paid well below their actual cost. This payment inequity may result in a substantial decrease in access to care for Medicaid recipients. Moreover, because of the structural impediment of discriminatory pricing, as described above, retail pharmacies do not have access to the lower prices of these other classes of trade and will be economically disadvantaged and harmed by the overly-broad and artificial definition of the retail pharmacy class of trade as construed by CMS in the final rule.

27. CMS' overly-broad and self-styled definition of prices to be considered in the AMP calculation has created a situation where:

- firms that are not licensed as wholesalers are called wholesalers,
- firms that are not licensed as pharmacies are called pharmacies,
- physicians, clinics, hospital outpatient, and home infusion firms are called pharmacies,
- consumers are considered as both wholesalers and pharmacies, and
- manufacturers are considered as both wholesalers and pharmacies.

28. Two government agencies have evaluated the AMP-based FULs and concluded that payments to pharmacies will decrease substantially. The GAO found that AMP-based FULs (even with the 250% multiplier applied to the lowest AMP) were below the lowest acquisition cost available to retail pharmacies for 43 of the 77 study drugs. These findings indicate that pharmacies are likely to lose money on more than one-half of the generic prescriptions subject to the new AMP-based FULs, even after the 250% multiplier is applied to the new AMP amount. A recent study by the DHHS, OIG assessed the change in FULs expected with the implementation of the new AMP-based FULs based on the final rule. The median decrease in the FUL amount was estimated to be 61%.

29. The method used by CMS to estimate the cuts in Medicaid payments was not described in sufficient detail to allow examination or evaluation. However, the reduction in pharmacy payments resulting from the final rule is expected to have a substantial incremental impact on cuts in pharmacy payments above and beyond the cuts that would have been expected had CMS used the plain meaning of the language or the

pharmaceutical market definitions of the "wholesaler" and "retail pharmacy class of trade" rather than their own greatly expanded interpretation of the statutes.

30. CMS explains "We estimate that 18,000 small retail pharmacies would be affected by this regulation. However, we are unable to estimate quantitatively effects on "small" pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. . . Because of the lack of evidence as to the true effect, we have retained our prior conclusion, that this proposed rule is likely to have a "significant impact" on some pharmacies."[2]

31. Reduction in payments will result in substantial loss, and even closures, for a number of pharmacies. In total, the loss of 20% of all retail pharmacies would not be unexpected from payment cuts of the magnitude that will result from the final rule. If a similar proportion of all types of retail pharmacies is affected, the retail pharmacy market may see the loss of 10,000 to 12,000 pharmacies (the vast majority of which would be pharmacies in rural or inner city urban areas and with high Medicaid volumes) over the next few years.

IV. OVERVIEW OF THE PHARMACEUTICAL MARKET

32. Prescription drugs are the most widely used method for treating medical and health related conditions. In 2006, the total retail prescription sales[3] in the U.S. were reported to be nearly $250 billion. The total number of outpatient prescriptions was 3.4 billion in 2006 and with adjustment for mail order prescriptions (that is, 3 months supply per prescription counted as 3 monthly prescriptions) was equal to about 3.9 billion prescriptions (as a monthly supply). This prescription volume represents about 13 prescriptions per person per year in the United States in 2006.

33. The expenditure on prescription drugs is a substantial share of the total national health expenditures. Outpatient prescription drugs accounted for about 10.1% of national health expenditures in 2005.[4] However, when prescription drug spending in all other sectors of the national health accounts (i.e., hospitals, physicians and clinics, long term care, home health, dentists, managed care, active military and military retirees, public health service, 340B facilities, the Veterans Administration and other settings) is taken into account, the expenditure on prescription drugs is approximately 17.5% of national health expenditures.

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2 Federal Register, Vol. 72, No. 136, July 17, 2007, p.39233-34.

3 Total retail pharmacy sales are from data published by IMS Health as reported by the National Association of Chain Drug Stores (NACDS) in its publication titled: *The Chain Pharmacy, Industry Profile*, 2007. This estimate includes all outpatient prescriptions sold through retail community pharmacies and mail order pharmacies, but does not include medications sold through other providers such as physicians, clinics, hospital inpatient, and government programs and facilities.

4 U.S. Department of Health & Human Services (DHHS), Office of the Actuary, National Health Accounts, 2004.

34. In a broad sense, the structure of the pharmaceutical market can be described by two major features: (1) the channels of distribution for prescription drugs, or how the drug products flow through the market, and (2) the sources of payment for prescription drugs, or how the dollars flow through the market. These two structural perspectives are discussed in one of my reports for the Centers for Medicare & Medicaid Services.[5]

A. Channels of Distribution

35. First, regarding channels of distribution, there are three primary levels in the distribution channel: (1) manufacturer or marketer, (2) wholesaler, and (3) pharmacy or other provider (i.e., classes of trade). Each of these channels of distribution and its role in the market was described in my 2004 report to CMS titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices.*[6] Excerpts from the 2004 CMS report are provided below.

36. The role of manufacturers and marketers in the pharmaceutical market was described in my 2004 report to CMS[7] as follows:

> The manufacturer level is the starting point for prescription drugs as they begin their movement through the various channels of distribution. Any firm that manufactures or sells a prescription drug in the United States must hold a new drug application (NDA) or an abbreviated new drug application (ANDA) issued by the U.S. Food & Drug Administration (FDA). However, other firms may market a prescription drug without holding either an NDA or an ANDA, if such a firm has entered into a licensing agreement with an NDA or ANDA holder. [8]
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> Every firm that markets a prescription drug in the United States must register with the FDA to obtain a unique national drug code (NDC) number (11-digits) for each drug product marketed. The first part of the NDC, the labeler code (5-digits), uniquely identifies the firm marketing the drug product. The second segment, the product code (4-digits), identifies a specific strength, dosage form, and formulation for a given drug product. The third segment, the package code (2-digits), identifies package sizes and package types (e.g., bulk, unit dose, or unit of use). Both the product and package codes are assigned by the firm and not by the FDA.
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> Manufacturers or marketers, who want to be assured that the Medicaid program will cover their drug products, must sign a national drug rebate

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5 Schondelmeyer, SW and Wrobel, MV, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* (CMS Contract # 500-00-0049, Task Order 1, August 30, 2004, pp. 9-13.

6 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp.9-11.

7 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 9-10.

8 Drug firms can also be licensed to market a biological product under a Biological License Application or under other special circumstances.

agreement with the Secretary of the Department of Health and Human Services in order for states to receive federal funding for outpatient drugs dispensed to Medicaid patients. Not all NDC holders participate in the Medicaid Drug Rebate program. Approximately 544 pharmaceutical companies (or labelers) currently participate in the Medicaid Drug Rebate Program.

37. The role of wholesalers and distributors in the pharmaceutical market was described in my 2004 report to CMS[9] as follows:

> Manufacturers or marketers of prescription drugs most often sell their drug products to a middleman, or intermediate level, before the drug product reaches the pharmacy or physician that will provide the drug to the patient. National wholesalers are the primary intermediate level in the channel of distribution process accounting for 45.7 percent of prescription drugs ($98.5 billion) in 2002, (see Exhibit 4) [*See* Exhibit 3A. in this report]. Other intermediate channels of distribution include chain warehouses with 32.3 percent ($69.8 billion) of the market, regional and specialty wholesalers with 9.3 percent ($20.2 billion) of the market, and group purchasing organizations that usually contract with a wholesaler to perform the distribution function on their behalf. About 12.6 percent of prescription sales by drug manufacturers are made directly to providers (e.g., physicians or hospitals) or pharmacies.
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> The principal trade organization representing wholesalers in the United States is the Healthcare Distribution Management Association (HDMA). In 2002, the HDMA reported that there were more than 72 distributor companies operating approximately 242 distribution centers. On average, these distribution centers handle more than 21,000 different healthcare items. More than one-half of the items distributed (about 11,000) are prescription pharmaceuticals and biologics, and the additional items include "over-the-counter and herbal products, health and beauty aids, medical and hospital supplies, durable medical equipment and home healthcare items." The three largest wholesalers (Cardinal Health, AmeriSource Bergen, and McKesson) each have about 32 percent of the national market and collectively account for 97 percent of the drug sales that flow through national wholesalers and 83 percent of all wholesalers (national, regional, and specialty). Wholesalers add a markup and fees to the manufacturer's drug product cost to cover the cost of distribution and other services they provide. The total wholesaler gross margin averaged about 4.3 percent in 2002 with a range from 3.7 to 5.5 percent for the 25th and 75th percentile.[10] These costs are added to the manufacturer's drug

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9 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 9-10 (internal footnotes omitted).

10 The gross margin for pharmaceutical wholesalers is reported annually in the publication: *HDMA Factbook, Industry Overview*. The data reported here are from 2004 as found in the 2005 edition, p.2.

product cost and passed on to the pharmacy or provider purchasing through a wholesaler.

In addition to full-line national wholesalers, there are also regional and specialty wholesalers that handle just under 10 percent of manufacturer drug sales. Regional wholesalers are usually similar to the national full-line wholesalers, but they typically have only one or a few distribution centers limited to a relatively small geographic region. Specialty wholesalers, in contrast, may have a national market presence, but instead limit the types of drug products stocked to a very narrow set. Specialty wholesalers may focus on generic drugs, biological agents, or drugs for a specific therapeutic purpose such as oncology, dialysis, or HIV therapy. Specialty wholesalers may also focus on serving certain facility types such as long term care pharmacies, home health agencies, or hospice facilities.

Group purchasing organizations (GPOs) may act on behalf of a group of providers to negotiate price with drug manufacturers. Most group purchasing organizations, however, do not ever take possession of, or handle, the drug product. Instead, GPOs often will contract with a traditional wholesaler to perform the wholesaling and distribution function on behalf of the GPO and its members.

A number of large chain pharmacies have developed and operate their own distribution centers rather than purchasing drug products through traditional wholesalers. Chain warehouses accounted for 32.3 percent ($69.8 billion) of all prescription drug sales by drug manufacturers in 2002. Chains that operate their own warehouses incur expenses similar to those seen by traditional wholesalers (range from 3.7 to 5.5 percent). When a chain pharmacy performs the warehousing function in addition to the retail distribution and counseling functions, the chain does have additional costs similar to those that a wholesaler would have added to the manufacturer's drug product cost.

38. The role of pharmacies and providers in the pharmaceutical market was described in my 2004 report to CMS[11] as follows:

The final step in the channel of distribution for pharmaceuticals comes when the pharmacist or physician provides the drug to the patient. In most cases, except for mail order pharmacies, this provision of the drug to the patient results from a face-to-face encounter with the patient. In addition to providing the drug product, the pharmacist is also responsible for taking steps to assure safe and effective drug use such as: development of a patient profile to screen for drug interactions, contraindications, and

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The gross margin range for 2005 was reported in the 2006 edition as 4.4% to 5.1% .

11 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 11.

duplicate therapy; counseling the patient on appropriate use; and other similar activities. The physician has similar responsibilities and, in most Part B cases, administers the drug in conjunction with other services.

There are a number of types of pharmacies and providers as shown in Exhibit 4 [*See* Exhibit 3A. in this report]. Community-based pharmacies accounted for the largest share (52.6 percent or $113.3 billion) of manufacturer prescription drug sales in 2002. Community pharmacy includes traditional chain pharmacies (e.g., Walgreen's or CVS), mass merchandise pharmacies (e.g., Wal-Mart or K-Mart), food and drug pharmacies (e.g., Kroger or Safeway), and independent pharmacies (i.e., locally-owned corner drug stores). Mail order pharmacies accounted for 13.3 percent ($28.7 billion) of manufacturer prescription drug sales in 2002.

Health plan pharmacies purchased only 1.0 percent ($2.3 billion) of all prescription drugs sold by manufacturers. These purchases were made by managed care plans (HMOs and PPOs) with their own in-house pharmacies where the health plan takes possession of drug product inventory and dispenses prescriptions directly to patients. The vast majority of managed care plans contract with a network of community pharmacies for provision of prescription drugs or with a pharmacy benefit manager (PBM) to administer the benefit for the managed care plan.

Other endpoints to the channels of distribution include: clinics and physicians' offices (1.0 percent; $2.3 billion); long term care pharmacies (4.4 percent; $9.5 billion); hospital pharmacies (15.9 percent; $34.3 billion); and government facilities and other government programs (4.4 percent; $9.6 billion).

B. Sources of Payment

39. There are three basic sources of payment for prescriptions: (1) self-pay or cash-pay individuals, (2) private third party insurance coverage, and (3) public (government) third party insurance coverage. The role of each source of payment in the prescription drug market was described in my 2004 report to CMS[12] as follows:

> Payments for prescription drug products may come from one, or more, sources including: the patient as an individual (termed "self-pay" or "cash-pay"); private insurance; public insurance (Medicaid and Medicare); or government delivered and financed health care. Various prescription drug programs are managed by Pharmacy Benefit Managers (PBMs) and engage networks of pharmacies and providers to deliver prescription drugs. [*See* Exhibit 3B. in this report.]

[12] Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 11.

40. The payment for prescriptions through cash or self-pay by individuals was discussed in my 2004 report to CMS[13] as follows:

> Self-pay, or cash, prescriptions represent a shrinking part of the outpatient prescription market. In 1992, more than one-half (55.6 percent) of all outpatient prescriptions were self-pay. By 1997, self-pay prescriptions had shrunk to 29.1 percent and in 2002 and 2003 they represent less than 15 percent of outpatient prescriptions. The dramatic reduction in cash pay prescriptions has also greatly reduced the pharmacy's pricing flexibility. The pharmacy has some control over setting the price for cash pay prescriptions, but it has little control over the prices paid by public and private third party programs. Although mail order programs, private PBMs and drug discount cards all claim to compare their prices against usual and customary retail prices, the disappearance of the cash pay retail prescription market renders the concept of "usual and customary retail price" almost meaningless.

41. The payment for prescriptions by private third parties (e.g., insurance and managed care) was discussed in my report to CMS[14] as follows:

> The share of outpatient prescriptions covered in part, or in whole, by private third party programs has grown substantially over the past decade from 30.1 percent in 1992 to 73.0 percent in 2002 and 2003. Most of these third party prescriptions are managed through PBMs and networks of pharmacies that have contracted to participate in these networks. Most pharmacists report that PBMs have most of the negotiating power in these networks, especially given their growing market share and the dominance of a few large PBMs.[15]

42. The payment for prescriptions through public third parties (e.g., Medicare and Medicaid) was discussed in my report to CMS[16] as follows:

> The Medicaid program is the single largest third party program (public or private) for prescription drug coverage. In 1992, Medicaid paid for 14.3 percent of all outpatient prescriptions and by 1997 the Medicaid share had dropped to 11.7 percent. The Medicaid share of outpatient prescription(s) has grown again over the last five years to 13.0 percent of outpatient prescriptions. Medicaid recipients in some states may pay modest co-payments. However, under certain circumstances if the patient can not pay the copay the pharmacy may still be required to dispense the

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13 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12.

14 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12.

15 Radford A, Slifkin R, Fraser R, Mason M, and Mueller K, "The Experience of Rural Independent Pharmacies with Medicare Part D: Reports from the Filed, Journal of Rural Health, Vol. 23, No. 4, Fall 2007, pp. 286-293.

16 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12-13.

prescription and the pharmacy may not be able to recover the lost copay from either the patient or the Medicaid program.[17]

43. Collectively, third party prescriptions (private and government, such as Medicaid) grew from 70% of the prescription dollars and 67% of the prescriptions in 1996 to 91% of the prescription dollars and 89% of the prescriptions in 2005. With the institution of the Medicare Part D prescription drug program in 2006, the public third party share of the source of payment for prescriptions had a substantial jump with all third parties (private and public) now covering the vast majority (greater than 92%) of all prescriptions.[18] Conversely, the share of prescriptions paid for entirely by cash or the individual shrank to well under 10% of all prescriptions in 2006.

V. OVERVIEW OF PHARMACEUTICAL PRICING

44. Observation of prices in the pharmaceutical market requires an understanding of the elements, or attributes, that define a specific drug price term and an awareness of the sources of variation in price in the market.

A. Elements and Attributes of Drug Pricing Terms

45. There are several important and essential elements, or attributes, to any drug price that must be understood in order to know the meaning of a specific price for a specific drug product. These elements of a drug price were described in my report to CMS titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*[19] as follows:

> * ***list or transaction***: list prices are published by manufacturers; transaction prices stem from actual transactions and hence represent both the supply and the demand side of the market;
>
> * ***level of the market involved***: drug product transactions occur at different levels in the market such as the manufacturer, wholesaler, or provider (e.g., pharmacy, physician, hospital, etc.) levels;
>
> * ***classes of trade eligible for the price***: providers are grouped by each manufacturer into various classes of trade based on the structure of the pharmaceutical market (e.g., independent pharmacies, chain pharmacies, mail order pharmacies, long term care pharmacies, hospitals, physicians, etc.) and the manufacturer's average selling price usually varies across classes of trade;[20]

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17 Since the implementation of the Medicare prescription drug benefit (January 1, 2006), Medicare (Parts B and D) has become the single largest third party program for prescription drugs easily surpassing the Medicaid program.

18 NACDS, *The Chain Pharmacy Industry Profile*, annual editions from 1998 to 2007. Data was from IMS Market View, as reported in Novartis Pharmacy Benefit Report for 1996 to 2001 and from NDC Health (a health care information company) from 2002 to 2006.

19 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 13-14.

20 The "retail class of trade" is open to the general public and is made up of independent, chain, mass

* ***type of drug product***: drug products may be grouped by their patent and exclusivity status into three broad groups that have different pricing patterns such as single source (patent and exclusivity protected brands), innovator multiple source (off-patent brands), and non-innovator multiple source (generics or branded generics) drug products;

* ***adjustments to price that have or have not been taken into account***: the invoice price for drug products may not reflect all adjustments to prices such as discounts, rebates, purchasing allowances or other forms of economic consideration;

* ***source of the price information***: price information can be collected from different sources such as the manufacturer, wholesaler, provider, or a third party program;

* ***effective time when price is available***: manufacturers determine when and how much the price of a drug product will change and the providers' costs are affected by price changes immediately upon implementation of a price change. The timing of when third party programs update their price reimbursement files (e.g., immediately or based on retrospective data) can have a substantial impact on providers; and

* ***relationship to other prices***: AWP and WAC are primarily used as benchmark prices rather than as actual transaction prices, but most other types of prices, discounts, rebates, and methods of third party reimbursement are expressed in relationship to one of these benchmark prices (AWP or WAC).

B. Determining Acquisition Costs

46. In 2004, at the request of CMS, I conducted a study of methods to estimate acquisition costs for pharmaceuticals.[21] This study set forth several criteria that would assist in determining the validity and reliability of the estimation method. Ideally, the method used for determining "estimated acquisition cost" should produce cost information for each drug product with prices that are: accurate and reliable, generally and widely available, current and up-to-date, transparent and accessible, adequate compensation to providers and pharmacies, incentives for pharmacies and providers to supply drugs, and incentives for key parties to provide data. For purposes of this report, three of these criteria are especially critical in this case: (1) the concept of generally and

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merchandise, and food & drug pharmacies. "The Retail Perspective audit (formerly U.S. Drugstore) is a continuing monthly audit designed to measure, in projected dollars and units, pharmaceutical products purchased by independent pharmacies, chain store pharmacies, and food and drug store pharmacies in all 50 states." (*Retail Perspectives, Appendix A: IMS Audit Information*, 2006.)

[21] Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 18-19.

widely available, (2) adequate compensation for pharmacies and providers, and (3) differentiation by class of trade.

47. The concept of "generally and widely" available prices was described in my 2004 CMS report[22] as follows:

> **Generally and Widely Available**
> Any price list used by the Medicaid or Medicare program should reflect 'generally and widely available prices,' that is, any provider paid according to the payment policy should be able to procure drugs at the published payment amount.

48. The role of "adequate compensation to providers and pharmacies" was described in my 2004 CMS report[23] as follows:

> **Adequate Compensation to Providers and Pharmacies**
> While the drug product component of the payment policy should be based on actual acquisition costs, the payment policy as a whole should adequately compensate providers for the storage, handling, dispensing, and administration of prescription drugs and for their professional services. This is essential to ensure that beneficiaries have access to quality care, without triggering perverse incentives. At present, the margins, or spreads, between drug product payment amount and actual acquisition cost may compensate providers (physicians and pharmacies) for deficiencies elsewhere in the payment system. If and when the method for estimating acquisition costs is altered, it may be desirable to reconsider the payment policy as a whole.

49. The importance of separately estimating prices by "class of trade" was described in my 2004 CMS report[24] as follows:

> **Estimated Separately by Class of Trade**
> Because actual acquisition costs vary by class of trade, the estimation methodology must take into account these differentials in order to generate drug product payments that are both accurate and reflect generally and widely available prices. For example, when a drug manufacturer sets lower prices for one class of trade (e.g., physicians) versus another class of trade (e.g., community pharmacies), the result is that the average of the prices across these two classes of trade will overpay the class with the lower price (physicians) and will under pay the class with the higher price (pharmacies). In addition to class of trade differences, drug product prices may differ for other reasons such as geographic or regional (urban versus rural) variations. A payment policy that does not account for different

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22 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 19.
23 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 20.
24 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 19.

acquisition costs by class of trade, or other factors, may preclude certain providers from the market for reasons beyond their control. For providers within the same class of trade, the concept of 'generally and widely available prices' is appropriate and helpful to assure that a wide spectrum of physicians or pharmacies will be willing to participate in the program.

C. Class of Trade and Variation in Drug Prices

50. Drug prices will typically vary over time. Other sources of variation at any specific point in time may be related to: (1) the type of purchaser (i.e., also referred to as classes of trade), (2) the type of drug product, and (3) geographic variation.

51. The type of purchaser of a drug product may determine the price level that is available to that purchaser. The role of purchaser type was described in my 2004 report to CMS[25] as follows:

> Nearly all drug manufacturers divide the channels of distribution into groups known as 'classes of trade'. The 'classes of trade' at the broadest level are the groups identified on the pharmacy-provider level of the channels of distribution chart (Exhibit 4) [*See* Exhibit 3A. in this report] including: chain pharmacies, mass merchandise pharmacies, food and drug pharmacies, independent pharmacies, mail order pharmacies, health plan and HMO (in-house) pharmacies, long term care pharmacies, hospital pharmacies, physicians and clinics, government facilities, and other settings. [26] The structural differences in actual prices charged to each of these 'classes of trade' can differ considerably and appear to be arbitrary and are usually unrelated to volume of drug product purchased.[27]
>
> In most markets, when one buyer can purchase a product at a lower price than other purchasers, there is the potential for arbitrage. That is, the buyer with access to the lower price is able to purchase the product at the low price and resell it, at a profit, to the party without access to the lower price. This drives down the price differentials both directly (because the high-price buyers get lower prices) and indirectly (because manufacturers no longer gain from the differential pricing and hence desist from the practice). This practice of arbitrage across classes of trade is explicitly

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25 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 16-17.

26 The "retail class of trade" is open to the general public and is made up of independent, chain, mass merchandise, and food & drug pharmacies. The "retail class of trade" is open to the general public and is made up of independent, chain, mass merchandise, and food & drug pharmacies. "The Retail Perspective audit (formerly U.S. Drugstore) is a continuing monthly audit designed to measure, in projected dollars and units, pharmaceutical products purchased by independent pharmacies, chain store pharmacies, and food and drug store pharmacies in all 50 states." (*Retail Perspectives, Appendix A: IMS Audit Information*, 2006.)

27 Wrobel MV, Schondelmeyer SW, Agarwal S, and Cooper J, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report* (CMS Contract # 500-00-049, Task Order 1, September 26, 2005).

prohibited by re-sale limitations established in the pharmaceutical marketplace by the Prescription Drug Marketing Act of 1988.

Both the monopoly position of patent (or exclusivity) protected drug products and the prohibition on arbitrage enable drug firms to use 'discriminatory pricing', which seeks to maximize the price to each individual buyer or group of similarly situated buyers. There are sometimes volume discounts within a class of trade, but volume does not usually explain the difference in price across classes of trade. A physician purchasing drug product direct from the manufacturer will usually get one of the lowest prices in the market, especially for drug products administered in the physician's office, while independent and chain community pharmacies often pay the highest prices in the market. This pattern occurs even when the chain pharmacy purchases far more volume (millions of dollars) nationally than an individual physician purchases in a year (i.e., hundreds or thousands of dollars). Volume may get one physician a better price than another physician. Volume, however, does not explain why a chain pharmacy pays a higher price, even though it purchases a substantially larger volume of a drug product than an individual physician typically purchases. The structural barriers of monopoly position and statutory prohibitions on price arbitrage mean that the purchasers who get the lowest price in the market are not necessarily the most efficient purchasers in the market. Because class-of-trade differentials exist and are outside of the control of the purchaser, an accurate approach to estimating actual acquisition costs must take into account the class of trade pricing practices of drug firms. . .

52. In 2005, I completed a study at the request of CMS which examined the relative prices across various classes of trade.[28] In conducting this study, I relied upon data from IMS Health's Retail Perspective and Provider Perspective databases[29] for the year 2004. This analysis of prices across classes of trade showed that prices differed across the structural classes of trade and that the classes of trade with the largest volume did not necessarily have the lowest prices. The "class of trade" pricing practices of pharmaceutical companies are considered proprietary and confidential and are not usually disclosed.

53. In summary, class of trade pricing operates based on structural criteria in the market and not necessarily efficiency-based criteria. In other words, the purchaser with the largest volume of purchases may not be the purchaser with the lowest purchase price. In a market based on efficiency, a given entity can engage in behaviors that increase its efficiency and thus lowers price. Contrary to widely held perceptions, prices in the pharmaceutical market are based more on structural position than on economic

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[28] Wrobel, Schondelmeyer, Agarwal, and Cooper, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report*, September 26, 2005.

[29] IMS Health, Retail Perspective, Appendix A, IMS Audit Information, pp. A-52 to A-58, 2006. Also, see IMS Health, Provider Perspective, Appendix A, IMS Audit Information, pp. A-46 to A-51, 2006.

efficiency. The structural nature of the pharmaceutical market is due to monopoly status of single source drugs, statutorily prohibited arbitrage (i.e., the PDMA), and discriminatory pricing across structural classes of trade. Consequently, a retail pharmacy (independent, chain, mass merchandise, or food & drug store pharmacy) can not purchase at the lower prices of other classes of trade and can not obtain those lower prices through market behavior or arbitrage.

54. A purchaser cannot change its structural position (i.e., a chain pharmacy cannot become a hospital without losing the very character of the entity).

VI. THE MEDICAID DRUG PROGRAM

55. Overall, Medicaid drug expenditures accounted for 15.3% of total outpatient drug expenditures in the U.S. in 2004. The number of Medicaid prescriptions represented 13.6% of all outpatient prescriptions in 2004.[30] Medicaid outpatient prescription drug expenditures in the U.S. were $32.1 billion in 2005.[31]

56. Medicaid has historically been the single largest payer for prescription drugs in the United States—although with the advent of the Medicare Part D prescription drug program in 2006 that role has now been supplanted.

57. Over the past 15 years, Medicaid ultimately paid for approximately 10% to 15% of outpatient drug purchases in this country. The advent of the Medicaid program in 1965 and the Medicare Part D prescription drug program in 2006 has extended coverage and expanded the number of prescriptions dispensed. Both Medicaid and Medicare have enabled large populations of Americans to have increased access to prescription drugs through government financed and subsidized programs. These government drug programs have provided access to prescription drugs to many people who could not have afforded the drugs before, thus increasing total sales for drug manufacturers.

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[30] NACDS, *The Chain Pharmacy Industry Profile*, annual edition, 2005. Data was from NDC Health (a health care information company) for 2004.

[31] NACDS, *The Chain Pharmacy Industry Profile*, annual editions from 2004 to 2005. Data was from NDC Health (a health care information company) from 2004 to 2006.

A. Medicaid Drug Reimbursement

58. The State Medicaid programs reimburse for covered pharmaceutical products through various formulas that are designed to estimate the acquisition cost of the drug product to the provider submitting the claim for reimbursement. Medicaid programs, then, determine the amount to pay on a specific claim for prescription pharmaceuticals by setting an amount intended to compensate the provider for the estimated acquisition cost of the drug product plus an additional amount, also set by the applicable Medicaid reimbursement method, to compensate the provider for profit and overhead related to the cost of dispensing prescriptions and counseling patients.

59. The setting of payments for prescription drugs is also critical to providing access to prescriptions and pharmaceutical care. For example, the Medicaid program wants to ensure that enough community-based pharmacy providers open to the general public choose to participate so that patients will have access to the drug products they are prescribed within a reasonable distance from the patient's home or work. (42 U.S.C. § 1396a(a)(30)(A)).

B. Medicaid Drug Rebate Program and AMP

60. The term AMP was first introduced as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) which established the Medicaid Drug Rebate program (Section 1927 of the Social Security Act). A drug manufacturer must enter into a rebate agreement with the Centers for Medicare & Medicaid Services (CMS) in order for the manufacturer's drug products to be covered outpatient drugs eligible for Federal Medicaid funding. Each drug manufacturer with a rebate agreement must report the AMP to CMS on a quarterly basis (and now under the final rule on a monthly basis). Section 1927(k)(1) defines AMP as "the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." The AMP is then used as the basis for calculating the per unit rebate amount that a drug manufacturer owes to CMS. The States then multiply the unit rebate amount times the number of units dispensed to determine the total rebates owed by the manufacturer in a given period (quarter).

61. Over time since 1991, the methods for calculating or determining AMP have been found to be unclear and incomplete. The DRA required that the Office of the Inspector General (OIG) review the manner in which AMP is determined and recommend appropriate changes. The OIG found that different manufacturers define and calculate AMP in different ways.[32] One of the major points of confusion in calculating AMP was the treatment of pharmacy benefit manager (PBM) rebates. Another source of confusion was the treatment of sales to pharmacies of drug products that are used for Medicaid patients or for patients under State Pharmaceutical Assistance Programs. Other issues raised were concerns over administrative and service fees, lagged price concessions, the

[32] Office of Inspector General, Department of Health and Human Services, *Determining Average Manufacturer Prices for Prescription Drugs Under the Deficit Reduction Act of 2005*, OIG A-06-06-00063, May 2006.

frequency of AMP reporting (monthly versus quarterly), and AMP restatements. The OIG also recommended to the Secretary that CMS "*encourage States to analyze the relationship between AMP and pharmacy acquisition cost to ensure that the Medicaid program appropriately reimburses pharmacies for estimated acquisition costs.*"

C. The Social Security Act and Deficit Reduction Act of 2005

62. The Deficit Reduction Act of 2005 (DRA) addresses a number of changes to the Medicaid program including the method and amount of payment for certain prescription drugs under Medicaid. This report provides a description of the certain issues raised by implementation of the statutory provisions related to definition of average manufacturer price (AMP) and its role in the determination of federal upper limits (FULs) for multiple source drug products under Medicaid.

1. Average Manufacturer Price in Medicaid: Two Roles

63. The AMP is a manufacturer-reported transaction price that serves two functions in the Medicaid program: (1) AMP is one of the basic price points used for determining the amount of rebates that drug manufacturers must pay to the Medicaid program, and (2) AMP will serve as the new base price for determining the FULs for payments to pharmacies for multiple source prescription drugs provided to Medicaid recipients. The Social Security Act as amended by the Deficit Reduction Act of 2005 included provisions related to both of these functions of AMP. A brief discussion of the background of these two functions is provided here, followed by comments on the final rule which re-defines AMP and describes the method for determining the FUL for drug ingredient costs of multiple source prescriptions under Medicaid.

2. Historical Definition of AMP

64. AMP was an average price received by the manufacturer from wholesalers who distribute to pharmacies in the retail pharmacy class of trade. Thus, AMP is based on transaction prices and is not a list price like the average wholesale price (AWP) or the wholesale acquisition cost (WAC). However, the average price received by the manufacturer is not the same as the average price paid by a pharmacy. The operating cost of the wholesaler, if one is used, as well as other costs of acquisition experienced by the pharmacy, need to be taken into account when estimating the pharmacy's acquisition cost.[33] The CBO report found that independent pharmacies use wholesalers for about 98% of their purchases, while wholesaler purchases accounted for 85% in mail order pharmacies, 53% in food stores with pharmacies, and 25% in chain pharmacies.[34]

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[33] The state of Minnesota has a wholesale drug tax which adds 2% on to the wholesale price paid by all pharmacies or purchasers at the wholesale level. Also, if a chain of pharmacies purchases drug products direct from the manufacturer and operates its own wholesale distribution centers, which chain pharmacy experiences additional costs above the AMP similar to the operating costs a wholesaler would charge and add on to AMP.

[34] Congressional Budget Office, *Prescription Drug Pricing in the Private Sector*, Publication No.2703, January 2007, Table 2, p.6.

65. The statutory definition of the term Average Manufacturer Price (AMP) is "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." (*See* Social Security Act § 1927(k)(1), 42 U.S.C. § 1396r-8(k)(1)).

66. To the degree that the AMP calculation contains factors that lower the AMP below the most efficient acquisition cost available to a specific pharmacy, that pharmacy will be faced with losing money or refusing all prescriptions whose drug product payment amount is based on an inadequate and unadjusted AMP. Since the average price for revenue to the manufacturer is not the same as the average acquisition cost to the pharmacy as noted above, the AMP can be more accurately focused on only one of these two purposes (manufacturer rebates or pharmacy payments) and use of AMP for the other purpose will require adjustments and estimation.

VII. DEFINITION OF AMP IN THE STATUTE AND FINAL RULE

67. This statutory definition of AMP, then, establishes a three part test that can be used to determine if specific types of drug prices, and related price concessions, should be included in calculation of AMP: (1) What price was paid to the manufacturer? (2) Was the payer a "wholesaler?" and (3) Was the drug purchased for distribution to the "retail pharmacy class of trade?" In order for a price to be included in the AMP calculation, all three conditions must be met, that is, the price must be "paid" to the manufacturer, the purchaser must be a "wholesaler" and the drug must be distributed to the "retail pharmacy class of trade."

68. The AMP final rule published on July 17, 2007 (Federal Register, Vol. 72, No. 136, July 17, 2007, pp. 39142-39245) promulgated definitions for key terms used in the statutory definition of the AMP including "average price paid to manufacturer," "wholesaler," and "retail pharmacy class of trade." As defined in the final AMP rule, these key terms are not consistent with the original statutory language of the Social Security Act and DRA, numerous other federal and state statutes and regulations, the plain meaning and common usage of the terms, and the use of the terms in the pharmaceutical market context.

69. The CMS final rule for prescription drugs under the Medicaid program implementing provisions of the DRA has included revisions to the definition of, and method for calculation of, AMP.[35] The final AMP rule acknowledges that with the advent of the DRA, "AMP will serve two distinct purposes: for drug rebate liability and for payments (to pharmacies)."[36] The CMS analysis goes on to note that the drug manufacturers would benefit from a broad definition of the "retail pharmacy class of trade" that would result in a lower AMP which would lead to lower drug manufacturer

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[35] Centers for Medicare & Medicaid Service, Department of Health and Human Services, 42 CFR Part 447, CMS-2238-P], RIN 0938-A020, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Vol. 71, No. 246, December 22, 2006, pp. 77174-77200.

[36] CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77178.

rebate liabilities. At the same time, however, there is tension in the opposite direction for pharmacies from this broad definition of the retail pharmacy class of trade that results in a lower AMP for use in estimating retail pharmacy actual acquisition costs.

70. For each of the key terms a summary is presented stating the essential elements defining that term based upon information from various sources which are examined and compared including: (1) federal and state statutory and regulatory definitions, (2) the plain meaning or common usage of these terms, (3) the use of these terms within the pharmaceutical market, and (4) the definitions and provisions in the final AMP rule.

A. Definition of Price Paid to the Manufacturer

71. The meaning of the term "average price paid to the manufacturer" can be understood by examining the elements essential to defining the term as found in federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context.

1. Price Paid to Manufacturer: Essential Elements

72. Based upon federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context, a test for the "average price paid to the manufacturer" can be constructed using the following essential elements. For each pharmacy or provider setting each of the following questions should be examined. Regarding the "average price paid to the manufacturer":

(1) Is the manufacturer paid a price for the drug?
(2) Are the drugs "covered outpatient drugs"?
(3) Are there discounts or other price considerations that should be included in AMP?
(4) Are there discounts or other price considerations that should be excluded from AMP?
(5) Are rebates, or other price considerations, compensation for *bona fide* services?

2. Price Paid to Manufacturer: Federal and State Statutes and Regulations

73. The "average price paid to the manufacturer" is limited to covered outpatient drugs. Drugs provided in certain settings are not included among "covered outpatient drugs." (42 U.S.C. §1396r-8(k)(3)) However, CMS has included these non-covered drugs in the calculation of AMP. Drugs provided "incident to," or in connection with, physician services, hospital outpatient services, or renal dialysis services are not covered outpatient drugs.

3. Price Paid to Manufacturer: Plain Meaning and Common Usage

74. The plain meaning of the term "price" is the "amount of money given or set as consideration for the sale of a specified thing;" "the terms for the sake of which

something is done or undertaken;" or "the cost at which something is obtained."[37] "Paid" is the "past simple or past participle of pay." The "price paid" then is the amount being, or having been, given for the good or service.[38]

75. "Average" has the plain meaning of being "a single value (as a mean, mode, or median) that summarizes or represents the general significance of a set of unequal values." The "average is the quotient obtained by dividing the sum total of a set of figures by the number of figures." Synonyms for average include: mean, median, norm, or "something that represents a middle point."[39]

76. The average can be estimated as a simple arithmetic mean of a set of numbers or in this case, prices. This average is calculated by adding the total amount paid for all units and dividing by the number of units purchased. If the price data reported and summed is accurate, this will yield an "average price."

4. Price Paid to Manufacturer: Use in the Pharmaceutical Market Context

77. In the pharmaceutical market, it is common for the amount on invoices (e.g., manufacturer to wholesaler, wholesaler to pharmacy, etc.) to be a benchmark price or an invoice price (e.g., AWP, WAC, or sometimes referred to as a list or catalog price), but not the actual amount paid, or to be paid, for the drug product.[40]

78. The AWP and WAC prices are benchmark prices from which discounts, rebates and other price concessions are negotiated between manufacturers and wholesalers, and between manufacturers and private payers.[41]

79. Benchmark prices and invoice prices require adjustment for discounts and other economic considerations in order to determine the "price paid" to the manufacturer. The other forms of economic consideration have to be evaluated to determine which actually lower the price of the drug product versus those that are compensation for some type of *bona fide* service.

80. Rebates paid to a pharmacy benefit manager (PBM) may be for services provided such as formulary placement or preferred status, market share movement, or other types of services related to operation of a drug benefit plan. Rebates paid after the fact on mail order prescriptions through a PBM may be for *bona fide* services, rather than a reduction in price paid to the manufacturer.

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37 Merriam-Webster's Online Dictionary (http://www.merriam-webster.com/dictionary/price, accessed on October 23, 2007.

38 Cambridge Advanced Learner's Dictionary, Cambridge University Press, 2007, http://dictionary.cambridge.org/define.asp?key=58172&dict=CALD, accessed on October 23, 2007.

39 Merriam-Webster's Online Dictionary (http://www.merriam-webster.com/dictionary/average, accessed on October 23, 2007.

40 Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 25.

41 Academy of Managed Care Pharmacy, *AMCP Guide to Pharmaceutical Payment Methods*, Comprehensive Edition, Version 1.0, October 2007, p. 3.

5. Price Paid to Manufacturer: Final AMP Rule

81. As noted above, the AMP means "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." The final rule specifies that in calculating the AMP, the calculation shall "include all sales and associated discounts and other price concessions provided by the manufacturer for drugs distributed to the retail pharmacy class of trade unless the sale, discount, or other price concession is specifically excluded by statute or regulation or is provided to an entity specifically excluded by statute or regulation." (AMP Rule § 447.504 (a)). Notably, the final rule definition, as quoted above, does not explicitly mention rebates, even though rebates are included in the calculation of the AMP.

B. Definition of Wholesaler

82. The meaning of the term "wholesaler" can be understood by examining the elements essential to defining the term as found in federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context.

1. Wholesaler: Essential Elements

83. The term "wholesaler" has been examined by reviewing federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context. There are several elements that emerge as distinguishing features of the term "wholesaler" in the context of the pharmaceutical market:

(1) Is this entity or type of entity a wholesaler or licensed as a wholesaler?
(2) Does this wholesaler or entity purchase drug product from manufacturers?
(3) Does this entity sell to pharmacies, providers or other entities that dispense or administer prescription drugs to the end consumer?
(4) Does this entity sell directly to the consumer?
(5) Does this entity sell to entities that are in the retail pharmacy class of trade?
(6) Can the sales of this entity to the "retail pharmacy class of trade" be identified as distinct from sales to other purchasers?

2. Wholesaler: Federal and State Statutes and Regulations

84. There are numerous statutory and regulatory definitions of drug wholesalers including definitions related to the Federal Food, Drug & Cosmetic Act and the Prescription Drug Marketing Act (PDMA). Federal law requires every drug wholesaler to be licensed in a state. Also, nearly every state either through its dangerous drug act, its pharmacy practice act, or both has a statutory definition of a wholesaler. There is considerable uniformity among the various state laws and the federal statutory and regulatory language with respect to the definition of a "wholesaler." The Healthcare Distribution Management Association (HDMA, the national trade association for drug

wholesalers) provided comments to CMS on the proposed rule and recommended that CMS follow the definitions of wholesaler and wholesale distribution as already set forth in statutes related to the Prescription Drug Marketing Act of 1988. (21 CFR 203.3(cc)) (HDMA, Comments on the Proposed Rule, pp. 8-9). Also, AmerisourceBergen (one of the top three drug wholesalers) recommended in comments to the proposed rule that CMS "should follow PDMA and FDA definitions of wholesale distributor and distribute."

85. Moreover, 42 U.S.C. §1396r8(k)(5) defines wholesaler and specifically excludes manufacturers from the definition.

86. According to the regulations promulgated by HHS pursuant to the Prescription Drug Marketing Act of 1988, "wholesale distribution means distribution of prescription drugs to persons other than a consumer or a patient . . . " (21 CFR 203.3(cc)) The definition describes "wholesale distribution" as excluding sale, purchase, or trade by or for: (1) intracompany sales, (2) group purchasing organizations, (3) charitable organizations, (4) among health care entities under common control, (5) emergency medical reasons, (6) pursuant to a prescription by a provider, (7) distribution of samples by a manufacturer's representatives, (8) blood components intended for transfusion, (9) drug returns by a hospital, health care entity or charitable institution, or (10) sale of minimal quantities by a retail pharmacy to licensed practitioners for office use.

87. At least 42 states have a statutory or regulatory definition of "wholesale distribution" that is similar, or identical, to the definition put forth in federal regulations.[42] Six of the 8 remaining states have very brief definitions of wholesaler or wholesale distribution, but none of these include sales to consumers. The other two states do not have a definition of these terms. Clearly, federal and state statutes and regulations explicitly exclude sales from manufacturers to consumers as a wholesale distribution function.[43]

88. Also, distribution directly to consumers does not fit within the meaning of distribution to "the retail pharmacy class of trade." In fact, provision of a prescription drug to a consumer is "dispensing," rather than "distribution." Consequently, prices paid by consumers to manufacturers or wholesalers are not within the plain meaning of "the average price paid to the manufacturer . . . by wholesalers for drugs distributed to the retail pharmacy class of trade."

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[42] At least 42 states have substantially the same definition of wholesaler as is found in the Prescription Drug Marketing Act of 1988. Those states are Alabama, Alaska, Arkansas, Colorado, Delaware, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

[43] Colorado and other states have statutes and regulations that define "wholesaler" as "a corporation, individual, or other entity with facilities in this state that buys drugs or devices for resale or distributes drugs or devices to corporations, individuals, or entities entitled to possess such drugs or devices, other than consumers." (Colo. Rev. Stat. Ann. §12-22-102(34) (for pharmacy practice generally)).

3. Wholesaler: Plain Meaning and Common Usage

89. The term "wholesaler" has the plain meaning of being a merchant middleman that sells commodities in quantity to retail merchants. Merriam-Webster's Online Dictionary describes "wholesale" as "the sale of commodities in quantity usually for resale (as by a retail merchant)." This definition involves "sale of commodities" for "resale." Also, the definition distinguishes that a wholesaler sells to, but is not the same as, "a retail merchant." In addition, the term "wholesaler" is used to describe "a merchant middleman who sells chiefly to retailers, other merchants, or industrial, institutional, and commercial users mainly for resale or business use." In this case, the common language definition describes a wholesaler as "a merchant middleman" who sells chiefly to retailers.[44]

90. Another reputable dictionary defines the term "wholesale" as an adjective (or adverb) related to "the selling of goods in large amounts at low prices to shops and businesses, rather than the selling of goods in shops to customers."[45] Practical usage examples cited by this dictionary are: "wholesale prices," "a wholesale supplier/business," and "We only sell wholesale, not to the public." The entry for "wholesale" ends by recommending that one "compare (wholesale to) retail." This reference to "compare to retail" indicates that wholesale is distinct from retail.

4. Wholesaler: Use in the Pharmaceutical Market Context

91. Wholesalers are middle men who buy drugs from manufacturers and sell those drugs to pharmacies, providers, and other entities that in turn sell the drugs to the ultimate consumer. Drugs may be distributed from manufacturers to pharmacies and providers by several pathways including: (1) through a national, regional or specialty wholesaler, or warehouse; (2) through a chain warehouse, or (3) through direct sales to pharmacies or providers. Wholesalers, according to the pharmaceutical market structure, are highlighted in Exhibit 3D. In 2000, wholesalers accounted for about 56.0% of manufacturer prescription drug sales, chain warehouses represented 23.3% of manufacturer sales, and direct purchases by providers and pharmacies were 15.0% of manufacturer sales.[46]

92. There is a national association of wholesale drug distributors now known as the Healthcare Distribution Management Association (HDMA) and, formerly known as the National Association of Wholesale Druggists. Active membership in this trade association requires the following qualification: "The primary business of the distributor

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[44] Merriam-Webster's Online Dictionary (http://www.merriam-webster.com/dictionary/wholesale, accessed on October 23, 2007.

[45] Cambridge Advanced Learner's Dictionary, Cambridge University Press, 2007, http://dictionary.cambridge.org/define.asp?key=90438, accessed on October 23, 2007.

[46] The IMS Health publication *DDD Annual Class-of-Trade Analysis*, 2000 reported that NWDA member warehouse accounted for 48.0% of the pharmaceutical purchasers from manufacturers in 2000, while non-NWDA warehouse accounted for 8.0%, chain warehouse accounted for 23.3% and direct sales from manufacturer to provider or pharmacy represented 15.0% of pharmaceutical purchasers from manufacturers.

must be to purchase or receive pharmaceutical and health-related products in bulk quantities, inventory the products, distribute them in individual package quantities, and provide other value-added services including information technology to its suppliers and healthcare providers."[47] The HDMA reported that in 2006 there were 40 HDMA corporate (wholesale) distributor members and they operated 147 distribution centers. The HDMA member wholesale distributors were reported to have accounted for 48% of manufacturer prescription drug sales in 2000, while non-member wholesale warehouses distributed 8% of manufacturer prescription sales.[48]

93. Federal law requires that a wholesaler be licensed in at least one state. Every state requires every wholesaler to be licensed by at least one state in order to distribute prescription drugs in the state.[49]

94. Based on the pharmaceutical market context, a wholesale drug distributor can be identified by the role it serves in the market. A wholesale distributor is an entity that purchases drugs from a manufacturer and distributes those drugs to pharmacies, providers, and other entities that may provide drugs to the end-consumer. These wholesale distributors may be independent firms in the market or they may be a vertically integrated corporate division of a firm operating at a different level in the market. Some drug companies operate warehouses that sell drugs direct to pharmacies, providers, and other purchasers. Also, many chain pharmacies operate their own drug warehouses through facilities that distribute drugs to the chain's own retail pharmacies. Another indicator of being a wholesale distributor is whether or not an entity holds a state license as a wholesale drug distributor.

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[47] The definition of an active member in the Healthcare Distribution Management Association was reported on the associations website at http://www.healthcaredistribution.org/membership/member_companies.asp) and viewed on October 24, 2007.

[48] The IMS Health publication *DDD Annual Class-of-Trade Analysis*, 2000 reported that NWDA member warehouse accounted for 48.0% of the pharmaceutical purchasers from manufacturers in 2000, while non-NWDA warehouse accounted for 8.0%, chain warehouse accounted for 23.3%, and direct sales from manufacturer to provider or pharmacy represented 15.0% of pharmaceutical purchasers from manufacturers.

[49] Many states require both in-state and out-of-state wholesale distributors or warehouses to be licensed by the state.

5. Wholesaler: Final AMP Rule

95. The final AMP rule as published in the Federal Register[50] states "*Wholesaler* means any entity (including those entities in the retail pharmacy class of trade) to which the manufacturer sells the covered outpatient drugs, but that does not re-label or repackage the covered outpatient drug." (To be codifed in 42 CFR § 447.504 (f)) Clearly, this promulgated definition of "wholesaler" is overly broad because it encompasses virtually any purchaser who buys from the manufacturer. Wholesalers as defined by the final rule are highlighted in Exhibit 3E. The definition in the final rule is much broader than the statutorily specified definition of "wholesaler" or the commonly accepted use of the term in the pharmaceutical market. (*Compare* Exhibits 3D. and 3E.)

C. Retail Pharmacy Class of Trade

96. The meaning of the term "retail pharmacy class of trade" by Congress and the industry can be understood by examining the elements essential to defining the term as found in federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context.

1. Retail Pharmacy Class of Trade: Essential Elements

97. The term "retail pharmacy class of trade" has been examined by reviewing federal and state statutes and regulations, the plain meaning and common usage of the term, and the use of the term in the pharmaceutical market context. There are several essential elements that emerge as distinguishing features of the term "retail pharmacy class of trade" in the context of the pharmaceutical market:

(1) Is this entity a pharmacy or licensed as a pharmacy?
(2) Is a licensed pharmacist present at the entity at all times it is open?
(3) Does this entity sell to the end consumer?
(4) Does this entity sell to the "general public" (i.e., all patients) or a limited population of patients (e.g., an enrolled population)?
(5) Is this entity a "provider" (i.e., physician, clinic or hospital) rather than a "pharmacy"?
(6) Has the entity been identified and distinguished from a retail pharmacy in other statutes or regulations?
(7) Is this entity a hospital, other institutional facility, or managed care plan?
(8) Is this entity eligible to provide covered outpatient drugs?
(9) Is this entity in the structurally-defined "class of trade" known as the "retail pharmacy classes of trade" (i.e., independent, chain, mass merchandise, or food & drug store pharmacies)?

98. The AMP final rule has included entities from many different channels by which prescription drugs can be distributed to consumers. This final rule for calculating AMP

[50] Federal Register, Vol. 72, No. 136, July 17, 2007, p.39241.

includes prices paid by entities that are "non-retail" settings, entities that are "not a licensed pharmacy," and entities that "do not serve the general public."

2. Retail Pharmacy Class of Trade: Federal and State Statutes and Regulations

99. The use of the terms "retail pharmacy" and "pharmacy" in federal statutory language can be instructive as to the industry's view of the meaning of the term "retail pharmacy class of trade." Several examples showing how the term "retail pharmacy" is used in statutes in relation to other entities that sell prescription drugs are described below.

100. A Congressional study of drug purchasing and billing activities of various health care systems was mandated as part of Public Law 101-508 (§4401(d) of Pub.L. 101-508, as amended Pub.L. 104-316, Title I, § 122(i), Oct. 19, 1996, 110 Stat. 3837 (1)(A)). That law required that "The Comptroller General shall conduct a study of the drug purchasing and billing practices of hospitals, other institutional facilities, and managed care plans which provide covered outpatient drugs in the Medicaid program. The study shall compare the ingredient costs of drugs for Medicaid prescriptions to these facilities and plans and the charges billed to medical assistance programs by these facilities and plans compared to retail pharmacies." The language here lists separately "hospitals, other institutional facilities, and managed care plans" and then requires that the prices of these entities be "compared to retail pharmacies." This enumeration of purchaser types and request for their comparison to retail pharmacy prices indicates that Congress viewed retail pharmacy as not including the enumerated entity types—that is, "hospitals, other institutional facilities, and managed care plans."

101. When defining the term "covered outpatient drug" for the Medicaid program the regulation identifies certain drugs not covered when they are provided as part of, or as incident to and in the same setting as, any of the following: (A) inpatient hospital services; (B) hospice services; (C) dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs; (D) physicians' services; (E) outpatient hospital services; (F) nursing facility services and services provided by an intermediate care facility for the mentally retarded; (G) other laboratory and x-ray services; and (H) renal dialysis. (42 U.S.C. § 1396r-8 (k)(3)) Some of these settings for which prescriptions are not covered under Medicaid have been included in the promulgated final AMP rule as prices that should be included in calculating the AMP. Prescription drugs provided through the settings listed above are not covered by Medicaid and these settings are not part of the "retail pharmacy class of trade."

102. The Social Security Act as amended by the DRA (used in the Medicaid drug rebate program) includes regulations describing prices to be considered when determining the "best price." The type of entities whose prices are included in determining the "best price" is an extensively enumerated list as follows: "(1) Prices to wholesalers; (2) Prices to any retailer, including rebates, discounts or other price concessions that adjust prices either directly or indirectly on sales of drugs; (3) Prices to

providers (for example, hospitals, HMOs/MCOs, physicians, nursing facilities, and home health agencies); (4) Prices available to non-profit entities; (5) Prices available to governmental entities within the United States; (6) Prices of authorized generic drugs; (7) Prices of sales directly to patients; (8) Prices available to mail order pharmacies; (9) Prices available to outpatient clinics; (10) Prices to other manufacturers who act as wholesalers and do not repackage/relabel under the purchaser's NDC, including private labeling agreements; and (11) Prices to entities that repackage/relabel under the purchaser's NDC, including private labeling agreements, if that entity also is an HMO or other non-excluded entity." (42 CFR §447.505) Note that this list includes "prices to any retailer" and proceeds to list ten other entity types whose prices are also to be included in determining the "best price." The existing best price regulations considered ten other categories of entities to be distinct from "prices to any retailer." Now, a different section of the final AMP rule has taken the term "retail pharmacy class of trade" and defined it to encompass most or all of these ten distinct entities.

103. Federal statutes and regulations have recognized that the prices paid by retail pharmacy are different from, and can be compared to, prices for hospitals, other institutional facilities, and managed care plans. A number of provider and distribution entities that have been included in the final AMP rule definition of "retail pharmacy class of trade" are excluded from coverage under Medicaid. The inclusion of these excluded prices in calculating AMP is unwarranted. The history of statutory and regulatory recognition of retail pharmacy as distinct from many other providers and distributors of prescription drugs is contrary to the overly broad definition of the "retail pharmacy class of trade" as published in the final AMP rule. Moreover, because of the structural impediment of discriminatory pricing as described above, retail pharmacies do not have access to the lower prices of these other classes of trade and will be economically disadvantaged and harmed by the overly-broad and artificial definition of the retail pharmacy class of trade as construed by CMS in the final rule.

104. In the Medicare Part D program, CMS defines "retail pharmacy" as "any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy." (42 C.F.R. § 423.100, the Medicare Part D prescription drug program regulations). This definition of retail pharmacy is clearly more consistent with the use of the term "retail pharmacy" than is the CMS interpretation which re-writes the statutory criteria of the Social Security Act in the final rule.

105. The terms "retail" and "retail pharmacy" are terms defined in state statutes and regulations. The states, and not the federal government, are responsible for defining the term "pharmacy" and for licensing pharmacies. CMS cannot by the stroke of its pen re-define "pharmacy" or "retail pharmacy" to be different from the definition of these terms in the states, individually or collectively. State boards of pharmacy are responsible for licensure of pharmacies (entities that dispense, compound, prepare, and administer prescription drug products). In every state, a pharmacy must be licensed and a licensed pharmacist must be present at the entity in order to dispense prescription medications

within the state. Across the states there are many types (or categories) of pharmacy licenses such as a "retail pharmacy" license, hospital (or institutional), charitable clinic, long term care, nuclear, mail order, HMO, and other types of pharmacy licenses.[51] The fact that each type of pharmacy is issued a unique license type indicates that "retail pharmacy" is distinct from, and not inclusive of, the other types of pharmacies for which specific licenses are available and required. Many of the entities whose prices are included in the definition of AMP are not licensed as retail pharmacies, and some may not be licensed as a pharmacy of any type, or even have a licensed pharmacist present at the entity during normal business hours.

106. The use of the word "pharmacy" in the federal statutory language defining how AMP will be calculated carries special meaning. In every state an entity must be a "licensed pharmacy" in order to dispense and administer medications to the end consumer. In fact, it is illegal for any entity not licensed as a pharmacy by the state to call itself a "pharmacy" or a "drug store." This would imply that only entities that are licensed pharmacies should be taken into account in calculating the AMP which is to be "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail *pharmacy* (emphasis added) class of trade." (*See* Social Security Act §1927(k)(1) 42 U.S.C. § 1396r-8(k)(1)).

3. Retail Pharmacy Class of Trade: Plain Meaning and Common Usage

107. "Retailer" is defined by the Cambridge Advanced Learner's Dictionary as "a person, shop or business that sells goods to the public."[52] Another dictionary source uses the term "retail" to have a plain language meaning "to sell in small quantities directly to the ultimate consumer" and the term "retailer" to mean "to sell at retail."[53]

108. "Public" means "relating to, or involving, people in general, rather than being limited to a particular group of people."[54] Public also means "of, relating to, or affecting all the people" or "relating to people in general." Additionally, public means "accessible to or shared by all members of the community."[55]

109. Both the dictionary definitions, above, and the CMS final AMP rule describe "retail" as selling or providing drugs "to the general public." (42 CFR § 447.504 (e)) This stipulation that retail means a firm that "sells or provides the drugs to the general public," means that merely selling to the end consumer is not sufficient to define a retail pharmacy or the "retail pharmacy class of trade."

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51 *Survey of Pharmacy Law*, National Association of Boards of Pharmacy, 2007, pp. 49-50.

52 Cambridge Advanced Learner's Dictionary, Cambridge University Press, 2007, http://dictionary.cambridge.org/define.asp?key=90438, accessed on October 23, 2007)

53 Merriam-Webster's Online Dictionary, http://www.merriam-webster.com/dictionary/retail, accessed on October 23, 2007.

54 Merriam-Webster's Online Dictionary (http://www.merriam-webster.com/dictionary/public, accessed on October 23, 2007.

55 Cambridge Advanced Learner's Dictionary, Cambridge University Press, 2007, http://dictionary.cambridge.org/define.asp?key=public*1+0&dict=A, accessed on October 23, 2007.

110. Therefore, to be included in the plain meaning of "retail pharmacy" or CMS' definition of the "retail pharmacy class of trade" it is not sufficient to dispense prescriptions to a limited group of patients, such as members of a particular health plan. Instead, to be included in the "retail pharmacy class of trade" a pharmacy must dispense prescriptions to any customer who chooses to use the pharmacy. In other words, the dictionary and plain meaning of retail means selling or providing goods or services to the ultimate consumer and that the goods and services are accessible to all people in the community.

111. Another component of the plain meaning of the term "retail pharmacy class of trade" is the word "pharmacy." A pharmacy is an entity that is licensed by the state to dispense prescription medications.

4. Retail Pharmacy Class of Trade: Use in the Pharmaceutical Market Context

112. The term "class of trade" has a specific meaning in the context of the pharmaceutical market. IMS Health (a pharmaceutical market research firm) tracks nearly the entire universe of pharmaceutical sales throughout the United States at all levels in the market. The sales from manufacturers to wholesalers and direct sales to virtually every other type of pharmacy, provider and other entity type are tracked for every prescription drug product. IMS Health and pharmaceutical companies in the United States group the sales of their products according to the type of purchaser. This grouping system for pharmaceutical purchasers is called the "class of trade" system and IMS Health uses a uniform set of "classes of trade" across all pharmaceutical firms. The class of trade of a given purchaser is a function of various "structural" criteria such as type of entity (e.g., pharmacy versus hospital versus clinic); type of ownership (e.g., for profit versus non-profit); and type of financing (e.g., private versus government). The detailed Outlet Subcategory Codes for the class of trade system are presented in a document maintained by DDD, a division of IMS Health.[56] (*See* Exhibit 4). Notice that this coding scheme groups outlets by their description and definitions of the type of facility. However, nowhere in this document is the volume of business of any given class of trade presented. In other words, "class of trade" has a specific structural meaning in the pharmaceutical market and the classes of trade are differentiated by structural and not economic efficiency criteria.

113. The pharmaceutical market structure involves several distinct groups of players including: (1) manufacturers, marketers, and distributors; (2) wholesalers and warehouses; (3) retail pharmacies; (4) mail service pharmacies; (5) outpatient providers; and (6) institutional providers. (*See* Exhibit 3C.)

114. The "Retail Perspective" is an IMS Health data product that describes the "retail pharmacy class of trade" as including the following types of pharmacies: (1) independent pharmacies, (2) chain pharmacies, (3) food & drug store pharmacies, and (4) mass merchandise pharmacies (sometimes combined with chain pharmacy data). The

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[56] IMS Health, DDD Outlet Subcategory Codes, Updated October 2002.

retail pharmacy class of trade, according to the pharmaceutical market structure, is highlighted in Exhibit 3F. Data from the "retail pharmacies open to the general public" is collected by IMS Health by a common method and is reported separately from other pharmaceutical sales data.[57] (*See* Exhibits 5 and 6). Retail pharmacies typically carry a full line of drug products including chronic and acute medications, oral and topical medicines, insulin, vaccinations and other biologicals, etc. In contrast, many of the other entities, force-fitted into the "retail class of trade" definition by CMS, do not carry a full line of drugs but only a limited supply of drugs for special patient populations such as dialysis patients, home infusion patients, long term care patients, etc.

115. Data from "Mail Service Pharmacies" is collected by IMS Health separately from the retail pharmacy data included in the "Retail Perspective". (*See* Exhibit 7). Although mail service pharmacy data is sometimes grouped with the retail classes of trade, mail service pharmacy data is collected by different methods and is almost always reported separately from retail pharmacy data.[58] In general, mail service pharmacies constitute retail pharmacies with limited distribution or special populations. The largest mail service pharmacies serve enrolled and special populations (e.g., PBM-owned mail service pharmacies serve the members of an insured group being served by a given PBM, also there are mail service pharmacies for special populations such as the Federal TriCare program for military dependents and retirees) and are not open to the general public.

116. The "Provider Perspective" is an IMS Health data product that describes the following classes of trade as "non-retail providers": (1) clinics (i.e., physician's offices, group practices, and specialty clinics), (2) healthcare plans (staff model HMOs, hospitals, and clinics), (3) home health agencies, (4) long term care settings, (5) non-federal hospitals, (6) federal hospitals, and (7) miscellaneous (i.e., prisons, universities, and others). (*See* Exhibit 8). Note that this report refers to the Provider Perspectives classes of trade as "non-retail."

117. Market trend analysis information is published by IMS Health in an annual volume titled *DDD Annual Class-of-Trade Analysis*.[59] (*See* Exhibit 9). In general, IMS Health divides the various classes of trade into two broad categories: (1) retail and (2) providers (or sometimes referred to as "non-retail"). These two broad groups form the basis of market data products known as the Retail Perspective™[60] and Provider Perspective™.[61] These two data products provide manufacturers and others with market volume and market share data through the various channels of distribution for their drug products in the pharmaceutical market.[62] (*See* Exhibits 5 and 8). Although mail service pharmacy is sometimes listed under the retail sector, mail service pharmacy, as noted

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57 U.S. Chain and Independent Pharmacies, Mass Merchandisers, Proprietary Stores and Foodstores with Pharmacies, IMS Health, March 2006.

58 Mail Service Sales, IMS Health, 2006.

59 IMS Health, DDD™ Class of Trade Report, 2003, p. 13. (*See* Exhibit 9).

60 IMS Health, Retail Perspectives. (*See* Exhibit 6).

61 IMS Health Provider Perspectives. (*See* Exhibit 8).

62 IMS Health, DDD[J] Class of Trade Report, 2003. (*See* Exhibit 9).

above, is a distinct class of trade from other retail pharmacies and does not serve the general public, but rather an enrolled and limited segment of the public.

118. Several comments noted that the CMS proposed, and now final, rule definition of "retail pharmacy class of trade" was in conflict with the use of this term in the pharmaceutical market. The CMS response to these comments makes it clear that CMS has chosen to create its own definition of AMP rather than follow the definition in the statutes or in the pharmaceutical market. The CMS Response was "We believe that the definition of retail pharmacy class of trade included in this rule at § 447.504(e) is defined for the purpose of the Medicaid Drug Rebate Program consistent with our interpretation of the applicable statutory requirements." CMS has focused on their over-interpretation and not the statutory language, *per se*. (Fed. Reg., Vol. 132, No. 39164).

5. Retail Pharmacy Class of Trade: Final AMP Rule

119. The final AMP rule states: "*Retail pharmacy class of trade* means any independent pharmacy, chain pharmacy, mail order pharmacy, or other outlet that purchases drugs from a manufacturer, wholesaler, distributor, or other licensed entity and subsequently sells or provides the drugs to the general public." This definition re-defines the term "retail pharmacy class of trade" to encompass virtually all pharmacies and providers who dispense or administer drugs to the end consumer. (Fed. Reg., Vol. 132, No. 39241). The retail pharmacy class of trade, according to the final rule definition, is highlighted in Exhibit 3G.

120. This re-definition stands in stark contrast to the use of the term "retail pharmacy class of trade" in the pharmaceutical market. The inclusion of different classes of trade with pricing based on different structural positions in the market will result in some classes of trade being overpaid while other classes of trade (especially retail pharmacies, that is independent, chain, mass merchandise, and food & drug store pharmacies) will be paid below their actual cost and may result in a substantial decrease in access to care for Medicaid recipients.

121. CMS' response to comments published with the final rule states "we define retail pharmacy class of trade more broadly to include, for example, direct sales to physicians and outpatient hospital sales, to the extent that they provide drugs to the general public." (Fed.Reg., Vol.72, No. 136, July 17, 2007, p. 39177.) This statement reflects the intent of CMS to change the definition of "retail pharmacy class of trade" from the plain meaning and use of the term in the pharmaceutical industry. The definition in the final rule is much broader than the statutorily specified definition of "retail pharmacy class of trade" or the commonly accepted use of the term in the pharmaceutical market. (*Compare* Exhibits 3F. and 3G.)

D. Particular Examples

122. The promulgated final rule expands the statute by adding, *inter alia*, definitions and rules related to key terms. These promulgated definitions and rules,

however, are not always consistent with the original statutory language. For example, the definition and rules related to "wholesaler" includes many entities and related price transactions that are not generally considered to be wholesalers by other federal and state statutes and regulations, that are not consistent with the plain meaning of the term based on dictionary definitions, and that are not consistent with the use of the term in the pharmaceutical market context.

123. Similarly, the promulgated definition and rules related to the "retail pharmacy class of trade" includes many entities that are not generally considered to be retail pharmacies. The retail pharmacy class of trade as defined in the final rule includes many types of providers who are clearly not in the "retail pharmacy class of trade" as the term is commonly and routinely used in the pharmaceutical market.

124. Also, the final rule definitions create confusion about the definition of a "wholesaler" versus entities within the "retail pharmacy class of trade." The final regulation essentially declares that all entities in the retail pharmacy class of trade are also wholesalers as well as retailers.

125. The final rule has re-defined several key terms such as "manufacturer," "wholesaler," and "retail pharmacy class of trade," to have meanings contrary to that found in other federal and state statutes and rules, contrary to that found in the plain language and common usage of the terms, and contrary to that found in the use of the terms in the pharmaceutical market.

126. This re-definition of key terms will have a substantial and material impact upon the definition and calculation of the Average Manufacturer Price (AMP) and the amount of payment that pharmacies and other providers will receive from Medicaid for generic medications provided to recipients.

127. Examination of the entities whose prices are to be included in the AMP calculation according to the final rule is compared below with the statutory language describing the AMP and its calculation, with the plain meaning or common usage of key terms, and with the use of the key terms within the pharmaceutical market.

128. The following examples from the final rules involve prices paid by non-wholesalers to manufacturers, drugs distributed to non-retailers, or both.

1. Sales to Other Manufacturers Who Act As Wholesalers (42 CFR §447.504 (g)(2))

129. Certain manufacturers sell their drug products to another manufacturer who serves merely as a wholesaler or distributor. These "other manufacturers" may then sell the drug product to retail pharmacies, other outlets, or other entities that may or may not distribute drugs to the end consumer or the general public.

130. This category of transactions (e.g., sales to other manufacturers) should not be included in AMP because: (1) the Social Security Act excludes manufacturers from the

definition of wholesaler, (2) the entities may not be licensed as wholesalers, and (3) the sales may not be for distribution to the "retail pharmacy class of trade."

131. Inclusion of this group of entities in effect defines "other manufacturers who act as a wholesaler" as both a "wholesaler" and a "retail pharmacy." So in this case, the same firm is a manufacturer, a wholesaler, and a pharmacy, even though the firm may not be licensed as either a wholesaler or a retail pharmacy. Since these firms are not necessarily licensed as wholesalers, they are not wholesalers. And, since these firms are not necessarily licensed as pharmacies, they are not pharmacies. Additionally, there is no indication that these sales of drugs must be distributed to the "retail pharmacy class of trade."

2. Direct and Indirect Sales to Hospital Outpatient Pharmacies, Clinics and "Affiliated Entities" (42 CFR §447.504 (g)(3))

132. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," (3) these entities are not often licensed as retail pharmacies, (4) these entities primarily serve the hospital's or health system's own patients, but do not serve the general public, and (5) the manufacturer can not distinguish whether the drugs sold will be used for inpatient or outpatient purposes.

133. Hospital outpatient pharmacies, clinics, and affiliated entities clearly are not wholesalers. The sales in this category bypass the wholesaling function. While hospital pharmacies may be licensed as a pharmacy, most states designate "hospital pharmacies" as distinct from "retail pharmacies." The statute defining AMP referred to: sales for "distribution to the retail pharmacy class of trade." The statute does NOT read: sales for "distribution to the *hospital* (emphasis added) pharmacy class of trade." Clinics may dispense drugs under the authority of the physicians who practice in the clinic without having a licensed pharmacy in the clinic. Likewise, "affiliated entities" related to hospital and health systems are not necessarily licensed as pharmacies.

134. The entities enumerated in (42 CFR §447.504(g)(3)) are able to purchase drug products at lower prices than other classes of trade including the retail class of trade (i.e., independent, chain, mass merchandise, and food & drug pharmacies). Clinics, for example, were able to purchase a Medicaid-weighted market basket of patented brand name drug products at 30.5% below AWP in July 2004, while the retail class of trade were only able to purchase the same market basket of Medicaid-used drugs at about 20.2% below AWP.[63] This difference in prices was due to the structurally defined classes of trade and the manufacturer's practice of price discrimination across classes of trade and sustained by the statutory prohibition of arbitrage (PDMA) across, and within, classes of trade.

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[63] Wrobel, Schondelmeyer, Agarwal, and Cooper, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report,* CMS, September 26, 2005, p. 47.

135. The general public can not obtain prescription drugs from these entities. Sale of drugs provided at the lower prices for these classes of trade is limited to patients who meet the "own use" criteria for the facility—that is, the patient is one who is being treated by providers affiliated with the facility. A person from the general public being treated by a provider not affiliated with the entity is not supposed to be able to walk into the facility with a prescription and have that prescription filled. Consequently, these entities do not serve the "general public," but rather only those persons being treated by providers affiliated with the facility.

136. In a related matter, hospital outpatient pharmacies are not open to the general public. These pharmacies may dispense only to hospital patients (inpatient or outpatient) by providing outpatient services in a manner that is integrated with inpatient pharmacy services. (Medicare Hospital Conditions of Participations, 42 CFR §482.54)

137. When a sale is made to one of these entities (i.e., hospital outpatient pharmacies, clinics, and affiliated entities), the manufacturer can not distinguish whether the drugs sold will be used for inpatient or outpatient purposes.

3. Sales at Nominal Prices to "Any Entity" (42 CFR §447.504 (g)(4))

138. This category of transactions should not be included in AMP because: (1) most of the entities encompassed by "sales at nominal prices to any entity" are not licensed as wholesalers, and (2) most of the entities encompassed by "sales at nominal prices to any entity" are not licensed as retail pharmacies.

139. Sales at "nominal prices" exist in the market for two primary purposes. First, to provide drug products to charitable (non-profit) organizations at an extremely low cost. Many of the charitable organizations that may be dispensing drugs are not licensed wholesalers or licensed pharmacies. For this reason alone these sales do not meet the statutory test for inclusion in the calculation of AMP.

140. In addition, nominal prices are not "negotiated" or awarded based on economic efficiency, but rather are provided by a manufacturer for promotional purposes. If the drug company can get doctors in the hospital to prescribe their oral medication, through lower (i.e., nominal) prices, then when the patient is discharged to the outpatient market, the patient will be on a chronic medication that generates a much greater revenue for the manufacturer for the rest of the time the patient continues to use the medication.

141. Nominal prices are rarely, if ever, provided to wholesalers for drugs distributed to traditional "retail pharmacy class of trade" entities. Therefore, the inclusion of nominal prices in AMP will assure that the resulting AMP will be below the price to the retail pharmacy class of trade for reasons that are not related to market efficiency and below the price that is attainable by the actions of retail pharmacies.

4. Direct Sales to Retail Pharmacies (42 CFR §447.504 (g)(5))

142. This category of transactions should not be included in AMP because these entities are generally not licensed as wholesalers.

143. Retail pharmacies are not wholesalers. The sales in this category bypass the wholesaler function.

5. Sales and Discounts to PBMs for their Mail Order Pharmacies (42 CFR §447.504 (g)(6))

144. Pharmacy benefit management companies (PBMs) are defined as "organizations that manage pharmaceutical benefits for managed care organizations (MCOs), other medical providers, or employers. PBMs contract with clients who are interested in optimizing the clinical and economic performance of their pharmacy benefit. PBM activities may include some or all of the following: benefit plan design, creation/administration of retail and mail service networks, claims processing, and managed prescription drug care services such as drug utilization review, formulary management, generic dispensing, prior authorization (PA), and disease and health management."[64] PBMs do not, generally, purchase, take possession of, or dispense prescription drugs to their covered members, except in the case where the PBM owns their own mail order pharmacy.

145. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," (3) these entities serve only the PBM enrolled patients and not the general public.

146. This category involves mail order pharmacies that are affiliated with a PBM. These pharmacies do not generally function as, and are not generally licensed as, wholesalers.

147. Mail order pharmacies usually serve enrolled members in a PBM or insurance program and not the general public. Also, mail order pharmacies get differential prices compared to traditional retail pharmacies (i.e., independent, chain, mass merchandise and food & drug pharmacies). Mail order pharmacies paid on average 27.9% below AWP for a Medicaid-weighted market basket of drugs in July 2004. In contrast, traditional retail pharmacies paid on average 20.2% below AWP for the same market basket of drugs. The difference in this payment is due primarily to the structural class of trade pricing used by drug manufacturers to carry out their discriminatory pricing scheme supported by patent monopolies and a prohibition on arbitrage (PDMA) across various settings in the pharmaceutical market. Inclusion of prices to mail order pharmacies in the AMP

64 Pharmacy benefit management companies are defined in the *AMCP Guide to Pharmaceutical Payment Methods*, Comprehensive Edition, Version 1.0, October 2007, p. 55.

calculation will mean that the AMP will be lower than the actual acquisition cost for entities in the traditional retail pharmacy class of trade.

148. PBM rebates are typically based on factors such as market share movement, preferred formulary status, or other services. The rebates are compensation for the service provided, and are not a discount to the price. Absent transparent information on rebates and the basis for those rebates, it is not possible to determine what portion of a rebate is attributable to price versus other *bona fide* services. Manufacturers do not know when rebates paid to PBMs are for drugs dispensed by mail or by the retail pharmacy class of trade.

149. The PBM rebates are not passed on to the pharmacies in the retail pharmacy network. PBM rebates may reduce the health plans' costs, but typically do not reduce the cost to the pharmacy. The inclusion of PBM mail order rebates in the final rule is in conflict with past policy announced in Medicaid Releases No. 28 & 29.[65]

6. Sales To Mail Order Pharmacies (42 CFR §447.504 (g)(9))

150. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," and (3) these entities typically serve only the PBM or insured enrolled members and not the general public.

151. These mail order pharmacies do not generally function as, and are not generally licensed as, wholesalers.

152. Mail order pharmacies usually serve enrolled patient populations in an insurance program and not the general public. Moreover, except in very rare circumstances, these mail order pharmacies do not typically serve Medicaid recipients.

153. Mail order pharmacies get differential prices compared to traditional retail pharmacies (i.e., independent, chain, mass merchandise, and food & drug pharmacies). Mail order pharmacies paid on average 27.9% below AWP for a Medicaid-weighted market basket of drugs in July 2004. In contrast, traditional retail pharmacies paid on average 20.2% below AWP for the same market basket of drugs.[66] The difference in this payment is due primarily to the structural class of trade pricing used by drug manufacturers to carry out their discriminatory pricing scheme supported by patent monopolies and a prohibition on arbitrage (PDMA) across various settings in the pharmaceutical market. Inclusion of prices to mail order pharmacies in the AMP

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[65] The Medicaid Releases are memoranda from CMS to drug manufacturers that contain every instruction issued by CMS to participating drug companies related to the National Drug Rebate Agreement. A complete archive of these Medicaid Releases can be found on the CMS Medicaid website at: http://www.cms.hhs.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp.

[66] Wrobel, Schondelmeyer, Agarwal, and Cooper, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report*, CMS, September 26, 2005, p. 47.

calculation will mean that the AMP will be lower than the actual acquisition cost for entities in the traditional retail pharmacy class of trade.

154. Rebates paid to mail order pharmacies are based on factors such as market share movement, preferred formulary status, or other services. The rebates are compensation for the service provided, and not a discount to the price. Absent transparent information on rebates and the basis for those rebates, it is not possible to determine what portion of a rebate is attributable to price versus other *bona fide* services.

7. Sales Directly To Patients (42 CFR §447.504 (g)(7))

155. This category of transactions should not be included in AMP because: (1) patients are not licensed as wholesalers, and (2) patients are not licensed as pharmacies and are not in the retail pharmacy class of trade.

156. Furthermore, federal and state statutes and regulations explicitly exclude sales from manufacturers to consumers as a wholesale distribution function.[67] Also, distribution directly to consumers does not fit within the meaning of distribution to "the retail pharmacy class of trade." Consequently, inclusion of prices paid by patients directly to manufacturers is not within the plain meaning of "the average price paid to the manufacturer . . . by wholesalers for drugs distributed to the retail pharmacy class of trade."

157. Certain drugs are distributed through specialty pharmacies that never really purchase the drug and maintain it in inventory. Rather, the drug remains under the ownership of the manufacturer until the drug is sold to a patient. This constitutes direct sales to the patient by the manufacturer.

158. Manufacturers hire certain distributors to provide services related to these direct sales to the patient. However, these distributors never purchase the drug nor maintain it in their inventory. Rather, the drug remains under of the ownership of the manufacturer until the drug is sold to a patient. Therefore, these distributors can not be considered wholesalers.

[67] Colorado and other states have statutes and regulations that define "wholesaler" as "a corporation, individual, or other entity with facilities in this state that buys drugs or devices for resale or distributes drugs or devices to corporations, individuals, or entities entitled to possess such drugs or devices, other than consumers." (Colo. Rev. Stat. Ann. §12-22-102(34) (for pharmacy practice generally)).

8. Sales to Outpatient Facilities (42 CFR §447.504 (g)(8))

159. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," (3) some, but not all, of these entities may be licensed as pharmacies, (4) these entities may serve a health system's own patients, but they do not serve the general public, and (5) the manufacturer can not distinguish whether the drugs sold will be used for inpatient or outpatient purposes.

160. This category of transactions may include: clinics, surgical centers, ambulatory care centers, dialysis centers, and mental health centers. These entities do not function as, and are not licensed as, wholesalers. In general, these entities are not licensed as a pharmacy. These entities are not part of the traditional retail pharmacy class of trade.

161. Unlike traditional retail pharmacies (i.e., independent, chain, mass merchandise, and food & drug store pharmacies), these providers (entities) generally provide drugs "incident to" providing medical services to persons who are their private patients, although some physician practices sell self-administered products to patients who take the products home. Drugs provided as "incident to" the provider visit are not covered drugs under the Medicaid program. Therefore, it is not proper to include these prices in the calculation of AMP.

9. Sales to Home Infusion Providers (42 CFR §447.504 (g)(10))

162. Home infusion providers are entities "specializing in supplying members with home-infusion therapy medications and supplies."[68]

163. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," (3) many of these entities are not licensed as pharmacies, and (4) these providers do not serve the general public.

164. Medicare Part D regulations specify that ..."home infusion pharmacies" are not "retail" pharmacies, and are excluded from the definition of "retail" pharmacies due to the "ongoing clinical monitoring, care coordination and home infusion nursing that is provided by staff of, or affiliated with, the home infusion therapy provider." (42 C.F.R. § 423.120)

165. Most specialty and home infusion pharmacies are located in industrial areas, where there is little, if any, general consumer traffic.

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[68] Home infusion providers are defined in the *AMCP Guide to Pharmaceutical Payment Methods*, Comprehensive Edition, Version 1.0, October 2007, p. 52.

10. Sales To Specialty Pharmacies (42 CFR §447.504 (g)(11))

166. A specialty pharmacy is a "pharmacy that dispenses generally low-volume and high-cost medicinal preparations to patients who are undergoing intensive therapies for illnesses that are generally chronic, complex, and potentially life threatening. These therapies often require specialized delivery and administration."[69]

167. This category of transactions should not be included in AMP because: (1) the entities are not wholesalers or licensed as wholesalers, (2) the sales are not be for distribution to the "retail pharmacy class of trade," and (3) these entities typically serve an enrolled, or insured, population of patients, but do not serve the general public.

168. Most specialty pharmacies are located in industrial or warehouse business districts, where there is little, if any, consumer traffic from the general public.

169. Specialty pharmacies do not function as wholesalers, and they are not usually licensed as wholesalers.

170. Specialty pharmacies are not retail pharmacies within the "retail pharmacy class of trade" and they do not serve the general public. These specialty pharmacies serve a small, and usually enrolled, patient population with unique medication needs. Specialty pharmacies do not usually have a store-front capacity for serving walk-in clientele.

11. Sales To Home Health Providers (42 CFR §447.504 (g)(12))

171. Home health providers are entities that provide patient care services at the patient's home including assistance with activities of daily living and medication administration and use. These services are often delivered by visiting nurses or other health providers.

172. This category of transactions should not be included in AMP because: (1) the entities are not wholesalers or licensed as wholesalers, (2) the sales are not for distribution to the "retail pharmacy class of trade," (3) these entities are not usually pharmacies or licensed as pharmacies, and (4) these entities serve a small specialized group of patients, but can not and do not serve the general public.

173. Home health providers do not function as wholesalers and are not licensed as wholesalers. Home health providers do not function as retail pharmacies, and are not licensed as retail pharmacies.

174. Home health providers serve a specialized group of patients with special medical and service needs, but do not dispense prescriptions to the general public. There

[69] Specialty pharmacies are defined in the *AMCP Guide to Pharmaceutical Payment Methods*, Comprehensive Edition, Version 1.0, October 2007, p. 56.

usually is no store-front location for home health providers to interface with the general public in a manner that would allow dispensing of prescriptions to the general public or Medicaid recipients.

12. Sales to Physicians (42 CFR §447.504 (g)(13))

175. This category of transactions should not be included in AMP because: (1) the entities are not licensed as wholesalers, (2) the sales are not be for distribution to the "retail pharmacy class of trade," (3) physicians are not licensed as pharmacies, and (4) physicians may dispense for their own patients, but can not dispense drugs to the general public.

176. Physicians are not wholesalers and are not usually licensed as wholesalers. Physicians are not retail pharmacies and are not licensed as a pharmacy or retail pharmacy.

177. A manufacturer's drug product sales to physicians are not for "distribution to the retail pharmacy class of trade."

178. Physicians may serve the medication needs of their own patients, but they do not serve the medication needs of the general public.

13. Rebates, etc. "Associated With" Sales of Drugs to the Retail Pharmacy Class of Trade (42 CFR §447.504 (g)(14))

179. This category of transactions should not be included in AMP because the rebates are not prices paid to manufacturers by wholesalers.

180. Rebates paid by manufacturers and associated with sales of drugs to the retail pharmacy class of trade are based on factors such as moving market share for a specific generic drug. These rebates are compensation for the service provided, and not a discount to the price. Absent transparent information on rebates and the basis for those rebates, it is not possible to determine what portion of a rebate is attributable to price versus other *bona fide* services.

14. Sales of Drugs Reimbursed By 3rd Party Payers (42 CFR §447.504 (g)(15)), (but not related discounts (42 CFR §447.504 (h)(23))

181. Third party payers are "public or private organization(s) (such as Blue Cross and Blue Shield, Medicare, Medicaid, commercial insurer, self-insured employer, Taft-Hartley Trust, or Multiple Employer Trust) that pay for or underwrite coverage for health care expenses for an individual or group. The individual enrollee generally pays a premium for coverage in all private and some public health insurance programs, and the

organization pays claims on the patient's behalf."[70] Third party payers do not, generally, purchase, take possession of, or dispense prescription drugs to their covered members.

182. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution into the retail pharmacy class of trade. Third party payers are not wholesalers, or licensed as wholesalers. Also, third party payers are not retail pharmacies, or licensed as pharmacies.

15. Manufacturer Patient Assistance Programs, in some circumstances (42 CFR §447.504 (h)(15))

183. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution to the retail pharmacy class of trade.

184. Consumers receiving prescriptions through a manufacturer patient assistance program are not wholesalers or part of the retail pharmacy class of trade. Manufacturer patient assistance programs do no affect the prices paid by wholesalers for drugs distributed to the retail pharmacy class of trade. The pharmacy does not receive any gain on the drug product cost from dispensing prescriptions pursuant to a manufacturer's patient assistance program. The pharmacy is merely a pass through entity.

16. Manufacturer Coupons (42 CFR §447.504 (h)(15))

185. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution to the retail pharmacy class of trade.

186. Consumers receiving coupons are not wholesalers or part of the retail pharmacy class of trade. At most, coupons could be included only if they affect the prices paid by wholesalers for drugs distributed to the retail pharmacy class of trade. The pharmacy does not receive any gain on the drug product cost from dispensing prescriptions pursuant to a manufacturer's coupons. The pharmacy is merely a pass through entity.

17. Manufacturer Vouchers are included in some circumstances (42 CFR §447.504 (h)(16))

187. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution to the retail pharmacy class of trade.

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[70] Third party payers are defined in the *AMCP Guide to Pharmaceutical Payment Methods*, Comprehensive Edition, Version 1.0, October 2007, p. 56.

188. Consumers receiving vouchers are not wholesalers or part of the retail pharmacy class of trade. At most, vouchers could be included only if they affect the prices paid by wholesalers for drugs distributed to the retail pharmacy class of trade. The pharmacy does not receive any gain on the drug product cost from dispensing prescriptions pursuant to a manufacturer's voucher. The pharmacy is merely a pass through entity.

189. Manufacturer's vouchers may be used as a promotional tool to increase the prescribing and dispensing of a given drug. These manufacturer vouchers may also be used to deliver a charitable benefit to a certain limited set of persons, but these vouchers are not available to the general public.

190. CMS has previously held that vouchers do not need to be included in best price or AMP calculation if there is no net income to the wholesaler or pharmacy from participation in the program.

18. Manufacturer Discount Cards are Included in Some Circumstances (42 CFR §447.504 (h)(17))

191. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution to the retail pharmacy class of trade.

192. Consumers receiving prescriptions through a manufacturer discount card program are not wholesalers or part of the retail pharmacy class of trade. Manufacturer discount card programs do no affect the prices paid by wholesalers for drugs distributed to the retail pharmacy class of trade. The pharmacy does not receive any gain on the drug product cost from dispensing prescriptions pursuant to a manufacturer's discount card program. The pharmacy is merely a pass through entity.

19. Rebates, Discounts, and Other Price Concessions (42 CFR §447.504 (i))

193. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler.

194. For example, this provision appears to include certain fees paid to group purchasing organizations (GPOs). GPOs are not wholesalers, but rather serve as a broker or middleman between manufacturers and hospitals or other providers. GPOs rarely, if ever, take possession of the drug product. GPOs are not typically wholesalers or licensed as wholesalers.

20. Lagged Price Concessions – 447.510(d)(2), 447.502 (definition).

195. This category of transactions should not be included in AMP because it includes drugs that have not been sold by a manufacturer to a wholesaler for distribution to the retail pharmacy class of trade.

196. CMS' response to lagged price concessions says "Lagged price concessions are not limited to discounts or rebates offered to wholesalers." (Federal Register, Vol. 72, No. 136, p. 39210). If the lagged price concession was offered to any entity other than a wholesaler, then the lagged price concession is not part of the "price paid by the wholesaler."

E. "Adequate Documentation" Issue (42 CFR §447.504 (g)(1))

197. CMS modified the final rule at § 447.504(g)(1) to state that "where the manufacturer can identify with adequate documentation that subsequent sales from the wholesaler are to an excluded entity, the manufacturer can exclude such sales from AMP." This provision creates an opportunity for manufacturers to favor their own economic interests to the detriment of Medicaid and the retail pharmacies that serve Medicaid recipients.

198. According to the final rule, all sales are included in the AMP calculation unless there is adequate documentation to prove that the price should not be included in AMP. By lowering the AMP, the manufacturer can reduce the amount of rebate it has to pay to the Medicaid drug program. Therefore, manufacturers have an economic interest in avoiding documentation of sales (at higher prices) that they wish to exclude from the AMP calculation.

199. A prudent manufacturer, acting in accordance with the provisions of the final rule will likely not have adequate documentation, and not have an interest in developing adequate documentation, for prices and sales that raise the AMP and thus the manufacturer's rebate liability. In particular, drug manufacturers usually lack adequate documentation to demonstrate whether PBM rebates are for mail order or retail pharmacy network prescriptions.

VIII. "In The State" versus Nationally Available

200. The Social Security Act has a definition of "multiple source drug" that says a drug does not constitute a multiple source drug in a particular State unless two or more equivalent drug products are "sold or marketed in the State." The statute explains that "a drug product is considered to be sold or in a State if it appears in a published national listing of average wholesale prices selected by the Secretary, provided that the listed product is generally available to the public through retail pharmacies in the State." (*See* Social Security Act § 1927(k)(7), 42 U.S.C. § 1396r-8(k)(7)).

201. The final AMP rule, however, contradicts this statutory language in three principal ways: (1) the statute requires that the drug be "sold or marketed in the State" while the final rule has substituted the requirement that the drug must be "sold or marketed in the United States;" (2) despite specific statutory language mandating that a drug price can only be used to set an FUL if it "appears in a published national listing of average wholesale prices selected by the Secretary," the final rule does not mandate use of any listing of prices or drug availability in the market; and (3) the final rule fails to ensure that FULs are applied in each State *only* to multiple source drugs that are "generally available to the public through retail pharmacies in the State."

202. There are at least two reasons why drug products can not be assumed to have national availability: (1) regional manufacturers, marketers, distributors, and wholesalers, and (2) certain drug products, at the NDC level, may be sold exclusively to entities in a specific class of trade and thus may not be "generally available" to any, or all, pharmacies in a given state or to the general public.

203. First, small regional manufacturers, marketers, or wholesalers may re-package and re-label drug products with a new NDC number and charge a price that is only available within the geographic scope of the firm's limited distribution market. These regional NDCs may be listed in the national price compendia (e.g., First DataBank, MediSpan, or Red Book), but they may not be available outside of the geographic region served by the firm. Because there are certain regional marketers and wholesalers, who list in the national compendia, one can not assume that all prices listed in these national compendia are available to all pharmacies across the nation. Consequently, the drug products and prices that are actually available "in the State" may vary from the drug prices that are listed in national price compendia.

204. A second situation may lead to drug products being listed in the national drug compendia, but not being available to all types of pharmacies nationwide. Certain NDCs are sold only to a certain class of trade (e.g., some NDCs are sold only to physicians). These limited 'class of trade' NDCs may still be listed in the national price compendia, but no pharmacy can order or purchase these drug products. This practice of having specific NDCs for a specific 'class of trade' is used as a way to implement class of trade discriminatory pricing and to track sales to certain classes of trade.

205. In those cases where an NDC is limited to a specific class of trade, the special class of trade typically gets a much lower price, thus lowering the AMP with prices from an NDC that is not available to traditional retail pharmacies (independent, chain, mass merchandise, or food & drug store pharmacies) in the state or the nation.[71]

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[71] Wrobel MV, Schondelmeyer SW, Jureidini S, Agarwal S, Sayko R, Doyle AC, *Sales of Drugs and Biologicals to Large Volume Purchasers: Final Report* (CMS Contract #500-00-0049, Task Order 1, September 19, 2005, , p. 11)

IX. Web Site Posting of FULs and AMPs

206. The AMP information collected pursuant to the final rule will be posted by CMS on a web site for each drug product and will be updated monthly. In general, transparency of price information is usually a good thing for consumers and for the market. However, when disclosed information is complex, confusing, or even inaccurate the transparency loses its value or even becomes counterproductive.

207. In the case of the AMP data that would be collected and posted under the final rule, the data would be confusing and not constructive in encouraging an efficient market with pricing pressure in the right places. There would be two primary types of users for the data on the website: (1) consumers and (2) third party payers. Consumers examining the website would in all likelihood be looking for information to make an informed decision based on the expected cost of their prescription from the pharmacy. Instead, what the consumer would find is prices paid to manufacturers by wholesalers (and non-wholesalers) for drugs by a collection of various pharmacy and provider types, some of which the consumer is totally unaware of, and from which the consumer can not even buy a prescription as an individual. The "retail pharmacy class of trade" defined by the final rule is not reflective of either the structure of the pharmaceutical market from the perspective of the supply side (i.e., manufacturers, wholesalers, and pharmacies and providers) or from the perspective of the demand side (i.e., consumers and the place where they usually get their prescriptions filled—independent, chain, mass merchandise, and food & drug store pharmacies).

208. The prices that would be posted would not be directly applicable at the consumer level—that is, the prices posted (i.e., AMP) would not be prices that could be expected for the prescription the consumer is planning to purchase. The individual consumer can not even purchase a prescription from many of the providers whose price data has been defined by CMS as being in the "retail pharmacy class of trade." Absent this clarity in information and applicability to the 'real' price that will be charged for a prescription, consumers will: (1) blame the pharmacy for charging a price different than what is posted on the web site, (2) ignore the website as irrelevant or too complex, (3) get frustrated when the web site price is found to be wrong, or (4) some combination of the above.

209. The second group that may use the web site and information posted there, would be third party programs looking for pricing information to serve as a benchmark for determining a reasonable payment level for pharmacies delivering their prescription drug benefit. The broad and detached definition of the "retail pharmacy class of trade" in the final rule muddles the actual data from various distinct groups (actual classes of trade) of purchasers in a manner that renders the actual data nearly useless in reflecting the structure and pricing patterns that are functional in the pharmaceutical market. Most third party programs deliver their prescription drug benefit through a large network of retail pharmacies (that is, independent, chain, mass merchandise, and food & drug store pharmacies). Therefore, they need a price benchmark that can serve as an appropriate and reliable reflection of the prices being paid by these pharmacies for prescription drugs.

Instead, however, the final rule 'piles on' so many other drug purchaser types, who have different prices and who serve different special groups of patients, that the 'average' price has very little meaning for the 'retail pharmacy' network serving the third party's drug program recipients.

210. Once the FULs based on AMP, as defined in the final rule, are published on the web site, other third parties are likely to adopt the Medicaid FULs, or even the brand and generic AMPs in some manner, and use them for their reimbursement caps within their own drug benefit program. Use of this benchmark price by other third parties will further reduce payments to retail community pharmacies and will squeeze their margins. The private market has historically observed new payment methods adopted by Medicare and Medicaid and, after determining their effect, the private market has adapted these new payment methods for their own use. The maximum allowable cost (MAC) method for capping the payment for generic drug products was first created by Medicaid in the 1970s, but is now widely used by virtually all (public and private) third party drug programs.

X. Economic Impact of DRA on Medicaid Access and Pharmacy Providers

211. The economic impact of the final rule on Medicaid reimbursement has two major effects: (1) it will reduce Medicaid drug program expenditures and (2) it will subsequently reduce payments to pharmacies and other providers. Moreover, AMP has been re-defined and its calculation method will change substantially upon implementation of the final rule. The new method for calculating the AMP will affect (i.e., reduce, in general) the amount of rebates collected from manufacturers under the Medicaid program. The new AMP will continue to be used as the basis for determining drug manufacturer rebates under Medicaid.

212. The new AMP will also be used for the first time to set the Medicaid FUL payment limits to pharmacies for multiple source drug products. Other changes have been made to the method of identifying drug product groups that will be subjected to an FUL. The final AMP includes discounts and rebates to both PBM owned and stand alone mail order pharmacies. CMS acknowledged that pharmacies within the retail pharmacy class of trade (independents, chains, mass merchandise, and food & drug store pharmacies) do not have access to these discounts and rebates.[72]

213. Prior to 2007, the AMP data has not been publicly available so that "retail pharmacies cannot determine what the relationship will be between AMP-based FULs and the prices pharmacies pay to acquire these drugs."[73] The GAO conducted an analysis of this relationship using the highest expenditure and highest use drugs for Medicaid. I have reviewed this analysis and find it to be a reasonable estimate given the limited data available. GAO found that the AMP-based FULs were "lower than the average retail pharmacy acquisition costs from the same period for 59 of the 77 drugs."[74] For the 27

[72] CMS, *Medicaid Program; Prescription Drugs*, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77178.
[73] GAO, *Medicaid Outpatient Prescription Drugs*, December 22, 2006, p.2.
[74] GAO, *Medicaid Outpatient Prescription Drugs*, December 22, 2006, p.4.

drug products with the highest expenditures, the AMP-based FULs averaged 65% below the average retail pharmacy acquisition cost. For the 27 drug products with the highest number of prescriptions, the AMP-based FULs averaged 15% below the average retail pharmacy acquisition cost. And, for the 23 drug products with high expenditures and high use, the AMP-based FULs averaged 28% below the average retail pharmacy acquisition cost. The AMP-based FULs (even with the 250% multiplier applied to the low AMP) were below the lowest acquisition cost available to retail pharmacies for 43 of the 77 study drugs. These findings indicate that pharmacies are likely to lose money on more than one-half of the generic prescriptions subject to the new AMP-based FULs, even after the 250% multiplier is applied to the new AMP amount.

214. A more recent study by the DHHS, OIG assessed the change in FULs expected with the implementation of the new AMP-based FULs based on the final rule.[75] I have reviewed the methods of this study and find them to be a reasonable basis for analyzing the expected impact of the final rule. The median decrease in the FUL amount was estimated to be 61%. OIG found that 492 of 521 drugs under review (94%) would experience a decrease in the FUL amount, even after the 250% multiplier for AMP. Nearly two-thirds of the drugs (334 of 521) would have a decrease in excess of 50% and 90 of the 521 drugs would have a decrease of greater than 90%. Importantly, OIG found that only 6 of the top 25 generic drugs could be purchased by pharmacies at or below the new FUL amount. Twelve of the top 25 drugs had pharmacy acquisition costs that were more than double the new FUL reimbursement limit. Although the AMPs used by OIG in this report were the old AMP data and formulas, the new AMP method in the final rule is expected to create AMPs and FULs that are even lower than these estimates by the OIG.

215. The Regulatory Impact Analysis section of the CMS proposed rule noted that "Retail pharmacies would be affected by this regulation as the law will result in lower FULs for most drugs subject to the limits, thus reducing Medicaid payments to pharmacies for drugs."[76] The regulatory impact analysis goes on to say that "The savings to the Medicaid program would largely be realized through lower payments to pharmacies." CMS estimated that the effect of lower FULs is expected to be $800 million in 2007 (not realized due to delay in publishing the final rule) and will increase to more than $2 billion annually by 2011 with a total revenue cut of $8.04 billion over 5 years (actually over 4 years without any savings in 2007 due to delay in publishing the final rule). The New York Times correctly observed that "90 percent of the savings would come from pharmacies."[77]

216. CMS' Office of the Actuary has estimated the Federal and state savings from implementation of the DRA and the new AMP and FUL definitions. These estimates were first published as part of the proposed rule (Fed Reg, Vol. See CMS, Medicaid

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[75] DHHS, OIG, *Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program*, OEI-03-06-00400, June 2007.

[76] CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77192.

[77] Robert Pear, "U.S. Is Proposing to Cut Medicaid's Drug Payments," *New York Times*, December 18, 2006.

Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77192.). The estimates examined a five-year period with partial-year cuts for 2007 and full-year savings estimates for the years 2008 to 2011. Across the total period 2007 to 2011 the total federal and state savings resulting from Section 6001—Federal Upper Payment Limits and Other Provisions, a savings of $8.04 billion is expected. The payment cuts were to phase in during 2007 and 2008, but reached their full amount in 2009 to 2011. By the year 2011, the annual payment cuts were expected to be $2.14 billion.

217. The $8.04 billion over 5 years (now actually 4 years; i.e., 2008-2011) was estimated by CMS to be the payment reduction to Medicaid from the change in the FUL calculation according to the proposed rule.[78] A number of changes were made to the AMP calculation method in the final rule published by CMS when compared with the proposed rule published by CMS. For example, providers from several channels of distribution were added to the CMS-defined retail class of trade definition to be used for purposes of calculating the AMP and FUL payment rates. The sales to outpatient facilities, clinics, surgical centers, ambulatory care centers, dialysis centers, mental health centers, home infusion providers, specialty pharmacies, home health care providers, and physicians were clarified or added to the list of sales included in AMP. These additional sales added to the AMP are, for the most part, sales that occur at a lower price than for the traditional retail pharmacy class of trade (i.e., independent, chain, mass merchandise, and food & drug store pharmacies). A study I conducted for CMS in 2005 found that clinics could purchase single source drugs at an average of 30.5% less than AWP, while traditional retail pharmacies average a purchase price of only 20.2% below AWP for the same market basket of drug products.[79]

218. The final rule's addition of sales to these other settings is likely to lower the AMP even further than the originally proposed rule would have. There should have been additional price cuts from adding these lower-priced sales to the AMP calculation, however, the estimated savings reported in the final rule were identical to the savings reported in the proposed rule. This would suggest the CMS did not bother to update their savings estimate in the final rule.

219. The CMS comments attempt to minimize the effect on retail pharmacy from the AMP and FUL changes in the final rule. CMS cites that "total retail prescription sales in the United States, including chain drug stores, independent drug stores and supermarkets totaled about $200 billion in 2006."[80] Actually the total outpatient prescription sales in 2006 including independent, chain, mass merchandise, food & drug, and mail order pharmacy were estimated to have been $258.0 billion and for the traditional retail class (excludes mail order) the 2006 prescription sales were about $206 billion.[81] When projected forward to 2011 using a conservative growth rate of 5% per

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78 See CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77192.

79 Wrobel, Schondelmeyer, Agarwal, and Cooper, *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report*, CMS, September 26, 2005, p. 47.

80 Federal Register, Vol. 72, No. 136, July 17, 2007, p.39233.

81 Wolters Kluwer Health Pharmaceutical Source Audit Suite, data accessed 6/21/06 as reported in NACDS, *The Chain Industry Profile*, 2007, pp. 67-68.

year,[82] the annual sales will be over $263 billion in 2011 and will total about $1,197 billion for the 5-year period 2007 to 2011. (*See* Exhibit 12). Since the 2007 savings will not be realized, the impact of this new rule will be felt over the four year period 2008 to 2011. The total sales from 2008 to 2011 are expected to be about $981 billion. When comparing the $8.04 billion in expected savings over 4-years to the total prescription sales of $981 billion, the savings represent about 0.6% of the prescription revenue in the United States. From this estimate, CMS concludes "Thus, the effect of this rule will be to reduce retail prescription drug revenues by less than one percent." Assuming the CMS estimate of the impact is correct, this is a true statement, but it is not a fair characterization of the impact this revenue loss will have on retail pharmacies.

220. Medicaid outpatient drug expenditures in 2006 dropped to about one-half of their level in 2005, due to the advent of the new Medicare Part D drug program. Consequently, Medicaid outpatient drug expenditures in 2006 were about $19.6 billion compared to $32.2 billion in 2005.[83] Medicaid outpatient drug expenditures from 2008 to 2011 are expected to be about $93.1 billion. The Medicaid reduction in payments to retail pharmacies from the new AMPs and FULs is estimated to be $7.25 billion for the years 2008 to 2011. (*See* Exhibit 12). This total reduction in payments from 2008 to 2011 amount to a reduction of total Medicaid prescription expenditures of 7.8%. This means that on average pharmacies will be paid 7.8% less for each Medicaid prescription. Again, assuming the CMS estimate of the impact is correct, retail pharmacies will experience a substantial 7.8% reduction in revenue from Medicaid prescriptions.

221. Not only will the reduction in payments from the final rule come from retail pharmacies and the Medicaid prescriptions that they dispense, but this reduction will actually come from the generic prescriptions with FUL limits. CMS estimated that 8.3% of total Medicaid drug expenditures were for drugs with FUL limits.[84] For the years 2008 to 2011, the Medicaid expenditures on FUL drug products would be about $9.20 billion. The total reduction from implementation of the new AMP-based FULs will come exclusively from these generic prescriptions. The 4-year reduction of $7.25 billion represents a 78.7% reduction in payments for FUL-paid generic prescriptions. (*See* Exhibit 12). In other words, the reduction in payments to retail pharmacies will be more than 75% of the current payment rate for generic prescriptions. This represents a *very substantial reduction* in payments to retail pharmacies for generic drug products dispensed to Medicaid recipients.

222. As described above, the reduced payments by Medicaid would come from decreases in the payments to pharmacies for multiple source prescriptions with FUL payment limits. The reduction in generic payments would be about 65% in 2008 and would average greater than 80% in 2009, 2010, and 2011. These reductions in pharmacy payments, if spread evenly across all pharmacies in the United States would mean a loss of more than $22,500 per pharmacy in 2008, $32,300 per pharmacy in 2009, and would

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82 Federal Register, Vol. 72, No. 136, July 17, 2007, p.39233.

83 Wolters Kluwer Health Pharmaceutical Source Audit Suite, data accessed 6/21/06 as reported in NACDS, *The Chain Industry Profile*, 2007, pp. 67-68.

84 Federal Register, Vol. 72, No. 136, July 17, 2007, p.39236 and 39238.

grow to more than $37,000 per pharmacy in 2011. In reality, however, these losses will not be spread evenly across U.S. pharmacies, but rather will be distributed across pharmacies in proportion to the number of Medicaid recipients served. Those pharmacies serving the most Medicaid recipients will be the pharmacies most affected by these payment cuts.

223. The AMP-based FULs, as described in the final rule, will result in payments to pharmacies that are below the pharmacy's actual costs for many generic prescriptions. I agree with the statement of Steven C. Anderson, President and CEO of the National Association of Chain Drug Stores, who warned of "dramatic under-reimbursements to community pharmacy as a result of the rule." [85] After examining the payment rates that are expected, I also agree with the comment of Bruce T. Roberts, executive vice president of the National Community Pharmacists Association, who said "The new limits on Medicaid reimbursement will be way below what drugstores typically pay for those drugs." Because pharmacies will face a real loss on many generic prescriptions, they will be less inclined to encourage use of generic prescriptions when a brand name prescription would pay their full cost. Again, I agree with the assessment of Bruce T. Roberts when he said that "The proposed rules would have the perverse effect of discouraging the use of generics."[86]

224. CMS explains "we are unable to estimate quantitatively effects on "small" pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. . . Because of these uncertainties, we have concluded that this proposed rule is likely to have a "significant impact" on some pharmacies."[87] "We estimate that 18,000 small retail pharmacies would be affected by this regulation. However, we are unable to specifically estimate quantitative effects on small retail pharmacies, particularly those in low income areas where there are high concentrations of Medicaid beneficiaries."[88] These 18,000 pharmacies affected by the implementation of the final rule would account for about one-third of the traditional retail community pharmacies in the United States.

225. Pharmacies, on average, will be paid substantially less for multiple source (generic) prescriptions under the new FUL payment system. The effect, however, will not be even across all pharmacies. Those pharmacies most likely to be affected by the final rule AMP-based FULs are those who serve a large share of Medicaid recipients (e.g., greater than 15% of their patients are Medicaid recipients) and those with a limited number of prescriptions per day due to a geographically limited patient population (e.g., chain or independent pharmacies in rural areas).

226. Reduction in payments will result in substantial losses, and even closures, for a number of pharmacies. The new payment method reduces pharmacy payments without a significant lowering of expenses; therefore, the reduced payments will result in lower

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85 "AMP Makes Things Tougher for Rx," *Chain Drug Review*, July 23, 2007.

86 *New York Times*, December 18, 2006.

87 CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77193.

88 CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77193.

net profit before taxes for retail pharmacies. In 2001, the NCPA-Pharmacia Digest reported that 13% of independent pharmacies had an operating loss, 28% had a net profit of less than 2%, 33% had a net profit between 2% and 5%, and 26% had a net profit of 5% or more.[89] Many of these pharmacies are already economically vulnerable and the changes due to the final rule reductions in payments for generic prescriptions are expected to have a significant impact on the pharmacy's long term viability. The majority of pharmacies already operating at a loss (13%) are likely to be closed within 1 to 3 years of the final rule implementation. Additionally some portion of pharmacies in the next two profit level categories (i.e., less than 2%, and 2% to 5%) are expected to be seriously harmed from the final rule cuts. Even if only 10% to 20% of the pharmacies with low net profit (before taxes) become unsustainable and go out of business, that would be 7% to more than 15% of pharmacies, in addition to the 13% already operating at a loss, that may cease to exist. In total, the loss of more than 20% of all retail pharmacies would not be unexpected from payment cuts of the magnitude in the final rule. If a similar proportion of all types of retail pharmacies is affected, the retail pharmacy market may see the loss of 10,000 to 12,000 pharmacies (the vast majority of which would be pharmacies in rural or inner city urban areas) over the next few years.

227. The majority of pharmacies will not be able to make up the lost revenue on sales elsewhere in the pharmacy as suggested by CMS.[90] In fact, a statement made by CMS in the proposed rule is factually wrong. That statement was "Actual revenue losses would be even smaller for two reasons. First, almost all of these stores sell goods other than prescription drugs, and overall sales average more than twice as much as prescription drug sales." Actually, in 2006, the average independent pharmacy derived 98.1% of its sales from prescriptions and the traditional chain pharmacy received 70.9% of its revenue from prescription sales. These pharmacies can not make up losses from 98.1% and 70.9% of their revenue by increased sales in the 1.9% or 29.1% non-prescription side of their pharmacy.[91]

228. Pharmacies faced with these dire economic choices would either refuse to serve Medicaid recipients, or even cease to exist as viable businesses.

229. The loss of a few thousand pharmacies in the United States, especially in rural and inner city areas, would be disruptive to access for many Medicaid recipients.[92] (*See* Exhibit 10). These pharmacies are most likely to be those in rural areas or in low income areas where there are high concentrations of Medicaid beneficiaries. These are the critical access pharmacies for the Medicaid program and the replacement of these critical access pharmacies, once lost, is not easily reversible.[93] (*See* Exhibit 11).

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89 2002 NCPA-Pharmacia Digest, National Community Pharmacists Association, p. 31.

90 CMS, Medicaid Program; Prescription Drugs, Proposed Rule, *Fed. Reg.*, Dec. 22, 2006, p. 77192.

91 NACDS, *The Chain Pharmacy Industry Profile*, 2007, p. 51.

92 National Rural Health Association, Protecting Rural Beneficiaries with a Medicare Prescription Drug Benefit, 2003, p.3.

93 Rural Pharmacy Preservation Act, Minnesota Pharmacists Association, 2005. Minnesota loses 38 pharmacies per year; 10-12 of those community pharmacies are not replaced. From July 2004 to February 2005, Minnesota lost 22 pharmacies.

230. Pharmacies are likely to be unwilling to provide prescriptions when the total payment falls short of the total actual drug product costs and the actual costs of dispensing and related additional costs. Pharmacies can be expected to refuse Medicaid recipients because the payments based on the new FUL reimbursement levels are too low, unless an adjustment is made to assure adequate total payments.

231. CMS, in a comment to the final rule, suggests that pharmacies can take steps to mitigate the effect of the sales loss by lowering (acquisition) costs. CMS stated "Actual revenue losses will be even smaller because pharmacies have the ability to mitigate the effects of the rule by changing purchasing practices. The 250 percent FUL will typically be lower than the prices available to pharmacies only when one or more very low cost generic drugs are included in the calculation. Pharmacies will often be able to switch their purchasing to the lowest cost drugs and mitigate the effect of the sales loss by lowering costs." (FR 39233, final rule) Unfortunately, CMS' suggested mitigation is not possible in many cases because the lowest prices that influence setting of the FUL are offered only to a specific class of trade, such as physicians and clinics, and are these lower prices are not available to retail pharmacies under the drug manufacturer's discriminatory pricing structure.

232. In fact, the studies of OIG and GAO have found that even with the 250 percent multiplier times the AMP, there will be a substantial number of drugs that have FUL amounts that are set lower than the lowest acquisition cost available to traditional retail pharmacies. This situation with lower FULs than the lowest acquisition cost available to traditional retail pharmacies results in part because the overly-broad definition of AMP, incorporating drug prices to pharmacies and providers who are not in the traditional retail pharmacy class of trade (e.g., physicians, clinics, nominal prices to charities and others, PBM mail order, non-profit organizations, and others), lowers the AMP in a way that retail pharmacies can not mitigate by their drug purchasing behavior.

233. Also, as mentioned earlier, when certain NDCs are sold only to specific classes of trade, there may be NDCs appearing to be on the market at lower prices, but these lower-priced NDCs may not be available to all pharmacy purchasers. Traditional retail pharmacies will not be able to modify their purchasing behavior to take advantage of all of the lower prices included in AMP since many of those lower prices are only available to specific classes of trade (i.e., physicians, clinics, hospital outpatient, and others).

234. The method used by CMS to estimate the reduction in payments to Medicaid was not described in sufficient detail to allow in depth examination or evaluation. However, the reduction in pharmacy payments resulting from the final rule is expected to have a substantial incremental impact on cuts in pharmacy payments above and beyond the cuts that would have been expected had CMS used the plain language or pharmaceutical market definitions of the "retail pharmacy class of trade" rather than their own greatly expanded interpretation of the statutes.

Dated: Nov. 13, 2007

STEPHEN W. SCHONDELMEYER, PHARM.D., PH.D.

Exhibit 1

Curriculum Vitae
Stephen W. Schondelmeyer, Pharm.D., Ph.D.

CURRICULUM VITAE

STEPHEN W. SCHONDELMEYER

PERSONAL DATA

Current Positions:
College of Pharmacy, University of Minnesota
* Professor of Pharmaceutical Management & Economics
* Century Mortar Club Endowed Chair in Pharmaceutical Management & Economics
* Department Head, Department of Pharmaceutical Care & Health Systems
* Director, *PRIME* Institute

Business Address:
PRIME Institute, 7-159 Weaver-Densford Hall, 308 Harvard Street, SE
College of Pharmacy, University of Minnesota, Minneapolis, MN 55455
Phone: (612) 624-9931; FAX: (612) 625-9931; e-mail: schon001@umn.edu
Home Address: 3507 Rae Court, Woodbury, MN 55125 Phone: (651) 731-5161
Date of Birth: August 9, 1950 **Place of Birth:** Sedalia, Missouri

LICENSURE

Registered as a pharmacist by examination in Missouri (since 1975) and Kentucky (since 1975).

EDUCATION

1968 **Honor Graduate**, Smith-Cotton High School, Sedalia, Missouri
1974 **Bachelor of Science in Pharmacy**
School of Pharmacy, University of Missouri-Kansas City, Kansas City, Missouri
1976 **Fellow, National Endowment for the Humanities** (History of Medicine)
Ohio State University, Columbus, Ohio
1977 **Doctor of Pharmacy and ASHP Residency Programs**
College of Pharmacy, University of Kentucky, Lexington, Kentucky
(Major areas: Clinical Pharmacy Practice, Clinical Research)
1979 **Master of Arts in Public Administration**
School of Public Administration, Ohio State University, Columbus, Ohio
(Major areas: Health Care Policy, Cost-Benefit Analysis)
1984 **Doctor of Philosophy in Administrative and Social Sciences in Pharmacy**,
College of Pharmacy, Ohio State University, Columbus, Ohio
(Major areas: Health Care Economics, Behavioral Epidemiology)

PROFESSIONAL MEMBERSHIPS

Current Memberships

1970-present American Pharmacists Association (APhA)
1977-present APhA–Academy of Pharmaceutical Research and Science (APhA-APRS)
1977-present APhA–Economic, Social & Administrative Sciences Section (APhA-APRS-ESAS)
1971-present American Society of Health System Pharmacists (ASHP)
1973-present American Public Health Association (APHA)
1975-present American Society for Pharmacy Law (ASPL)
1984-present Drug Information Association (DIA)
1976-present American Institute of the History of Pharmacy (AIHP)
1976-present American Association of Colleges of Pharmacy (AACP)
1991-present Minnesota Pharmacists Association (MPhA)
1991-present Minnesota Society of Hospital Pharmacists (MSHP)
1992-present AcademyHealth (*formerly Association for Health Services Research, AHSR*)
1992-present Academy of Managed Care Pharmacy (AMCP)
1995-present International Society for Pharmacoeconomics & Outcomes Research (ISPOR)
(*founding member; formerly Association for Pharmacoeconomics & Outcomes Research*)
1997-present Federation Internationale Pharmaceutique (FIP)
2004-present American Health Economics Association
2004-present International Health Economics Association

Previous Memberships

1984-1998 American Management Association (AMA)
1984-1998 American Marketing Association (AMA)
1984-1994 Academy for Health Services Marketing (ASHM)
1984-1987 APhA - Academy of Pharmaceutical Management (APhA-APM)
1980-1988 American Society for Public Administration (ASPA)
1976-1986 APhA - Academy of Pharmacy Practice (APhA-APP)
1971-1974 Phi Delta Chi, Beta Epsilon Chapter

HONORS AND AWARDS

2006 **APhA-APRS Research Achievement Award in Pharmaceutical Sciences**, March 19, 2006
(Awarded every three years by the American Pharmacists Association and the Academy of Pharmaceutical Sciences to recognize and encourage outstanding, meritorious achievement in the economic, social, and administrative sciences related to pharmaceuticals.)

2004 **Pharmacy Alumni Society's Faculty Recognition Award, University of Minnesota**, Oct. 16, 2004
(Given annually to a faculty member who has contributed substantially to the success of the College of Pharmacy and its leadership in the profession of pharmacy within Minnesota.)

2004 **Key Thinker in Drug Pricing Debate**, named by National Journal as one of 12 "key thinkers who are helping to shape the drug pricing debate" (National Journal, Vol. 36, Issue 21, May 22, 2004).

2000 **Paul F. Parker Award, University of Kentucky**, December 5, 2000
(Given annually to an individual of high personal and professional ideals who has made significant contributions to pharmacy practice.)

2000 **Fellow, American Pharmacists Association**, Academy of Research and Science, March 12, 2000

1997 **Top 50 Pharmacists in 1997**, named as one of: "a select group of professionals who have directly affected the way pharmacy is practiced today and will be tomorrow. These pharmacists have conducted research proving to those outside the profession that pharmacy, at its heart, is a cost-effective discipline that improves clinical outcomes . . ." (Am Druggist, Vol. 214, No. 10, Oct 1997, pp 36-57)

1996 **James L. Beal Post-Baccalaureate Distinguished Alumni Award**
Ohio State University, College of Pharmacy, 1996

1996 **Top 10 Pharmacists-1995**, Honorable Mention, "Top 10 Pharmacists, Making a Difference: Pharmacists at the Forefront" (Drug Store News for the Pharmacist, May 1995, pp. 40-47).

1993 **Who's Who Registry of Global Business Leaders**, 1993-95

1987 **Pharmacist of the Year**, Indiana Pharmacists Association, 1987

1977 **American Foundation for Pharmaceutical Education Fellowship**
Ohio State University, College of Pharmacy, 1977-1979

1977 **Outstanding Pharm.D. Award**, University of Kentucky, College of Pharmacy, May 1977
(Bluegrass Pharmaceutical Association award to a graduating Pharm.D. based on scholarship, leadership, attitude and personality)

1977 **Impact Award**, University of Kentucky, College of Pharmacy, May 1977
(Selected by the Pharm.D. residents as the one most likely to have the greatest impact on the profession of pharmacy)

1975 **Outstanding Young Men of America**, recognized in the 1975 edition

1974 **Who's Who Among Students in American Universities and Colleges**, 1974-75

1973 **Outstanding Senior Award**
University of Missouri-Kansas City, School of Pharmacy, Alumni Association, 1973

1973 **Dean of Students Honor List**, 1973, University of Missouri-Kansas City, one of 20 selected from more than 1,100 seniors at UMKC for outstanding scholarship and contribution to the University

PROFESSIONAL ACTIVITIES

Education (*current to oldest experience*)

1998-present **Department Head**, Department of Pharmaceutical Care & Health Systems,
College of Pharmacy, University of Minnesota

1996-1998 **Associate Dean for Research and Graduate Programs**,
College of Pharmacy, University of Minnesota

1991-present **Professor**, Pharmaceutical Economics & Management,
College of Pharmacy, University of Minnesota

1991-present **CMC Endowed Chair** in Pharmaceutical Management & Economics,
College of Pharmacy, University of Minnesota

1991-present **Director**, *PRIME* Institute, College of Pharmacy, University of Minnesota
1986-1991 **Associate Professor**, Department of Pharmacy Practice,
School of Pharmacy and Pharmacal Sciences, Purdue University
1986-1991 **Director**, Pharmaceutical Economics Research Center (PERC), Purdue University
1982-1986 **Assistant Professor**, Department of Pharmacy Practice,
School of Pharmacy and Pharmacal Sciences and
Center for Public Policy and Public Administration, Purdue University
1980-1982 **Assistant Professor**, Department of Pharmacy Practice,
College of Pharmacy, University of Arizona
1977-1980 **Graduate Teaching Associate**, College of Pharmacy, Ohio State University
1977 (spring) **Instructor**, College of Nursing, University of Kentucky
(taught Drugs and Drug Administration for senior nursing students)
1975-1976 **Patient Health Educator**, Trover Clinic, Madisonville, Kentucky

Graduate Education

1998-present **Senior Member**, Graduate Faculty in Gerontology, Center on Aging, Univ. of Minnesota
1998-present **Adjunct Professor**, Graduate Faculty in Social & Administrative Pharmacy,
College of Pharmacy, Khon Kaen University, Khon Kaen, Thailand
1996-present **Adjunct Professor**, Graduate Faculty in Social & Administrative Pharmacy,
College of Pharmacy, Chulalongkorn University, Bangkok, Thailand
1991-present **Senior Member**, Graduate Program in Social, Administrative & Clinical Pharmacy,
College of Pharmacy, University of Minnesota
M.S. (3 students: 1-advisor, 2-committee member)
Ph.D. (25 students: 18-advisor, 7-committee member)
M.S., Health Services Research (1 student: 1-committee member)
Ph.D., Health Services Research (1 student: 1-committee member)
Ph.D., Economics (1 student: 1-committee member)
Research Fellows (9 fellows: 5-advisor, 4 contributing faculty)
Courses taught: Health Care Reform and Pharmacy; Pharmaceutical Economics and Public Policy;
Pharmacy & Its Environment; Economic Evaluation of Pharmaceuticals; Pharmacy & the Health Care System
1982-1986 **Full Member**, Graduate Program in Public Policy & Public Administration,
Center for Public Policy & Public Administration, Purdue University
M.Pub.Adm. (2 students: 2-advisor)
1982-1991 **Full Member**, Graduate Faculty in Pharmaceutical Administration,
School of Pharmacy & Pharmacal Sciences, Purdue University
M.S. (7 students: 3-advisor, 4-committee member)
Ph.D. (10 students: 5-advisor, 5-committee member)
Courses taught: Health Care Economics and Public Policy; Consumer Behavior and Health Care;
Policy Management Strategies in Health Care; Post Marketing Surveillance Research; Pharmacy in the 21st Century;
Trends in the Pharmaceutical Industry; Cost Factors in Health Care Decisions; World Health Care Systems;
Marketing in Health Care; Review & Critical Evaluation of the Literature; Institutional Pharmacy Management
1980-1981 **Full Member**, Graduate Program in Pharmacy Practice, College of Pharmacy, Univ. of Arizona
M.S. (6 students: 4-advisor, 2-committee member)
Courses taught: Professional Practice Management; Controversies in Therapeutics; Health Care Organization;
Applied Hospital Pharmacy Management; Economic Aspects of Health Care; Pharmacy and the Professions

Pharmacy Practice (*current to oldest experience*)

1980-1982 **Community Pharmacist**, Gemco Pharmacy, Tucson, Arizona
1979-1980 **Assistant Director for Clinical Pharmacy Services**
Lancaster-Fairfield County Hospital, Lancaster, Ohio
1978-1980 **Community Pharmacist**, Wolfe's Drug, Baltimore, Ohio
1974-1977 **Clinical and Hospital Pharmacy Resident**, College of Pharmacy and
Albert B. Chandler Medical Center, University of Kentucky, Lexington, Kentucky
1971 (summer) **Pharmacy Intern**, Kansas City General Hospital & Medical Center, Kansas City, MO.
1970 (summer) **Pharmacy Intern**, Warren's R_x (community prescription shop), Sedalia, MO.

Consultation (*current to oldest experience*)

2006-present **Chrysler, Health Benefits and United Auto Workers**, Corporation-Union
Committee on Health Care Benefits, Detroit, MI
(Consultation on Rx tools and drug therapy decisions related to drug benefit management.)

2005-present **University of Minnesota, Health Benefits Department**, Minneapolis, MN
(Consultation on design & management of the pharmacy benefit for the University's self-insured employee & beneficiary health plan.)

2005-present **General Motors, Health Benefits and United Auto Workers**, Corporation-Union Committee on Health Care Benefits, Detroit, MI
(Consultation on Rx tools and drug therapy decisions related to drug benefit management.)

2003 **World Bank**, *Consultant*, Washington, DC
(Advise on bank policies that would increase and encourage improved access to essential drugs in developing countries.)

2002 **Massachusetts Department of Health Care Financing**, Commonwealth of Massachusetts, *Technical Consultant*, Boston, Massachusetts.
(Advised on implementation of legislation related to Medicaid pharmacy payment and prescription drug user fee.)

2001-present **Minnesota Attorney General**, *Technical Consultant*, Minneapolis, MN
(Drug policy and pricing issues related to state activities and interests.)

2001 **Federal Employee Health Benefit Program**, (administered by)
Blue Cross Blue Shield Association, *Technical Consultant*, Washington, DC
(Review and evaluation of bids from PBMs competing for the plan's pharmacy benefit service contract.)

2000-2001 **Priority Prescription Savings Program**, Iowa Department of Public Health, *Technical Consultant*
(Provided technical advice on program design, operation, and vendor selection.)

1999-2000 **Blue Cross Blue Shield Association**, *Consultant*, Washington, DC
(Review and selection of contractor to conduct research on the impact of pipeline drugs on future pharmacy costs.)

1999 **Kansas Pharmacy Services Corporation, Inc.,** *Strategic Planning Consultant*, Topeka, KS
(Conducted strategic planning workshop for pharmacy network and drug buying group.)

1999 **PCS Inc., Clinical Advisory Committee**, *Member*, Scottsdale, AZ.
(Advise on clinical and administrative aspects of PCS programs and policies.)

1996-1997 **U-Care HMO**, *Technical Advisor*, Minneapolis, MN
(Review and evaluation of bids from PBMs competing for the HMO's pharmacy benefit contract.)

1994 **Office of the Actuary, Health Care Financing Administration**, Department of Health & Human Services & Actuarial Research Corporation, *Technical Panel Member*
(Advise and comment on methods for revising the estimates of prescription drugs, non-prescription drugs, and non-durable medical supplies as part of the National Health Accounts for HCFA.)

1993-1998 **Abt Associates & Health Care Financing Administration**, *Technical Consultant*
(Review of plans for and progress of project titled "Evaluation of Medicaid Prospective Drug Utilization Review and Cognitive Services Demonstration Projects.")

1993-1994 **Centro Industrial de Laboratorios Farmaceuticos-Argentina**, *Consultant*, Buenos Aires, Argentina.
(Public policy and economic aspects of Argentinean-based pharmaceutical producers.)

1992-1996 **Pharmaceutical Assistance Contract for the Elderly (PACE)**, *Committee Member*, Prospective Drug Utilization Review Technical Advisory Committee, Department of Aging, Commonwealth of Pennsylvania.
(Oversight and advise on operation of point-of-service, on-line prospective drug utilization system for the PACE program providing prescription benefits to elderly Penn. citizens.)

1992 **Enhanced Pharmacy Care**, *Strategic Planning Consultant*, Jackson, MS.
(Conducted strategic planning workshop for retail pharmacy network and buying group.)

1992 **PACE Alliance, Inc.**, *Strategic Planning Consultant*, Lawrence, KS.
(Conducted strategic planning workshop for Board of this retail pharmacy buying group.)

1992-present **National Association of Chain Drug Stores**, *Economic Consultant*, Alexandria, VA.
(Advised on strategic planning, changes in the pharmaceutical market, economic impact of legislative and market changes, public policy analysis, and other issues.)

1991-1995 **U.S. General Accounting Office**, *Consultant*, Washington, DC.
(Advised GAO on various projects related to the impact of OBRA '90 on Medicaid, VA hospitals, and HMOs; and international & historical drug price comparisons.)

1991-1993 **United Health Care**, *Research Consultant*, Minneapolis, MN.
(Reviewer and advisor on pharmacoeconomic and pharmacoepidemiological research studies using the UHC pharmaceutical and other health care databases.)

1991-1994 **Center for the Study of Drug Development**, *Board Member*, Boston, MA.
(Reviewer and advisor on research issues and strategies.)

1991 **Auditor General of California**, *Consultant*, Sacramento, CA.
(Prepared report on the role of formularies in managing prescription drug expenditures. The report was incorporated in a report on "How Medi-Cal and Other Health Care Providers Manage Their Pharmaceutical Expenditures," August 1991.)

1991 **QA, Inc.**, *Strategic Planning Consultant*, Des Moines, IA.
(Conducted strategic planning workshop for this drug utilization review organization.)

1990-1992 **Health Economics Research & National Association of Chain Drug Stores**, *Consultant*, Alexandria, VA & Boston, MA.
(Provided expert advise on the development of an econometric model of the retail prescription market incorporating the impact on consumers, pharmacies, wholesalers, manufacturers, insurers, and payers.)

1986-present **Legislative and Government Agencies**.
(Numerous requests for information, interpretation, and technical assistance have been received from federal and state Congressional members and their staffs and from personnel at governmental agencies including Health Care Financing Administration, Congressional Budget Office, Congressional Research Service, Office of Technology Assessment, General Accounting Office, Food and Drug Administration, and State Medicaid agencies.)

1985-present **Expert Witness and Consultation Activities**
(Consultant and expert witness to cases involving pharmaceutical economics, marketing, manufacturer and retail pricing, third party reimbursement, postmarketing surveillance mergers and acquisitions, antitrust, and criminal behavior in the pharmaceutical market.)

1988-1989 **Prescription Drug Payment Review Commission**, *Commissioner*, Washington, DC
(This was an 11 member independent Congressional commission which served as an advisory body to Congress with respect to the outpatient drug program established by the Medicare Catastrophic Coverage Act of 1988.)

1986-1996 **MediSpan, Inc.**, *Consultant*, Indianapolis, IN
(Strategic planning for drug price and drug knowledge databases.)

1987 **Kansas Pharmacy Services Corporation, Inc.,** *Strategic Planning Consultant*, Topeka, KS
(Conducted strategic planning workshop for pharmacy network and drug buying group.)

1986 **Boehringer-Ingelheim Pharmaceuticals, Inc.**, *Pharmacy Education Advisory Board Member,* Ridgefield, CT
(Development of asthma care education programs and materials for pharmacists)

1985 **APhA Commission on Third Party Programs**, *Consultant*,
American Pharmaceutical Association, Washington, DC
(Consultant and author of paper on third party reimbursement.)

1984-1987 **Argus Computing, Inc**. and **Argus PMS, Inc.**, *Consultant*, Kansas City, MO
(Developed and managed Post Marketing Surveillance and Health Product Monitoring System.)

1984 **Texas Pharmaceutical Association** and **The Upjohn Company**, *Consultant*
(Developed an audiovisual tape, titled "JOIN" (Jump On In), which is an orientation to professional associations intended for recruitment of new and student members.)

1984 **Kansas Pharmacists Association**, *Strategic Planning Consultant*, Topeka, KS
(Membership marketing and strategic planning consultant.)

1984-1986 **American Pharmaceutical Association**, *Consultant*, Washington, DC
(Membership development and consultant on reimbursement policies for Medicaid)

1983-1988 **Indiana Pharmacists Association**, *Consultant*, Indianapolis, IN
(General consultant and special projects.)

1978 **Mid-Ohio Health Planning Federation**, *Consultant*, Columbus, OH
(Defined performance standards and measures and a self-evaluation process.)

1977-1979 **Lile and Heaton**, Attorneys at Law, *Expert Consultant*, Bellefontaine, OH
(Interpretation and evaluation of medical and disability cases.)

1977 **Cardinal Hill Hospital**, *Consultant*, Lexington, Kentucky
(Designed pharmacy services in 100-bed rehab. Hospital.)

1975-1977 **Kentucky Drug Formulary Council**, Department for Human Resources,
Commonwealth of Kentucky, *Drug Product Evaluation Consultant*, Frankfort, Kentucky
(Developed criteria for comparing bioavailability of drug products and evaluated "bioequivalence" of various drug products.)

Management (*current to oldest experience*)

1994-1995 **Pharmacy Direct Network**, *Board Member*, Alexandria, VA.
(PDN was a nationwide network of community pharmacies, both chains and independents, that marketed prescription distribution, management, and services to employers and managed care firms.)

1994-1995 **Pharmacy Care Associates of Minnesota**, *Board Member*, St. Paul, MN.
(PCA-MN is a Minnesota pharmacy provider network focused on delivering quality pharmaceutical care that assures improved patient outcomes while using resources efficiently.)

1992-1996 **Pharmacy Care Management Group, Inc.**, *Board Member*, Marshalltown, IA.
(PCMG is pharmacy benefits management firm which supports state-level pharmacy provider networks focused on delivering quality pharmaceutical care that assures improved patient outcomes while using resources efficiently.)

1991-present ***PRIME* Institute**, *Director*, College of Pharmacy, University of Minnesota
(The *PRIME* Institute is dedicated to being at the forefront of research and education related to pharmaceutical economic trends, competition in pharmaceutical markets, access and affordability of medicines, and financing and design of drug therapy benefits under insured and managed care programs.)

1986-1991 **Pharmaceutical Economics Research Center**, *Director*
Department of Pharmacy Practice, School of Pharmacy, Purdue University
(PERC served as a coordinated focus for research and scholarly study of economic issues related to pharmacy and the pharmaceutical industry.)

1986-1988 **The Prescription Network of Indiana, Inc.**, *President*, Indianapolis, IN 46204
(This for-profit pharmacy network provides for contracting to HMOs, PPOs, and other purchasers of pharmacy service benefits. The corporation is wholly-owned by the Indiana Pharmacists Association.)

1985-1986 **Indiana Pharmacy Services, Inc.**, *Secretary-Treasurer*, Indianapolis, IN 46204
(This for-profit buying group provides member pharmacies with economical access to pharmaceuticals and related products. The corporation is wholly-owned by the Indiana Pharmacists Association.)

1985-1987 **Argus PMS, Inc.**, *Vice President for Research and Development*,
Purdue Research Park, West Lafayette, IN
(Development/design of postmarketing surveillance system and research projects, Argus Health Product Monitoring System.)

1983-1988 **Department of Pharmacy Practice**, *Computer System Manager*,
School of Pharmacy and Pharmacal Sciences, Purdue University
(Designed, acquired, and supervised the operation and use of a multi-user computer system which included a network of microcomputers being used for word processing, data base management, graphics applications, and data storage.)

1977 (summer) **Center for Comprehensive Health Systems Development**, *Fellow*
Department for Human Resources, Commonwealth of Kentucky
(Served as a health planner in the office of Grace G. Eddison, M.D., Director of the Center; initiated and developed a drug-related data system and a State Health Plan for Pharmacy Services during the three-month experience.)

1975-1976 **Pennyrile Area Health Education System**, *Administrative Residency*, Madisonville, KY
(Developed health manpower data and needs assessment program.)

1973 (summer) **Indian Health Service, U.S. Public Health Service**, *Administrative Intern*, Rockville, MD
(Administrative training in the office of Allen J. Brands, Chief Pharmacy Officer, USPHS.)

1972 (summer) **Student American Pharmaceutical Association**, *Administrative Intern*, Washington, DC
(Development of association projects and programs.)

RESEARCH ACTIVITIES (*chronological order*)

1. Project IDEAS (International Drug Education Awareness for Students), Bureau of Educational and Cultural Affairs, U.S. Department of State, Aug.-Sept. 1972; grant to study and stimulate interest of health professional students in Europe in drug abuse education programs (8 countries).
   [*Note*: Items 2-10 represent bioavailability, pharmacokinetic, and Phase I, II, and III clinical research that was conducted through the Drug Product Evaluation Unit, College of Pharmacy, University of Kentucky under the direction of Thomas S. Foster, Pharm.D., Spring 1977.]
2. "Disposition of C^{14}-Cefatrizine in Human Volunteers," Bristol Laboratories, Jan. 23, 1977, Clinical Monitor
3. "Bioavailability Study of Digitoxin Oral Dosage Forms," FDA, Jan. 30 to Apr. 24, 1977, Clinical Coordinator.
4. "Pharmacokinetic Evaluation of Isosorbide Dinitrate Oral Dosage Forms," Ives Laboratories, Feb. 6-20, 1977, Clinical Coordinator.
5. "A Double Blind Evaluation of Efficacy and Safety of Proquazone (43-715) Compared to Aspirin in Outpatients with Osteoarthritis," Sandoz Pharmaceuticals, Spring 1977, Protocol Development.

6. "Bioavailability of Ketoprofen Oral Dosage Forms," Ives Laboratories, Apr. 17-24, 1977, Clinical Coordinator.
7. "Bioavailability and Pharmacokinetic Pilot Study of Chlorothiazide and Hydro-chlorothiazide," Food and Drug Administration, Feb. 27 to Mar. 1, 1977, Clinical Coordinator.
8. "Comparative Efficacy and Safety of Proloprim versus Macrodantin in Patients with Acute Uncomplicated Urinary Tract Infections," Burroughs Wellcome Co., Spring 1977, Protocol Development.
9. "Bioavailability Evaluation of Theophylline Oral Dosage Forms in a Normal Adult Population," Central Pharmacal Co., Mar. 27, 1977, Clinical Coordinator.
10. "Trasicor (BA-39089), Evaluation of Anti-Anginal Effects," Ciba-Geigy Corp., Spring, 1977, Clinical Coordinator.
11. "How Effective Are Drug Formularies? A Descriptive and Normative Study," Research Pharmacist under the direction of T. Donald Rucker and James A. Visconti, Ohio State University, Grant No. 1 RO1 FD00784-01, FDA, DHEW, Feb. 1976 to Mar. 1978.
12. "Program Evaluation of Pharmaceutical Services under Ohio Medicaid," Ohio Department of Public Welfare, Co-Principal Investigator, 1979.
13. "Quality Indicators for Drug Therapy in Nursing Homes: Development and Application of a Method," Co-Principal Investigator, 1979.
14. "An Evaluation of Alternatives for the Provision of On-Site Pharmaceutical Services in a Nursing Home," Handmakers Jewish Geriatric Center, Tucson, Arizona, $1,000, Principal Investigator, Apr. 1981 to Mar. 1982.
15. "Consumer Demand for and Economic Feasibility of Pharmacist-Provided Prescription Counseling," NIH Biomedical Research Support Grant, College of Pharmacy, University of Arizona, $9,500, Principal Investigator, Jul. 1981 to Dec. 1982.
16. "Arizona Pharmacy Manpower Study," College of Pharmacy, University of Arizona, $1,200, Principal Investigator, May to Nov., 1982.
17. "Professional Association Membership Decisions Among Pharmacists," School of Pharmacy and Pharmacal Sciences, Purdue University, $2,200, Principal Investigator, Dec. 1982 to Jan. 1984.
18. "Standard Reporting Terminology for a Pharmacy Database," AACP Special Projects Grant, $2,000, Principal Investigator, Sept. 1983 to Aug. 1985.
19. "Indiana Third Party Experience Survey," Indiana Pharmacists Association, $686 Principal Investigator, Spring 1984.
20. "Third Party-Induced Cost-Shifting in Community Pharmacy," Department of Pharmacy Practice, Purdue University, $2,000, Co-Investigator, May 1984 to Aug. 1985.
21. "A Community Pharmacy-Mediated Drug Monitoring Methodology," Pharmaceutical Manufacturers Association Foundation, $151,186, Co-Investigator, Mar. 1984 to Feb. 1986.
22. "R_X-to-OTC Switch: Industry Expectations and Impact Study," NIH Biomedical Research Support Grant, School of Pharmacy and Pharmacal Sciences, Purdue University, $2,000, Principal Investigator, May 1984 to Mar. 1985.
23. "Postmarketing Surveillance of OTC Analgesics," McNeil Consumer Products Company through Argus PMS, Inc., West Lafayette, IN, $410,000, Principal Investigator, May 1985 to Dec. 1986.
24. "Pharmaceutical Economic Trend Indicator Database Project," Pharmaceutical Economics Research Center (multiple sponsor project), $33,000, Principal Investigator, Jul. 1986 to 1991.
25. "Enhancement of Pharmacy Student Problem-Solving Ability Utilizing a Problem-Based, Self-Directed Learning Approach," David Ross XR Grant, Purdue University, $16,300, Co-Principal Investigator, Aug. 1986 to Jun. 1988.
26. "Analysis of Policy Alternatives under Proposed Rule for Limits on Payments for Drugs by the Health Care Financing Administration," American Pharmaceutical Association, $3,217, Principal Investigator, Oct. 1986.
27. "Development and Marketing of the Prescription Network of Indiana," Prescription Network of Indiana, Inc., $1,862, Principal Investigator, Oct. 1986 to Jun. 1988.
28. "Cost Effectiveness of Pharmaceuticals," Burroughs Wellcome, $500, Principal Investigator, Nov. 1986.
29. "Economic Consequences of Drug Therapy Decisions," Pracon, Inc., $2,783, Principal Investigator, Dec. 1986 to Jun. 1987.
30. "Changes in Unsponsored Hospital Care: 1981-1986," Center for Public Policy and Public Administration, Purdue University, Co-Investigator, Jan. 1987 to Feb. 1988.
31. "Prescription Event Intervention by Community Pharmacists in Indiana," Indiana Pharmacists Association, $500, Co-Principal Investigator, Feb. to Nov. 1987.
32. "Economic Impact of R_X-to-OTC Switches on Community Pharmacies," Pracon, Inc., $3,000, Principal Investigator, Jul. 1987 to Sept. 1988.

33. "Membership Survey of the Academy of Pharmaceutical Research and Science," American Pharmaceutical Association, $583, Principal Investigator, Jul. 1987 to Jan. 1988.
34. "Pricing Patterns of Generic Pharmaceutical Products," MediSpan, Inc., $6,000, Principal Investigator, Sept. 1987 to Dec. 1988.
35. "Impact of the Changing Health Care System on Marketing of Pharmaceuticals," Bristol-Myers Co., $300, Co-Principal Investigator, Jan. to Mar. 1988.
36. "Development of a Database Management System for Pharmaceutical Benefit Plans," American Financial Consulting Co., $23,750, Co-Principal Investigator, Spring 1988.
37. "National Pharmacists' Compensation Survey," American Pharmaceutical Association, $24,466, Co-Principal Investigator, Oct. 1988 to Jun. 1990.
38. "Pricing Patterns of Theophylline and Other Products," Schering-Plough Corporation, $45,855, Principal Investigator, Oct. 1988 to Jun. 1990.
39. "NACDS Resource Guide: The Chain Drug Store Industry and the Retail Pharmacy Market," National Association of Chain Drug Stores, $12,989, Co-Principal Investigator, Dec. 1988 to Nov. 1989.
40. "NACDS State of the Industry Report," National Association of Chain Drug Stores, $34,114, Co-Principal Investigator, Dec. 1988 to Nov. 1989.
41. "Report to Congress on Manufacturers' Prices and Pharmacists' Charges for Outpatient Drugs Covered by Medicare," Health Care Financing Administration, U.S. DHHS, $21,118, Co-Principal Investigator, Jan. to Feb. 1989.
42. "Membership Marketing for State Pharmacy Associations," Marion Laboratories, $30,000, Co-Principal Investigator, Mar. to Sept. 1989.
43. "Pharmacists Attitudes Toward and Performance of Patient Care Functions," Purdue University, Co-Investigator, Jul. 1989 to Aug. 1990.
44. "A Multi-center Study of Prescribing Errors in Community Pharmacy Practice," American Pharmaceutical Association Foundation, $30,000, Co-Principal Investigator, Jun. 1989 to Aug. 1990.
45. "Economic Life Cycle of Products Upon Facing Multiple Source Competition," Purdue University, Co-Investigator, Apr. 1989 to Aug. 1990.
46. "Economic Impact of Third Party Reimbursement Upon Chain Pharmacies," National Association of Chain Drug Stores, $79,406, Co-Principal Investigator, Jul. 1989 to Jun. 1990.
47. "Report to Congress on Manufacturers' Prices and Pharmacists' Charges for Prescription Drugs Used by the Elderly," Health Care Financing Administration, U.S. DHHS, $321,446, Co-Principal Investigator, Aug. 1989 to Jun. 1990.
48. "1990-91 National Pharmacists' Compensation Survey," American Pharmaceutical Association, $26,626, Co-Principal Investigator, Oct. 1990 to Sept. 1991.
49. "Analysis of Prescription Expenditures at the Dalton Foundries, Inc.: 1989 vs. 1990," Bill's Pill Box Pharmacy, $500, Principal Investigator, Jul. to Nov. 1990.
50. "Economic Impact of Multiple Source Competition on Originator Products: 1980 to 1988," Office of Technology Assessment, U.S. Congress, $10,000, Principal Investigator, Oct. 1990 to Jun. 1991.
51. "Current Pharmaceutical Discounting Practices: Impact of Discount Elimination on Institutional Pharmacies, American Society of Hospital Pharmacists, $2,000, Co-Principal Investigator, Jan. to May 1991.
52. "The 1990 Outpatient Prescription Market: Definition and Description," Eckerd Corporation, $1,000, Principal Investigator, Jul. 1991.
53. "Economic Impact of Multiple Source Competition on Originator Products: 1989 to 1990,"" Office of Technology Assessment, U.S. Congress, $10,000, Principal Investigator, Aug. 1991 to Dec. 1991.
54. "Pricing Trends of Pharmaceutical Products in 1985-92," MediSpan, Inc., $9,600, Principal Investigator, Jul. 1991 to Jun. 1992.
55. "The NACDS-PRIME Index: A System for Monitoring Drug Pricing Trends," National Association of Chain Drug Stores, $59,984, Principal Investigator, Sept. 1991 to Dec. 1992.
56. "Annual Prescription Survey of Chain Pharmacies,"" American Druggist, $5,000, Principal Investigator, Jan. to Mar. 1992.
57. "Effect of the Medicaid Drug Rebate on Generic Pharmaceutical Firms," Generic Pharmaceutical Industry Assoc., $10,000, Principal Investigator, Mar. to Jun. 1992.
58. "Price Changes of Drugs in the Top 200: 1987-1992," MediSpan, Inc., Total: $9600; Principal Investigator, Jul. 1992 to Jun. 1993.
59. "The Cost of Bill C-91: Economic Impact Analysis of the Elimination of Compulsory Licensing of Pharmaceuticals in Canada," Canadian Drug Manufacturers Association, Total: $35,000; Principal Investigator, Aug. 1992 to Jan. 1993.

60. "Research Center Master Contract," Health Care Financing Administration, RFP-92-015/PK, Total: $43,150; Direct: $35,301; Co-Investigator with Institute for Health Services Research, University of Minnesota, Aug. 1, 1992 to Jul. 31, 1995.
61. "Development of a Report on the Tax Impact of the Wholesale Drug Distributor Tax on the Pharmaceutical Market," Minnesota Department of Revenue, MNDR/67239-53131, Total: $19,957; Principal Investigator (with Judy A. Johnson), Sept. 1992 to Mar. 1993.
62. "Cost Efficiency of Mail Order versus Community Pharmacy Services," National Association of Chain Drug Stores, Total: $160,000, U of M $13,000; Co-Principal Investigator (with Jerry Cromwell of Health Econ. Research), Sept.1992 to Jun. 1993.
63. "Annual Prescription Survey of Chain Pharmacies," Hearst Publishing (American Druggist), Total: $5,000; Principal Investigator (with Judy A. Johnson), Jan. to Apr. 1993.
64. "The NACDS-*PRIME* Index: Tracking Changes in Drug Prices, 1993," National Association of Chain Drug Stores, Total: $25,279; Principal Investigator, Jan. 1993 to Feb. 1994.
65. "Cross-National Comparison of Brand and Generic Drug Prices: United States, Canada, and Venezuela," Marcel Curiel Foundation, Total: $3,000; Principal Investigator (with Dong-Churl Suh), Feb. to Jun. 1993.
66. "Economic Implications of Switching Oral Contraceptives to OTC Status," The Henry J. Kaiser Family Foundation, Total: $4,963; Principal Investigator (with Judy A. Johnson), Mar. to Jul. 1993.
67. "Evaluation of Drug Use Review Demonstration Projects," Health Care Financing Administration, RFP-HCFA-93-002-EE, Total: $2.3 million-Penn State University and Abt Associates; S.W. Schondelmeyer, ~$36,000; Principal Consultant, Apr. 1993 to Jun. 1998.
68. "Insurance Coverage of Oral Contraceptives and Economic Implications of Switching Oral Contraceptives to Over-the-Counter Status," Henry J. Kaiser Family Foundation, $5,000, Principal Investigator, Apr. 1993 to Jul. 1993.
69. "Annual Prescription Survey of Chain and Independent Pharmacies," Hearst Publishing (American Druggist), Total: $15,000; Principal Investigator (with Judy A. Johnson), Jul. 1993 to Apr. 1994.
70. "Impact of the Medicaid Drug Rebate Policy on Expenditures, Utilization and Access," Health Care Financing Administration, RFP-HCFA-93-077-PK, Total: $339,848; U of M: $128,180, Principal Investigator, Oct. 1, 1993 to Jun. 27, 1994.
71. "The NACDS-*PRIME* Index: Tracking Changes in Drug Prices, 1994," National Association of Chain Drug Stores, Total: $25,279; Principal Investigator, Jan. 1994-Feb. 1995.
72. "Evaluation of Prescription Pricing Trends," MediSpan, Inc., Total: $11,000, Principal Investigator, Jun. 1994 to May 1995.
73. "Impact of the Medicaid Drug Rebate Policy on Expenditures, Utilization and Access: Part II," Health Care Financing Administration, RFP-HCFA-93-077-PK no-cost extension; Principal Investigator, Jun. 27, 1994 to Oct. 31, 1994.
74. "Annual Prescription Survey of Chain and Independent Pharmacies," Hearst Publishing (American Druggist), Total: $5,000; Principal Investigator (with Judy A. Johnson), Jul. 1994 to Apr. 1995.
75. "The NACDS-*PRIME* Index: Tracking Changes in Drug Prices, 1995," National Association of Chain Drug Stores, Total: $25,279; Principal Investigator, Jul. 1, 1994 to Jun. 30, 1995.
76. "Aetna Pharmacoeconomic/Managed Care Fellowship," Marion Merrell Dow, 2-year post-Pharm. D. fellowship, $60,000 ($30,000 in 1994-95 and $30,000 in 1995-96) Fellowship Preceptor, Jul. 1994 to Jun. 1996.
77. "Impact of U.S. Health Care Reform and European Patent Law Changes on Accessibility to and Prices of Generic Pharmaceuticals in the United States," National Association of Pharmaceutical Manufacturers, Total: $29,684; Direct: $26,986, Stephen W. Schondelmeyer, Principal Investigator and John M. Coster Co-PI, Jul. 1994 to Jan. 1995.
78. "Impact of U.S. Health Care Reform on the Pharmaceutical Marketplace," American Association of Retired Persons, Total: $24,598; Direct: $22,362, John M. Coster, Principal Investigator and Stephen W. Schondelmeyer, Co-PI, Jul. 1994 to Dec. 1994.
79. "Pharmacy Reimbursement Trends Before and After the OBRA '90 Moratorium on Fee Decreases," American Pharmaceutical Association, Total: $5,000, Stephen W. Schondelmeyer, Principal Investigator and John M. Coster, Co-PI, Oct. 1, 1994 to Dec. 31, 1994.
80. "Impact of the Medicaid Drug Rebate Policy on Expenditures, Utilization and Access: Part II," Health Care Financing Administration, RFP-HCFA-93-077-PK continuation award, Total: $56,349; Direct: $54,033, Principal Investigator, Nov. 1, 1994 to Apr. 30, 1995.
81. "Economic Impact of GATT Patent Extension on Currently Marketed Drugs," National Association of Pharmaceutical Manufacturers and National Pharmaceutical Alliance, Total: $15,000, Stephen W. Schondelmeyer, Principal Investigator, Dec. 1994 to Mar. 1995.

82. "Survey of Hospital-Based Pharmaceutical Services in Spain," Sociedad Espanola de Farmacia Hospitalaria, Enrique Seoane and Stephen W. Schondelmeyer, Co-Principal Investigators, co-sponsored project between the PRIME Institute and the Spanish Society of Hospital Pharmacy, Feb. 1995 to Jun. 1995.
83. "Survey of Hospital-Based Pharmaceutical Services in Spain," Sociedad Espanola de Farmacia Hospitalaria, $10,000, Enrique Seoane and Stephen W. Schondelmeyer, Co-Principal Investigators, co-sponsored project between the PRIME Institute and the Spanish Society of Hospital Pharmacy, Feb. to Sept. 1995.
84. "Is Pharmacist Monitoring of Epoetin and Iron Cost-Effective?" Research Institute of the American College of Clinical Pharmacy, Research Award, $10,000, Wendy L. St. Peter, Pharm.D., Principal Investigator, Stephen W. Schondelmeyer, Co-Investigator, Jul. 1995 to Jun. 1996.
85. "The NACDS-*PRIME* Index: Tracking Changes in Drug Prices, 1996," National Association of Chain Drug Stores, Total: $35,895; Principal Investigator, Jul. 1995 to Dec. 1996.
86. "Assessment of Impact of Pharmacy Benefit Managers," Total Direct: $500; Health Care Financing Administration, U.S. DHHS, (HCFA-95-023/PK), Expert Panel, Jul. 12, 1995 to Jul. 11, 1996.
87. Impact of Formulary Restrictiveness on Pharmaceutical and Health Care Expenditures in Managed Care Plans, Total Direct: (funded as part of Pharmacoeconomic Fellowship), Mark V. Siracuse and Stephen W. Schondelmeyer, Co-Principal Investigators, and Jody Hessen, Co-Investigator, Aug. 1995 to Jun. 1996.
88. Market Potential and Business Development Assessment of a Potential Drug Product, Total Direct: $2,000, Upsher-Smith Laboratories, Stephen W. Schondelmeyer, Principal Investigator, and Enrique Seoane-Vazquez, Co-investigator, Aug. to Sept. 1995.
89. "Annual Prescription Survey of Chain and Independent Pharmacies," Hearst Publishing (American Druggist), Total: $5,000; Principal Investigator (with Judy A. Johnson), Dec. 1995 to May 1996.
90. "State Level Trends in Medicaid Drug Expenditures," Total Direct: $1,000, National Association of Chain Drug Stores, Stephen W. Schondelmeyer, Principal Investigator; Enrique Seoane-Vazquez, Co-Investigator, Dec. 1995 to Jan. 1996.
91. "Impact of Cooperative Purchasing on the Pharmaceutical Market: Section 1555 of the Federal Acquisition Streamlining Act," Public Hospital Pharmacy Coalition, Total: $20,000, Stephen W. Schondelmeyer, Principal Investigator with Ronald S. Hadsall and Darwin Zaske (Co-Investigators) Oct. to Dec., 1996.
92. "Generic Pharmaceutical Use in Venezuela," Total: $41,641 ($38,200 + $3,441), Fundacion Elias Morris Curiel, Stephen W. Schondelmeyer, Principal Investigator; Enrique Seoane-Vazquez, Co-Investigator, Oct. 1996 to Mar. 1997.
93. "Pharmacy Benefit Evaluation for U-Care," Total: $4,575, U-Care HMO, Stephen W. Schondelmeyer, Principal Investigator and Mark Siracuse, Co-Investigator, Nov. to Dec. 1996.
94. "A System for Monitoring Drug Prices Trends in 1997: The NACDS-*PRIME* Index," National Association of Chain Drug Stores, Total: $27,030; Principal Investigator, Jan. 1997 to Dec. 1997.
95. "Annual Prescription Survey of Chain and Independent Pharmacies, 1997" Hearst Publishing (American Druggist), Total: $5,000; Principal Investigator (with Enrique Seoane), Jan. to Jun. 1997.
96. "Trends in Medicaid Pharmaceutical Benefit Expenditures, 1995," National Association of Chain Drug Stores, Total: $1,500, Principal Investigator, Jan. 1997.
97. "Cost of Rheumatoid Arthritis," Economic Advisory Group, Ltd. (London, England), Total: $1,970, Stephen W. Schondelmeyer & Enrique Seoane-Vazquez, Co-Principal Investigators, May to Jun. 1997.
98. "Historical Development of Pharmacy," American Institute of the History of Pharmacy, $1,000, Mary Indritz, dissertation grant, June 1997.
99. "Epilepsy in the Elderly," NIH-NINES, Direct Cost: $650,000, James Cloyd, Principal Investigator, et al., Stephen W. Schondelmeyer, consultant (5% salary release, ~$6,000 per year), July 1997 to June 2002.
100. "Understanding the Costs of HIV Drugs and Identifying Purchasing Arrangements," Henry J. Kaiser Family Foundation through subcontract with Montefiore Medical Center, Total: $15,000; Principal Investigator, Oct. 1997 to Sept., 1998.
101. "Annual Prescription Survey of Chain and Independent Pharmacies, 1998" Hearst Publishing (American Druggist), Total: $5,300; Principal Investigator (with Enrique Seoane), Jan. 1998 to June 1998.
102. "A System for Monitoring Drug Prices Trends in 1998: The NACDS-PRIME Index," National Association of Chain Drug Stores, Total: $20,000 (C-U); Principal Investigator, January 1998-December 1998.

103. "Two Perspectives on Satisfaction: Patients and Pharmacists," American Pharmaceutical Association, APhA Foundation and Quality Center, Total: $34,570 (C-U); Principal Investigator (with Jill Acosta), Feb. 1, 1998 to May 31, 1999.
104. "HIV-Related Pharmaceuticals in the U.S. Market: Expenditures, Channels of Distribution, and Prescribing Trends," Henry J. Kaiser Family Foundation, Total: $61,500; Principal Investigator, March 15, 1998 to December 31, 1998 (extended to July 2000).
105. "Positioning and Pricing Hectorol in the Vitamin D Analog Market, Bone Care International, Inc., Madison, Wisconsin and Nephrology Pharmacy Associates, Inc., Ann Arbor Michigan, Total: $14,500; Principal Investigator (with Enrique Seoane), July 1998 to January 1999.
106. "The Financial Impact of Third Party Prescriptions on Community Pharmacies," National Community Pharmacists Association Foundation, Alexandria, VA, Total: $10,103, Co-Principal Investigator with Sam Wagner, Sept. 1998 to May 1999.
107. "Economic Consequences of Bone Marrow Transplants in the U.S., Economic Advisory Group, Bedford, England, Total: $5,450, Enrique Seoane and Stephen W. Schondelmeyer, Principal Investigators, December 1998 to January 1999.
108. "Minnesota Pharmacist Survey of Compensation and Patient-Centered Services," Minnesota Pharmacists Association, Total: $1,250 ($500 in-kind services), JC Schommer, RS Hadsall, T Larson, SW Schondelmeyer, DL Uden, Co-Investigators, 1999.
109. "Pharmaceutical Database Research Facility," College of Pharmacy, University of Minnesota, Total: $26,000, SW Schondelmeyer, RS Hadsall, JC Schommer, Co-Investigators, 1999.
110. "Legislative Strategies to Lower Drug Prices for All Vermonters," State of Vermont, Health Access Oversight Committee, Montpelier, Vermont, Total: $22,000, Principal Investigator, Aug. to Nov. 1999.
111. "Drug Expenditures of the Elderly: Projections from 1996 to 2010," Families USA Foundation, Washington, DC, Total: $20,900, Principal Investigator, January to June 2000.
112. "Survey of Pharmacists' Handling of Partial Fill Prescriptions Over the Past Decade," Eckerd Corporation, Salt Lake City, UT, Total: $78,831.33, Principal Investigator, May 2000 to Feb. 2001.
113. "Effects of Collaborative Pharmaceutical Care on Achieving Therapeutic Outcomes," Fairview Health System & University of Minnesota Academic Health Center, Grant 99-27, Minneapolis, MN, Total: $181,191, Brian Isetts, Principal Investigator; Stephen W. Schondelmeyer, Co-Investigator, Aug 2000 to June 2003.
114. "Pharmacoeconomic Fellowship Grant," Tsu Chiang Tu, Taipei, Taiwan, Total: $20,000, Sept. 2000 to May 2001.
115. "State Medicaid Drug Expenditure Trends, 1988-1998," National Association of Chain Drug Stores, Alexandria, VA, Total: $12,000, Principal Investigator, Dec. 2000 to June 2001.
116. "Product Characteristics of Top 300 Prescribed Drugs," Medquest, Inc., St. Paul, MN, Total: $5,000, Principal Investigator with Enrique Seoane, June to September, 2001.
117. "Pharmocoeconomic Analysis of Parecoxib for Pain Treatment in Outpatient Surgery and Emergency Room Departments," Pharmacia through Data Intelligence Consultants, Eden Prairie, MN, Total: $47,148.22, Principal Investigator with Enrique Seoane, July to December 2001.
118. "Managed Care Pharmaceutical Outcomes Dissertation Fellowship," Pharmacia Corporation, Total: $109,657, JC Schommer, RS Hadsall, SW Schondelmeyer, Co-Advisors, July 2001 to June 2003.
119. "Pharmacoeconomic Fellowship Grant," Fusiung Tsai, Taipei, Taiwan, Total: $25,000, Sept. 2001 to May 2002.
120. "Rate and Extent of Generic Penetration for Drug Entities Facing First Generic Competition: 1992-2001," Apotex, Inc., (provided data for analysis), Principal Investigator, August 2002 to June 2003.
121. "Prescription Drug Utilization In Medicaid: Using Medicaid Claims Data To Develop Prescription Drug Monitoring," Centers for Medicare & Medicaid Services, U.S. Department of Health & Human Services, RFP No. CMS-02-008/VAC, Mathematica Policy Research, Principal Investigator; Stephen W. Schondelmeyer, Technical Consultant, Sept. 2002 to Aug. 2004.
122. "State Medicaid Drug Expenditure Trends, 1982-2002," National Association of Chain Drug Stores, Alexandria, VA, Total: $15,000, Principal Investigator, Dec. 2002 to June 2003.
123. "Managed Care Pharmaceutical Outcomes Dissertation Fellowship," Pfizer Inc., Total: $144,250, JC Schommer, RS Hadsall, SW Schondelmeyer, R Cline, Co-Advisors, July 2003 to June 2006.
124. "Medicaid and Medicare Drug Pricing and Implementation Strategies," Centers for Medicare & Medicaid Services, U.S. Department of Health & Human Services, CMS-06-012/VAC, sub-contract through Abt Assoc,, Inc., Project Total: $157,000; UM Total: $57,667, Co-Principal Investigator with Marian Wrobel (Abt Assoc.), Oct. 1, 2003 to June 30, 2004.
125. "Tracking Senior Drug Prices: 2000-2004," AARP, Total: $45,000, Principal Investigator, January 1, 2004 to December 31, 2004.

126. "Evaluation of the Medicare Prescription Drug Discount Card and Transitional Assistance Program: Stakeholders Perspectives—Phase I," Centers for Medicare & Medicaid Services, U.S. Department of Health & Human Services, CMS 04-001/DTB, Project Total: $424,000, UM Total: $25,492, Senior Advisor (subcontract with Abt Assoc.), May 1, 2004 to March 31, 2005.
127. "Sales of Drugs & Biologicals to Large Volume Purchasers," Centers for Medicare & Medicaid Services, U.S. Department of Health & Human Services, CMS #500-00-0049, Task Order 1 modification, Project Total: $349,000, UM Total: $41,652, Co-Principal Investigator with Marian Wrobel (Abt Assoc.), July 1, 2004 to June 30, 2005.
128. "Case Study of Texas Vendor Drug Program," Centers for Medicare & Medicaid Services, U.S. Department of Health & Human Services, CMS #500-00-0049, Task Order 1 modification, Project Total: $142,000, UM Total: $42,878, Co-Principal Investigator with Marian Wrobel (Abt Assoc.), September 7, 2004 to June 30, 2005.
129. "Development of a Drug Price Database," Office of Inspector General, Department of Health & Human Services, Project Total: $24,999, Principal Investigator, September 15, 2004 to September 30, 2005.
130. "Tracking Senior Drug Prices: 2005 Quarterly Updates," AARP, Total: $20,000, Principal Investigator, January 1, 2005 to December 31, 2005.
131. "Evaluation of the Medicare Prescription Drug Discount Card and Transitional Assistance Program: Stakeholders Perspectives—Phase II," Centers for Medicare & Medicaid Services, U.S. Department of Health & Human Services, CMS 04-001/DTB, Project Total: $319,000, UM Total: $22,310, Senior Advisor (subcontract with Abt Assoc.), April 1, 2005 to February 28, 2006.
132. "Evaluation of Pharmaceutical Pricing Under Medicare Drug Card," Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services, Task Order Contract #100-03-0106, Project Total: $112,000, UM Total: $68,606, Principal Investigator (subcontract with Abt Assoc.), September 15, 2005 to August 31, 2006.
133. "Tracking Senior Drug Prices: 2006 Quarterly Updates," AARP, Total: $20,000, Principal Investigator, January 1, 2006 to December 31, 2006.
134. "Medicare Part D Impact on Pharmacies and Beneficiaries," College of Pharmacy, University of Minnesota, Total: $25,000, Co-Principal Investigator with MM Worley and RR Cline, July 2006 to June 2008.
135. "Evaluation of Best buy Drug Outreach Project," Attorneys General Consumer and Prescriber Education Grant Program, Total: $399,954, Co-Principal Investigators (Stephen W. Schondelmeyer and Jon C. Schommer), November 2006 to November 2008.
136. "Tracking Senior Drug Prices: 2007 Quarterly Updates," AARP, Total: $20,000, Principal Investigator, January 1, 2007 to December 31, 2007.
137. "Evaluating Effectiveness of the Minnesota Medication Therapy Management Care Program," State of Minnesota, Department of Human Services, Total: $47,781, Co-Investigator (Stephen W. Schondelmeyer) with Principal Investigator (Brian J. Isetts), March 1, 2007 to November 30, 2007.

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72. Alternatives for the Development of Access to Generic Pharmaceuticals in Venezuela, Stephen W. Schondelmeyer and Enrique Seoane-Vazquez (Caracas, Venezuela: Fundacion Elias Morris Curiel, Mar. 1997), 40 pp.
73. Medicamentos Genericos en Venezuela: Realidades y Perspectivas de Produccion, Distribucion y Consumo [Generic Medicines in Venezuela: Realities and Perspectives of Production, Distribution, and Consumption]. Stephen W. Schondelmeyer & Enrique Seoane-Vazquez, Proceedings of Invitational Conference sponsored by Venezuelan Minister of Health & Social Assistance with Fundacion Elias Morris Curiel. (Caracas, Venezuela: Fundacion Elias Morris Curiel, Mar. 1997), 27 pp.
74. Venezuelan Drug Products Which Are Available in the U.S. at Lower Prices, Stephen W. Schondelmeyer & Enrique Seoane-Vazquez (Caracas, Venezuela: Fundacion Elias Morris Curiel, Mar. 1997), 130 pp.
75. Mechanisms to Increase the Consumption of Generic Pharmaceuticals in Venezuela, Report to the President of the Republic of Venezuela (Dr. Rafael Caldera) Stephen W. Schondelmeyer and Enrique Seoane-Vazquez (Caracas, Venezuela: Fundacion Elias Morris Curiel, Mar., 1997), 10 pp.
76. Economics of Arthritis and Radiographic Progression, Stephen W. Schondelmeyer and Enrique Seoane-Vazquez (Minneapolis: *PRIME* Institute, University of Minnesota, Jun. 1997), 19 pp.
77. Economics of Arthritis and Radiographic Progression: Bibliographic Review, Stephen W. Schondelmeyer & Enrique Seoane-Vazquez (Minneapolis: *PRIME* Institute, Univ. of Minnesota, June, 1997), 35 pp.
78. Positioning and Pricing Hectorol in the Vitamin D Market. C Johnson, W St.Peter, S Schondelmeyer and E Seoane (Minneapolis: *PRIME* Institute, University of Minnesota, January 29, 1999), confidential report prepared for Bone Care International, Inc., Madison, Wisconsin, 62 pp.
79. Patent Extension of Pipeline Drugs: Impact on U.S. Health Care Expenditures. Stephen W. Schondelmeyer, (Minneapolis: *PRIME* Institute, University of Minnesota, July 28, 1999).
80. Kansas Pharmacy Services Corporation: Strategic Planning. SW Schondelmeyer (Minneapolis: *PRIME* Institute, University of Minnesota, September 1999).
81. Hard to Swallow: Rising Drug Prices for America's Seniors, Ron Pollack, Kathleen Haddad, (Washington, DC: Families USA Foundation, November, 1999), data analysis and charts prepared by Stephen W. Schondelmeyer, 16 pp.
82. Legislative Strategies to Lower Drug Prices for All Vermonters. Health Access Oversight Committee, State of Vermont. Stephen W. Schondelmeyer (Minneapolis: *PRIME* Institute, University of Minnesota, November 12, 1999), 58 pp.
83. A Description of Minnesota Pharmacists' Salaries and Work Activities, RS Hadsall, TA Larson, JC Schommer, SW Schondelmeyer, DL Uden, MM Worley, (Minneapolis, MN: *PRIME* Institute, University of Minnesota, November 9, 1999), published at: http://www.pharmacy.umn.edu/seoan001/prime/MNSalaries/sld001.htm
84. Still Rising: Drug Price Increases for Seniors, 1999-2000. Amanda McCloskey and Ron Pollack, (Washington, DC: Families USA Foundation, April 2000), data analysis and charts prepared by Stephen W. Schondelmeyer, 13 pp.
85. Cost Overdose: Growth in Drug Spending for the Elderly, 1992-2010. A McCloskey, et. al., Families USA Publication 00-107 (Washington, DC: Families USA Foundation, July 2000), data analysis and charts prepared by Stephen W. Schondelmeyer, 21 pp.
86. Pharmaceutical Discounts Under Federal Law: State Program Opportunities, William H von Ohesen, III, data analysis and charts prepared by Stephen W. Schondelmeyer, (Oakland, CA: Public Health Institute, May 2001), 48 pp.

87. Enough To Make You Sick: Prescription Drug Prices for the Elderly. A McCloskey, et. al., Families USA Publication 01-103 (Washington, DC: Families USA Foundation, June 2001), data analysis and charts prepared by Stephen W. Schondelmeyer, 19 pp.
88. Pharmacoeconomic Analysis of Parecoxib for Pain Treatment in Outpatient Surgery and Emergency Room Departments, Enrique Seoane and Stephen Schondelmeyer, (Minneapolis: *PRIME* Institute, University of Minnesota, Sept. 2001) confidential report prepared for Pharmacia-Upjohn, 116 pp.
89. Bitter Pills: The Rising Prices of Prescription Drugs for Older Americans. A McCloskey, et. al., Families USA Publication 02-104 (Washington, DC: Families USA Foundation, June 2002), data analysis and charts prepared by Stephen W. Schondelmeyer, 19 pp.
90. Market Exclusivity & Access to Pharmaceutical Products: 1980-2001, Stephen W. Schondelmeyer and Enrique Seoane (Washington, DC: Blue Cross Blue Shield Association, April 2002). 6 pp.
91. Worklife of Pharmacists in Minnesota, JC Schommer, RS Hadsall, TA Larson, SW Schondelmeyer, DL Uden, R Cline, (Minneapolis, MN: *PRIME* Institute, University of Minnesota, 2003), published at: http://www.pharmacy.umn.edu/seoan001/prime
92. Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2000 to 2003, DJ Gross, SW Schondelmeyer, SO Raetzman, AARP Public Policy Institute Report, June 2004, 45 pp.
93. Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans—First Quarter 2004 Update, DJ Gross, SW Schondelmeyer, SO Raetzman, AARP Public Policy Institute Issue Brief, June 2004, 4 pp.
94. Trends in Manufacturer List Prices for Generic Prescription Drugs Used by Older Americans, 2001 to 2003, DJ Gross, SW Schondelmeyer, SO Raetzman, AARP Public Policy Institute Report, October 2004, 42 pp.
95. Trends in Manufacturer List Prices of Generic Prescription Drugs Used by Older Americans—First Quarter 2004 Update, DJ Gross, SW Schondelmeyer, SO Raetzman, AARP Public Policy Institute Issue Brief, October 2004, 4 pp.
96. Trends in Manufacturer List Prices of Generic Prescription Drugs Used by Older Americans—Second and Third Quarter 2004 Update, DJ Gross, SW Schondelmeyer, SO Raetzman, AARP Public Policy Institute Data Digest, February 2005, 4 pp.
97. Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans—Second and Third Quarter 2004 Update, DJ Gross, SW Schondelmeyer, SO Raetzman, AARP Public Policy Institute Data Digest, April 2005, 16 pp.
98. Trends in Manufacturer List Prices of Generic Prescription Drugs Used by Older Americans—2004 Year-End Update, DJ Gross, SW Schondelmeyer, SO Raetzman, AARP Public Policy Institute Data Digest, April 2005, 5 pp.
99. Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans—2004 Year-End Update, DJ Gross, SW Schondelmeyer, SO Raetzman, AARP Public Policy Institute Issue Brief, June 2005, 17 pp.
100. Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices, Final Report, SW Schondelmeyer, MV Wrobel, (Abt Associates, Inc.), Centers for Medicare and Medicaid Services, Project # 500-00-0049, Task Order 1, June 21, 2004, 60 pp.
101. "Pharmacy Looks to the Future," Chapter 18 in Pharmacy and the U.S. Health Care System, Jack E. Fincham and Albert Wertheimer, Editors, (New York: Pharmaceutical Products Press, 2005), JC Schommer, RR Cline, DL Uden, TA Larson, RS Hadsall, and SW Schondelmeyer, pp 417-443.
102. Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans—First Quarter 2005 Update, DJ Gross, SW Schondelmeyer, SO Raetzman, AARP Public Policy Institute Data Digest, July 2005, 14 pp.
103. Trends in Manufacturer Prices of Generic Prescription Drugs Used by Older Americans—First Quarter 2005 Update, DJ Gross, SW Schondelmeyer, SO Raetzman, AARP Public Policy Institute Data Digest, July 2005, 4 pp.
104. Sales of Drugs and Biologicals to Large Volume Purchasers: Final Report, Marian V. Wrobel, Stephen W. Schondelmeyer, Susan Jureidini, Shuchita Agarwal, Rachel Sayko, A.C. Doyle, CMS Contract #500-00-0049, Task Order 1, September 19, 2005.
105. Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report, Marian V. Wrobel, Stephen W. Schondelmeyer, Shuchita Agarwal, and Janice Cooper, CMS Contract # 500-00-049, Task Order 1, September 26, 2005.

106. Evaluation of Pharmaceutical Pricing Under Medicare Drug Card: Final Report, Stephen W. Schondelmeyer, Margaret Artz, Shriram Parashuram, Lois Olinger, and Sarah Shoemaker, U.S. Dept. of Health & Human Services, Assistant Secretary for Planning and Evaluation, Task Order Contract #100-03-0106, November 16, 2006.
107. Implementation of pharmacy Payment Reform in the Minnesota Medicaid Program: Recommendations to the Legislature, Pharmacy Payment Reform Advisory Committee, SW Schondelmeyer (member), Minnesota Department of Human Services, January 15, 2007. 33pp. (plus attachments)

Book Reviews

1. Schondelmeyer, Stephen W., "Carolyn H. Asbury. Orphan Drugs: Medical Versus Market Value (Lexington, MA: D.C. Heath and Company, 1985), xvi + 219 pp.," American Journal of Pharmaceutical Education 49(3):338, Fall 1985.

Published Proceedings of Symposia and Conferences

1. "Health Professions Mobility," Proceedings of the National Student Conference on Health Manpower, Bureau of Health Manpower Education, NIH, DHEW, Mar. 11-12, 1972, Chicago, IL.
2. "Prospects for Postmarketing Surveillance of Multisource Drugs," Proceedings of Conference on Postmarketing Surveillance of Multisource Drugs, Center for the Study of Drug Development, Jul. 9-10, 1986, Boston, MA.
3. "Trends with Third Parties and Managed Health Care: A Pharmacy Perspective," Midwestern Conference on the Changing Health Care Environment: Its Impact on Pharmacy and the Pharmaceutical Industry, Nov. 12, 1987, Indianapolis, IN.
4. "The Impact of the Catastrophic Coverage Act of 1988," Proceedings of the IMS Client Conference, pp. 4, May 1989, (published Jul. 1989), Lake George, NY.
5. "The Changing Health Care Environment and Its Impact on the Role of the Pharmacist," Proceedings of the NABP-AACP District Three, Annual Meeting, Aug. 14, 1989, Charleston, SC.
6. "Economic Aspects of Switch," Proceedings of Drug Information Association Workshop on Rx-to-OTC Switch, May 8, 1989, Rockville, MD, pp. 37-44, (published Nov. 1989).
7. "Rx-to-OTC Switch: Question and Answer Session," Proceedings of Drug Information Association Workshop on Rx-to-OTC Switch, May 8, 1989, Rockville, MD, pp. 44-47, (published Nov. 1989).
8. "The Affordability of Medicines," Proceedings of Institute for Alternative Futures Congressional Foresight Seminar, Washington, DC, Mar. 14, 1990.
9. "Drug Information and Unlabeled Uses - 3rd Party Payment Requirements and Policies," Stephen W. Schondelmeyer, Proceedings of Drug Information Association Workshop on Unlabeled Uses of Marketed Prescription Drug, Rockville, MD, pp. 41-46, Oct. 22-23, 1990.
10. "Future Strategies for Dealing With Unlabeled Uses - Public Policy Alternatives and Private Initiatives," J. Richard Crout, Richard M. Cooper, Stephen W. Schondelmeyer, Louis Lasagna, Edward J. Huth, Proceedings of Drug Information Association Workshop on Unlabeled Uses of Marketed Prescription Drug, pp. 129-150, Oct. 22-23, 1990, Rockville, MD.
11. "Pharmacists' Reimbursement Under the Medicaid Prudent Pharmaceutical Purchasing Program," Stephen W. Schondelmeyer, Proceedings of Conference on Medicaid Prudent Pharmaceutical Purchasing: Implementation Issues, Center on Drugs and Public Policy, University of Maryland, pp. 61-68, Feb. 14, 1991, Baltimore, MD.
12. "Pricing Trends in the Pharmaceutical Industry," Stephen W. Schondelmeyer, Proceedings of the IBC Conference on Price Controls and Pricing Strategies for Pharmaceutical & Biotechnology Companies, Feb. 28, 1991, Washington, DC.
13. "Drug Utilization Evaluation Primer: Conceptual and Operational Aspects," William N. Yates, Michael T. Rupp, Stephen W. Schondelmeyer, Group Health Association of America, pp. 771-790, Jun. 25, 1991, New York, NY.
14. "The Future Direction of Healthcare and Managed Care's Bottom Line," Proceedings of Managed Care Advisory Board, Miles Laboratories, Stephen W. Schondelmeyer, Workshop Facilitator, Oct. 16-17, 1992, Chicago, IL.
15. "Prescription for Growth of Retail Drug Chains in the 1990s," Stephen W. Schondelmeyer, pp. 13-31, in Prescription for Growth: Retail Drug Seminar Review, Part 3 of 3, R. Duane Norris and Robert E. Miller, Salomon Brothers, Nov. 1992, New York, NY.

16. "Changes in the Drug Distribution System and the Economic Environment Since 1979," Unit-of-Use Packaging Contemporary Issues: Conference Proceedings, pp 10-23, University of Maryland Center on Drugs and Public Policy and the United States Pharmacopoeia, Dec. 13-15, 1992, Baltimore, MD.
17. "Pharmaceutical Price Indices: Changes Over Time and in Various Countries," Stephen W. Schondelmeyer, Conference on Pharmaceutical Industry Research, Innovation, and Public Policy, Kennedy School of Government, Harvard University, Feb. 25, 1993, Boston, MA.
18. "Impact of Mandated Changes on the Pharmaceutical Marketplace," Stephen W. Schondelmeyer, Valued Customer Workshop, Lederle Laboratories, Feb. 27, 1993, Park City, UT. pp 20-48.
19. "The Gift of Panakeia: Expanding Access to Pharmaceuticals & Ensuring Fair Prices," Working Group on Pharmaceuticals and National Health Reform, Mar. 19-20, 1993, Washington, DC.
20. "Health Care 2020: A Long Range Forecast - Reaction," 2020 Visions: Health Care Information Standards and Technologies, Stephen W. Schondelmeyer, United States Pharmacopoeia, Inc. (Rockville, MD: 1993), p. 40.
21. "Pitfalls in the Use of Socio-Economic Data Related to Pharmaceuticals," Proceedings of Symposia Series on the Socio-Economic Aspects of Drug Therapy Innovation, The Rhone-Poulenc Rorer Foundation (Antony, France: Jul. 1994).
22. "Prescription Prices -- Are They Competitive?" Proceeding of the 39th Annual Ohio Pharmaceutical Seminar on Managed Competition and Pharmaceutical Care: A Challenge for the Profession, Apr. 18, 1994, Columbus, OH.
23. "Gene Therapy: Socioeconomic Questions", Symposium Proceedings, Rhone Poulenc Foundation, June 1995, Yves Champey and Alan L. Hillman, editors; Stephen W. Schondelmeyer, panelist.
24. "New Visions, New Ventures: Pharmacy's Role in HEDIS and Performance Measurement," Advisory Panel, CIBAGeneva, Mar. 27, 1996, Washington, DC.
25. International Symposium Series: The 1998 National Health Care Symposium, Foundation Highlights, Rhone-Poulenc Rorer Foundation, Antony, France.
26. "Where is the Pharmaceutical Industry Taking Us?" Invited Presentation, Forum on Health Policy, University of Michigan, April 3, 1998, Ann Arbor, Michigan.
27. "Controlling Pharmacy Costs: Monitoring Drug Utilization and Outcomes in a Managed Care Environment," Participant, Healthcare Business Roundtable, March 4, 1999, San Francisco, CA.
28. "Price Transparency Issues in the Pharmaceutical Market," Pharmaceutical Costs and Pricing Practices, Invited Presentation and Invited Participant, Invitational Conference, U.S. Department of Health and Human Service, George Washington University, August 8, 2000, Washington, DC.
29. "Pharmacy Benefit Management," Participant, Minnesota Health Care Roundtable (April 19, 2002), Minnesota Physician,pp.20-25.
30. "Pharmaceuticals & Healthcare: An Evolving Relationship," Moderator, Health Leaders Conference, May 7, 2002, New York, NY.
31. Executive Roundtable on Pharmaceuticals, Institute of the Americas, October 2, 2002, Santiago, Chile.

Symposia and Workshop Planning and Participation

1. National Pharmacy Symposium on High Blood Pressure, Planning Committee Member, National Heart and Lung Institute, 1973-74.
2. Pharmacy in the 21st Century Conference, Project Hope, Mar. 25 to 28, 1984, Millwood, VA (One of 40 pharmacy leaders invited to participate in this assessment of pharmacy's future.)
3. Midwestern Conference on the Changing Health Care Environment: Its Impact on Pharmacy and the Pharmaceutical Industry, Planning Committee Member, Nov. 11-14, 1987, Indianapolis, IN.
4. Enhancing Executive Leadership in Schools of Pharmacy, Workshop Leader, Academic Management System, American Association of Colleges of Pharmacy, Feb. 18 to 20, 1988, San Diego, CA.
5. PMA Coordinated Industry Program for Pharmacy Faculty, two week visitation to The Upjohn Company, June 20 to 30, 1988, Kalamazoo, MI.
6. Strategic Planning Workshop on Catastrophic Coverage and Induced Demand for Prescription Drugs, invited participant, Institute for the Future, Jan. 29-30, 1989, Menlo Park, CA.
7. Quality of Pharmaceutical Care Invitational Conference, CA Pharmacists Association, Feb. 9-12, 1989, Monterey, CA.
8. Enhancing Executive Leadership, Academic Management System, Workshop Leader, American Association of Colleges of Pharmacy, Mar. 2-9, 1989, Dana Point, CA.
9. AWP Task Force, National Assoc. of Retail Druggists, Mar. 10, 1989, Alexandria, VA.
10. Health Care Outlook Workshop, Invited Participant, Institute for the Future, Jun. 14-16, 1989, Washington, DC.

11. Health Care Financing Administration Research Agenda Seminar, Invited Participant, American Pharmaceutical Institute, Jul. 25, 1989, Washington, DC.
12. Round Table Discussion on Financing Drug Therapy for the Elderly, Invited Participant, The John A. Hartford Foundation, Jul. 17, 1989, New York, NY.
13. DUR and Medicare Workshop, Invited Participant, American Pharmaceutical Institute, Sept. 12, 1989, Washington, DC.
14. Enhancing Executive Leadership, Workshop Leader, Academic Management System, American Association of Colleges of Pharmacy, Feb. 15-18, 1990, Monterey, CA.
15. Defining Multiple Levels of Medical Care, Invited Panelist, University of Michigan and National Academy of Sciences, Feb. 25-27, 1990, Ann Arbor, MI.
16. Drug Information and Unlabeled Uses - 3rd Party Payment Requirements and Policies, Session Moderator, Drug Information Association Workshop, Oct. 22, 1990, Washington, DC.
17. International Conference on Price Controls and Pricing Strategies for Pharmaceutical & Biotechnology Companies, Program Co-Chairman, International Business Communications, Feb. 28 - Mar. 1, 1991, Washington, DC.
18. 1992 Wharton Health Care Conference: What Price Innovation? Pharmaceuticals in the Era of Cost-Containment, Session Moderator, Measuring Competition in the Pharmaceutical Industry, The Wharton School, University of Pennsylvania, Feb. 21, 1992, Philadelphia, PA.
19. Pharmaceutical Pricing: Forces, Trends, & Strategies, Program Co-Chairman, International Business Communications, Mar. 26-27, 1992, Washington, DC.
20. Accountability in Health Care - Considerations for the Professions, Seventh Annual Health Care Public Policy Conference, Planning Committee, Apr. 7, 1992, Minneapolis, MN.
21. The Role of Pharmaceuticals in Health Care: Cost and Outcomes, Workshop Chairperson, Association for Health Services Research, Jun. 9, 1992, Chicago, IL.
22. USP 2020: Medicines and Technologies Conference, Invited Participant, United States Pharmacopoeial Convention, Sept. 9-11, 1992, Annapolis, MD.
23. Managed Care Advisory Board, Workshop Facilitator, Miles Laboratories, Oct. 16-17, 1992, Chicago, IL.
24. "Unit-of-Use Packaging Contemporary Issues," University of Maryland Center on Drugs and Public Policy and the United States Pharmacopoeia, Dec. 13-15, 1992, Baltimore, MD.
25. "Pharmaceutical Price Indices: Changes Over Time and in Various Countries," Conference on Pharmaceutical Industry Research, Innovation, and Public Policy, Kennedy School of Government, Harvard University, Feb. 25, 1993, Boston, MA.
26. "Impact of Mandated Changes on the Pharmaceutical Marketplace," Valued Customer Workshop, Lederle Laboratories, Feb. 27, 1993, pp 20-48, Park City, UT.
27. "The Gift of Panakeia: Expanding Access to Pharmaceuticals & Ensuring Fair Prices," Working Group on Pharmaceuticals and National Health Reform, Mar. 19-20, 1993, Washington, DC.
28. "Pharmaceutical Pricing '93: Pricing and Operational Strategies," Conference Chairperson, Third Annual IBC Conference, Mar. 25-26, 1993, Washington, DC.
29. Wintergreen Research Conference II, Invited Participant, University of Maryland, Apr. 15-18, 1993, Charlottesville, VA.
30. Canadian Collaborative Workshop on Pharmacoeconomics, Invited Participant, Jun. 21-22, 1993, Sainte-Adele, Quebec, Canada.
31. Aetna's Third Annual Manufacturers' Orientation Program: Synergistic Success, Participant, Aetna Health Plans, Jun. 29, 1993, Hartford, CT.
32. Forum on OTC Oral Contraceptives, Kaiser Family Foundation, Invited Participant, Jul. 7-9, 1993, Menlo Park, CA.
33. Working Group on Pharmaceuticals and National Health Reform, Participant, Nov. 4-5, 1993, Washington, DC.
34. "The Use of Socio-Economic Data on New Drug Therapies by Health Decision Makers," Invited Presenter, Symposia Series on the Socio-Economic Aspects of Drug Therapy Innovation, The Rhone-Poulenc Rorer Foundation, Nov. 10, 1993, Antony, France.
35. "Principles of Paying for Pharmaceutical Services," Invited Presenter, Seminar on Pharmaceutical Remuneration: Paying Pharmacists to Meet Patients' Needs, Pharmacy Practice Research Resource Centre, Royal Pharmaceutical Society of Great Britain, Dec. 2, 1993, London, England.
36. Task Force on Principles for Economic Analysis, Task Force Member, Leonard Davis Institute for Health Economics, Mar. 22-23, 1994, Philadelphia, PA.
37. Public Policy Track, Pharmaceutical Pricing and Healthcare Reform Legislation, Session Chairperson, 30th Annual Meeting, Drug Information Association, Jun. 9, 1994.

38. Public Policy Track, Restructuring in the Pharmaceutical Marketplace: Impact on Pharmaceutical Pricing, Session Chairperson, 30th Annual Meeting, Drug Information Association, Jun. 9, 1994.
39. Task Force on Principles for Economic Analysis of Health Care Technology, Task Force Member, Leonard Davis Institute, University of Pennsylvania, 1993-1994.
40. CA Bioscience and Health Care Reform Conference, Univ. of California, Jul. 8, 1994, Los Angeles, CA.
41. Midwest Pharmacy Administration Conference, University of Iowa, Aug. 27, 1994, Iowa City, IA.
42. "An Evaluation of Medicaid Drug Expenditures under OBRA 90," and "Understanding Expenditure and Distribution Channels in the Pharmaceutical Market," Wintergreen Research Conference III, Oct. 13-16, 1994, Wintergreen, VA.
43. International Workshop on Pharmacoepidemiology and Pharmacoeconomics for the Implementation of National Drug Policy, Ministry of University Affairs, Invited Speaker, Apr. 17-21, 1995, Chiang Mai, Thailand.
44. Relationship Between Public and Private Sectors in Drug Development, National Science Foundation Working Group, Albert Einstein College of Medicine, Yeshiva Univ., June 2, 1995, New York, NY.
45. Workshop on Gene Therapy: Socioeconomic Questions," Rhone Poulenc Rorer & Leonard Davis Institute, University of Pennsylvania, Jun. 26, 1995, Philadelphia, PA.
46. New Visions, New Ventures: Pharmacy's Role in HEDIS and Performance Measurement, Advisory Panel, CIBAGeneva, Mar. 27, 1996, Washington, DC.
47. Wintergreen Research Conference IV, Center on Drugs and Public Policy, University of Maryland, May 2-5, 1996, Wintergreen, VA.
48. PBMs: Reshaping the Pharmaceutical Distribution Network, A Roundtable (invited participants only), American Academy of Arts and Sciences and the Center for the Study of Drug Development, Tufts University, Oct. 24, 1996, Boston, MA.
49. Free Trade Area of the Americas (FTAA), Invited Participant, III Americas Business Forum, Workshop on Technology and Intellectual Property, May 13-15, 1997, Belo Horizonte, Brazil.
50. National Health Care Symposium, 1998, Planning Committee Member, International Symposium Series, Rhone-Poulenc Rorer Foundation, January 29-30, 1998, Philadelphia, PA.
51. Managing the Pharmacy Benefit, participant, 1999 University of Arizona Conference, January 25-27, 1999, Tucson, AZ.
52. "Compensation for Pharmaceutical Care and Professional Activities," Strategic and Tactical Analysis Team on Pharmacy Payment and Empowerment, American Pharmaceutical Association, September 23, 2000, Washington, DC.
53. Policy Issues in Prescription Drug Benefit Design and Implementation, Session Chair, Policies & Pastries Session, Annual Meeting, American Pharmaceutical Association, March 18, 2001, San Francisco, CA.
54. Medicare Prescription Drug Issues Workshop, Invited Presentation, American Public Health Association, October 21, 2001, Atlanta, GA.
55. Synthesis of Health Services Research for Policy Makers, Invited Participant, sponsored by Agency for Healthcare Research & Quality and Robert Wood Johnson Foundation, November 27, 2001, Washington, DC.
56. Pharmacogenomics: The Legal, Ethical, & Clinical Challenges, Panel Commentator, sponsored by the Consortium on Law and Values in Health, Environment & the Life Sciences, University of Minnesota, February 26, 2002, Minneapolis, MN.
57. Pharmacy Benefit Management, Invited Participant, Minnesota Health Care Roundtable, April 19, 2002, Minneapolis, MN.
58. Pharmaceuticals & Healthcare: An Evolving Relationship, Moderator, Health Leaders Conference, May 7, 2002, New York, NY.
59. Executive Roundtable on Pharmaceuticals, Institute of the Americas, October 2, 2002, Santiago, Chile.

Government Hearings and Public Service Presentations

1. "Statement of the Student American Pharmaceutical Association Regarding Health Manpower Legislative Proposals," U.S. House of Representatives, Committee on Interstate-Foreign Commerce, Subcommittee on Public Health and Environment, 93rd Congress, Second Session, May 23, 1974.
2. Testimony on drug product selection bills before the House and Senate, Ohio State Legislature, 1976.
3. Testimony on drug product selection and third party insurance bills before the House and Senate, Indiana General Assembly, 1983 & 1984.
4. Statement before the Indiana General Assembly Interim Committee to Study Licensing of Health-Related Occupations, Jul. 18, 1984. A 24-page statement was prepared and presented describing the 17 health-related education programs at Purdue University, Indianapolis, IN.

5. "Concept Paper on a New Basis for Reimbursement of Pharmaceutical Services," 6 pp., presented to the Indiana Department of Public Welfare, Medicaid Office (Sept. 1984).
6. "Medication Use by the Elderly: A Review of Issues and the Pharmacist's Role," 13 pp., submitted to the Indiana State Board of Health upon a request for information on medication use by the elderly (Sept. 1984).
7. "Comments on Over-the-Counter Marketing of Beta-Adrenergic Bronchodilators in Metered-Dose Inhalers," presented to the Pulmonary-Allergy Drugs Advisory Committee, Food and Drug Administration, May 19, 1986, Bethesda, MD.
8. "Statement of the American Pharmaceutical Association on Proposed Rule for Limits on Payments for Drugs by the Health Care Financing Administration," Stephen W. Schondelmeyer, Joseph Thomas III, and Jack Schlegel, American Pharmaceutical Association, Policy Statement, Oct. 1986.
9. "Impact of Alternative Reimbursement Limits for Coverage of Multi-source Prescriptions Under Medicare," prepared for the Finance Committee, United States Senate, Feb. 22, 1988.
10. "Review and Comment on the Reimbursement Procedures Used by Louisiana Medicaid," expert testimony at Health Care Financing Administration Administrative Hearing, Sept. 19 and 20, 1988, Dallas, TX.
11. "Policy Paper on Pharmacy Reimbursement Issues Under the Medicare Catastrophic Coverage Act," American Pharmaceutical Association, Washington, DC, Apr. 1989, 10 pp, written by Stephen W. Schondelmeyer.
12. "Prescription Drug Coverage Under Medicaid," Statement before Joint Subcommittee Studying Pharmaceutical Costs in the Virginia Medical Assistance Program pursuant to HJR403, General Assembly, Commonwealth of Virginia, Aug. 8, 1989.
13. "Pharmaceutical Pricing and Reimbursement," Invited Seminar, Senate Finance Committee, Health Staffers Luncheon, May 15, 1990, Washington, DC.
14. "Medicaid Drug Prices and Expenditures: Issues and Options," Statement before the Subcommittee on Health of Families and Uninsured, Committee on Finance, United States Senate, Sept. 17, 1990, Washington, DC.
15. "Impact of Mail Order Option on Medex Drug Program," Administrative Hearing before Hearing Officer, Massachusetts Insurance Commissioner, Jan. 2, 1991, Boston, MA.
16. "Estimated Impact of the Medicaid Prudent Pharmaceutical Purchasing Program on the Arkansas Medicaid Program," prepared for Special Committee on Aging, United States Senate, Feb. 1991.
17. "Prescription Drug Prices and the PACE Program," Hearing before Pharmaceutical Assistance Review Board, Commonwealth of Pennsylvania, Mar. 21, 1991, Harrisburg, PA.
18. "Manufacturer Price Inflation for Prescription Drugs: 1985-1995," prepared for the Special Committee on Aging, United States Senate, Mar. 1991.
19. "Prescription Drug Insurance Programs: Costs and Benefits," Hearing before the House State Health Benefit Plan Pharmacy Program Study Committee, GA House of Representatives, Aug. 6, 1991, Atlanta, GA.
20. "Statement on the Public Health Clinic Affordable Drug Act," Statement before the Committee on Labor and Human Resources, U.S. Senate, Oct. 16, 1991, Washington, DC.
21. "Prescription Drug Market and Price Trends," Health Financing and Policy Issues, Human Resources Division, U.S. General Accounting Office, Dec. 17, 1991, Washington, D.C.
22. "Quality Management of a Prescription Benefit for the Elderly," Pennsylvania Department of Aging, Jan. 14, 1992, Harrisburg, PA.
23. "Impact of Eroding Pharmaceutical Discounts on Healthcare Institutions," American Society of Hospital Pharmacists Congressional Seminar, Jan. 15, 1992, Wash., D.C.
24. "Buying Groups and Pharmaceutical Purchasing," Minnesota Multi-State Buying Group, State of Minnesota, Feb. 12, 1992, St. Paul, MN.
25. "Pharmaceutical Legislation and Regulation," Policy Rap Session, Health Care Financing Administration, Mar. 25, 1992, Washington, DC.
26. "Medicaid Rebates Expected in 1992," New York State Legislative Committees, Jun. 3, 1992, Albany, NY.
27. "Drug Prices, Polices, and Polemics: Perspective on the Industry," United States General Accounting Office, Comptroller General's Health Advisory Board, Jun. 4, 1992, Washington, D.C.
28. "Projections of Manufacturer Rebates Under the New York State Medicaid Program," Medicaid Committee, New York State Legislature, Jul. 14, 1992, Albany, NY.
29. "Effect of Bill C-91 on the Canadian Pharmaceutical Industry," Industry, Science, and Technology Canada, Aug. 26, 1992, Ottawa, ON, Canada.
30. "ISTC Analysis of Bill C-91 Impact on the Canadian Pharmaceutical Industry," Industry, Science, and Technology Canada, Sept. 16, 1992, Ottawa, ON, Canada.

31. "The Future of Pharmaceutical Pricing," Congressional Foresight Seminar, Institute for Alternative Futures, Sept. 21, 1992, Washington, DC.
32. "The Cost of Bill C-91: An Economic Impact Analysis of the Elimination of Compulsory Licensing of Pharmaceuticals in Canada," Legislative Committee on Bill C-91, House of Commons, Parliament, Canada, Dec. 1, 1992, Ottawa, ON, Canada.
33. "Fair Drug Pricing for Drugs Developed in Conjunction with the NIH," 66th Meeting, Advisory Committee to the Director, National Institutes of Health, Dec. 2, 1992, Bethesda, MD.
34. "The Cost of Bill C-91: An Economic Impact Analysis of the Elimination of Compulsory Licensing of Pharmaceuticals in Canada," Senate Standing Committee on Banking, Trade, and Commerce, Parliament, Canada, Jan. 21, 1993, Ottawa, ON, Canada.
35. "Drug Pricing and the Contribution of the Government to Drug Development," Statement before the Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business, U.S. House of Representatives, Jan. 25, 1993, Washington, DC.
36. "How Do Pharmacists Determine a Prescription Price?" Congressional Member and Staff Seminar, Special Committee on Aging, U.S. Senate, Feb. 19, 1993, Washington, DC.
37. "International Prescription Drug Prices: Implications for U.S. Policy," Statement before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, Feb. 22, 1993, Washington, DC.
38. "Pharmacy Opportunities in Health Care Systems of the 1990s," Invited Presentation, Health Care Decisions for the 90s Committee, a joint committee of the Kansas House of Representatives and Senate, Aug. 19, 1993, Topeka, KS.
39. "Implications of Pharmaceutical Coverage and Expenditures for U.S. Health Care Reform," Statement before Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, Feb. 8, 1994, Washington, DC.
40. "Pharmaceuticals Under Health Care Reform," statement before the Finance Committee, United States Senate, Apr. 19, 1994, Washington, DC.
41. "Impact of the Argentinean Pharmaceutical Industry on Consumer Access to Pharmaceuticals," statement before the Health Committee of the Argentinean Congress, May 10, 1994, Buenos Aires, Argentina.
42. "Competition and Pricing in the Pharmaceutical Industry," invited presentation to Congressional members and staffers, House of Representatives, U.S. Congress, Aug. 4, 1994, Washington, DC.
43. "Competition and Pricing in the Pharmaceutical Industry," invited presentation to Congressional members and staffers, Senate, U.S. Congress, Aug. 4, 1994, Washington, DC.
44. "Vertical Integration Issues in the Pharmaceutical Market," Federal Trade Commission, meeting with Chairman, Commissioners, and staff, Oct. 5, 1994.
45. "Impact of Vertical Integration in the Pharmaceutical Market on Consumers," Federal Trade Commission, meeting with Commissioner and staff, Oct. 24, 1994.
46. "Changes in the Health Care Landscape: Impact on Pharmaceutical Manufacturers and the Pharmaceutical Market," Changes in the Health Care Landscape Workshop, U. S. General Accounting Office, Nov. 14, 1994, Washington DC.
47. "Medicaid Reimbursement of Pharmacy Services in Minnesota," Minnesota Legislature members, staff and administration staff; technical advice provided upon request, fall 1994 and spring 1995.
48. "Spanish Hospital Pharmacy Needs and Experience from the U.S.," Galician Health Authority, Jun. 24, 1996, Santiago de Compostello, Spain.
49. "Situation and Perspectives on Spanish Hospital Pharmacy: An Overview," Joint Symposium of Sociedad Espanola de Farmacia Hospitalaria and the Sociedad Espanola de Medicina, Presentation to the Spanish Minister of Health (Jose Manuel Romay Beccaria), Jun. 27, 1996, Madrid, Spain.
50. "Economic and Policy Issues Related with Access to AIDS Therapy," Presidential Advisory Council on HIV & AIDS, Sept. 9, 1996, Bethesda, MD.
51. "PBMs Activities and Impact on the Pharmaceutical Marketplace," meeting with Federal Trade Commission Chairman Robert Pitofsky, Nov. 14, 1996, Washington, DC.
52. "Generic Pharmaceuticals in Venezuela: Issues and Directions," presentation to the Venezuelan Minister of Health and Social Assistance (Ministerio de Sanidad y Asistencia Social, Dr. Pedro Rincon Gutierrez), Feb. 3, 1997, Caracas, Venezuela.
53. "Mechanisms to Increase the Consumption of Generic Pharmaceuticals in Venezuela," private presentation to the President of the Republic of Venezuela (Dr. Rafael Caldera), Feb. 3, 1997, Caracas, Venezuela.
54. "The Impact of Bill C-91: Actual Economic Impact from Elimination of Compulsory Licensing of Pharmaceuticals in Canada," testimony to committee of House of Commons, Parliament, Canada, April 8, 1997, Ottawa, ON, Canada.

55. "Comments on Report: Technology & Intellectual Property Rights, Competition Policy, Standards and Non-Tariff Barriers to Trade," Free Trade Area of the Americas Conference, May 14, 1997, Belo Horizonte, Brazil.
56. "Future Leadership on Access to Care and Treatment Issues," Services Subcommittee, Presidential Advisory Committee on HIV and AIDS, November 18, 1998, Washington, DC.
57. "Affordability and Access to Pharmaceuticals," Prescription Drug Task Force, Congress of the United States, Panel Discussion, February 24, 1999, Washington, DC.
58. "Rx Drug Expenditures: Role of Generics." S. W. Schondelmeyer, Ph.D., Congressional Briefing on Role and Impact of Generics, Washington, DC, October 6-7, 1999.
59. "Structure and Behavior of the Pharmaceutical Market: Factors Affecting Price and Expenditures," testimony before the Health Access Oversight Committee, Legislative Council, State of Vermont, June 21, 1999, Montpelier, VT.
60. "Prescription Drug Costs," testimony before the Health Access Oversight Committee, Legislative Council, State of Vermont, August 18, 1999, Montpelier, VT.
61. "Exploring Options for State Action on Prescription Drug Expenditures," testimony before the Health Access Oversight Committee, Legislative Council, State of Vermont, Sept. 24, 1999, Montpelier, VT.
62. "Rx Drug Expenditures: Role of Generics," Congressional Briefing, Generic Drug Equity Caucus, United States Congress, October 7, 1999, Washington, DC.
63. "Legislative Strategies to Lower Drug Prices for All Vermonters," testimony before the Health Access Oversight Committee, Legislative Council, State of Vermont. Stephen W. Schondelmeyer, ***PRIME*** Institute, University of Minnesota, Montpelier, VT, November 5, 1999.
64. "Prescription Drug Expenditures and Costs," executive staff meeting, U.S. Department of Health and Human Service, December 9, 1999, Washington, DC.
65. "Structure and Behavior of Pricing in the Pharmaceutical Market," Health Committee, House of Representatives, State of Vermont, March 29, 2000, Montpelier, VT.
66. "Impact of Options for Drug Coverage Under Medicare," Seminar for Congressional Senate Staffers, June 7, 2000, Washington, DC.
67. "Drug Pricing, Import, and Safety Issues," testimony before the Committee on Health, Education, Labor, and Pensions, United States Senate, June 13, 2000, Washington, DC.
68. "Coverage of Prescription Drugs Under Medicare," testimony before the Committee on Ways and Means, U.S. House of Representatives, June 13, 2000, Washington, DC.
69. "PBMs: Who Are They? What Do They Do?," Indiana Rx Drug Advisory Committee, State of Indiana, July 11, 2000, Indianapolis, IN.
70. "Patents, Intellectual Property Protection, Innovation and Prescription Drugs—Are the Rules Fair?" Congressional Briefing Seminar, sponsored by the National Institute for Health Care Management Foundation, September 25, 2000, Washington, DC.
71. "Economic Impact of Drug Coverage Provisions Under Medicare," Staff Seminar, Congressional Budget Office, January 26, 2001, Washington, DC.
72. "Iowa Rx Coop," testimony before the Senate Health & Human Rights Appropriations Sub-Committee, State of Iowa, February 6, 2001.
73. "Prescription Drug Access for Low-Income Seniors," testimony before Senate Health & Family Security Committee, Minnesota Legislature, State of Minnesota, March 14, 2001, St. Paul, MN.
74. "Impact of Rx Discount Cards on Rural Citizens and Their Access to Pharmacies," Congressional Briefing Seminar, House Rural Caucus, U.S. House of Representatives, October 15, 2001, Washington, DC.
75. "Medicare Prescription Drug Cards: What Are They? What Are They Worth?" Congressional Briefing Seminar, Alliance for Health Reform, October 18, 2001, Washington, DC.
76. "Current Assessment of Prescription Drug Policies and Issues," testimony before the Legislative Health & Human Services Committee, State of New Mexico, October 24, 2001, Santa Fe, NM.
77. "The Chilean Pharmaceutical Market and Access to Pharmaceuticals," briefing provided to Sr. Guido Girardi, President, Commission on Health, House Chamber, Chilean Parliament, November 20, 2001, Santiago, Chile.
78. "The Chilean Pharmaceutical Market and Public Health," briefing provided to Sra. Jeanette Vega, Director, Institute of Public Health of Chile, November 20, 2001, Santiago, Chile.
79. "The Chilean Pharmaceutical Market and Intellectual Property Issues," briefing provided to Sr. Alvara Diaz, Undersecretary of Economy, Chile, November 20, 2001, Santiago, Chile.
80. "Sources of Growth in Medicaid Drug Expenditures," briefing provided to Senate Health Committee, State of Minnesota, January 29, 2002, St. Paul, MN.

81. "PBMs. Discount Cards, & a Medicare Prescription Benefit: Implications for Seniors in Rural Communities," Congressional Briefing, House Rural Caucus, U.S. House of Representatives, October 7, 2002, Washington, DC.
82. "Medicaid Growth Trends and Targets," meeting with Medicaid staff, Department of Human Services, State of Minnesota, January 13, 2003, St. Paul, MN.
83. "Minnesota's Budget Crisis and Drugs Under Medicaid," meeting with Commissioner, Department of Human Services, State of Minnesota, February 26, 2003, St. Paul, MN.
84. "Prescription Drug Expenditures: What Do We Really Know?" testimony provided before Assembly Committee on Health, California Legislature, State of California, March 11, 2003, Sacramento, CA.
85. "Need for Price Transparency to Facilitate Improved Drug Price Negotiations with Drug Manufacturers," testimony before the Senate Committee on Health, State of Minnesota, April 3, 2003, St. Paul, MN.
86. "Drug Use and Expenditures by Seniors in America," Congressional Budget Office, April 22, 2003, Washington, DC.
87. "The Economics of the Pharmaceutical Industry in the United States," testimony before the Subcommittee on Human Rights and Wellness, Committee on Government Reform, United States House of Representative, June 25, 2003, Washington, DC
88. "Drug Expenditures: Sources of Growth in Public & Private Sectors," South Dakota Governor & Staff, State of South Dakota, October 8, 2003, Pierre, SD.
89. "Prescription Drug Market Access & Re-importation," Congressional Field Forum, October 27, 2003, Boston, MA
90. "PBM Self-Dealing Issues," Federal Trade Commission, meeting and discussion with staff, November 20, 2003, Washington, DC.
91. "Medicaid Drug Expenditures: Sources of Growth," Georgia Legislature, Joint Committees on Health, December 3, 2003, Atlanta, GA.
92. "Skyrocketing Costs of Prescription Drugs: Is Importation from Canada an Answer?" testimony before Health Committee, California Assembly, January 20, 2004,Sacramento, CA.
93. "Pharmaceutical Prices, Imports & Safety," testimony before Judiciary Committee, United States Senate, July 14, 2004, Washington, DC.
94. "Medicaid Drug Expenditures: Sources of Growth," Senate Health Committee, Florida Legislature, January 27, 2005, Tallahassee, FL.
95. "Medicaid Drug Expenditures: Sources of Growth," House of Representatives, Health Committee, Florida Legislature, February 23, 2005, Tallahassee, FL.
96. "Medicaid Drug Expenditures: Sources of Growth," Tennessee State Forums Partnerships, Legislators Forum, March 30, 2005, Nashville, TN.
97. "Prescription Drug Price Disclosure," testimony before House and Senate Health & Human Services Working Group, June 9, 2005, St. Paul, MN.

Other Scholarly Activities

1. "Treatment of Asthma with Cromolyn" and "Seizure Prophylaxis with Phenytoin," University of Kentucky, College of Pharmacy, Nov. 1976 (slide-tape, self-instructional, patient education programs).

Invited Presentations

(See Appendix A: Invited Presentations of Stephen W. Schondelmeyer for a complete list.)

Expert Witness and Consultation Activities for Legal Matters

(See Appendix B: Expert Witness Activities of Stephen W. Schondelmeyer for a complete list.)

Peer Review Activities

Editorial Review Board

Journal of Pharmacoepidemiology, 1988-1992
Drug Information Journal, 1985-1990
Journal of Health Care Marketing, 1985-1989
American Druggist, 1988-1996
Pharmacy Business, 1990-1994
P & T (Journal of Pharmacy & Therapeutics Committees) 1991-2002
Drug Outcomes & Managed Care, Faulkner & Gray, New York, 1995-1996
Medical Outcomes & Guidelines Alert, Faulkner & Gray, New York, 1995
Spanish Hospital Pharmacy Journal, 1996-present
Drug Topics, Editorial Advisory Committee, 1998-present
Managed Care, 1999-present
Journal of Generics, 2003-present

Manuscript Reviewer

American Journal of Health System Pharmacy (was American Journal of Hospital Pharmacy), 1985-
American Journal of Pharmaceutical Education, 1985-
American Pharmacy, 1986-
Journal of Social and Administrative Pharmacy, 1987-
Journal of Pharmaceutical Marketing and Management, 1987-
Drug Information Journal, 1985-
Journal of Health Care Marketing, 1985-1994
Pharmacy in History, 1989-
Health Care Financing Review, 1989-
Health Affairs, 1991-
Journal of the American Medical Association, 1991-
PharmacoEconomics, 1991-
Inquiry, 1992-
Journal of Health Politics, Policy, and Law, 1994-
Pharmaceutical Research, 1995-96 (3)

Reviewed research and policy reports for:

U.S. Congressional Research Service
U.S. Congressional Budget Office
American Association of Retired Persons, Policy Institute
Commonwealth Fund
United Senior Coalition (Washington, DC)
U.S. General Accounting Office
National Association of Chain Drug Stores
Minnesota Department of Health
Decision Resources, Inc.
Pracon, Inc.
Office of the Inspector General, U.S. Dept. of Health and Human Services (DHHS)
Food & Drug Administration, Office of Asst. Secretary for Planning and Evaluation, U.S. DHHS
Food & Drug Administration, Office of the General Counsel, U.S. DHHS
Office of the Actuary, U.S. Dept. of Health & Human Services

Reviewed abstracts for presentations:
Association for Health Services Research, Annual Meeting, 1993
Wintergreen Conference III, Center for Study of Drugs and Public Policy, Oct. 1994

Panel participation and proposal review:
Technical Panel Member, Health Care Financing Administration, Office of the Actuary, Estimates of National Expenditures for Prescription Drugs, Actuarial Research Corporation (contractor), 1994.
Technical Consultant, Health Care Financing Administration, Office of Research & Demonstrations, "Evaluation of Medicaid Prospective Drug Utilization Review and Cognitive Services Demonstration Projects," 1993 to 1998.
Drug Program Grant Review Panel, Health Care Financing Administration, USDHHS, Apr. 3-5, 1989.
Research Grants in Hospital Pharmacy Administration, Selection Panel.
ASHP Research and Education Foundation, proposal review, 1984, 1985.
Technical Merit Review Panel, Epilepsy Branch, NINCDS, NIH, 1983.
Drug Monograph Reviewer, American Hospital Formulary Service, 1977.

Special Review Activities:
* The FDAs Review Process: An International Comparison, Karyn L. Feiden, Food & Drug Administration, U.S. Department of Health and Human Services, November 1995.
(Invited by FDA to provide review and comment prior to publication.)
* "A Retrospective, Clinical and Pharmacoeconomic Data Collection from Patients," Orphan Medical, Inc., February 1996, review and comment provided on project proposal.
(Invited by Orphan Medical to provide review and comment prior to proposal submission.)
* "Determining Appropriate Reimbursement for Prescription Drugs: Off Label Uses and Investigational Therapies," Raiford, Drusilla S., Sheila R. Shulman, and Louis Lasagna, *Food and Drug Law Journal*, Vol. 49, No. 1, pp. 37-76. (Invited by authors to provide review and comment prior to article submission.)
* "Changing Prescription Drug Sector: New Expenditure Methodologies," James S. Genuardi and Jean M. Stiller, submitted to *Health Care Financing Review.*
(Cited as a source for method of estimating drug rebates paid in the private sector.)
* "Delayed Generic Introduction Due to Market Exclusivity: Impact on Pharmaceutical Firms and Upon Payers," Laura Brice, Asst. Secretary for Planning and Evaluation, U.S. Department of Health and Human Services.
(Provided input to, and evaluation of, model for estimation of economic impact of delayed generic introduction due to market exclusivity extensions.)
* Experiences of HMOs with Pharmacy Benefit Management Companies, June Gibbs Brown, Office of the Inspector General, U.S. Dept. Of Health and Human Services, April 1997
(Technical advice and consultation, Fall 1996 and Spring 1997)
* Drug Prices: Effects of opening Federal Supply Schedule for Pharmaceuticals Are Uncertain, Bernice Steinhardt, U.S. General Accounting Office, June 1997
(Invited by GAO to review and comment on document prior to publication.)
* Health Care 2004, Taylor Nelson AGB, 1998
(Interviewed by study author as an expert on the pharmaceutical market.)
* Weiderholt Award (Initial Award, CRAP, Midwest Pharmacy Administration Meeting, 2004)

CITATION OF WORK IN PUBLIC MEDIA

Research findings, invited presentations, and other work have been quoted widely in both the lay public and professional trade press. A Lexis-Nexis search on S.W. Schondelmeyer found more than 200 citations between 1988 and 1995. Quotes and citations include: ABC Evening News, ABC 20/20, NBC News, Jim Lehrer News Hour, CNBC News, Bloomberg Press, Prime Time Live, National Public Radio, Time; U.S. News & World Report; Forbes; Fortune; Money; Wall Street Journal; New York Times; Washington Post; Minneapolis Star Tribune; St. Paul Pioneer Press; Indianapolis Star; Lafayette Journal and Courier; The Pink Sheet; The Green Sheet; Drug Store News; American Druggist; Scrip World Pharmaceutical News; Pharmaceutical Executive; American Medical News; and many other public sources.

PROFESSIONAL AND SCIENTIFIC ORGANIZATION OFFICES

American Pharmaceutical Association (APhA)
Annual Meeting, attended every year since 1970
House of Delegates, Vice Speaker, 1981-1982
House of Delegates, Delegate, 1971, 1973, 1975, 1977, 1980, 1982, 1983, 1984, 1985, 1986, 1987, 1988, 1989, 1990, 1991, 1994, 1998, 1999, 2000, 2001, 2002
Public Affairs Policy Committee, Chairman, 1990-1991
House of Delegates, Member, Nominations Committee, 1990
Communications Advisory Committee, Member, 1988-1989
Scientific Affairs Policy Committee, Member, 1987-1988
Scientific Affairs Reference Committee, Member, 1987, 1988
Scientific Affairs Reference Committee, Chairman, 1984
Education Policy Committee, Member, 1999-2000
Publications Committee, Member, 2000-2001; Chair, 2001-2002

Academy of Pharmaceutical Research and Science (APRS)
Policy Committee, Member, 1988-1989
Economic, Social and Administrative Sciences Section, Best Paper Judge, 1997, 1998, 1999 (Chair)
Economic, Social and Administrative Sciences Section, Chair-elect, 1999-2000
Economic, Social and Administrative Sciences Section, Chair, 2000-2001
Economic, Social and Administrative Sciences Section, Immediate Past Chair, 2001-2002
APRS Executive Committee, 2001-2002

American Association of Colleges of Pharmacy (AACP)
Annual Meeting, 1992, 1993, 1995, 1996, 1997, 1998

Federation International Pharmaceutique (FIP)
Annual Meeting, 1972, 1997

American Pharmaceutical Institute
Forum Planning Committee, Member, 1988-1989

International Society for Pharmacoeconomics and Outcomes Research (ISPOR)
(formerly Association of Pharmacoeconomics and Outcomes Research)
Founding Member, 1995

American Institute of the History of Pharmacy (AIHP)
Council Member, 1991-1994

Indiana Pharmacists Association (IPhA)
Third Party Affairs Committee, Member, 1983, 1984, 1985, 1986

Ohio State Pharmaceutical Association (OSPhA)
Legislative Affairs Committee, Member, 1974-1975

American Society of Health System Pharmacists (ASHP)
(formerly American Society of Hospital Pharmacists)
House of Delegates, Delegate, 1974
Mid-Year Clinical Meeting, 1995
Annual Meeting, 1995

Student American Pharmaceutical Association (SAPhA)
(presently known as APhA Academy of Students of Pharmacy)
Regional Delegate, 1971-1972
President (national), 1973-1974
President-elect (national), 1972-1973
Chapter Advisor, Purdue University Chapter, 1984, 1985

Bureau of Health Manpower Education
Student Advisory Committee, NIH, DHEW, 1973-1974

UNIVERSITY ADMINISTRATIVE AND SERVICE POSITIONS

University of Minnesota
A Tribute to Excellence (invited guest at this celebration honoring the University's faculty and contributors to endowed professorships), Minneapolis, MN, October 25, 1996
Council of Research Associate Deans, 1997-1998

Academic Health Center, University of Minnesota
Quality, Re-engineering, and Technology Committee, Jun. to December, 1995
(Redefined mission, priorities, and operating structure for the Academic Health Center which includes 7 professional schools and the University Hospital and Clinics.)
Management Information Systems & Information Technology Team, QRTC, Jan. to Aug. 1996
Search Committee for Chief Financial Officer, Academic Health Center, Feb. To May 1996
Programs and Interdisciplinary Programs Task Force, Spring 1996 to December 1997
Strategic Initiative Programs, Core Team, Jul. to Sept. 1996
Clinical Trials Advisory Committee, Spring 1997 to 1998
Task Force on Legislative Authority to Prescribe and Dispense Medications, 2003

College of Pharmacy, University of Minnesota
Central Council, 1998-present
College Education Implementation Committee, 1998-present
Search Committee for Weaver Endowed Chair in Treatment of Rare Diseases, 2004-05
Search Committee for Endowed Chair in Pharmacotherapy of the Elderly, Member, 1992
Search Committee for College Chief Financial Officer, Chair, 1999, 2002, 2004
Search Committee for Weaver Endowed Chair in Treatment of Rare Diseases, Chair, 2002-2003
Health Care Public Policy Conference, Planning Committee, 1991-present
Centennial Development Committee, 1992
Management Track Task Force, Educational Policy Committee, Chairperson, 1993
Century Mortar Club (CMC), Board Member, 1992-present
CMC Management Conference, Planning Committee, 1992-present
Grievance Committee, 1992-1993
Promotion and Tenure Committee, member 1993-1994; chairman, 1994-1995
Education Policy Committee, 1995-1996
Managed Care Pharmacy Liaison with Academy of Managed Care Pharmacy, 1993-present
Chain Drug Store Liaison with National Association of Chain Drug Stores, 1993-present

Department of Pharmaceutical Care & Health Systems, University of Minnesota
(prior to 1998 was Department of Pharmacy Practice)
Executive Committee, Member, 1991-1993
Department Head, Department of Pharmaceutical Care & Health Systems, 1998-present
Chair, Search Committee for Pharmaceutical Outcomes Faculty Position, 2000

Purdue University
Participating Faculty Member, Center for Public Policy and Public Administration, Purdue University, 1984-1986

School of Pharmacy and Pharmacal Sciences, Purdue University
School Grievance Committee, Member, 1986-1987, 1989-1990
Computer Committee, Member, 1983-present
ACPE Self-Study Evaluation Committee on Evaluation via Outcomes, Chairman, 1984-85, (Authored self-study report on "Evaluation Via Outcomes," 104 pp)
Liaison Committee, Member, 1984-1986
Liaison with English Core Course Faculty, 1984-1986
Recruitment and Retention Committee, Member, 1983-1985
Career Counseling Advisory Committee, Member, 1983-1985
Purdue Chapter of the Student American Pharmaceutical Association, Faculty Advisor, 1982-1985

Department of Pharmacy Practice, Purdue University
Computer Committee, Member, 1983-present
Graduate Affairs Committee, Member, 1982-present

CIVIC AND COMMUNITY ACTIVITIES
Indiana Economic Development Congress, Regional Conference Participant, Indiana Economic Development Council, Lafayette, IN, April 22, 1986.
Public Relations and News Staff, 7th National Jamboree, Boy Scouts of America, Farragut, ID, 1969.
Drug Abuse Education Programs, given to various groups and schools, 1972-1985
Pharmacist, Medical Service Section, 8th National Jamboree, Boy Scouts of America, Farragut, ID, 1973.
Director, College Department Sunday School, Casas Adobes Baptist Church, Tucson, AZ, 1981-1982.
Southern Arizona Health Systems Agency, Technical Assistance Task Force and Wellness Committee, Tucson, AZ,1981-1982
National Medication Awareness Test, presented to consumer and civic groups, 1982-1986
Chancel Choir Member, Covenant Presbyterian Church, West Lafayette, IN, 1982-1991
Elder, Covenant Presbyterian Church, West Lafayette, IN, 1987-1989
Chancel Choir Member, New Life Church, Woodbury, MN, 1991-2000
Pastor-Teacher, Encouragers' Small Church, New Life Church, Woodbury, MN, 1992-2001
Steering Committee, Christian Faculty-Staff Network, Univ. of Minnesota, 1992-1993
Antitrust Task Force, Minnesota Health Care Commission, 1992-1993
Minnesota Senior Federation, Technical Advisor, 1993-present
Joint Task Force on Health Care Costs and Quality, Cost Drivers Committee, State of Minnesota, Committee Member, 2002

APPENDIX A
Invited Presentations of
Stephen W. Schondelmeyer

1. "A Student's Challenge: Professional Change," Annual Meeting, Iowa Pharmacists Association, May 5, 1973, Des Moines, IA.
2. "Selected Health Professions: View on Current Health Issues," Conference on Practicing Administrators View on Current Health Issues, School of Administration, University of Missouri-Kansas City, Mar. 28, 1974, Kansas City, MO.
3. "OTC Review Panel: Internal Analgesics--A Summary and Commentary," Ohio Pharmaceutical Seminar, Ohio State University, College of Pharmacy, Apr. 26, 1978, Columbus, OH.
4. "Impact of the Drug Regulation Reform Act of 1978 on the Practicing Pharmacist," Alumni Day, Ohio State University, College of Pharmacy, May 6, 1978, Columbus, OH.
5. "Analysis of Clinical Pharmacy as a Health Sciences Specialty," Keynote Address, First Annual Meeting, American College of Clinical Pharmacy, Jul. 30, 1980, Boston, MA.
6. "Applications of BMDP Computer Programs," Section of Teachers of Clinical Instruction, Am. Assoc. of Colleges of Pharmacy, Jul. 1, 1981, Scottsdale, AZ.
7. "A Legislative Strategy to Effect Change in Pharmacy Practice," Arizona State Council of Hospital Pharmacists, Oct. 4, 1981, Phoenix, AZ.
8. "Quality Assurance in Hospital Pharmacy," presented to the Southern Arizona Society of Hospital Pharmacists, Apr. 22, 1982, Tucson, AZ.
9. "Compensation for Clinical Services in Community Pharmacy Practice," Arizona Chapter, American College of Apothecaries, Sept. 12, 1982, Flagstaff, AZ.
10. "A Pharmacist-Conducted Prescription Counseling Service," Tippecanoe County Pharmaceutical Association, Sept. 8, 1983, W. Lafayette, IN.
11. "Pharmacy in the 21st Century: Transformed Society," Working Group Report, Pharmacy in the 21st Century Conference, Project Hope, Mar. 25 to 28, 1984, Millwood, VA.
12. "Cost Containment, DRGs, and Long Term Care: Impact and Survival Strategies," Consultant Pharmacists' Conference, Purdue University, Apr. 26, 1984, West Lafayette, IN.
13. "Economic Implications of the Rx-to-OTC Switch," Mid-Year Meeting, Indiana Pharmacists Association, Apr. 29, 1984, Indianapolis, IN.
14. "Current Trends in Third Party Programs in Indiana," Mid-Year Meeting, Indiana Pharmacists Association, Apr. 29, 1984, Indianapolis, IN.
15. "Association Membership Development: Marketing Your State Association," National Council of State Pharmaceutical Association Executives, May 5, 1984, Montreal, Canada.
16. "Pharmacists, Pharmaceuticals, and Drug Information in the Twenty-first Century," Drug Information Association Workshop on The Impact of the Rx-to-OTC Switch Process - Present and Future, Sept. 18, 1984, Arlington, VA.
17. "Developing A Membership Marketing Plan," National Council of State Pharmaceutical Association Executives, Feb. 16, 1985, San Antonio, TX.
18. "Pharmacists, Pharmaceuticals, and the Twenty-First Century," First Annual Pharmacy Alumni Seminar, Purdue University, Apr. 13, 1985, W. Lafayette, IN.
19. "University/Technology Resources," Resources for Emerging Medical Companies Conference, Indiana Institute for New Business Ventures, Inc., Apr. 18, 1985, Indianapolis, IN.
20. "Pharmacy in the Twenty-First Century," St. John's University, Faculty Seminar, May 13, 1985, Jamaica, NY.
21. "Prospects for Prospective Postmarketing Surveillance," Food and Drug Administration Seminar, Jun. 5, 1985, Rockville, MD.
22. "Efficient and Effective Postmarketing Surveillance," Drug Information Association, Annual Meeting, Jun. 19, 1985, Atlanta, GA.
23. "Strategies for Professional Survival: Coping with Change in the Structure of Health Care," Indiana Society of Hospital Pharmacists, Summer Meeting, Jul. 13, 1985, Indianapolis, IN.
24. "HMOs and PPOs: How Can Pharmacy Survive?" Indiana Pharmacists Association, Annual Meeting, Sept. 7, 1985, Indianapolis, IN.
25. "Change in the Professional Practice of Pharmacy: 1960 to 2010," Centennial Celebration, University of Missouri - Kansas City, Oct. 19, 1985, Kansas City, MO.
26. "HMOs and PPOs: Success Through Pharmacy Networks," Seminar on Pharmacy Third Party Programs, GA Pharmaceutical Association, Nov. 24, 1985, Atlanta, GA.

27. "Strategies for Professional Success: Coping with Change in the Structure of Health Care," Seminar on Keeping Up With the Rapid Changes in Health Care Reimbursement, Kansas Pharmacists Association, Jan. 19, 1986, Wichita, KS.
28. "HMOs and PPOs: Success Through Pharmacy Networks," Seminar on Keeping Up With the Rapid Changes in Health Care Reimbursement, Kansas Pharmacists Assoc., Jan. 19, 1986, Wichita, KS.
29. "The Prescription Network of Indiana," Indiana Pharmacists Association, Midyear Meeting, Mar. 15, 1986, Indianapolis, IN.
30. "The OTC Switch: The Pharmacist's Perspective," 31st Annual, Ohio Pharmaceutical Seminar, Public Policy and Drug Distribution: Contemporary Issues, Apr. 16, 1986, Columbus, OH.
31. "Networking of Networks or Inter-PSAO Relationships," 1st Annual PSAO Conference, National Association of Retail Druggists, May 20, 1986, Kansas City, MO.
32. "Change in the Structure of Health Care and the Pharmaceutical Market," Marketing Seminar, Riker Laboratories, May 22, 1986, St. Paul, MN.
33. "HMOs and PPOs: Pharmacy Networks and the Marketing of Pharmaceuticals," Marketing Seminar, Riker Laboratories, May 22, 1986, St. Paul, MN.
34. "Prospects for Prospective Postmarketing Surveillance in Institutional Settings," SIG on Drug and Poison Information, Session on Adverse Drug Reaction Surveillance, 43rd Annual Meeting, American Society of Hospital Pharmacists, Jun. 5, 1986, Denver, CO.
35. "The Pharmacist's Role in Postmarketing Surveillance," Annual Meeting, Minnesota State Pharmaceutical Association, Jun. 12, 1986, Edina, MN.
36. "Pharmacy Networks and Changes in Health Care Reimbursement," 112th Annual Meeting, Rhode Island Pharmaceutical Association, Jun. 21, 1986, Plymouth, MA.
37. "Keeping Up With the Rapid Changes in Health Care Reimbursement," 79th Annual Meeting, Oklahoma Pharmaceutical Association, Jun. 28, 1986, Tulsa, OK.
38. "Managed Health Care's Impact on Community Pharmacy Economics," 106th Annual Meeting, Illinois Pharmacists Association, Oct. 25, 1986, Springfield, IL.
39. "Cost Effectiveness: Who's Asking? The Role of Cost Impact Analysis in the Medical Marketplace," Invited Seminar, Burroughs Wellcome Co., Nov. 14, 1986, Research Triangle Park, NC.
40. "Third Party Opportunities through the Prescription Network of Indiana," Indiana Pharmacists Association, District Meetings, 9 meetings in 5 Indiana cities, Nov. and Dec. 1986.
41. "Strategies for Professional Success: Coping with Change in the Structure of Health Care," Senior Awards Banquet, Kansas City Society of Hospital Pharmacists, Dec. 2, 1986, Kansas City, MO.
42. "Update on Physician Dispensing," Third Annual Purdue University Pharmacy Alumni Seminar, Apr. 4, 1987, West Lafayette, IN.
43. "Pharmacy-Based Postmarketing Surveillance Methods," Invited Seminar, The Upjohn Company, May 13, 1987, Kalamazoo, MI.
44. "Marketing a Pharmacy Network: The Local Pharmacist's Role," Carolina Pharmacy Network, Jun. 12, 1987, Charleston, SC.
45. "Evolving Health Care System: Organizational and Economic Patterns," Section of Teachers of Pharmacy Administration, 88th Annual Meeting, American Association of Colleges of Pharmacy, Jul. 12, 1987, Charleston, SC.
46. "Managed Health Care: Impact on Community Pharmacy Economics," 104th Annual Meeting, Michigan Pharmacists Association, Aug. 17, 1987, Traverse City, MI.
47. "Implementing and Complying with the New HCFA Guidelines," Western Medicaid Pharmacy Administrators' Association, Oct. 1, 1987, Vail, CO.
48. "The Cost Containment Environment: Implications for Pharmacists and the Pharmaceutical Industry," The Management Conference for the Pharmaceutical Industry, Purdue University, Oct. 8, 1987, West Lafayette, IN.
49. "Trends with Third Parties and Managed Health Care: A Pharmacy Perspective," Midwestern Conference on the Changing Health Care Environment: Its Impact on Pharmacy and the Pharmaceutical Industry, Nov. 12, 1987, Indianapolis, IN.
50. "Generic Pricing: AWP and the Future," National Pharmaceutical Alliance, Annual Meeting, Mar. 10, 1988, San Antonio, TX.
51. "PSAO Interventions: Altering Prescribing and Dispensing Behaviors," American Pharmaceutical Association, Annual Meeting, Mar. 14, 1988, Atlanta, GA.
52. "Pharmacy and the Changing Health Care Environment," Seminar on Changing Economics of Pharmacy, GA Pharmacists Assoc., Mar. 22, 1988, Perry, GA.

53. "Future of the Generic Drug Market: Changing Demand and Pricing Strategies," Symposium on Investment Opportunities in the Generic Drug Industry, Swergold, Chefitz, & Sinsabaugh, Inc., Mar. 24, 1988, New York, NY.
54. "Drug Benefit Plan Cost Management and Utilization Review," General Motors, Corporate Headquarters, Apr. 27, 1988, Detroit, MI.
55. "Managing Pharmaceutical Benefits in Managed Health Care," United Healthcare Corporation, May 6, 1988, Minneapolis, MN.
56. "Cost Containment and Drug Utilization Review," Pharmaceutical Card Systems, May 25, 1988, Scottsdale, AZ.
57. "Impact of Medicare Drug Coverage on Pharmacy and the Pharmaceutical Industry," Legislative Impact Seminar on the Catastrophic Care Act of 1988, sponsored by the FDC Pink Sheet and Medical Economics, Jun. 28, 1988, Princeton, NJ.
58. "Medicare and the Changing Health Care Environment: Impact on Drug Prices and Price Databases," Medical Economics/Redbook, Jul. 25, 1988, Oradell, NJ.
59. "Third Party Payors and Pharmaceutical Pricing Strategies," Marketing Executive Workshop, Glaxo, Jul. 27, 1988, Research Triangle Park, NC.
60. "Chain Pharmacy and the Medicare Catastrophic Coverage Act of 1988," Government Affairs Committee, National Assoc. of Chain Drug Stores, Jul. 28, 1988, Boston, MA.
61. "Medicare and Pharmaceutical Pricing," Invited Seminar, Schering Corp., Aug. 8, 1988, Kenilworth, NJ.
62. "Pricing of Pharmaceuticals: Impact of MCCA," National Symposium for Medicaid Pharmacy Administrators, Aug. 18, 1988, Chicago, IL.
63. "Impact of Medicare on Drug Prices and Drug Price Databases," MediSpan, Inc., Aug. 25, 1988, Indianapolis, IN.
64. "Health Care's Changing Environment," Symposium on Third Party Programs Today and Tomorrow, Iowa Pharmacists Association, Aug. 28, 1988, Des Moines, IA.
65. "Catastrophic Health Insurance," 1988 Pharmaceutical Conference, National Association of Chain Drug Stores, Aug. 31, 1988, San Diego, CA.
66. "Prescription Benefits of the Medicare Catastrophic Coverage Act," Health Programs Committee, National Pharmaceutical Council, Sept. 14, 1988, Arlington, VA.
67. "Drug Wholesalers and the Medicare Drug Program," Government Affairs Committee, National Wholesale Druggists Association, Sept. 14, 1988, Alexandria, VA.
68. "Economic Research Using Prescription Claims Databases," Invited Seminar, Penn State University, Sept. 30, 1988, State College, PA.
69. "Prescriptions: A Vital Part of Health Care," Professional Insurance Mass-Marketing Association, Oct. 3, 1988, Las Vegas, NV.
70. "Demystifying the Pharmacy Component of Medicare Expansion," 90th Annual Convention, National Association of Retail Druggists, Oct. 12, 1988, Atlanta, GA.
71. "The Pharmaceutical Industry and the Medicare Catastrophic Coverage Act," Invited Seminar, Merck & Co., Inc., Oct. 21, 1988, West Point, PA.
72. "Pricing of Multiple Source Products," Thirteenth Annual Meeting, Western Medicaid Pharmacy Administrator's Association, Oct. 27, 1988, Lake Tahoe, NV.
73. "Pharmacy Reimbursement Under Medicare," Pharmacy Division Managers Meeting, Rite Aid Corporation, Oct. 28, 1988, Harrisburg, PA.
74. "Role of Drug Information Publications in the Changing Health Care Environment," Facts and Comparisons, Inc., Nov. 4, 1988, St. Louis, MO.
75. "Implications of MCCA for Pharmacy and Boards of Pharmacy," 1988 Executive Officers Conference, National Association of Boards of Pharmacy, Nov. 8, 1988, Orlando, FL.
76. "Pharmaceutical Databases in a Changing Health Care Environment," IMS America, Inc., Nov. 17, 1988, Plymouth Meeting, PA.
77. "Prescription Coverage Under Medicare," Management Counsel, Thrift Drug Company, Nov. 18, 1988, Pittsburgh, PA.
78. "Pharmacy and the Medicare Catastrophic Coverage Act," Ferris State University, Nov. 21, 1988, Big Rapids, MI.
79. "Pharmacists and the Medicare Catastrophic Coverage Act," Invited Lecture, Contemporary Issues in Pharmacy Practice, Philadelphia College of Pharmacy and Science, Nov. 29, 1988, Philadelphia, PA.
80. "Evaluating the Realities of Drug Use in a Particular Managed Healthcare Setting," Drug Therapy Management and Evaluation Workshop, Dec. 3, 1988, Dallas, TX.
81. "Marketing of Pharmaceuticals under the Medicare Catastrophic Coverage Act," Hoechst-Roussel Pharmaceuticals, Inc., Dec. 14, 1988, Somerville, NJ.

82. "Impact of Medicare on Pharmaceutical Pricing," Bristol-Myers, Dec. 15, 1988, Evansville, IN.
83. "Prescription Coverage under the Medicare Catastrophic Coverage Act," McNeil Pharmaceutical, Dec. 16, 1988, Philadelphia, PA.
84. "Prescription Pricing and Medicare," G.D. Searle, Dec. 19, 1988, Skokie, IL.
85. "The Changing Environment of Health Care," Changing Healthcare Economics Seminar, Arizona Pharmacists Association, Jan. 15, 1989, Phoenix, AZ.
86. "Medicare: Impact of the Drug Coverage Program," Changing Healthcare Economics Seminar, Arizona Pharmacists Association, Jan. 15, 1989, Phoenix, AZ.
87. "Marketing Pharmaceuticals in the Medicare Era," Pharmaceutical Advertising Council, Jan. 19, 1989, New York, NY.
88. "Changes in Managed Care and Its Impact on Pharmacy," Pharmaceutical Division Annual Meeting, A.H. Robins, Jan. 31, 1989, Newport Beach, CA.
89. "Pharmacy and Drug Coverage under Medicare," Ohio State University, Feb. 3, 1989, Columbus, OH.
90. "The Changing Health Care Delivery System," Visions for the Future Conference, American Society of Consultant Pharmacists, Feb. 5, 1989, Birmingham, AL.
91. "Pharmaceutical Pricing and the Impact of the Catastrophic Health Legislation," Generic Drug Conference, Swergold, Chefitz & Sinsabaugh, Feb. 7, 1989, New York, NY.
92. "Pricing Pharmaceuticals," Invited Seminar, CIBA-Geigy, Feb. 13, 1989, Summit, NJ.
93. "Pharmacy Practice and the Catastrophic Health Care Act," CE Seminar, South Carolina Society of Hospital Pharmacists, Feb. 16, 1989, Columbia, SC.
94. "Medicare Catastrophic Health Insurance--Implications for Pharmacy," Mid-year Conference, American College of Apothecaries, Feb. 24, 1989, Kansas City, MO.
95. "Mail Service Pharmacy and Medicare," Invited Seminar, Medco, Mar. 1, 1989, Harrisburg, PA.
96. "Pharmacy Claims Processing Issues and the Medicare Outpatient Drug Program," First Databank Subscriber's Seminar, Mar. 6, 1989, San Francisco, CA.
97. "Costs of Dispensing a Third Party Prescription," Board Meeting, National Association of Chain Drug Stores, Mar. 9, 1989, Washington, DC.
98. "How to Succeed: Pharmacy's Third Party Dilemma," Managed Care Conference, CA Pharmacists Association, Mar. 11, 1989, Monterey, CA.
99. "The Economic Landscape: Medicare Catastrophic Coverage Act of 1988," Marketing Section, Pharmaceutical Manufacturers Assoc., Mar. 13, 1989, Laguna-Niguel, CA.
100. "Overview of the Medicare Catastrophic Coverage Act of 1988," Tenth Annual Northeast Pharmaceutical Conference, Mar. 30, 1989, Reading, PA.
101. "The Catastrophic Drug Component--Opportunities for Pharmacy," Supermarket Pharmacy Seminar, Food Marketing Institute, Apr. 3, 1989, Chicago, IL.
102. "Recent Federal Legislation: Economic Impact," Eggs & Economics Workshop, Academy of Pharmaceutical Research and Science, American Pharmaceutical Association, Apr. 10, 1989, Anaheim, CA.
103. "Pharmacy Education and the Catastrophic Health Act," College of Pharmacy Advisory Council, University of Iowa, Apr. 10, 1989, Iowa City, IA.
104. "Reimbursement and DUE Under Medicare Catastrophic Drug Coverage," Annual Meeting, American Pharmaceutical Association, Apr. 11, 1989, Anaheim, CA.
105. "Health Policy and Economics: Cost Containment and Fiscal Strategies," Graduate Lecture, Idaho State University, May 3, 1989, Pocatello, ID.
106. "Economic Aspects of Switch," Workshop on Rx-to-OTC Switch, Drug Information Association, May 8, 1989, Rockville, MD.
107. "Pharmaceutical Sales in the Medicare Era," IMS Sales Management Meeting, May 9, 1989, Phoenix, AZ.
108. "Policy Issues Raised by the Medicare Catastrophic Coverage Act," Invited Seminar, Pfizer Pharmaceuticals, May 17, 1989, New York, NY.
109. "Current Status of the Medicare Catastrophic Coverage Act," Staff Meeting, Pharmaceutical Manufacturers Association, May 23, 1989, Washington, DC.
110. "The Role of Market Researchers in Understanding the Catastrophic Health Legislation," IMS Client Meeting, May 24, 1989, Lake George, NY.
111. "Catastrophic Drug Program: The Funding Controversy Grows," 2nd Annual Pharmaceutical Industry Conference, Bear Stearns, Jun. 8, 1989, Chicago, IL.
112. "Catastrophic Health Insurance: Impact on Patients and Providers," Annual Meeting, American Association of Colleges of Pharmacy, Jul. 9, 1989, Portland, OR.
113. "The PMA Coordinated Faculty Visitation Program: A Faculty Participant's View," Annual Meeting, American Association of Colleges of Pharmacy, Jul. 9, 1989, Portland, OR.

114."Impact of the Medicare Outpatient Drug Program," Invited Seminar, Geneva Generics, Jul. 17, 1989, Broomfield, CO.
115."Changing Health Care Environment and Growth of Third Parties," Invited Seminar, Geneva Generics, Jul. 17, 1989, Broomfield, CO.
116."Generic Pricing Patterns," Invited Seminar, Geneva Generics, Jul. 17, 1989, Broomfield, CO.
117."Medicare Provision of Outpatient Drugs," Annual Meeting, Texas Pharmaceutical Association, Jul. 18, 1989, Corpus Christi, TX.
118."The Role of Wholesalers in the Medicare Drug Program," Board of Directors Meeting, National Wholesale Druggists Association, Jul. 24, 1989, Vancouver, BC.
119."Impact of the Medicare Drug Program," Invited Seminar, Hoffman-LaRoche, Jul. 27, 1989, Nutley, NJ.
120."Recent Developments in Implementation of the Catastrophic Drug Insurance Program," Third National Symposium for Medicaid Pharmacy Administrators, Aug. 3, 1989, Chicago, IL.
121."Financing Geriatric Health Care: Future Effects on Pharmacy Practice," Contemporary Issues in Geriatric Pharmacotherapy Seminar, American College of Clinical Pharmacy, Aug. 6, 1989, Kansas City, MO.
122."The Changing Health Care Environment and Its Impact on the Role of the Pharmacist," Annual Meeting, District 3, AACP/NABP, Aug. 14, 1989, Charleston, SC.
123."Third Party Impact on Cost of Dispensing," Annual Pharmaceutical Conference, National Association of Chain Drug Stores, Aug. 30, 1989, Washington, DC.
124."Impact of Medicare Drug Coverage," Invited Seminar, Smith Kline-Beecham, Sept. 11, 1989, Philadelphia, PA.
125."Impact of the Catastrophic Health Program on Pharmacy," Northeast Indiana Pharmacists Association, Sept. 16, 1989, Ft. Wayne, IN.
126."Policy Implications of Medicare for Wholesalers," Government Affairs Committee, National Wholesale Druggists' Association, Sept. 20, 1989, Washington, DC.
127."The Erosion of Pharmaceutical Product Pricing," Martin Barr Lecture Program, Wayne State University, Sept. 27, 1989, Detroit, MI.
128."Impact of the Catastrophic Health Coverage Act," The Management Conference for the Pharmaceutical Industry, Purdue University, Sept. 28, 1989, West Lafayette, IN.
129."The Medicare Catastrophic Coverage Act: What Is It?," Annual Meeting, Wisconsin Pharmacists Association, Oct. 3, 1989, Kohler, WI.
130."Prescription Drug Provisions of the Medicare Catastrophic Coverage Act of 1988," Vice Presidents' Meeting, Bergen Brunswig Corporation, Oct. 4, 1989, Orange, CA.
131."How to Prepare for 1991: Effect of the Medicare Catastrophic Coverage Act of 1988," 10th Annual Western Pharmacy Education Faire, CA Pharmacists Association, Oct. 6, 1989, Palm Springs, CA.
132."Prescription Drug Expenditures Under Medicaid," Annual Meeting, Western Medicaid Pharmacy Administrators Association, Oct. 11, 1989, Tucson, AZ.
133."Pharmacy Economics 1990," Purdue President's Council Annual Weekend Back to Class Program, Oct. 13, 1989, West Lafayette, IN.
134."What Happened to MCCA?," Invited Seminar, Rorer Pharmaceuticals, Oct.19, 1989, Ft. Washington, PA.
135."The Medicare Catastrophic Coverage Act: Its Economic Impact Upon Pharmacists and the Pharmaceutical Industry," Annual Meeting, American Public Health Association, Oct. 26, 1989, Chicago, IL.
136."Catastrophic Health Care Legislation," 26th Annual Seminar, Maryland Society of Hospital Pharmacists, Oct. 28, 1989, Philadelphia, PA.
137. "Results of the NACDS Third Party Impact Study," Government Affairs Committee, National Association of Chain Drug Stores, Nov. 2, 1989, St. Louis, MO.
138."Third Party Growth and Its Impact on Retail Pharmacy," 109th Annual Meeting, Illinois Pharmacists Association, Nov. 3, 1989, Chicago, IL.
139."After Catastrophic... The Pharmaceutical Economic Issues That Will Not Go Away," Health Programs Committee, National Pharmaceutical Council, Nov. 10, 1989, Washington, DC.
140."Reimbursement Issues Affecting the Pharmaceutical Industry," Account Management Workshop, Sandoz Pharmaceuticals, Nov. 15, 1989, LaCosta, CA.
141."Growth of Third Party Reimbursement," Conference on Pharmaceutical Markets for the Nineties, Nov. 28, 1989, Washington, DC.
142."Third Party Impact Upon Prescription Dispensing Costs," Press Conference, National Association of Chain Drug Stores, Dec. 7, 1989, New York, NY.
143."The Future of the Retail Pharmacy Market," Business Strategy Group, IMS America, Inc., Dec. 12, 1989, Plymouth Meeting, PA.

144."The Medicare Program: Current and Future Status of Drug Coverage," Clinical Economics Conference, Philadelphia Assoc. for Clinical Trials (PACT), Jan. 17, 1990, Philadelphia, PA.
145."Economics of Health Care and Pharmacy," VHA Hospital Pharmacy Management Institute, Auburn University, Jan. 21, 1990, Auburn, AL.
146."Trends in Pharmaceutical Pricing," 3rd Annual Generic Drug Conference, Furman Selz Mager Dietz & Birney, Inc., Feb. 6, 1990, New York, NY.
147."Growth of Third Party Programs: Impact on the Pharmaceutical Market," Visiting Professor, University of Puerto Rico, Feb. 6-9, 1990, San Juan, PR.
148."Economic Trends in the Pharmaceutical Industry," Invited Seminar, DuPont, Feb.19, 1990, Wilmington, DE.
149."Pharmaceutical Reimbursement Issues," Annual Meeting, American Society for Pharmacy Law, Mar. 11, 1990, Washington, DC.
150."Growth of Third Party Programs: Impact in the Pharmaceutical Market," Annual Meeting, American Pharmaceutical Association, Mar. 13, 1990, Washington, DC.
151."The Affordability of Medicines," Congressional Foresight Seminar, Institute for Alternative Futures, Mar. 14, 1990, Washington, DC.
152."Economic Impact of Biotechnology and the Practice of Pharmacy," First Charles C. Rabe Symposium, Biotechnology and the Future, St. Louis College of Pharmacy, Apr. 17, 1990, St. Louis, MO.
153."Drug Pricing, Economics, and Health Care Cost Containment," Sixth Annual San Diego Biotechnology Conference, Apr. 26, 1990, San Diego, CA.
154."Pharmacy Economics 101: Facts and Fiction About Third Party Drug Programs," Managed Care Conference, CA Pharmacists Association, Apr. 28, 1990, Dana Point, CA.
155."Drug Therapy for the Elderly: Who Will Pay?", Geriatric Medicine Update '90, Methodist Hospital of Indiana, Inc., Jun. 8, 1990, Indianapolis, IN.
156."The Changing Pharmaceutical Marketplace," Health Industry Issues Advisory Group, Smith Kline-Beecham, Jul. 27, 1990, Philadelphia, PA.
157."Research and Information on the Retail Prescription Marketplace," National Association of Chain Drug Stores Pharmaceutical Conference, Aug. 29, 1990, Anaheim, CA.
158."The Elderly and Affordability of Drug Therapy," National Committee to Preserve Social Security and Medicare, Sept. 21, 1990, Washington, DC.
159."Changing Economics of Health Care and Pharmacy," VHA Management Institute, Sept. 23, 1990, Auburn, AL.
160."Strategic Change and the Economic Transformation of Pharmacy Practice," University of Minnesota, Sept. 25, 1990, Minneapolis, MN.
161."Future Strategies for Dealing with Unlabeled Uses - Public Policy and Private Initiatives," Drug Information Association Workshop, Oct. 23, 1990, Washington, DC.
162."Economic Transformation of the Pharmaceutical Marketplace," keynote address, Bristol Myers-Squibb national account strategic planning workshop, Nov. 5, 1990, Plainsboro, NJ.
163."Can We Afford the Drugs We Need? The Conflict between Cost and Availability," Gerontological Society of America, Economics of Aging Interest Group Symposium, Nov. 17, 1990, Boston, MA.
164."Trend Data: An Overview of US Drug Prices," National Health Policy Forum's "Drug Pricing in the Context of a Changing Pharmaceutical Marketplace," Dec. 14, 1990, Washington, DC.
165."Changing Economics of Health Care and Pharmacy," VHA Hospital Pharmacy Management Institute, Jan. 13, 1991, Auburn, AL.
166."Pharmacist Reimbursement Under Medicaid," University of Maryland, Center of Drugs and Public Policy, Medicaid Prudent Pharmaceutical Purchasing: A Conference on Implementation Issues, Jan. 14-15, 1991, Baltimore, MD.
167."Cost Benefit Considerations in Transplant Drug Therapy," Sandoz Pharmaceuticals Corporation, Jan. 22, 1990, New York, NY.
168."Pricing Trends in the Pharmaceutical Industry," IBC USA Conferences, Inc., Feb. 28, 1991, Washington, DC.
169."New Medicaid Drug Rebate Law: Impact on Pharmacy," American Pharmaceutical Association Annual Meeting, Mar. 11, 1991, New Orleans, LA.
170."The Economic Impact of Biotechnology on Pharmacy Practice," Ohio Society of Hospital Pharmacists Annual Meeting, Mar. 18, 1991, Ft. Mitchell, KY.
171."Impact of OBRA '90 on Hospital Pharmacy," American Society of Hospital Pharmacists, Mar. 20, 1991, Bethesda, MD.
172."Impact of the New Medicaid Pricing Legislation," Furman Selz Generic Drug Conference, Apr. 16, 1991, New York, NY.

173."Pricing Trends in the Pharmaceutical Industry," Pharmaceutical Marketing Research Group Spring Meeting, Apr. 22, 1991, Williamsburg, VA.
174."Why Do Drugs Cost What They Do?", NIH/PMA Technology Transfer Conference, Apr. 25, 1991, Bethesda, MD.
175."Minnesota Health Care Challenges," Minnesota Pharmacists Association 107th Annual Meeting, Apr. 26, 1991, St. Cloud, MN.
176."Third Party Payers and the Future of Drug Store Pharmacy," National Association of Chain Drug Stores Annual Meeting, May 1, 1991, Palm Beach, FL.
177."Medicaid Drug Rebate Law," Healthcare Distributors of America, May 4, 1991, White Sulphur Springs, WV.
178."Market Trends: Pharmacy Practice," Fourth Annual Japanese Pharmaceutical Executive Seminar, University of Mississippi, May 9, 1991, University, MS.
179."The Economics of Hospital Pharmacy," New England Council of Hospital Pharmacists, 38th Annual Spring Seminar, May 14, 1991, Nashua, NH.
180."Impact of Medicaid Pricing Legislation," Mercy National Hospital Purchasing Group, May 15, 1991, St. Louis, MO.
181."Pharmaceutical Economics, Pricing and Reimbursement," Bristol Myers-Squibb Pharmaceuticals, May 16, 1991, Evansville, IN.
182."Pharmaceutical Industry Update," Rhone-Poulenc Rorer, 1991 Strategic Summit, May 29, 1991, Fort Washington, PA.
183."Update on Medicaid Rebate Law," National Association of Pharmaceutical Manufacturers, Mid-Year Meeting, Jun. 6, 1991, Washington, DC.
184."The Economics of Managed Care Programs," McKesson Trade Show, Jul. 15, 1991, Las Vegas, NV.
185."The Changing Health Care Economy," Central Ohio Society of Hospital Pharmacists, Jul. 20, 1991, Columbus, OH.
186."Impact of the Medicaid Drug Rebate Program," Central Ohio Society of Hospital Pharmacists, Jul. 20, 1991, Columbus, OH.
187."Pricing Strategies in the New Health Care Environment," Rhone-Poulenc Rorer, Jul. 24, 1991, Ft. Washington, PA.
188."Pharmacy Economics and Managed Care," Pennsylvania Pharmaceutical Association, Jul. 25, 1991, Phoenix, AZ.
189."Trends in Prescription Drug Benefits," GA State Legislature, Aug. 6, 1991, Atlanta, GA.
190."Pharmacy Economics and Managed Care," Michigan Pharmaceutical Association, Aug. 11, 1991, Lincolnshire, IL.
191."Pharmacy Economics and Managed Care," Florida Southeastern Conference, Aug.13, 1991, Destin, FL.
192."Clinical Pharmacy Practice and Health Care Management: Are They Compatible?," American College of Clinical Pharmacy Annual Meeting, Aug. 21, 1991, Minneapolis, MN.
193."Strengthening the Drug Store Pharmacy," National Association of Chain Drug Stores Pharmaceutical Conference, Aug. 26, 1991, San Francisco, CA.
194."OBRA 90's Impact on Healthcare Economics and Hospital Pharmacy," Wisconsin Society of Hospital Pharmacists, Sept. 14, 1991, Oconomowoc, WI.
195."The Economics of Managed Care Programs," CA Pharmacists Association Western Pharmacy Education Faire, Sept. 20, 1991, San Francisco, CA.
196."Economics of Healthcare," VHA Executive Management Institute, Sept. 22, 1991, Auburn, AL.
197."Managed Healthcare Revolution," IMS America - American Strategy Group Meeting, Sept. 26, 1991, Key Largo, FL.
198."Managing Prescription Drug Care in the 90's," Illinois Pharmacists Association, Oct. 5, 1991, St. Charles, IL.
199."Impact of Federal Legislation on Pricing Strategies," Owen Healthcare Annual Meeting, Oct. 11, 1991, Houston, TX.
200."Economic Transformation of Pharmacy Practice," Arkansas Association of Hospital Pharmacists, Oct. 12, 1991, Fayetteville, AR.
201."Statement on the Public Health Clinic Affordable Drug Act," before Committee on Labor and Human Resources, United States Senate, Oct. 16, 1991, Washington, D.C.
202."Impact of Government Legislation on the Profession of Pharmacy," University of Kentucky, Oct. 22, 1991, Lexington, KY.
203."Pricing Trends in the Pharmaceutical Industry," Western Medicaid Pharmacy Administrators Association, Oct. 24, 1991, Breckenridge, CO.
204."Hospital Pharmacy and the Changing Health Care System," Central Minnesota Society of Hospital Pharmacists, Oct. 30, 1991, Prescott, WI.

205."Pharmaceutical Prices and Expenditure Trends" Southern Medicaid Pharmacy Administrators Association, Oct. 31, 1991, Atlanta, GA.
206."Overview of the Pharmaceutical Marketplace," Upsher-Smith, Nov. 5, 1991, Minneapolis, MN.
207."Drug Utilization Review," PMA Education and Research Institute. Nov. 5, 1991, Minneapolis, MN.
208."Current Legislative Environment," The Marketing Institute - Pharmaceutical Marketing Conference, Nov. 13, 1991, New York, NY.
209."Economic Evolution of Pharmacy," Rho Chi Lecture, University of Kentucky, Dec. 5, 1991, Lexington, KY.
210."Pharmacists in the New Health Care System," Rho Chi Banquet, University of Kentucky, Dec. 5, 1991, Lexington, KY.
211."Prescription Drug Market and Price Trends," U.S. General Accounting Office, Dec. 17, 1991, Washington, D.C.
212."Pharmaceutical Database Needs," IMS Market Development Workshop, IMS America, Dec. 19, 1991, Plymouth Meeting, PA.
213."Quality Management of a Prescription Benefit for the Elderly," Pennsylvania Department of Aging, Jan. 14, 1992, Harrisburg, PA.
214."Impact of Eroding Pharmaceutical Discounts on Healthcare Institutions," American Society of Hospital Pharmacists Congressional Seminar, Jan. 15, 1992, Washington, D.C.
215."Economic Transformation of the Pharmaceutical Market -- Implications for Generics," National Association of Pharmaceutical Manufacturers Annual Meeting and Educational Conference, Jan. 22, 1992, Key Largo, FL.
216."Economics of Health Care," Auburn University, VHA Executive Management Institute, Feb. 1, 1992, Auburn, AL.
217."The Capitalism of the Pharmaceutical Industry vs. Patient Benefits: Can Making Money and providing Patient Care Reside in the Same House?" Student Committee on Bioethics, University of Minnesota, Feb. 6, 1992, Minneapolis, MN.
218."Current Legislative Environment in Washington Relating to Prescription Drug Industry and What to Expect in the Future," 3M Pharmaceuticals National Accounts Seminar, Feb. 10, 1992, St. Paul, MN.
219."Buying Groups and Pharmaceutical Purchasing," Minnesota Multi-State Buying Group, State of Minnesota, Feb. 12, 1992, St. Paul, MN.
220."Health Care and Pharmacy Economics," Glaxo, St. Paul Mid-Winter Conference, Feb. 23, 1992, St. Paul, MN.
221."Product Pricing: Balancing Corporate Objectives with Society's Needs," Panel member, 1992 Wharton Health Care Conference, Feb. 21, 1992, Philadelphia, PA.
222."Impact of Generic Competition on the Originator Market," IBC Conference, Mar.13, 1992, Washington, DC.
223."Pharmaceutical Companies: What Is Right and What Could Be Better," 3M Pharmaceuticals, Mar. 24, 1992, St. Paul, MN.
224."Pharmacoeconomics and Pharmaceuticals," Merck, Inc., Mar. 25, 1992, Ft. Washington, PA.
225."Pharmaceutical Legislation and Regulation," Policy Rap Session, Health Care Financing Administration, Mar. 25, 1992, Washington, DC.
226."Pricing Trends in the Pharmaceutical Industry," IBC Pharmaceutical Pricing Conference, Mar. 26, 1992, Washington, D.C.
227."Economic Trends in the Retail Pharmacy Market," Strategic Planning Workshop, PACE Alliance, Mar. 28, 1992, Denver, CO.
228."Purchasing Groups in the Changing Pharmaceutical Market," Minnesota Multi-State Buying Group, State of Minnesota, Apr. 1, 1992, St. Paul, MN.
229."The Changing Pharmaceutical Market," Federation of American Health Systems, Apr. 2, 1992, Las Vegas, NV.
230."Accountability in Health Care - Considerations for the Profession," Seventh Annual Health Care Public Policy Conference, Apr. 7, 1992, Minneapolis, MN.
231."Pharmaceutical Economic Trends and Research Needs," United Health Care, Apr. 9, 1992, Minneapolis, MN.
232."Pharmacy Associations: Evolution, Revolution, and Solution," Minnesota Pharmacists Association Annual Meeting, Apr. 11, 1992, Minneapolis, MN.
233."The Third Party Marketplace," Food Marketing Institute 1992 Supermarket Pharmacy Conference, Apr. 14, 1992, Coronado, CA.
234."The Changing Pharmaceutical Market," University of North Carolina, Apr. 15, 1992, Chapel Hill, NC.
235."The Nation's Economy and the Politics of Health Care Reform," Century Mortar Club Management Conference, May 3, 1992, Minneapolis, MN.

236."Managing a Pharmacy in the Managed Care Era," Century Mortar Club Management Conference, May 3, 1992, Minneapolis, MN.
237."The Changing Pharmaceutical Marketplace and Wholesalers," Healthcare Distributors of America, Network Group Meeting, May 8, 1992, White Sulphur Springs, WV.
238."Political and Legal Overview of the Health Care Market," MediSpan Users Meeting, May 12, 1992, Indianapolis, IN.
239."Pharmaceutical Pricing Trends and Regulations," U.S. Army Pharmacoeconomics Conference, May 13, 1992, Aurora, CO.
240."Changing Economics of Health Care and Pharmacy," Mississippi Pharmacists Association, May 30-31, 1992, Jackson, MS.
241."Medicaid Rebates Expected in 1992," New York State Legislative Committees, Jun. 3, 1992, Albany, NY.
242."Drug Prices, Polices, and Polemics: Perspective on the Industry," United States General Accounting Office Comptroller General, and Health Advisory Board, Jun. 4, 1992, Washington, D.C.
243."Pharmaceuticals: Regulation, Innovation, and Pricing," Association for Health Services Research, Jun. 9, 1992, Chicago, IL.
244."Economic Impact of OBRA '90 on Generic Pharmaceutical Firms," Generic Pharmaceutical Industry Association, Board Meeting, Jun. 9, 1992, New York, NY.
245."Overview of the Changing Pharmaceutical Market," Chief Financial Officers' Conference, Sun Health Group, Jun. 10, 1992, Naples, FL.
246."Pharmaceutical Pricing: Great Expectations," Arizona Pharmacists Association, Annual Meeting, Jun. 11, 1992, Phoenix, AZ.
247."Health Care Industry Profitability and R & D Profitability," First Global Forum on the Business Implications of Technology, Decision Resources, Jun. 22, 1992, Boston, MA.
248."Pharmaceutical Pricing Issues: Why Do Drugs Cost What They Do?" Drug Pricing and Cost Containment Seminar, Smith-Barney, Harris, Upham & Co., Inc., Jul. 1, 1992, New York, NY.
249."Projections of Manufacturer Rebates Under the New York State Medicaid Program," Medicaid Committee, New York State Legislature, Jul. 14, 1992, Albany, NY.
250."The Pharmacist's Role in Public Policy," 13th Annual NPC-APhA Student Industry Internship Weekend, Merck, Inc., Jul. 25, 1992, West Point, PA.
251."Managed Pharmacy Benefits: Five Year Outlook and Outcome Measures," Diversified Pharmacy Services, Annual Client Conference on Pharmacy Benefits Management, Aug. 17, 1992, Minneapolis, MN.
252."Strategic Changes in the Pharmaceutical Marketplace," ALZA Corporation, Aug. 18, 1992, Palo Alto, CA.
253."Effect of Bill C-91 on the Canadian Pharmaceutical Industry," Industry, Science, and Technology Canada, Aug. 26, 1992, Ottawa, ON, Canada.
254."Measuring the Impact of a Pharmacy Preferred Provider Network in an HMO Environment," HMO Iowa, Sept. 1, 1992, Des Moines, IA.
255."Health Care 2020: A Long Range Forecast," USP 2020: Medicines and Technologies Conference, Invited Participant, USP 2000 Conference, Sept. 10, 1992, Annapolis, MD.
256."ISTC Analysis of Bill C-91 Impact on the Canadian Pharmaceutical Industry," Industry, Science, and Technology Canada, Sept. 16, 1992, Ottawa, ON, Canada.
257."The Future of Pharmaceutical Pricing," Congressional Foresight Seminar, Institute for Alternative Futures, Sept. 21, 1992, Washington, DC.
258."Profitability of Community Pharmacy in the 1990s," Business & Management Issues and Answers for the 90s Seminar, Schering Corporation, Sept. 26, 1992, Naples, FL.
259."Prescription Drug Cost Containment in the 1990s," National Association of State Purchasing Officials, Annual Meeting, Sept. 29, 1992, Indianapolis, IN.
260."OBRA '90, Medicine and Pharmacy: Opportunities for Teamwork," District II NABP/AACP Meeting, Oct. 16, 1992, East Rutherford, NJ.
261."Hospitals and the Economics of Health Care," VHA Executive Management Institute, Auburn University, Oct. 18, 1992, Auburn, AL.
262."The 3 Ms of Generic Use: Medicaid, Managed Care, & Marketing," International Business Communications Conference on Generic Drugs: Competitive Strategies for Pharmaceutical Companies, Oct. 23, 1992, Philadelphia, PA.
263."Prescription for Growth of Retail Drug Chains in the 1990s," Retail Drug Seminar, Salomon, Brothers, Oct. 27, 1992, New York, NY.
264."Pharmaceutical Marketing and Payment in the New Era," Glaxo, Inc., Nov. 9, 1992, Research Triangle Park, NC.
265."Pharmaceutical Pricing Issues," UCLA School of Public Health, Seminar Series, Nov. 12, 1992, Los Angeles, CA.

266."Drug Prices and the Elderly," United Senior Action of Indiana, Nov. 17, 1992, Indianapolis, IN.
267."The Role of the Community Pharmacy in the Changing Health Care System," Medicine Shoppes International, Nov. 24, 1992, St. Louis, MO.
268."The Cost of Bill C-91: An Economic Impact Analysis of the Elimination of Compulsory Licensing of Pharmaceuticals in Canada," Legislative Committee on Bill C-91, House of Commons, Parliament, Canada, Dec. 1, 1992, Ottawa, ON, Canada.
269."Fair Drug Pricing for Drugs Developed in Conjunction with the NIH," 66th Meeting, Advisory Committee to the Director, National Institutes of Health, Dec. 2, 1992, Bethesda, MD.
270."Health Care Reform: What Can Pharmacy Expect from the Clinton Presidency?" Pharmacy Administration Resident's Program, ASHP Mid Year Meeting, Glaxo, Dec. 7, 1992, Orlando, FL.
271."Evolution of Economic Trends in Hospital Pharmacy: 1950-1990," ASHP-AIHP History of Hospital Pharmacy Symposium, Dec. 9, 1992, Orlando, FL.
272."Changes in Drug Distribution Systems and the Economic Environment," USP-University of Maryland Unit-of-Use Conference, Dec. 14, 1992, Baltimore, MD.
273."Prescription Drugs and Health Care Reform," Group Health, Inc., Medical Continuing Education Seminar, Jan. 14, 1992, Minneapolis, MN.
274."The Cost of Bill C-91: An Economic Impact Analysis of the Elimination of Compulsory Licensing of Pharmaceuticals in Canada," Senate Standing Committee on Banking, Trade, and Commerce, Senate, Parliament, Canada, Jan. 21, 1993, Ottawa, ON, Canada.
275."Drug Pricing and the Contribution of the Government to Drug Development," Statement before the Subcommittee on Regulation, Business Opportunities and Energy, Committee on Small Business, U.S. House of Representatives, Jan. 25, 1993, Washington, DC.
276."OBRA '90 and Beyond: Opportunities for Generics," National Association of Pharmaceutical Manufacturers, 1993 Annual Meeting, Jan. 26, 1993, Naples, FL.
277."Health Care Reform: What's Ahead for Pharmacy?" American College of Clinical Pharmacy, Winter Practice and Research Forum, Feb. 7, 1993, Ft. Lauderdale, FL.
278."The Economics of Health Care and the Future of Pharmacy Benefits," Annual Meeting, National Council of Prescription Drug Programs, Feb. 17, 1993, Scottsdale, AZ.
279."How Do Pharmacists Determine a Prescription Price?" Congressional Member and Staff Seminar, Special Committee on Aging, U.S. Senate, Feb. 19, 1993, Washington, DC.
280."International Prescription Drug Prices: Implications for U.S. Policy," Statement before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, Feb. 22, 1993, Washington, DC.
281."Pharmaceutical Price Indices: Changes Over Time and in Various Countries," Conference on Pharmaceutical Industry Research, Innovation, and Public Policy, Kennedy School of Government, Harvard University, Feb. 25, 1993, Boston, MA.
282."Impact of Mandated Changes on the Pharmaceutical Marketplace," Valued Customer Workshop, Lederle Laboratories, Feb. 28, 1993, Park City, UT.
283."Economic Aspects of Medication Use in the Elderly," MAGEC Faculty and Fellows Workshop, Mar. 5, 1993, Minneapolis, MN.
284."Pricing Strategies in the New Health Care Environment," Pricing Strategy and Executive Committees, Glaxo, Inc. Mar. 9, 1993, Research Triangle Park, NC.
285."Pharmaceutical Pricing '93: Pricing and Operational Strategies," Third Annual IBC Conference, Mar. 25, 1993, Washington, DC.
286."Prescription Benefits and Health Care Reform," Mayo Administrative Group, Mayo Clinic, Mar. 31, 1993, Rochester, MN.
287."Pharmaceutical Pricing: Changing Times," ALZA Management Group, ALZA Corporation, Apr. 2, 1993, Palo Alto, CA.
288."How Will Health Care Reform Affect Hospital Pharmacy?" Indiana Society of Hospital Pharmacy, Annual Meeting, Apr. 24, 1993, Indianapolis, IN.
289."Prescription Benefits in the Health Care Reform Era," Challenges & Opportunities in Prescription Benefit Management Workshop, Kansas Pharmacy Services Corp., Apr. 29, 1993, Kansas City, MO.
290."Why Is the Federal Government Intervening in the Practice of Pharmacy?" Annual Meeting Minnesota Pharmacists Association, May 2, 1993, Minneapolis, MN.
291."Health Care Reform and Hospital Pharmacy," Hospital Pharmacy Advisory Board, Glaxo, Inc., May 6, 1993, Washington, DC.
292."Issues in Health Care Reform and Their Impact on the Pharmaceutical Wholesaler," Healthcare Distributors of America, May 15, 1993, Greenbrier, WV.

293."Health Care Reform: How Can Hospital Pharmacy Take the Lead?", Illinois Council of Hospital Pharmacists, 18th Annual Meeting, May 17, 1993, Chicago, IL.
294."Health Care Economics and Unit of Use Packaging," National Symposium on Patient Compliance, Health Compliance Packaging Council, May 18, 1993, Somerset, NJ.
295."Drug Pricing Fallout from OBRA '90," MediSpan User's Meeting, May 22, 1993, Indianapolis, IN.
296."Health Care Reform Directions and Implications for Hospital Pharmacy," Allied Pharmacy Management, May 23, 1993, Dallas, TX.
297."Politics, Pharmacy & Health Care Reform," Upsher-Smith Pharmaceuticals, May 26, 1993, Plymouth, MN.
298."Reimbursement: How Do We get Paid?," Iowa Pharmacists Association, Jun. 19, 1993, Dubuque, IA.
299."Economic Implications of Switching Oral Contraceptives from Prescription to Over-the-Counter," Forum on OTC Oral Contraceptives, Kaiser Family Foundation, Jul. 7-9, 1993, Menlo Park, CA.
300."Role of Generics in the Pharmaceutical Market," Centro Industrial de Laboratorios Farmaceuticos-Argentina, Press Conference, Jul. 20, 1993, Washington, DC.
301."Health Care Reform: A National Perspective," Wisconsin Pharmacists Association, Aug. 13, 1993, Appleton, WI.
302."Economic Realities of the Pharmaceutical Market," National Association of Chain Drug Stores, Board Meeting, Aug. 14, 1993, Colorado Springs, CO.
303."Pharmacy Opportunities in Health Care Systems of the 1990s," Invited Presentation, Health Care Decisions for the 90s Committee, a joint committee of the Kansas House of Representatives and Senate, Aug. 19, 1993, Topeka, KS.
304."Pharmacy and Cost Containment," Pharmaceutical Economics Workshop, University of British Columbia, Sept. 1, 1993, Vancouver, British Columbia, Canada.
305."Generics in a Dynamic Global Pharmaceutical Marketplace," Canadian Drug Manufacturers Association, Annual Meeting, Sept. 14, 1993, Toronto, Ontario, Canada.
306."Pharmacy, Managed Competition, and the Health Care Reform Agenda," Academy of Managed Care Pharmacy, Regional Academy Program, Sept. 18, 1993, Springfield, MA.
307."Health Care Reform and the Dynamic Pharmaceutical Marketplace," Annual Conference on Pharmacy Benefit Management, Diversified Pharmaceutical Services, Sept. 20, 1993, Minneapolis, MN.
308."American Health Care Reform and the Value of Pharmacists," Annual Pharmacy Congress, Pharmaceutical Society of Singapore, Sept. 25, 1993, Singapore.
309."Health Care Reform in the U.S. and Observations About Health Care in Singapore," Invitational Lecture, Pharmaceutical Society of Singapore, Sept. 27, 1993, Singapore.
310."International Comparison of Pharmaceutical Prices," IBC Technical Services, The 2nd Annual Conference on Pricing and Reimbursement of Pharmaceuticals, Oct. 8, 1993, London, England.
311."National Health Care Reform and Pharmaceutical Care," 1993 Fall Preceptors Conference, Department of Pharmacy Practice, University of Minnesota, Oct. 16, 1993, Minneapolis, MN.
312."Managed Health Care -- The Challenge for Community Pharmacy," 12th Annual George S. Maggio Memorial Breakfast, Pharmacists Planning Services, Inc., Oct. 26, 1993, Indianapolis, IN.
313."Pharmacy Benefit Management Firms: Future Scenarios," National Association of Chain Drug Stores, Board Meeting, Oct. 27, 14, 1993, New York, NY.
314."Health Care Reform & Pharmacy," Seminar on Pharmacy and Health Care Reform -- 1993, Century Mortar Club, University of Minnesota, Nov. 7, 1993, Bloomington, MN.
315."The Use of Socio-Economic Data on New Drug Therapies by Health Decision Makers," Symposia Series on the Socio-Economic Aspects of Drug Therapy Innovation, The Rhone-Poulenc Rorer Foundation, Nov. 10, 1993, Antony, France.
316."Health Care Reform and Hospital Pharmacy," VHA North Central Region, Pharmacy Managers' Meeting, Nov. 17, 1993, Minneapolis, MN.
317."Evaluation of the Medicaid Drug Rebate Program," Fall Symposium, Medicaid Pharmacy Administrators, Nov. 18, 1993, Research Triangle Park, NC.
318."Principles of Paying for Pharmaceutical Services," Seminar on Pharmaceutical Remuneration: Paying Pharmacists to Meet Patients' Needs, Pharmacy Practice Research Resource Centre, Royal Pharmaceutical Society of Great Britain, Dec. 2, 1993, London, England.
319."Managed Competition and the Health-Care Reform Agenda," Mid Year Clinical Meeting, American Society of Hospital Pharmacists, Dec. 6, 1993, Atlanta, GA.
320."National Health Policy: Focus on Drug Pricing Issues," Mid Year Clinical Meeting, American Society of Hospital Pharmacists, Dec. 7, 1993, Atlanta, GA.
321."Future of Pharmacy in Health Care," Executive Officers, Jack Eckerd Corporation, Dec. 14, 1993, Clearwater, FL.

322."Managing Pharmacy in the Health Care Reform Era," Metro Professional Pharmacists Society, Jan. 18, 1994, Minneapolis, MN.
323."Implications of Pharmaceutical Coverage and Expenditures for U.S. Health Care Reform," statement before Subcommittee on Health and the Environment, Committee on Energy and Commerce, U.S. House of Representatives, Feb. 8, 1994, Washington, DC.
324."Pharmacy Practice in the Next Ten Years," Keystone Therapeutic Conference, University of Colorado, School of Pharmacy, Feb. 20, 1994, Keystone, CO.
325."Marketing High-Tech Drugs in the New Pharmaceutical Marketplace," Boulder Series in Managed Care, Synergen Corporation, Feb. 22, 1994, Boulder, CO.
326."Health Care Reform in Minnesota and Prescription Pricing," Glaxo National Accounts Meeting, Mar. 16, 1994, Minneapolis, MN.
327."Pharmaceutical Price Discrimination: Issues and Evidence," Pharmacists Planning Services, Inc., Mar. 21, 1994, Seattle, WA.
328."The Changing Pharmaceutical Marketplace and Pricing Patterns," press conference, American Association of Retired Persons, Mar. 24, 1994, Washington, DC.
329."Prescription Prices -- Are They Competitive?" 39th Annual Ohio Pharmaceutical Seminar on Managed Competition and Pharmaceutical Care: A Challenge for the Profession, Apr. 18, 1994, Columbus, OH.
330."Pharmaceuticals Under Health Care Reform," statement before the Finance Committee, United States Senate, Apr. 19, 1994, Washington, DC.
331."The Value of a Pharmaceutical Benefit," Challenges and Opportunities in Prescription Benefit Management Conference, Prescription Network of Kansas, Apr. 21, 1994, Kansas City, MO.
332."Dynamic Change in the Pharmaceutical Market," National Association of Chain Drug Stores, Annual Meeting, Board of Directors, Apr. 22, 1994, West Palm Beach, FL.
333."Impact of the Argentinean Pharmaceutical Industry on Consumer Access to Pharmaceuticals," statement before the Health Committee of the Argentinean Congress, May 10, 1994, Buenos Aires, Argentina.
334."Affordability and Access to Pharmaceuticals," IX Latin American Forum on the Pharmaceutical Industry, Association Latinoamericano de Industria Farmaceuticos, May 12, 1994, San Carlos de Bariloche, Argentina.
335."Health Care Reform and Hospital Pharmacy," Glaxo's first Annual Midwest Regional Advisory Board for Hospital Pharmacy, May 19, 1994, Chicago, IL.
336."Implications of the Administration's Health Care Reform Program on Prescription Distribution," Third Annual MediSpan User Meeting, May 20, 1994, Indianapolis, IN.
337."Contributions of Paul and Addie Catherine Parker to Hospital Pharmacy Residents," Paul F. Parker Seminar, May 20, 1994, Ann Arbor, MI.
338."Pharmaceutical Pricing and Healthcare Reform Legislation," Public Policy Track, Session Chair, 30th Annual Meeting, Drug Information Association, Jun. 9, 1994.
339."Restructuring in the Pharmaceutical Marketplace: Impact on Pharmaceutical Pricing," Public Policy Track, Session Chair, 30th Annual Meeting, Drug Information Association, Jun. 9, 1994.
340."Marketing Your Profession, Your Pharmacy, and Yourself," Rookie Training Camp, Thrifty-White Drug Stores, Inc., Jun. 15, 1994, Forest Lake, MN.
341."Shaping Pharmacy's Future in Managed Care," Managed Health Care Summit, Medicine Shoppes, Jun. 24, 1994, St. Louis, MO.
342."Biotechnology, Innovation, Investment, and Public Policy," CA Bioscience and Health Care Reform Conference, University of CA, Jul. 8, 1994, Los Angeles, CA.
343."Competition and Pricing in the Pharmaceutical Industry," invited presentation to Congressional members and staffers, House of Representatives, U.S. Congress, Aug. 4, 1994, Washington, DC.
344."Competition and Pricing in the Pharmaceutical Industry," invited presentation to Congressional members and staffers, Senate, U.S. Congress, Aug. 4, 1994, Washington, DC.
345."Trends in Medicaid Drug Expenditures and Rebates," Western Medicaid Pharmacy Administrators Association, Sept. 30, 1994, Park City, UT.
346."Vertical Integration Issues in the Pharmaceutical Market," Federal Trade Commission, meeting with Chairman, Commissioners, and staff, Oct. 5, 1994, Washington, DC.
347."An Evaluation of Medicaid Drug Expenditures under OBRA 90," Wintergreen Research Conference III, Oct. 15, 1994, Wintergreen, VA.
348."Understanding Expenditure and Distribution Channels in the Pharmaceutical Market," Wintergreen Research Conference III, Oct. 15, 1994, Wintergreen, VA.
349."Impact of Vertical Integration in the Pharmaceutical Market on Consumers," Federal Trade Commission, meeting with Commissioner and staff, Oct. 24, 1994, Washington, DC.

350."Medicaid Drug Expenditures Before and After the Rebate Program," American Public Health Association, Annual Meeting, Nov. 1, 1994, Washington, DC.
351."New Developments in Medicaid Prescription Drug Program," American Public Welfare Association, Annual Meeting, Nov. 2, 1994, Washington, DC.
352."Basics of Pharmacoeconomics," Cost Effective Medical Care in a Changing Environment Conference (continuing medical education and continuing pharmacy education), Preferred One & PCS Health Systems, Inc., Nov. 4, 1994, St. Paul, MN.
353."Changes in the Health Care Landscape: Impact on Pharmaceutical Manufacturers and the Pharmaceutical Market," Changes in the Health Care Landscape Workshop, U. S. General Accounting Office, Nov. 14, 1994, Washington DC.
354."Health Care Reform Issues and the Pharmaceutical Market," National Pharmaceutical Council, Board of Directors Meeting, Nov. 18, 1994, Chantilly, VA.
355."Drug Pricing and Drug Use by Senior Citizens," Minnesota Senior Federation, Committee of Drug Policy Issues, Nov. 21, 1994, St. Paul, MN.
356."Emerging Standards for Pharmacoeconomics: Academic Perspectives," American Society of Hospital Pharmacists, Mid-Year Clinical Meeting, Dec. 7, 1994, Miami Beach, FL.
357."Trends in Pharmacy Reimbursement and the Provision of Pharmacy Services Under the Medicaid Program," American Pharmaceutical Association, press briefing, Jan. 23, 1995, Washington, DC.
358."Economic Assessment of Market Forces, Regulatory, and Legislative Developments in the Generic Drug Market," National Association of Pharmaceutical Manufacturers, Annual Meeting, Feb. 2, 1995, San Juan, PR.
359."Multiple Source Drug Products and Their Future Role," National Pharmaceutical Alliance, Mar. 3, 1995, Phoenix, AZ.
360."Impact of Health Care Reform on Nuclear Pharmacy," American Pharmaceutical Association, Academy of Pharmacy Practice Management, Section on Nuclear Pharmacy, Annual Meeting, Mar. 20, 1995, Orlando, FL.
361."The Role of National Drug Policy in Managing Pharmaceutical Utilization and Expenditures," International Workshop on Pharmacoepidemiology and Pharmacoeconomics for the Implementation of National Drug Policy, Ministry of University Affairs, Apr. 17, 1995, Thailand, Chiang Mai, Thailand.
362."Effects of a National Health Insurance Scheme on Pharmacy," International Workshop on Pharmacoepidemiology and Pharmacoeconomics for the Implementation of National Drug Policy, Ministry of University Affairs, Apr. 19, 1995, Chiang Mai, Thailand.
363."Basic Principles of Pharmacoeconomics," International Workshop on Pharmacoepidemiology and Pharmacoeconomics for the Implementation of National Drug Policy, Ministry of University Affairs, Apr. 19, 1995, Chiang Mai, Thailand.
364."From Medicaid to Managed Care--The Impact on Pharmacy," Minnesota Health Care Update, Glaxo Regional Sales Meeting, Apr. 25, 1995, Bloomington, MN.
365."America's Health Care System: Who's in Control? Consolidation in the Drug Industry," A Conference on the Dangers of Health Industry Consolidation and Corporatization and the Affect on Quality, Access, and Cost, Citizens Fund, May 10, 1995, Washington, DC.
366."Evaluation of the Medicaid Drug Rebate Program," Open Seminar, Health Care Financing Administration, Jun. 7, 1995, Baltimore, MD.
367."Impact of the Medicaid Drug Rebate Program on Access, Utilization and Expenditures," Office of Research and Development, Health Care Financing Administration, Jun. 7, 1995, Baltimore, MD.
368."Formularies, Rebates, Generic and Therapeutic Substitution, and Reference Pricing," 4th International Symposium on Drug Development: Utilization and Costs of Medications, Faculty of Pharmacy, University of Montreal, Jun. 13, 1995 Montreal, Quebec, Canada.
369."Legal, Regulatory, and Professional Aspects of Pharmacy Incentive Programs," 1996 NACDS Pharmacy Conference, Aug. 25, 1995, Chicago, IL.
370."Pharmacoeconomics and Public Policy Issues Related to Immunotherapy", International Congress on New Immunosuppresive Drugs, Aug. 28, 1995, Minneapolis, MN.
371."Insurers Should Cover Medically Valid Off-Label Uses of Pharmaceuticals," Clinical Economics '95, Leonard Davis Institute, University of Pennsylvania, Sept. 13, 1995, Boston, MA.
372."Vertical Integration of Manufacturers & PBMs," MediSpan Annual Users Conference, Sept. 27, 1995, Indianapolis, IN.
373."PriceChek PC: Advanced Applications," MediSpan Annual Users Conference, Sept. 28, 1995, Indianapolis, IN.
374."Horizontal Mergers in the Pharmaceutical Market," Century Mortar Club Annual Management Conference, Jan. 13, 1996, Minneapolis, MN.

375. "The Role of Pharmacy in the Health Care System," South African Symposium on Pharmaceutical Care, Feb. 27, 1996, Johannesburg, South Africa.
376. "The Effect of Health Care Reform on An Academic Health Center," Marilyn K. Speedie and Stephen W. Schondelmeyer, Council of Deans, American Association of Colleges of Pharmacy, Feb. 29, 1996.
377. "Research in Pharmacoeconomics and Public Policy," Research Seminar, School of Pharmacy, University of Pittsburgh, Mar. 28, 1996, Pittsburgh, PA.
378. "Restructuring an Academic Health Center," Wintergreen Research Conference IV, Center on Drugs and Public Policy, University of Maryland, May 5, 1996, Wintergreen, VA.
379. "Approaches to the Evaluation of Bill C-91 and Its Impact on Canadians," Canadian Drug Manufacturers Association, May 24, 1996, Toronto, Canada.
380. "PBMs: Who's Managing What for Whom?" Public Policy Track: PBMs: What Have We Learned Since Merck-Medco? Drug Information Association, 32nd Annual Meeting, Jun. 10, 1996, San Diego, CA.
381. "Situation and Perspectives on Spanish Hospital Pharmacy: Comparison with the U.S.," Sociedad Espanola de Farmacia Hospitalaria, Symposium on the Future of Hospital Pharmacyx, Jun. 22, 1996, Santiago de Compostello, Spain.
382. "Pharmacoeconomics and Pharmaceutical Care," Universidad de Santiago, Jun. 24, 1996, , Santiago de Compostello, Spain.
383. "Economic Situation of Community Pharmacy: U.S.and Spain," FEFE Conference (Federacion Espanola de Farmaceuticos Empressarios) [i.e, Spanish Federation of Community Pharmacy Owners], Jun. 26, 1996, Madrid, Spain.
384. "Pharmaceutical Care, Disease State Management, and Restructuring the Global Pharmaceutical Market," Symposium for Lilly researchers and executives, Lilly Espana, Jun. 28, 1996, Madrid, Spain.
385. "Generic Pharmaceutical Use in Venezuela," Venezuelan Pharmaceutical Manufacturers, Sept. 20, 1996, Caracas, Venezuela.
386. "The Coming Millennium: Pharmaceuticals in the Year 2000," National Pharmaceutical Alliance, Fall Seminar, Oct. 7, 1996, Nashville, TN.
387. "Changes in Academic Health Sciences Centers: Minnesota Case Study," 1997 VA Conference, Department of Veterans Affairs and the University of Tennessee, Jan. 12, 1997, Memphis, TN.
388. "The Cost of Bill C-91 to Canadians: Part Deux," Conference on A Question of Balance, Canadian Drug Manufacturers Association, Jan. 30, 1997, Montreal, Quebec, Canada.
389. "Generic Medicines in Venezuela: Realities and Perspectives of Production, Distribution, and Consumption," Invitational Conference sponsored by the Venezuelan Minister of Health and Social Assistance with the Fundacion Elias Morris Curiel, Mar. 3, 1997, Caracas, Venezuela.
390. "Pharmacoeconomics: State of the Art and Future Directions," 98th Annual Meeting, American Society of Clinical Pharmacology and Therapeutics, Mar. 7, 1997, San Diego, CA.
391. "Who Pays for Health Care?" 1997 Ethics Conference, North Dakota State University, Mar. 18, 1997, Fargo, ND.
392. "Research and Public Policy Issues in Pharmacoeconomics," Invited Faculty and Research Seminar, University of Saskatchewan, Mar. 24, 1997, Saskatoon, Saskatchewan, Canada.
393. "Pharmacoeconomics: State of the Art and Practice," Invited Seminar for Professional Students, University of Saskatchewan, Mar. 24, 1997, Saskatoon, Saskatchewan, Canada.
394. "State Pharmacy Practice and Managed Care Concerns," National Association of Chain Drug Stores, April 11, 1997, Alexandria, VA.
395. "Collecting Outcomes Data to Obtain a Bigger Piece of the Health Care Pie," 10th Annual Food Marketing Institute Meeting, April 21, 1997, New Orleans, LA.
396. "Documenting Patient Outcomes: A New Role for Pharmacists on the Health Care Team," Tenth Annual Food Marketing Institute, Supermarket Pharmacy Conference, Apr. 21, 1997, New Orleans, LA.
397. "Shaping the Future: Making Your Vision a Reality," National Association of Chain Drug Stores, Board of Director's Meeting, Apr. 25, 1997, West Palm Beach, FL.
398. "Rx Case Solutions," Georgia Pharmacists Association, NCPA Conference, May 19, 1997, Atlanta, GA.
399. "Collecting Outcomes Data To Obtain a Bigger Piece of the Health Care Dollar Pie," Metropolitan Pharmacists Association, May 20, 1997, Minneapolis, MN.
400. "Shaping the Future: Making Your Vision a Reality," Coalition of American Pharmacies, July 21, 1997, Dallas, TX.
401. "Pharmacoeconomic Assessment of Cardiovascular Disease," Roundtable, Quality Research Services, Inc., August 1, 1997, Oak Brook, IL.
402. "The Minnesota Pharmaceutical Care Project Experience," Robert J. Cipolle and Stephen W. Schondelmeyer, Century Mortar Club Management Seminar, September 20, 1997, Minneapolis, MN.

403. "Current Status and Future Policy for New Drug Development," Bureau of Pharmaceutical Affairs, Ministry of Health and Welfare, Republic of South Korea, September 29, 1997, Seoul, Korea.
404. "Issues Relate to Current Drug Pricing System," Korean Institute for Health and Social Affairs, September 29, 1997, Seoul, Korea.
405. "Drug Pricing and National Medical Insurance Systems," Korean Pharmaceutical Manufacturers Association, September 29, 1997, Seoul, Korea.
406. "Trends in Worldwide Pharmaceutical Market," Seminar, Korean Drug Research Association, September 30, 1997, Seoul, Korea.
407. "Pharmaceutical Competition, R&D and Profits," Seminar, Korean Drug Research Associaiton, September 30, 1997, Seoul, Korea.
408. "Coverage & Expenditures for Prescription Drugs Under a National Health System," Korean National Medical Insurance Corporation, October 1, 1997, Seoul, Korea.
409. "HIV Drug Expenditures and Financing," Invitational Workshop, George Washington University, October 9, 1997, Washington, DC.
410. "Transfer Pricing and Multi-national Drug Distribution," Seminar, Economics Office, Internal Revenue Service, October 9, 1997, Washington, DC.
411. "Scanning and Shaping Your Professional Practice Environment," 30th Annual Seminar in Pharmacy Practice, College of Pharmacy, University of Toledo, October 17, 1997, Toledo, OH.
412. "International Lessons for Consideration in Canada: Pharmaceutical Benefits," National Conference on Pharmacare, Advocate Institute, November 5, 1997, Ottawa, Canada.
413. "Gestion de la Prestacion Farmaceutica: la Experiencia de los Estados Unidos de Norteamerica" ["Pharmaceutical Benefit Management: Experience in the U.S.], Pharmacoeconomic Roundtable, Cooperative de Consumo Entidades Medicas del Interior, November 29, 1997, Montevideo, Uruguay.
414. "Impacto de la Nueva Ley de Patentes Uruguaya en el Costo y Calidad de los Medicamentos" ["Impact of the New Uruguay Patent Laws on the Cost and Quality of Medications], Pharmacoeconomic Roundtable, Cooperative de Consumo Entidades Medicas del Interior, November 29, 1997, Montevideo, Uruguay.
415. "Economic Re-Forecast of the Pharmaceutical Market," National Council of Prescription Drug Programs, March 3, 1998, Scottsdale, AZ.
416. "New Perspectives on Technology in the Pharmaceutical Market," Grand Opening of new facility, Hosokawa Micron Powder Systems, May 19, 1998, Morristown, NJ.
417. "Pharmaceutical Benefits That Benefit Patients," Blue Cross Blue Shield of Michigan, June 1, 1998, East Lansing, MI.
418. "Role of Generics in the World Pharmaceutical Market," 1st Annual Conference, International Generic Pharmaceutical Association, June 4, 1998, Rome, Italy.
419. "Health Care Costs Due to Intellectual Property Extensions," 1st Annual Conference, International Generic Pharmaceutical Association, June 4, 1998, Rome, Italy.
420. "Public Protection Issues: Prescription and OTC Drug Advertising, Marketing & Pricing Practices," State of Minnesota, Attorney General, Continuing Education Program on Consumer Health Law Issues, June 19, 1998, St. Paul, MN.
421. "Implementation of a Sandwich Graduate Program in Pharmacy Administration Between U.S. and Thai Universities," Thai – U.S. Consortium Meeting, June 25, 1998, Chiang Mai, Thailand.
422. "Price Differentials Between Thai and U.S. Drug Products," Thailand Food & Drug Administration, June 29, 1998, Bangkok, Thailand.
423. "Access to Pharmaceuticals and the Economic Crisis," Thailand Food & Drug Administration, June 29, 1998, Bangkok, Thailand.
424. "Pharmacoeconomics and Pharmaceutical Pricing," National Defense Medical Center, Taiwan, July 2, 1998, Taipei, Taiwan.
425. "Sources of Growth in Prescription Drug Expenditures," National Bureau of Health Insurance, Taiwan, July 2, 1998, Taipei, Taiwan.
426. "Evaluating Pharmacy Service and Quality," Century Mortar Club Management Seminar, University of Minnesota, September 19, 1998, Minneapolis, MN.
427. "Impact Economia de la Atencion Farmaceutica" [Economic Impact of Pharmaceutical Care], Pharmaceutical Care Workshop, Pharmacists Association of Madrid, October 5, 1998, Madrid, Spain.
428. "Sistema Sanitario y Atencion Farmaceutico" [Health Care System and Pharmaceutical Care,], Joint Conference of the Pharmacists Association of Madrid and Spanish Minister of Health, October 6, 1998, Madrid, Spain.
429. "Benefits and Costs of Pharmaceutical Care," Faculty Seminar, Madrid College of Pharmacy, October 7, 1998, Madrid, Spain.

430. "Pharmaceutical Benefits That Benefit Patients," Fairview Physician Associates, Medication Management Seminar, October 13, 1998, Edina, MN.
431. "Prescription Drug Needs and Expenditures of the Elderly," Seminar, United Health Care, October 14, 1998, Minnetonka, MN.
432. "The FDA & Its Role in Providing Access to Prescription Drugs," Congressional Hearing sponsored by Senator Paul Wellstone and Representative Gil Gutknecht, Shoreview Community Center, October 27, 1998, Shoreview, MN.
433. "Impacto de un Mercado de Genericos Intercambiales" [Impact of An Interchangeable Generic Drug Market], 1st International Meeting on Interchangeable Generic Drugs, Consejo de Salubridad General y Facultad de Medicina, Universidad Nacional Autonoma de Mexico, October 29, 1998, Mexico City, Mexico.
434. "Prescription Drug Trends in Use and Expenditures," Seminar, ExpressScipts Rx, November 17, 1998, Plymouth, MN
435. "Development of a Graduate Program in Social & Administrative Pharmacy," Seminar, Chulalongkorn University, December 1, 1998, Bangkok, Thailand.
436. "National Health Insurance in Taiwan: Drug access & Expenditures," Taiwan Bureau of National Health Insurance, December 4, 1998, Taipei, Taiwan.
437. "Pharmacoeconomic Considerations in the Vitamin D Analog Market," Vitamin D Analog Focus Group Meeting, Bone Care International, Inc., December 16, 1998, Scottsdale, AZ.
438. "Pricing and Reimbursement in the Vitamin D Analog Market," Seminar, Bone Care International, January 11, 1999, Madison, WI.
439. "Analysis of the CBO Study: How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry," Annual Meeting, National Association of Pharmaceutical Manufacturers, February 1, 1999, San Juan, Puerto Rico.
440. "Is There a Role for the Federal Government in Overseeing the Price of Pharmaceuticals?" Pharmaceutical Pricing and Reimbursement Workshop, Drug Information Association, April 16, 1999, Washington, DC.
441. "Medicare & Prescription Drugs: What Can You Expect in the Future," Senior Citizen Meetings with Senator Paul Wellstone, July 6, 1999, (3 separate meetings) Duluth, MN; Moorehead, MN; and Alexandria, MN.
442. "Ethical Dilemmas in Pharmacy," Faculty of Pharmacy Seminar, Potchefstroom University, July 26, 1999, Potchefstroom, South Africa.
443. "Healing Y the Bible," Faculty of Economics Seminar, Potchefstroom University, July 27, 1999, Potchefstroom, South Africa.
444. "Pharmacoeconomics, Disease Management, DUR, and Managed Pharmaceutical Care: Ethical Issues," Pharmacy Practice Faculty Seminar, Potchefstroom University, July 28, 1999, Potchefstroom, South Africa.
445. "Academic Integrity, Professionalism, and Ethical Responsibility," Faculty of Pharmacy Seminar, Potchefstroom University, July 28, 1999, Potchefstroom, South Africa.
446. "Academic Integrity, Professionalism, and Ethical Responsibility," Pharmacy Students Association Seminar, Potchefstroom University, July 28, 1999, Potchefstroom, South Africa.
447. "Ethical Dilemmas in Pharmacy," Pharmacy Student Lecture, Potchefstroom University, July 29, 1999, Potchefstroom, South Africa.
448. "Healing & the Bible," Faculty of Theology Seminar, Potchefstroom University, July 29, 1999, Potchefstroom, South Africa.
449. "Healing & the Bible," Pharmacy Student Lecture, Potchefstroom University, July 30, 1999, Potchefstroom, South Africa.
450. "Perspectives on Health Care Needs and Work Force in Third World Countries," Faculty of Health Sciences, Strategic Planning Workshop, Potchefstroom University, July 30, 1999, Potchefstroom, South Africa.
451. "Pharmaceutical Care in the Third World—Policy and Ethics," Pharmacy Practice Seminar, Potchefstroom University, August 2, 1999, Potchefstroom, South Africa.
452. "Ethical Issues in Pharmaceutical Education & Pharmaceutical Care," Pharmacy Practice Seminar, Potchefstroom University, August 2, 1999, Potchefstroom, South Africa.
453. "Access to Pharmaceuticals in Developing Countries," Seminar at Prime Cure Clinics, August 3, 1999, Tsembisa, South Africa.
454. "Pharmaceutical Economic Trends and Development," Industry Seminar, August 4, 1999, Johannesburg, South Africa.

455. "Healing & the Bible," Faculty of Theology, Vaal Triangle Campus, Potchefstroom University, August 5, 1999, Vaal Triangle Campus, South Africa.
456. "Pharmacoeconomics: Access & Affordability Issues," Pharmacy Student Lecture, Potchefstroom University, August 10, 1999, Potchefstroom, South Africa.
457. "HIV and AIDS Therapy as a Pharmacist and as a Christian," Faculty of Nursing Seminar, Potchefstroom University, August 10, July 1999, Potchefstroom, South Africa.
458. "Development of Pharmaceutical Economics Methodologies," Pharmacy Practice Workshop, Potchefstroom University, August 11, 1999, Potchefstroom, South Africa.
459. "Ethical Dilemmas in Pharmacy," Faculty of Pharmacy Seminar, Potchefstroom University, August 11, 1999, Potchefstroom, South Africa.
460. ""HIV-Related Pharmaceuticals in the U.S. Market: Expenditures, Channels of Distribution, and Prescribing Trends," Staff Seminar, Henry J. Kaiser Family Foundation, November 9, 1999, Menlo Park, CA.
461. "Drug Pricing and Discount Programs: Where Are We Headed?," Public Hospital Pharmacy Coalition, Mid-Year Meeting, American Society of Health System Pharmacists, December 5, 1999, Orlando, FL.
462. "Trends in Pharmaceutical Costs & Utilization: What Can We Afford? How Do We Decide?" User Liaison Program, Agency for Health Care Policy & Research, U.S. Dept. of Health & Human Services, January 10, 2000, Atlanta, GA.
463. "Impact of Generic Pharmaceuticals on U.S. Health Care Expenditures," Annual Meeting, National Association of Pharmaceutical Manufacturers, January 31, 2000, Rio Grande, Puerto Rico.
464. "Drug Pricing: How Does It Work?" International Health Issue Group Meeting, Interfaith Center on Corporate Responsibility, February 10, 2000, New York, NY.
465. "State Legislation and Prescription Drug Access for Seniors," Health Action Committee, Minnesota Senior Federation, February 25, 2000, St. Paul, MN.
466. "Economics of Pharmaceutical Care," 1st International Meeting on Pharmaceutical Care, Colegio Oficial de Farmaceuticos de Madrid and the Peters Institute of Pharmaceutical Care—University of Minnesota, March 24, 2000, Madrid, Spain.
467. "Why Are Pharmacy Costs Rising?" Open Conference Call Seminar, User Liaison Program, Agency for Health Care Policy & Research, U.S. Dept. of Health & Human Services, Mar 28, 2000, Rockville, MD.
468. "Pharmacy Debate: Why Are Prescription Expenditures Rising So Much?" Health Care & Actuarial Symposium, Milliman & Robertson, April 11, 2000, Orlando, FL.
469. "Pipeline Pharmaceuticals: Assessing the Trends," Health Insurance Association of America Symposium, National Press Club, April 13, 2000, Washington, DC.
470. "Pipeline Pharmaceuticals: Assessing the Trends," Health Insurance Association of America Symposium, April 14, 2000, New York, NY.
471. "Meeting the Drug Therapy Needs of the Elderly: Economic & Public Policy Issues," Aging in the New Millennium Symposium, Geriatric Research, Education & Clinical Center, VA Medical Center, April 18, 2000, Minneapolis, MN.
472. "Economics, Outcomes and Politics," Stephen W. Schondelmeyer, Planned Pharmacists Services, Inc. Breakfast Meeting, April 26, 2000, Washington, DC.
473. "Prescription Drugs and Access," Brown Bag Seminar, Families USA, May 1, 2000, Washington, DC.
474. "Prescription Drug Dialogue," 25th Annual Convention, Minnesota Senior Federation, May 24, 2000, Duluth, MN.
475. "Medicaid Drug Rebate Program: Experience and Future Directions," Health Legislation Work Group, National Governors' Association, May 1, 2000, Washington, DC.
476. "Pharmaceuticals: How Can Regulation Cut Costs?" Summer Meeting, National Conference of Insurance Legislators, July 8, 2000, Burlington, VT.
477. "Costs and Coverage of Prescription Drugs," State Issues Forum, 2000 National Conference of State Legislators, July 17, 2000, Chicago, IL.
478. "Collaborative Research Opportunities Between Thailand and the United States," Seminar for Graduate Faculty in Social and Administrative Pharmacy, Faculty of Pharmaceutical Sciences, Chulalongkorn University, July 26, 2000, Bangkok, Thailand.
479. "The Concept of Pharmaceutical Care and Its Impact on the U.S. Health Care System," Tenth Year Establishment Anniversary, Faculty of Pharmaceutical Sciences, Naresuan University, July 27, 2000, Phitsanulok, Thailand.
480. "Pharmaceutical Care and Its Application in a Hospital Setting," Department of Pharmacy Seminar, Lampang Hospital, July 28, 2000, Lampang, Thailand.

481. "Global Perspectives of the Pharmaceutical Market and the Profession of Pharmacy," Seminar for the Departments of Community Pharmacy and Pharmacy Administration, Chiang Mai University, July 31, 2000, Chiang Mai, Thailand.
482. "Philosophy and Objectives of Post-Graduate Study in Social and Administrative Pharmacy," Faculty Seminar, Faculty of Pharmaceutical Sciences, Khon Kaen University, August 1, 2000, Khon Kaen, Thailand.
483. "Global Perspectives of the Pharmaceutical Market and the Profession of Pharmacy," Faculty Seminar, Faculty of Pharmaceutical Sciences, Khon Kaen University, August 2, 2000, Khon Kaen, Thailand.
484. "Internationalization of Social and Administrative Sciences and Potential for Academic Cooperation," Faculty Seminar, Faculty of Pharmaceutical Sciences, Khon Kaen University, August 2, 2000, Khon Kaen, Thailand.
485. "What's in the Federal / Legal Medicine Cabinet?" 13th Annual State Health Policy Conference, National Academy for State Health Policy, August 6, 2000, Minneapolis, MN.
486. "Average Wholesale Price and Pharmacy Reimbursement," Executive Seminar, Upsher-Smith Laboratories, Inc., August 25, 2000, Minneapolis, MN.
487. "Prescription Drug Prices," The Rotary Club of Minneapolis, September 15, 2000, Minneapolis, MN.
488. "Pharmaceutical Expenditures Under State Medical Assistance Programs," Pharmacy Technical Advisory Group, American Public Human Services Assoc., September 28. 2000, Washington, DC.
489. "Pharmacy Expenditures: Budgeting for the New Millennium," Joint Program of National Academy for State Health Policy and the Western Medicaid Pharmacy Administrators Association, October 4, 2000, San Antonio, TX.
490. "Prescription for Action: What's the Problem?" Midwest Conference, United Senior Action, October 24, 2000, Indianapolis, IN.
491. "Pharmaceutical Outcomes and the Elderly," Century Mortar Club Management Seminar, October 28, 2000, Minneapolis, MN.
492. "A New Business Model for Senior Drug and Discount Programs," Iowa Rx Cooperative Work Group, State of Iowa, November 10, 2000, Des Moines, IA.
493. "Pursuing A Passion: Practical Pointers from Paul F. Parker," Paul F. Parker Award Luncheon, University of Kentucky, American Society of Health Systems Pharmacists, December 5, 2000, Las Vegas, NV.
494. "Rational Management of Pharmaceutical Costs: Outcomes & the Elderly," An Invitational Conference sponsored by the Iowa Pharmacy Association and Wellmark Blue Cross and Blue Shield of Iowa, December 14, 2000, Des Moines, IA.
495. "Regulating Pharmaceutical Costs: Is It Good Policy?" American Medical Association, 27th Annual State Health Legislation Meeting, January 4, 2001, La Quinta, CA.
496. "Prescription Drugs: Demystifying the Industry," Health Action 2001, Families USA, January 27, 2001, Washington, DC.
497. "New Approaches in State Drug Assistance Programs," Wisconsin Family Impact Seminar, University of Wisconsin, March 1, 2001, Madison, WI.
498. "Legislative Reform on the Rising Cost of Prescription Drugs," 13th National Managed Health Care Congress, March 19, 2001, Atlanta, GA.
499. "Lunch and Drugs – How Can I Afford Both? Practical Approaches to Help the Elderly With Affordable Drug Therapy," Geriatrics for the Primary Care Provider Symposium, Geriatric Research, Education & Clinical Center, VA Medical Center, April 30, 2001, Minneapolis, MN.
500. "Science, Politics, and Money: What Would It Take to Bring Microbicides to Market?" Briefing Series for Journalists, Emerging Issues in Reproductive Health, The Henry J. Kaiser Family Foundation, May 4, 2001, New York, NY.
501. "Pharmaceutical Expenditure Trends and Policy Implications," Staff Seminar, American Society of Health System Pharmacists, May 30, 2001, Bethesda, MD.
502. "Current Pharmacy Actuarial Issues," Educational Meeting, Twin Cities Actuarial Club, June 5, 2001, Ham Lake, MN.
503. "The State of Community Pharmacy: Challenges & Opportunities for the Future," Keynote Address, Annual Meeting, Medicap Pharmacy, June 15, 2001, Des Moines, IA.
504. "The Future of Pharmacy & Drug Expenditures," Board of Directors Strategic Planning Session, Health Partners, June 27, 2001, Bloomington, MN.
505. "Do Drug Discount Programs Work?" Executive Board Meeting, Minnesota Senior Federation, July 9, 2001, St. Paul, MN.
506. "Access to Prescription Drugs: State and Federal Issues," Bureau of State Government Affaris, American Osteopathic Association, July 12, 2001, Chicago, IL.

507. "Prescription Drug Coverage & Access," Policy Strategy Session, Medicare Justice Coalition, Minnesota Senior Federation, July 17, 2001, Minneapolis, MN.
508. "Prescription Drugs: How Can I Afford Them?" Keynote Address, 23 Annual New Mexico Conference on Aging, August 22, 2001, Glorieta, NM.
509. "Medicaid Prescription Drug Expenditure Trends and Strategies for Their Management," Open Conference Call Presentation (due to Sept. 11, 2001 tragedy), Affiliated State Association Meeting, American Pharmaceutical Association, September 22, 2001, Minneapolis, MN.
510. "Access To Prescription Drugs for Seniors & Others," Public Policy Forum on Prescription Drugs, St. Mary's Hospital Medical Center, Legislative Task Force, October 12, 2001, Green Bay, WI.
511. "Prescription Drugs: Expenditures Trends and Recent State Initiatives," National Association of State Medicaid Directors, October 16, 2001, Washington, DC.
512. "Recent Developments and Trends in Pharmaceutical Pricing and Marketing," Northeast Legislative Association on Prescription Drug Prices, October 19, 2001, Montpelier, VT.
513. "Medicare Prescription Drugs: Where Do We Go From Here?" Medicare Prescription Drug Issues Workshop, American Public Health Association, October 21, 2001, Atlanta, GA.
514. "Pharmacy Benefit Options & Future Directions," Strategic Planning Seminar, Pharmacy Affairs Committee, Blue Cross Blue Shield of Michigan, October 22, 2001, Southfield, MI.
515. "Medicaid Drug Expenditure Management: Pharmacy's Perspective," Northwest State Pharmaceutical Association Executives, October 27, 2001, Boise, ID.
516. "Allocating Resources: Osteoporosis," Meeting the Challenge of Aging Seminar, University of Minnesota, November 3, 2001, Minneapolis, MN.
517. "Pharmaceutical Costs and Potential Solutions," North Central Medical Conference, November 3, 2001, Minneapolis, MN.
518. "Pharmacists and the Chilean Pharmaceutical Market," Seminar, SOFOFA (Chilean Society of Pharmacists), November 19, 2001, Santiago, Chile.
519. "Protecting Patients & Protecting Patents," Conference on the Chilean Pharmaceutical Market and Intellectual Property Rights, CILFA, November 20, 2001, Santiago, Chile.
520. "Purchasing Pharmacy Services: Purchasing What and From Whom?" CHCS Purchasing Institute, Center for Health Care Strategies, December 3, 2001, Berkeley, CA.
521. "De-Mystifying the Drug Industry," Plenary Session, Health Action 2002, National Grassroots Meeting, Families USA, January 18, 2002, Washington, DC.
522. "PRIME Institute and Pharmacy," Board of Directors, Minnesota Pharmacists Association, January 30, 2002, Minneapolis, MN.
523. "The State's Role in Prescription Drug Coverage," National Lieutenant Governors' Association, February 9, 2002, Washington, DC.
524. "Rx Expenditures and Patient Access," Graduate Program Seminar, College of Pharmacy, Ohio State University, February 19, 2002, Columbus, OH.
525. "Private Sector Strategies and Trends in Controlling Drug Costs: A National Perspective," Quarterly Educational Meeting, Northwest Medical Directors and Pharmacy Benefit Managers, February 22, 2002, Seattle, WA.
526. "Public Sector Strategies and Trends in Controlling Drug Costs: A National Perspective," Quarterly Educational Meeting, Northwest Medical Directors and Pharmacy Benefit Managers, February 22, 2002, Seattle, WA.
527. "Issues in Pharmacoeconomics & Drug Development," Workshop on Pharmacogenomics: The Legal, Ethical, & Clinical Challenges, sponsored by Consortium on Law and Values in Health, Environment & the Life Sciences, University of Minnesota, February 26, 2002, Minneapolis, MN.
528. "Rising Expenditures for Pharmaceuticals," Board of Directors Meeting, American Society of Health System Pharmacists, April 18, 2002, Bethesda, MD.
529. "Market Exclusivity & Access to Pharmaceutical Products: 1980-2001," Blue Cross Blue Shield Association Forum, Innovative Approaches to Improve Generic Drug Access, April 25, 2002, Washington, DC.
530. "Evaluating New Medicines: The Cost Side of Cost-Effectiveness," Conference on New & Old Drugs: Best Choices, Park Nicollet Institute, May 2, 2002, Bloomington, MN.
531. "Prescription Drugs: Innovation in Access," Midwest Senior Coalition, Midwest Academy Training, May 28, 2002, Madison, WI.
532. "Medicaid Pharmaceutical Expenditure Trends: Sources of Growth," Managed Health Care Solutions Forum, Center for Health Care Strategies, June 17, 2002, Washington, DC.
533. "Drug Use by Seniors in America," United Health, July 9, 2002, Eagan, MN.

534. "Prescription Drugs: Prices & Medicare," EPhECT Community Teacher Luncheon, College of Pharmacy, University of Minnesota, August 21, 2002, Roseville, MN.
535. "State Medicaid Drug Expenditure Crisis: What Can Be Done?" National Association of State Pharmaceutical Association Executives and American Pharmaceutical Association, September 22, 2002, Washington, DC.
536. "Pharmacoeconomics: The U.S. Experience," Executive Roundtable on Pharmaceuticals, Institute of the Americas, October 2, 2002, Santiago, Chile.
537. "Prescription Drugs, Prices and Medicare," University Women's Association, November 11, 2002, Owatanna, MN.
538. "Medicaid Pharmaceutical Expenditure Trends: Sources of Growth," Legislative Conference, National Association of Chain Drug Stores, November 15, 2002, Orlando, FL.
539. "Rising Expenditures for Pharmaceuticals: Public Policy and Pharmacy Practice Implications," Mid-Year Clinical Meeting, American Society of Health System Pharmacists, December 10, 2002, Atlanta, GA.
540. "A Hard Look at Prescription Drugs," Mary Hanson Show (a local access television program focusing on health care issues), January 6, 2003, Minneapolis, MN
541. "Pharmacoeconomics & Pharmacy," 2003 Annual Mid-Winter Convention, Pharmaceutical Society of the State of New York, January 10, 2003, Albany, NY.
542. "Economics Issues Facing Pharmacy Owners," 2003 Annual Mid-Winter Convention, Pharmaceutical Society of the State of New York, January 11, 2003, Albany, NY.
543. "Prescription Drugs: Affordability and Access," Minnesota Public Radio, January 13, 2004, St. Paul, MN.
544. "Rural Pharmacy Issues: Overview of the Market," Rural Pharmacy Issues Meeting, National Rural Health Association and Office of Rural Health Policy, U.S. Dept. of Health & Human Services, January 15, 2003, Washington, DC.
545. "Prescription Drugs: Prices & Medicare," St. Paul Men's Jewish League, February 3, 2003, St. Paul, MN.
546. "Drug Affordability, Access and Re-Importation," Mary Hanson Show (local access TV), February 3, 2003, Minneapolis, MN.
547. "Understanding the Drug Benefit Debate: How Will Affect Your Organization?" National Managed Health Care Congress, 7th Annual Congress on Medicare & Medicaid, March 10, 2003, Washington, DC
548. "Pharmaceutical Databases: Medicaid & Other Settings, Evaluating the Quantity & Quality of Drug Use Behaviors," Nephrology Analytical Service, U.S. Renal Dialysis System, March 13, 2003, Minneapolis, MN.
549. "Economic Factors Affecting Therapeutically Equivalent Biologicals," Conference on Exploring the Pathway to Generic Biologics, National Organization for Rare Diseases, March 19, 2003, Washington, DC
550. "Legislative Update: Understanding All Sides of the Pharmacy Benefits Debate and How It Will Impact Your Organization," 15th Annual National Managed Health Care Congress, March 20, 2003, Washington, DC.
551. "Prescription Drugs: Prices & Medicare," Red Wing Chapter, University of Minnesota Alumni Association, April 10, 2003, Red Wing, MN.
552. "Prescription Drugs & Medicare," 1st Annual National Health Issues Symposium, Nevada College of Pharmacy, May 4, 2003, Las Vegas, NV.
553. "Prescription Drugs & Medicare," 30th Anniversary Convention, Minnesota Senior Federation, May 5, 2003, Brooklyn Center, MN.
554. "Medicare & Rx Drugs Workshop," 30th Anniversary Convention, Minnesota Senior Federation, May 5, 2003, Brooklyn Center, MN.
555. "State Prescription Drug Programs," Agency for Health Research & Quality, User Liaison Program, Conference Call, June 9, 2005.
556. "The Role of Generics in the U.S. Pharmaceutical Market," World Bank, Workshop on Access to Generic Drugs, June 24, 2003, Washington, DC.
557. "Prescription Drugs: Why Do They Cost So Much?" Congressman Gil Gutenknecht Senior Health Symposium, Gideon Pond Presbyterian Home, August 25, 2005, Bloomington, MN.
558. "Medicaid Program: Pharmacy & Drug Spending," NACDS State Issues Conference: Medicaid Drug Program, National Association of Chain Drug Stores, Sept. 18, 2003, Seattle, WA.
559. "The Role of Generics in the U.S. Pharmaceutical Market," 1st International Colloquim in Interchangeability of Generic Medications, September 24, 2003, Cancun, Mexico.
560. "Potential State Roles in Drug Purchasing," Minnesota Senior Federation, Board Meeting, October 1, 2003, Minneapolis, MN.
561. "Medicaid Program: Pharmacy & Drug Spending," NACDS State Issues Conference: Medicaid Drug Program, National Association of Chain Drug Stores, October 8, 2003, Baltimore, MD.

562. "Prescription Drugs: How Can You Afford Them?" Mini Medical School, Academic Health Center, University of Minnesota, October 20, 2003, Minneapolis, MN.
563. "Prescription Drug Pricing Games: Discounts That Will Cost You," American Public Health Association, Special Session on Medicare Drug Benefit, November 18, 2003, San Francisco, CA.
564. "Prescription Drugs: How Can You Afford Them?" St. Croix Valley Alumni Association, University of Minnesota Alumni Association, December 1, 2003, Stillwater, MN.
565. "Prescription Drug Discounts That May Cost You," New England Benefits Council, December 16, 2003, Boston, MA.
566. "High Cost of Prescription Drugs," Minnesota Rural Health Association & Rice Memorial Hospital, January 9, 2004, Willmar, MN.
567. "Medicaid & Medicare Drug Pricing: Development of a Strategy to Determine Market Prices," Expert Panel Meeting, CMS Project, Abt Associates, Inc., January 27, 2004, Washington, DC.
568. "Prescription Drugs Issues in the Medicare Modernization Act," Roundtable on the Medicare Prescription Drug Improvement and Modernization Act, St. Thomas University, Jan. 30, 2004, Minneapolis, MN.
569. "Pharmaceutical Care Impact on Quality of Care," Minnesota Blue Cross Blue Shield, February 12, 2004, Minneapolis, MN.
570. "Prescription Drugs: Is Re-importation from Canada Safe?" Governor's Summit on Prescription Drugs, February 24, 2004, Washington, DC.
571. "The Reimportation Debate," National Medicare Rx Congress, February 25, 2004, Washington, DC.
572. "Opportunities & Challenges Under Medicare Rx Reform: Impact on Drug Prices," Conference on Prescription Drug & Medicare Improvement Act, Public Hospital Pharmacy Coalition, February 27, 2004, Washington, DC.
573. "Prescription Drugs: How Can You Afford Them?" Rochester Area Alumni & Friends, University of Minnesota Alumni Association, March 15, 2004, Rochester, MN.
574. "Prescription Drugs: How Can You Afford Them?" Mankato Area Alumni & Friends, University of Minnesota Alumni Association, March 22, 2004, Mankato, MN.
575. "Medicare Part D: Where Are We Going?" Special Medicare Prescription Workshop, Pharmacist Planning Service, Inc., March 27, 2004, Seattle, WA.
576. "Medicare Part D: Drug Coverage & Other 'Ds'," Health Care Caucus, Bear Stearns, March 30, 2004, New York, NY.
577. "Prescription Drugs: How Can You Afford Them?" Mini Medical School, Academic Health Center, University of Minnesota, April 12, 2004, Minneapolis, MN.
578. "What Is the Medicare Drug Benefit All About?" Conference on New Medicare Prescription Drug Benefit, Century Mortar Club, College of Pharmacy, Univ. of Minnesota, April 24, 2004, Minneapolis, MN.
579. "Now What? What Does the MDB Mean for the Future of Pharmacy?" Conference on New Medicare Prescription Drug Benefit, Century Mortar Club, College of Pharmacy, Univ. of Minnesota, April 24, 2004, Minneapolis, MN.
580. "What is the Medicare Drug Benefit All About?" 2nd Annual National Health Issues Symposium, Nevada College of Pharmacy, April 26, 2004, Henderson, NV.
581. "What is the Medicare Drug Benefit & How Will It Affect Pharmacists?" 2nd Annual National Health Issues Symposium, Nevada College of Pharmacy, April 26, 2004, Henderson, NV.
582. "Pharmaceutical Care Impact on Total Cost of Care," Minnesota Blue Cross Blue Shield, May 27, 2004, Minneapolis, MN.
583. "The Prescription Market: Flow of Drugs & Dollars," Twin Cities Press, Backgrounder Briefing, June 7, 2004, Minneapolis, MN.
584. "Economics of Prescription Drug Importation," National Health Policy Forum, June 8, 2004, Washington, DC.
585. "Medicare Modernization: Economic Impact on Pharmacies & Patients," 2004 Annual Meeting, Iowa Pharmacy Association, June 12, 2004, Dubuque, IA.
586. "Future of Drug Databases," MediSpan, Inc., a division of Wolters Kluwer, July 14, 2004, Indianapolis, IN.
587. "Prescription Drugs: How Can You Afford Them?" Edina Rotary Club, July 27,2004, Edina, MN.
588. "Implications of Pharmaceutical Trends & Pricing Patterns," Pharmacy Pre-Conference, National Academy of State Health Policy, August 1, 2004, St. Louis, MO.
589. "The Dynamic Pharmaceutical Market," MediSpan User's Conference, Sept. 15, 2004, Indianapolis, IN.
590. "Prescription Drugs: Can You Afford Them?" Annual Meeting, Retired Educators' Association of Minnesota, September 20, 2004, Owatonna, MN.
591. "State Drug Purchasing in a New World: The New World," Invitational Summit for State Policymakers, AcademyHealth, October 8, 2004, Philadelphia, PA.

592. "Prescription Drugs: What About Re-Importation?" Minnesota Senior Federation, October 13, 2004, Maple Grove, MN.
593. "Why Are Drug Prices Rising: Can You Afford Them?" St. Cloud Area Alumni & Friends, University of Minnesota Alumni Association, October 18, 2004, St. Cloud, MN.
594. "Why Are Drug Prices Rising: Can You Afford Them?" Glacier Ridge Chapter Alumni & Friends, University of Minnesota Alumni Association, October 20, 2004, Willmar, MN.
595. "Pharmaceutical Costs: What is the Answer?" Panel Discussion (videotaped), The Graduate College of Union University and the Albany College of Pharmacy of Union University, October 21, 2004, Latham, NY.
596. "Medicare Drug Benefit: Progress & Prospects," Annual Meeting, American Public Health Association, November 8, 2004, Washington, DC.
597. "Medicare Drug Benefit: Where Do We Go From Here?" Annual Meeting, American Public Health Association, November 8, 2004, Washington, DC.
598. "Unraveling the Mysteries of Prescription Drug Prices," Video Conference for National & State Policymakers, AARP, November 17, 2004, Washington, DC.
599. "The Dynamic New Pharmaceutical Marketplace," 25th Annual Arnold Schwartz Memorial Program, A& M Schwartz College of Pharmacy, Long Island University, Nov. 21, 2004, East Elmhurst, NY.
600. "Prescription Drugs: How Can You Afford Them?" Buffalo Rotary Club, January 5, 2005, Buffalo, MN.
601. "Impact of Reimbursement Policy for Drugs," Keynote Speaker, Legislative Day, Minnesota Pharmacists Association, February 8, 2005, St. Paul, MN.
602. "Medicare Prescription Drug Plan: What You Need to Know," VHA Pharmacy Directors Conference, March 11, 2005, Edina, MN.
603. "Emerging Trends in Pharmaceutical Expenditures," Seminar on Emerging Trends in Pharmacy Benefit Design, National Association of Chain Drug Store Foundation, March 24, 2005, Philadelphia, PA.
604. "Understanding Drug Pricing Methodologies," 2005 Rx Drug Utilization Conference, Pharmacy Benefit Management Institute, April 1, 2005, Phoenix, AZ.
605. "The Medicare Prescription Bill: Putting It All Together," PPSI, Workshop on Medicare Modernization Act, April 2, 2005, Orlando, FL.
606. "Paying for Public Health Pharmacy," PPSI, 2005 Distinguished Person of the Year Breakfast, April 5, 2005, Orlando, FL.
607. "Prescription Drug Benefit Management," Benefits Advisory Committee, University of Minnesota, April 7, 2005, Minneapolis, MN.
608. "The Pharmaceutical Market: Dynamic & Strategic Change," AARP, Rx Affordability Work Group, May 10, 2005, Washington, DC.
609. "Prescription Drugs: The Current System, Goldmines & Landmines," Northwest PBM Quarterly Educational Meeting, May 20, 2005, Seattle, WA.
610. "Pricing Trends & Medicare in the Dynamic Pharmaceutical Market," Wolters Kluwer Inform Me! Seminar, Wolters Kluwer Health (MediSpan), May 24, 2005, Edison, NJ.
611. "Pricing Trends & Medicare in the Dynamic Pharmaceutical Market," Wolters Kluwer Inform Me! Seminar, Wolters Kluwer Health (MediSpan), May 25, 2005, Parsippany, NJ.
612. "Pharmaceutical Care Evaluation Project Results," Blue Cross-Blue Shield of Minnesota, March 1, 2006, Eagan, MN.

APPENDIX B
Expert Witness Activities of
Stephen W. Schondelmeyer

1. McNeil v Bristol Myers Squibb, 1985, U.S. District Court, New York
   (BMS challenged advertising claims for Tylenol versus Advil.)
2. Mylan v. American Home, 1993, U.S. District Court
   (Claim of failure to provide best efforts in marketing a licensed product.)
3. Brand Name Antitrust Case, 1995, U.S. District Court, Chicago
   (Class action antitrust suit by pharmacies versus brand name drug firms for price discrimination.)
4. Idaho Pharmacists v BCBS of Idaho, Idaho State Court, 1995
   (Class action suit alleging inadequate payment to pharmacies for dispensing prescriptions.)
5. American Drug Stores v Harvard Pilgrim Health Plan, Inc., Massachusetts State Court, Aug. 1997
   (Economic impact of change in pharmacist payment method and amount.)
6. People v Levine et al, Aug 1997, Case No. BA108860, Los Angeles District Court
   (Economic impact of pharmacist fraud in billings to workers compensation program.)
7. Synthroid Marketing Litigation, 1997-1998, No. 97 C 6017, MDL No. 1182, U.S. District Court for the Northern District of Illinois, Eastern Division
   (Economic impact of delayed generic competition for Synthroid due to barriers and false information.)
8. (Sealed participants), 1998, Arbitration Board (AAA)
   (Economic impact from loss of a generic opportunity due to breach of contract.)
9. Rite Aid of Pa, Inc. v Houstoun (Commonwealth of PA), June 1998, 97-CV-2120, Penn. Dist. Court
   (Determination of pharmacy cost of dispensing for prescriptions under Pennsylvania Medicaid.)
10. Minnesota v _____, Aug 1998, Docket No. 6786, Minnesota Tax Court
    (Interpretation of state sales tax exemption on medications and diagnostic tests.)
11. KV v Copley, Sept. 1998, St. Louis, Mo. County Court
    (Impact of failure to honor a non-compete clause for research personnel.)
12. MediCap v Zaver, Dec 1998, Tennessee District Court
    (Assessment of factors related to breach of contract for a pharmacy franchise.)
13. Louisiana Wholesale Drug, Inc. v Hoechst & AndRx, 1999, U.S. District Court, Southern Florida
    (Class action certification for an antitrust suit related to Cardizem CD and barriers to generic entry.)
14. Allenmore, Inc., et al v Dept of Social & Health Services, State of Washington, Oct 1999, No. 95-2-00603-2, Superior Court of Washington County of Thurston
    (Determination of cost of dispensing prescriptions in WA Medicaid.)
15. Louisiana Wholesale Drug, Inc. v Abbott Laboratories, Nov 1999, 98-3125-CIV-SEITZ, U.S. District Court, Southern Florida
    (Class action certification for an antitrust suit related to Hytrin and barriers to generic competition.)
16. FTC v Mylan, 2000, U.S. District Court
    (Antitrust action related to attempt to monopolize the market for lorazepam and other products.)
17. Florida Medicaid v Eckerds, 2000-2001, Florida State District Court
    (Standard of practice related to partial fill situations.)
18. Commonwealth of PA v Dupont Pharm., 2000, Pennsylvania State District Court
    (Class action related to Warfarin false & misleading marketing.)
19. KV v Warner Chilcott, May 2000, U.S. District Court, Eastern District of Missouri, St. Louis County, Mo.
    (Economic impact of false & misleading statements by Warner Chilcott re: generic alternative products.)
20. Wal-Mart Stores, Inc v Kurt Knickrehm, in his capacity as Director, Arkansas Department of Human Services, May 2000, U.S. District Court for the Eastern District of Arkansas, Civil Action No. 4:00 CV 00 359 GTE
    (Arkansas Medicaid proposed regulation to adopt two-tiered Medicaid pharmacy payment rates lacked sufficient rationale or evidence to justify the rate structure.)
21. U.S. Food & Drug Adm. v Wyeth Ayerst, Sept. 2000
    (Disengorgement of Profits from Non-compliant plant.)
22. Public Citizen Health Research Group v National Institutes of Health and Johnson & Johnson, Jan. 2001, Civil Action No. 00-1847 (CKK), U.S. District Court for the District of Columbia (Release of royalty amounts or rates from NIH technology transfer agreements with private drug or biomedical firms.)
23. Cardizem CD Antitrust Litigation, Feb. 2001, Master File No. 99-md-1278, U.S. District Court, Eastern District of Michigan, Southern Division
    (Class certification hearing for an antitrust suit related to Cardizem and barriers to generic competition.)

24. Roxane Laboratories v Unimed Pharmaceuticals, March 2001, Case No. C2-00-125, U.S. District Court, Southern District of Ohio
    (Damages from termination of a contract for distribution and marketing.)
25. KV (Ethex) v HealthPoint, Ltd., March 2001, Civil Action No. SA 00 CA 0757 OG, U.S. District Court, Western District of Texas, San Antonio Division
    (Dispute over marketing claims and impact on market penetration by Ethezyme v. Accuzyme.)
26. National Association of Chain Drug Stores, et. al v Tommy G. Thompson, August 2001, U.S. Dept. HHS, Civil Action No. 01-1554 (PLF), U.S. District Court, District of Columbia
    (Economic impact on community pharmacies of US DHHS proposed drug discount card plan.)
27. U.S. Food & Drug Adm. v Schering-Plough, Sept. 2001
    (Disengorgement of Profits from Non-compliant plants.)
28. BuSpar Antitrust Litigation, Jan. 2002, MDL Docket No. 1410, Case 01-CV-7951 (JGK), U.S. District Court, Southern District of New York
    (Class certification expert report for an antitrust suit related to BuSpar and barriers to generic competition.)
29. Duramed Pharmaceuticals, Inc. v Wyeth-Ayerst Laboratories, July 2002, Civil Action No. C-1-00-735, U.S. District Court, Southern District of Ohio, Western Division at Cincinnati
    (Duramed alleges an antitrust violation by Wyeth-Ayerst as through exclusive contracts that kept the competing product out of the market.)
30. Courtney Litigation: Georgia Hayes v Courtney Pharmacy, Inc., et al., July 2002, Case No. 01-CV-218871-01, Circuit Court of Jackson County, MO in Kansas City,
    (Plaintiff asserts that defendants knew or should have known that Courtney's behavior endangered the health of patients receiving drugs.)
31. State of Texas ex rel Ven-A-Care of the Florida Keys, Inc. v Dey, Inc., Roxane Laboratories, Inc., et al., Oct. 2002, No. GV002327, District Court, Travis County, Texas, 53rd Judicial District
    (Plaintiffs allege defendants reported inflated prices that caused the state to overpay for prescription drugs used by Medicaid patients.)
32. Estate of Emma Born, et.al. v Beverly Health and Rehabilitation Services, Inc. Oct. 2002, Court File No. C6-99-10380, State of Minnesota, District Court, County of Anoka, Tenth Judicial District
    (Plaintiffs allege defendants (a nursing home firm) over charged residents for prescription drugs and did not notify residents that they had alternative sources for getting Rxs.)
33. Cardizem CD Antitrust Litigation, March 2003, Master File No. 99-MD-1278, Case No. 99-CV-75036 (CVS Meridien), 99-CV-73735 (Kroger), U.S. District Court, Eastern District of Michigan, Southern Division
    (Direct purchasers in antitrust suit related to Cardizem and barriers to generic competition.)
34. Relafen Antitrust Litigation, March 2003, Master File No. 01-12239-WGY, U.S. District Court, District of Massachusetts
    (Class certification hearing for an antitrust suit related to Relafen and barriers to generic competition.)
35. Relafen Antitrust Litigation, August 2003, Master File No. 01-12239-WGY, U.S. District Court, District of Massachusetts
    (Expert impact report for an antitrust suit related to Relafen and barriers to generic competition.)
36. Pharmaceutical Care Management Association v State of Maine, September 2003, No. 03-CV-153-B-W, U.S. District Court, District of Maine
    (Pharmaceutical market expert for State of Maine defending a state statute intended to make PBMs transparent and accountable.)
37. Remeron Antitrust Litigation, Master Docket No. 03-CV-0085 (FSH), United States District Court, District of New Jersey, March 2004.
    (Pharmaceutical market expert regarding the structure and behavior of the market for Remeron and generic equivalents.)
38. Harry Stetser, et al v TAP Pharmaceutical Products, Inc., Re: Lupron litigation, Civil Action No. 1-CVS-5268, State of North Carolina in the General Court, New Hanover Court of Justice Superior Court Division, March 2004.
    (Pharmaceutical economic and market expert regarding the economic impact of admitted actions of TAP upon purchasers of Luporn.)
39. J.B.D.L. Corp. d/b/a Beckett Apothecary, et al. v Wyeth-Ayerst Laboratories, Inc., et al., Re: Premarin Litigation, Civil Action No. C-1-01-704, United States District Court for the Southern District of Ohio, Western Division, April 2004.

(Pharmaceutical economic and market expert regarding the economic impact of Wyeth's actions to prevent entry of a drug product competing with Premarin.)

40. North Shore Hematology-Oncology Assoc, P.C., v Bristol-Myers Squibb Co., Re: Platinol litigation, Civil Action No. 1:04CV00248, United States District Court for the District of Columbia, May 2004.
(Pharmaceutical economic and market expert regarding the economic impact of delayed entry of generic equivalent versions of Platinol.)
41. Healthpoint, Ltd. V Ethex Corporation, July 2004, Civil Action No. SA 01 CA 0646 OG, U.S. District Court for the Western District of Texas, San Antonio Division
(Pharmaceutical market expert for Ethex regarding structure and behavior of the market for the drug products known as Accuzyme [Healthpoint] and Ethezyme 830 [Ethex].)
42. Pharmaceutical Industry, Average Wholesale Price Litigation, September 2004, MDL No. 1456, Civil Action No. 01-CV-12257 PBS, Judge Patti B. Saris.
(Pharmaceutical market expert regarding pricing and reimbursement for prescription drugs.)
43. Bernard Walker v TAP Pharmaceutical Products, Inc., Re: Lupron litigation, Civil Action No. CPM-L-682-01, Superior Court of New Jersey, Law Division, Cape May County, April 2005.
(Pharmaceutical economic and market expert regarding the economic impact of admitted actions of TAP upon purchasers of Lupron.)
44. Bernard Walker v TAP Pharmaceutical Products, Inc., Re: Lupron litigation, Civil Action No. CPM-L-682-01, Superior Court of New Jersey, Law Division, Cape May County, May 2005.
(Pharmaceutical economic and market expert supplemental report regarding the economic impact of admitted actions of TAP upon purchasers of Lupron.)
45. Nifedipine Antitrust Litigation, Civil Action No. 1:03MS00223 (RJL), U.S. District Court, District of Columbia, Jan 2006.
(Class certification expert report for an antitrust suit related to Nifedipine and barriers to generic competition.)
46. Longs Drug Stores, Inc. v. Ho Retail Properties, Inc.,Civil Action No. 03-1-0342, Circuit Court of the Third Circuit, State of Hawaii, Oct 2006.
(Pharmaceutical market expert for Plaintiff related to impact from breach of exclusivity provision in lease contract.)
47. James Clayworth, et al. v. Pfizer, Inc., et al.Civil Action No. RG04-172428 Superior Court of the State of California for the County of Alameda, Nov. 2006.
(Pharmaceutical market expert for Plaintiffs alleging price discrimination.)
48. Tricor Direct Purchaser Antitrust Litigation, Civil Action No. 05-340 (KAJ), U.S. District Court, District of Delaware, Dec. 2006.
(Class action expert report for an antitrust suit related to Tricor and barriers to generic competition.)
49. Altana Pharma AG and Wyeth v. Teva Pharmaceuticals USA, Inc., Consolidated Civil Action Nos. 04-2355 (JLL) (CCC), 05-1966 (JLL) (CCC), 05-3920 (JLL) (CCC), 05-3672 (JLL) (CCC), U.S. District Court, District of New Jersey, July 2007.
(Pharmaceutical market and economics expert for defendants regarding patent infringement action and evaluation of the commercial success of the alleged invention.)
50. The State of Texas, ex rel., Ven-A-Care of the Florida Keys, Inc. vs. Abbott Laboratories, Inc., District Court of Travis County Texas, 201st Judicial District, July 2007.
(Pharmaceutical market and economics expert regarding price reporting to the State of Texas Medicaid vendor drug program.)

Submitter : Ms. Mary Ellen Kleiman **Date:** 12/05/2007

Organization : National Association of Chain Drug Stores

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

The National Association of Chain Drug Stores (NACDS) submits the attached November 13, 2007 report by Stephen W. Schondelmeyer, Pharm.D., Ph.D., FAPHA (with exhibits) regarding Average Manufacturer Price and Federal Upper Limits for agency consideration. Due to its size, it will be submitted in multiple submissions of PDF files (more then the 4 originally thought). See Attachments. [THIRD OF SIX]

CMS-2238-FC3-7-Attach-1.PDF

#7

Exhibit 5

Audit of Chain and Independent Pharmacies, Mass Merchandisers, Proprietary Stores and Foodstores with Pharmacies
IMS Health, March 2006

Country: **United States**

Audit of: Chain and independent Pharmacies, Mass Merchandisers, Proprietary Stores and Foodstores with Pharmacies

Publication Cycle: Monthly (this update at March 2006)

Universe Size: Warehouses: 300 Wholesalers,
104 Drug Chains,
44 Food Chains.

Stores: 37,209 Independent and Chain Drugstore
8,511 Mass Merchandisers
1,074 Proprietary Stores
9,874 Food Stores with Pharmacies

Sample:

Size:
Changes in Sample: Changes to the panel (1992):
Increased number of drug wholesalers reporting non-census covered products from 24 to 39.

Increased number of drug chain warehouses reporting non-census covered products from 6 to 10.

Added five foodstore chain organisations with pharmacies.

Added Hawaii and Alaska

Type of Sampling: N/A

Stratification Type & Criteria: N/A

Selection Method: N/A

Reporting Time: N/A

Projection:

Projection methodology depends upon three sources of purchase data for each product.

1. Indirect Census

   The primary source of indirect data is a near census of warehouses accessed via the Drug Distribution Data (DDD ™) system.
   The census data is adjusted to reflect non-covered warehouses. The factor utilised varies each month according to the actual number of reporting warehouses.

2. Indirect Sample

A sample warehouse panel supplements the census data by providing sales of non-DDD covered products. Sample warehouse data are projected nationally to reflect non-covered warehouses. This projection factor varies each month relative to the dollar volume reported by the sample warehouses in comparison to universe dollar figures.

3. Direct Sample

Approximately 100 manufacturers provide direct sales to DDD™ which are used in this report.

Non-reporting manufacturer direct sales are not estimated. Based in 1998 data, this omission is approxiamtely 0.5% of National Sales Perspectives ™ national estimates.

Note: For those products with both direct and indirect distribution, each data source is projected using its own methodology and the resulting purchase figures are combined to determine national estimates.

Changes to Projected Data (1992)

Direct (microfilm) data projected to a reduced universe reflecting a decrease in independent pharmacies puchasing direct from the manufacturer. This results in decreased sales for direct data.

Indirect census coverage is now 98% (up from 94%) of the total dollar shipments made by drug wholesalers and chain warehouses. This increased coverage requires a lower projection factor, resulting in decreased sales for census covered products.

Regional projections (9 census regions) added for indirect data due to increase in indirect sample.

These changes in the database should be taken into consideration when trending data prior to 1992.

Local Currency: U.S. Dollars

Price Structure:

Price Level used to calculate Local Values:
Pharmacy Purchase Price

Price Level used to calculate US $:
N/A

Level of Printed Unit Price:
N/A

Price structure/conversion:

Relative to Wholesaler:

Based on annual information received from the HDMA [1], we estimate that the wholesaler's mark-up is approximately 5%. This indicates that Wholesaler's portion of IMS National Sales Perspectives ™ would be approximately 95%. IMS National Sales Perspectives ™ relative to the wholesaler dollars would be 105%.

	Wholesaler	**Pharmacy**
Wholesaler (PP=100)	100	105
Pharmacy (PP=100)	95	100

Relative to Manufacturer:

Based on both annual information received from the HDMA [1] and IMS National Sales Perspectives ™ channels' portion direct sales, the ex-manufacturer adjustment is updated annually and is currently 0.96. This indicates that the manufacturer's portion of IMS National Sales Perspective ™ would be approximately 96%. IMS National Sales Perspective ™ relative to the manufacturer dollars would be 104%.

	Manufacturer	**Pharmacy**
Manufacturer (PP=100)	100	104
Pharmacy (PP=100)	96	100

[1] 2004 HDMA Industry Profile & Healthcare Factbook. HDMA is the Healthcare Distribution Management Association.

Total Prescription Pharmaceutical Market Expressed in Percentage Terms(1):

	RETAIL			**NON-RETAIL**							
	Indep. Chain Mass Mer	**Food-store W/Pharm**	Mail Service	Non-Fed Facility	Fed. Facility	Clinics	HMO	LTC	Home Health Care	Oth	%
Total Rx Market	49%	9%	14%	10%	1.4%	10%	0.6%	4.7 %	1%	0.3%	100

All numbers are rounded.

Market Segments Covered by IMS National Sales Perspectives ™: Retail Pharmacies, channels in this book (Independents, Chains, Mass merchandisers and Foodstores with pharmacies) = **58%**
Market Segments Covered by IMS National Sales Perspective™ Retail - all channels = 72%
Market Segments Covered by IMS National Sales Perspective™ Non-retail - all channels = 28%

(1) Sources: Retail and Provider Perspective™. Rx. Sales.

Panel Design:

The data in this report represent the unit and dollar purchases made by retailers including foodstores with pharmacies of Rx, OTC, and generic pharmaceutical products. The purchase information obtained from warehouses and a sample of retail outlets is projected to nine census regions (50 states). The price reflected is the actual cost to retailers for the products, whether purchased from a manufacturer or a warehouse (98% of total pharmaceuticals purchased by retail outlets are from wholesalers and chain warehouses). However, prompt payment cash discounts and bottomline invoice discounts are not reflected in the dollar purchase amounts.

All data in the report are in thousands of units and dollars.

Warehouses

The national total of warehouses and the IMS representation is as follows:

Type of Warehouse	National Total	IMS Health Representation	Sample % of National Total
Wholesaler (d)	303	240	79.2%
Chain (e)	104	58	55.8%
Food Chain (f)	44	14	31.8%

The national total of warehouses and the IMS indirect sample is as follows:

Type of Warehouse	Sample % of National Total	National Total	IMS Representation	Store Representation
Wholesaler (g)	12.9%	303	39	N/A
Chain (h)	4.8%	104	5	399
Food Chain (i)	11.4%	44	5	152

(a) -The universe figures shown are based on store counts developed for the IMS National Prescription Audit.

(b) -The universe figures shown for mass merchandisers with pharmacies are based on store counts developed for the IMS National Prescription Audit. The universe figures for mass merchandisers without pharmacies are based on the 2004 Chain Store Guide Directory of Discount & General Merchandise Houses. The universe includes all stores in this directory with 10,000 or more square feet of floor space, at least three distinct merchandise lines and a drug and/or ethical pharmacy department.

(c) -The universe figures for proprietary stores without pharmacies were estimated based on the most recent Census of Business. The 2004 Chain Store Guide Directory of Drug Store and HBC Chains was used in refining the census data.

(d) -The universe of wholesale warehouses is based on the DDD™ Warehouse Master List (developed by Drug Distribution Data).

(e) -The universe of chain warehouses is based on the DDD™ Warehouse Master List (developed by Drug Distribution Data).

(f) -The universe of food chain warehouses is based on the DDD ™ Warehouse Master List (developed by Drug Distribution Data).

(g) -Data not collected at store level; independent pharmacies and chains not served by a chain warehouse are represented in the sample of 39 wholesalers, regionally projected and summed to a national total.

(h) -A sample of drugstores was selected from the five drug chains. Indirect purchases made by these stores are projected regionally and summed to a national level.

(i) - A sample of food stores with pharmacies was selected from the five food chains. Indirect purchases made by these stores are regionally projected and summed to a national total.

Exhibit 6

Retail Perspective: IMS Audit Information
IM Health, 2006

Retail Perspective

What Retail Perspective Is Designed to Do

The Retail Perspective audit (formerly U.S. Drugstore) is a continuing monthly audit designed to measure, in projected dollars and units, pharmaceutical products purchased by independent pharmacies, chain store pharmacies, and food store pharmacies in all 50 states.

All Retail Perspective data prior to January 1992 appears in the chain store channel. Starting with January 1992, this channel was split into two separate channels: one for chain stores and one for independent pharmacies. Food store channel data is available starting with January 1992.

Suggested Uses for Retail Perspective

This audit enables you to analyze market data at the product package level for your products and those of your competitors. Use Retail Perspective when you need to study:

- Market data, such as dollar or unit volume, pricing, market share, and percentage change
- Long-term market trends
- New product introductions, including distribution and the impact upon established products
- Effects of promotional deals
- Seasonality
- New packaging and new form presentations

Data Elements

The data elements are listed below in alphabetical order within their respective categories. Each Dataview name (in bold typeface) is followed by the IMSPACT name (in parentheses). Then a description of the element is given. Refer to the Dataview Help for more detailed information and special considerations for selecting the elements in database and report queries.

Classification

Anatomical Therapy Class 1 - 4 (ATC1, ATC2, ATC3, ATC4). The Anatomical Therapeutic Classification (ATC) of products is the international equivalent of the Uniform System of Classification (USC) scheme. (However, ATCs and USCs are mostly not interchangeable.) ATC categories often relate to human body organs or systems. Use ATCs to duplicate your European divisions' views of the U.S. markets, to combine products into markets where USCs are split, or to locate new products in areas of interest. The lowest level (ATC4) represents the finest level of product classification. Each higher level includes the level beneath it.

Uniform System of Classification 2 - 5 (USC2, USC3, USC4, USC5). This system of classification was developed by IMS to categorize all pharmaceutical products. In this system, USC5 (the lowest level) represents the finest level of product classification. Each higher level (USC4, USC3, and USC2) includes the level beneath it. All USC numbers have five places, as follows:

Class	# Digits	# Zeroes	Example
USC2	2 digits	3 zeroes	15000
USC3	3 digits	2 zeroes	15100
USC4	4 digits	1 zero	15130
USC5	5 digits	No zeroes	15131

You can review lists of USC codes using the Dataview Market Definition function.

Corporation/Manufacturer

Corporation (CRP). A corporation has divisions or subsidiaries that manufacture pharmaceutical products. Selecting the corporation will total sales from all subsidiaries.

Manufacturer/Company (MNF or MFR). This is the pharmaceutical company that manufactures or promotes a product. Choosing a manufacturer results in sales for each selected company.

Molecule/Chemical

Chemical Family (FAM). Chemical families are defined in the IMS publication, *Index of Drug Chemicals*. You can select a chemical family by either numeric code or family name. It is recommended that you select Molecule in your database contents if you intend to use Chemical Family.

Chemical Salt (SALT). Use Chemical Salt to qualify a molecule. You can select Chemical Salt by either numeric code or by salt name. It is recommended that you avoid adding Chemical Salt to your market definition, since this will create a very large database. To examine chemical salts in kilograms, you must select Molecule and Chemical Salt in your database contents.

Chemical Sub-Family (SUBFAM). Chemical sub-families are defined in the IMS publication, *Index of Drug Chemicals*. You can select a chemical sub-family by either numeric code or sub-family name. It is recommended that you select Molecule in your database contents if you intend to use Chemical Sub-Family.

Molecule (MOL). The molecule is the lowest level of the chemical family and sub-family classification. You can use this data element to examine products that contain a particular chemical entity. Molecules are defined in the IMS publication, *Index of Drug Chemicals*. You can select Molecule either by numeric code or molecule name. See the Dataview Help for guidelines on using this data element.

Molecule Composition (COMP). Use this element when you want to restrict chemical or product selections to one or more chemical components. Select *Plain* to restrict selections to single-entity products. Select *Combination* to restrict selections to products containing a specified molecule and one or more other molecules. You can use this element as a qualifier for Molecule, Chemical Family, Chemical Sub-Family, USC, Product, and so forth.

Others

Channel/Source (CHAN). You can select and/or display Retail Perspective data by channel. Valid channels for this audit are: independent pharmacies, chain stores pharmacies, and food store pharmacies. (All data prior to 1992 is displayed in the chain channel, since channel break-out is not available prior to the January 1992 data cycle. Food store data is available beginning in January 1992.)

- **Independent Pharmacies** (INDSTR). The independent channel includes all sales to independent pharmacies, as well as non-prescription product sales to proprietary stores that do not include a pharmacy.
- **Chain Store Pharmacies** (CHNSTR). The chain channel covers chain drugstores, mass merchandisers, and discount houses for both Rx and over-the-counter sales.
- **Food Stores w/Pharmacies** (FS). The food store channel includes only those sales to food stores with in-store pharmacies. These sales include both Rx and over-the-counter sales to the entire store.

Product

Ethical/Proprietary Indicator (EPI). This indicator enables you to limit selected data to only ethical or proprietary brands. Ethical products are marketed to healthcare professionals and often require a prescription. Proprietary products are marketed primarily to consumers and do not require a prescription.

Package (PCK). Packaging refers to the particular form, strength, and size of a product manufactured by a given company and purchased by stores for resale. The meaning of the three-digit package code varies from product to product. For example, a package code of 001 for Product A may indicate a bottle of 500 200-mg tablets, while the package code for Product B may indicate a bottle of 1,000 250-mg capsules.

Package Month (PCK-MTH). This is the data month in which a given product package first appeared in the audit. Package month recognition depends on the sales volume tracked by the audit, not upon promotional activity.

Package Size (PCK-SIZ). Package size refers to the number of individual units contained in the selling package of a particular product type. The meaning of "units" varies, depending on the form of the product.

- Tablets and capsules are shown as a single-package unit. For example, a bottle containing 500 capsules has a package size of 1. (The actual number of capsules in the bottle is measured by package volume, rather than package size.)
- Injectable products usually have package sizes greater than one. For example, a 10-pack of injectable vials has a package size of 10, and a dozen bottles of cough syrup has a package size of 12.

Product (PRD). This element includes the drugs or vitamins manufactured and sold by pharmaceutical companies. You can select a product by either a numeric code or the product name.

Product Age (PRD-AGE). Product age is the number of years the product has been on the market, based on its initial appearance in the sales audits..

Product Form 1 - 3 (FRM1, FRM2, FRM3). Product Form refers to the physical dosage form of a drug, such as oral or injectable. This system consists of three levels, with each successive level containing more detail about the product form. For example, Product Form 1 = O contains all orals, Product Form 2 = OL contains all oral liquids, and Product Form 3 = OLS contains all oral liquids in syrup form. You can review a list of form codes using the Dataview Market Definition function. To include different levels of product form in your database, select each level for which you want to see totals.

Product Strength (STR). Most products are available in different potencies or strengths. For example, a product may be offered in both a 250 mg tablet and a 500 mg capsule.

Product Year (PRD-YEAR). This is the year the product was first introduced into the market.

RX Status (RXSTATUS). Use this element if you want to include prescription status in your database or report. RX Status is most meaningful when used to limit Product or a USC to data having a particular prescription status. RX Status can be either *Legend* (prescription required) or *Non-Legend* (no prescription required).

Three-Letter Form Code 1 - 3 (TLC1, TLC2, TLC3). This is the application form for classifying a product. Product form encompasses two classification systems— Product Form and Three-Letter Form Code. Both systems consist of three levels, with each successive level containing more detail about the product form. For example, TLC1=D contains all systemic oral liquids, TLC2=DC contains oral drops, and TLC3=DCB contains long-acting oral drops. In general, Three-Letter Form Codes provide a finer breakdown of Product Form. You can review a list of Three-Letter Codes using the Dataview Market Definition function.

Measures

The Retail Perspective measures are listed below in alphabetical order. Refer to the Dataview Help for special considerations in using these measures.

Retail Diagnosis Value (DOL/DRG/DV). For each product/form/strength combination, this measure apportions the Retail Dollars by diagnosis based on the percentage of that product's NDTI drug uses each diagnosis represents. This measure is based on non-hospital drug uses for the product and does **not** include any food store sales dollars. This measure is available only in the Report Definition function and only if you subscribe to NDTI.

Retail Diagnosis Value - New (DOL/DRG/DVN). For each product/form/strength combination, this measure apportions the Retail Dollars by diagnosis based on the percentage of that product's "total consumption" each diagnosis represents. The total consumption is calculated by multiplying the signa by the length of therapy. This measure is based on non-hospital drug uses for the product and includes food store sales dollars. This measure is available only in the Report Definition function and only if you subscribe to NDTI.

Retail Dollars (DOL/DRG). This measure reports the amount of money pharmacies spent on a product acquired from manufacturers and drug wholesalers.

Retail Eaches (EA/DRG). This measure represents the number of single items (such as vials and syringes) contained in a unit or shipping package and purchased by pharmacies in a specific time period. An each may be the same as a unit if the unit does not subdivide into packages. Eaches are most meaningful at the package level, since packages and their subunits may contain different quantities of strengths and volumes.

Retail Eaches Average Price (DOL/DRG/EAAP). The measure is calculated by dividing purchase dollars by eaches. This measure is meaningful for injectables, powders, ointments, inhalants, and any other form shipped in packages containing single items that can be broken apart. The average each price prints to three decimal places. For example, 3.277 means an average each price of $3.277.

Retail Extended Units (EU/DRG). Extended units is the number of tablets, capsules, milliliters, or grams purchased. This number is calculated by multiplying the number of units by the volume and size of each package reported. Extended units are often meaningless above the form/strength level, because a product may have different forms and strengths and therefore a different type of unit. Eaches and units are most meaningful at the package level.

Retail Extended Units Average Price (DOL/DRG/EUAP). This is the average purchase price of a tablet, capsule, milliliter, or other extended unit in the specified time period. It is meaningful only at the package level.

Retail Historical Price (DOL/DRG/HP). This is the average price of a particular package within a specified time period. It is calculated by dividing dollars by units. Historical price is printed to two decimal places. For example, 14.48 means a package price of $14.48. Historical price is most meaningful at the package level.

Retail Kilograms (KG/DRG). This measure reports the chemical weight of quantities purchased. You must select Molecule, Chemical Family, and or Chemical Sub-Family in the database contents or report rows to obtain kilogram weight. Weights are reported in metric measures, using the following weight symbols:

A	-	Thousand Tons	Z	-	1,018 Units
T	-	Ton	Y	-	1,015 Units
K	-	Kilogram	U	-	1,012 Units
G	-	Gram	V	-	109 Units
M	-	Milligram	S	-	106 Units
X	-	Microgram	E	-	1,000 Units

Examples: 4T3 = 4.3 metric tons or 4 metric tons + 300 kilograms
24K9 = 24.9 kilograms or 24 kilograms + 900 grams

Retail Units (UN/DRG). This measure represents the number of individual shipping packages purchased by pharmacies in a specific time period. Units are most meaningful at the package level, since packages and their subunits contain different quantities of extended units.

Special Considerations

How Retail Perspective Relates to Factory Sales Figures

There are several reasons why analysts may encounter difficulty in attempting to match IMS estimates against factory sales:

- In many cases, it is difficult for companies to ascertain what portion of factory sales are made to the specific channels covered in Retail Perspective. The audit does not include purchases made by department store pharmacies, by mail order, or by dispensing HMOs or physicians.
- Timing of transactions is rarely comparable. Factory sales may be recorded in December, while retail outlet purchase of the same items may not occur until February.
- Translation of factory sales dollars to retail acquisition dollar levels is imprecise.
- Private label business may appear in the audit identified under the name on the label.
- Changes in wholesaler inventory levels may occur (inflow vs. outflow).

How Retail Perspective Data Relate to NPA Data

You may find instances where Retail Perspective data does not match NPA data. While annual trends for Retail Perspective and NPA are generally similar, month-to-month data may show different patterns. Retail Perspective captures purchases by pharmacies and stores; these may not immediately reflect the actual consumer purchase pattern captured by NPA.

Exhibit 7

Audit of Mail Service Sales
IMS Health, March 2006

Country: **United States**

Audit of: Mail Service Sales

Publication Cycle: Monthly (this update at March 2006)

Universe Size: Federal Government and Non-Government mail service pharmacies captured through DDD™. This includes approximately 90% of the mail service market.

Sample: **Indirect** Sample – the national total of warehouses and the IMS indirect sample of warehouses selling to mail service pharmacies is as follows:

Type of Warehouse	National Total	IMS Representation	Sample % of National Total*
Wholesaler (2)	303	240	79.2%
Chain (2)	104	58	55.8%

(2) The universe of wholesale warehouses is based on the DDD Warehouse Master List.

Direct Sample – for products with direct distribution to mail service pharmacies, approximately 100 manufacturers provide their direct sales data to DDD.

Note: For products with both direct and indirect distribution, each data source is combined to determine national estimates. Direct data cannot be isolated from indirect data in any report.

Changes in Sample: N/A

Type of Sampling: Indirect and direct.

Stratification Type & Criteria: N/A

Selection Method: N/A

Reporting Time: N/A

Projection: N/A

Local Currency: U.S. Dollars

Price Structure:

Price Level used to calculate local currency values:
Pharmacy purchase price, including product level discounts.
There are no bottom line discounts or subsequent off-invoice rebates reflected in the price.

Price Level used to calculate US $ values:
N/A

Level of Printed Unit Price:

The data in this report represent the unit and dollar purchases made by mail service pharmacies. The price reflected is the purchase price to the mail service pharmacies, whether purchased from a manufacturer or a wholesaler. Prompt payment case discounts and bottomline discounts are not reflected in the dollar purchase amounts.

All data are in thousands of unit and dollars.

The differences with DDD™ Mail Service Data are:

- IMS National Sales Perspectives: Mail Service Pharmacies dollars reflect pharmacy purchase prices versus DDD's WAC (Wholesale Acquisition Cost).
- At the national level, units in IMS National Sales Perspective: Mail Service Pharmacies may vary somewhat from DDD because of different data compilation methods. DDD, which is primarily a sub-national database, rounds fractional units, which may lead to minor variability for certain products.

Price structure/conversion:

Relative to Wholesaler:

Based on annual information received from the HDMA [1], we estimate that the wholesaler's mark-up is approximately 5%. This indicates that wholesaler's portion of IMS National Sales Perspectives ™ would be approximately 95%. IMS National Sales Perspectives ™ relative to the wholesaler dollars would be 105%.

	Wholesaler	**Pharmacy**
Wholesaler (PP=100)	100	105
Pharmacy (PP=100)	95	100

Relative to Manufacturer:

Based on both annual information received from the HDMA [1] and IMS National Sales Perspectives ™ channels' portion direct sales, the ex-manufacturer adjustment is updated annually and is currently 0.96. This indicates that the manufacturer's portion of IMS National Sales Perspective ™ would be approximately 96%. IMS National Sales Perspective ™ relative to the manufacturer dollars would be 104%.

	Manufacturer	**Pharmacy**
Manufacturer (PP=100)	100	104
Pharmacy (PP=100)	96	100

[1] 2004 HDMA Industry Profile & Healthcare Factbook. HDMA is the Healthcare Distribution Management Association.

Pharmaceutical Markets Expressed In Percentage Terms (1):

	RETAIL			NON-RETAIL							
	Independ Chain Mass Mer	Foodstore W/Pharm	Mail Sevice	Non-Fed Facility	Fed Facility	Clinics	HMOs	LTC	Home Health Care	Other	%
Total Rx Market	49%	9%	**14%**	10%	1.4%	10%	0.6%	4.7%	1%	0.3%	100

All numbers are rounded.

Market segment covered by IMS National Sales Perspective™ Mail Service Pharmacies, channel in this book = **14%**
Market segment covered by IMS National Sales Perspective™ Retail – all channels = 72%
Market segment covered by IMS National Sales Perspective™ – Non-Retail all channels = 28%

(1) Source: IMS National Sales Perspective™ , Rx sales

Panel Design:

The data in this report represents the unit and dollar purchases made by mail service pharmacies. The price reflected is the purchase price to the mail service pharmacies, whether purchased from a manufacturer or a wholesaler. Prompt payment cash discounts and bottomline discounts are not reflected in the dollar purchase amounts.

All data are in thousands of units and dollars.

Exhibit 8

Provider Perspective: IMS Audit Information
IM Health, 2006

Provider Perspective

What Provider Perspective Is Designed to Do

Provider Perspective (PROV) gives you comprehensive, projected information about sales of pharmaceuticals to healthcare facilities. It is designed to measure prescription, over-the-counter, and generic products in these channels: federal facilities, non-federal hospitals (formerly USH), long-term care facilities, clinics, and HMOs.

With the exception of non-federal hospitals, data for the Provider Perspective channels is available starting with January 1992 data.

Suggested Uses for Provider Perspective

This audit allows you to analyze market data at the product package level for your products and those of your competitors. Use Provider Perspective when you need to study:

- Market data, such as dollar or unit volume, pricing, market share, and percentage change
- Long-term market trends
- New product introductions, including distribution and the impact upon established products
- Seasonality
- New packaging and new form presentations
- Delivery methods for injectable pharmaceuticals

Data Elements

The data elements are listed below in alphabetical order within their respective categories. Each Dataview name (in bold typeface) is followed by the IMSPACT name (in parentheses). Then a description of the element is given. Refer to the Dataview Help for more detailed information and special considerations for selecting the elements in database and report queries.

Classification

Anatomical Therapy Class 1 - 4 (ATC1, ATC2, ATC3, ATC4). The Anatomical Therapeutic Classification (ATC) of products is the international equivalent of the Uniform System of Classification (USC) scheme. (However, ATCs and USCs are mostly not interchangeable.) ATC categories often relate to human body organs or systems. Use ATCs to duplicate your European divisions' views of the U.S. markets, to combine products into markets where USCs are split, or to locate new products in areas of interest. The lowest level (ATC4) represents the finest level of product classification. Each higher level includes the level beneath it.

Uniform System of Classification 2 - 5 (USC2, USC3, USC4, USC5). This system of classification was developed by IMS to categorize all pharmaceutical products. In this system, USC5 (the lowest level) represents the finest level of product classification. Each higher level (USC4, USC3, and USC2) includes the level beneath it. All USC numbers have five places, as follows:

Class	# Digits	# Zeroes	Example
USC2	2 digits	3 zeroes	15000
USC3	3 digits	2 zeroes	15100
USC4	4 digits	1 zero	15130
USC5	5 digits	No zeroes	15131

You can review lists of USC codes using the Dataview Market Definition function.

Corporation/Manufacturer

Corporation (CRP). A corporation has divisions or subsidiaries that manufacture pharmaceutical products. Selecting the corporation will total sales from all subsidiaries.

Manufacturer/Company (MNF or MFR). This is the pharmaceutical company that manufactures or promotes a product. Choosing a manufacturer results in sales for each selected company.

Molecule/Chemical

Chemical Family (FAM). Chemical families are defined in the IMS publication, *Index of Drug Chemicals*. You can select a chemical family by either numeric code or family name. It is recommended that you select Molecule in your database contents if you intend to use Chemical Family.

Chemical Salt (SALT). Use Chemical Salt to qualify a molecule. You can select Chemical Salt either by numeric code or by salt name. It is recommended that you avoid adding Chemical Salt to your market definition, because this will create a very large database. To examine chemical salts in kilograms, you must select Molecule and Chemical Salt in your database contents.

Chemical Sub-Family (SUBFAM). Chemical sub-families are defined in the IMS publication, *Index of Drug Chemicals*. You can select a chemical sub-family either by numeric code or by sub-family name. It is recommended that you select Molecule in your database contents if you intend to use Chemical Sub-Family.

Molecule (MOL). The molecule is the lowest level of the chemical family and sub-family classification. You can use this data element to examine products that contain a particular chemical entity. Molecules are defined in the IMS publication, *Index of Drug Chemicals*. You can select Molecule either by numeric code or molecule name. See the Dataview Help for guidelines on using this data element.

Molecule Composition (COMP). Use this element when you want to restrict chemical or product selections to one or more chemical components. Select *Plain* to restrict selections to single-entity products. Select *Combination* to restrict selections to products containing a specified molecule and one or more other molecules. You can use this element as a qualifier for Molecule, Chemical Family, Chemical Sub-Family, USC, Product, and so forth.

Others

Channel/Source (CHAN). Provider Perspective consists of five channels: federal facilities, non-federal hospitals (formerly USH), long-term care facilities, clinics, and HMOs. You can select and display Provider Perspective data by channel or in a combined report with Retail Perspective data. Access to channels other than non-federal hospitals is by separate subscription only. Data for channels other than non-federal hospitals is available beginning with January 1992.

Product

Ethical/Proprietary Indicator (EPI). This indicator enables you to limit selected data to only ethical or proprietary brands. Ethical products are marketed to healthcare professionals and often require a prescription. Proprietary products are marketed primarily to consumers and do not require a prescription.

Injectable Delivery System 2, 3 (DELSYS2, DELSYS3). Delivery system categories enable you to group injectable products. Note the differences between Delivery System 2 and Delivery System 3.

- Delivery System 2 contains 11 major categories for injectable products. These categories are based on the method of delivery, such as minibags and syringes. Each category has a corresponding two-digit numeric code.
- Delivery System 3 contains 22 subcategories of injectable products that fall within Delivery System 2 major categories. For example, Frozen Minibags and Other Minibags are subcategories of the major category, Minibags. Each category has a corresponding three-digit numeric code.

Package (PCK). Packaging refers to the particular form, strength, and size of a product manufactured by a given company and purchased by stores for resale. The meaning of the three-digit package code varies from product to product. For example, a package code of 001 for Product A may indicate a bottle of 500 200-mg tablets, while the package code for Product B may indicate a bottle of 1,000 250-mg capsules.

Package Month (PCK-MTH). This is the data month in which a given product package first appeared in the audit. Package month recognition depends on the sales volume tracked by the audit, not upon promotional activity.

Measures

The Provider Perspective measures are listed below in alphabetical order. Refer to the Dataview Help for special considerations in using these measures.

Provider Diagnosis Value (DOL/PROV/DV). For each product/form/strength combination, this measure apportions the Provider Perspective non-federal hospital dollars by diagnosis based on the percentage of that product's NDTI drug uses each diagnosis represents. This measure is based on NDTI drug uses where the visit location was a hospital. This measure is available only in the Report Definition function and only if you subscribe to NDTI.

Provider Diagnosis Value - New (DOL/PROV/DVN). For each product/form/strength combination, this measure apportions the Provider Perspective non-federal hospital dollars by diagnosis based on the percentage of that product's "total consumption" each diagnosis represents. The total consumption is calculated by multiplying the signa by the length of therapy. This measure is available only in the Report Definition function and only if you subscribe to NDTI.

Provider Dollars (DOL/PROV). This measure reports the amount of money non-federal hospitals, federal facilities, long-term care facilities, clinics, and HMOs spent on a product acquired from manufacturers and drug wholesalers.

Provider Eaches (EA/PROV). This measure represents the number of single items (such as vials and syringes) contained in a unit or shipping package and purchased by non-federal hospitals, federal facilities, long-term care facilities, clinics, and HMOs in a specific time period. An each may be the same as a unit if the unit does not subdivide into packages. Eaches are most meaningful at the package level, since packages and their subunits may contain different quantities of strengths and volumes.

Provider Eaches Average Price (DOL/PROV/EAAP). The measure is calculated by dividing purchase dollars by eaches. This measure is meaningful for injectables, powders, ointments, inhalants, and any other form shipped in packages containing single items that can be broken apart. The average each price prints to three decimal places. For example, 3.277 means an average each price of $3.277.

Provider Extended Units (EU/PROV). Extended units is the number of tablets, capsules, milliliters, or grams purchased. This number is calculated by multiplying the number of units by the volume and size of each package reported. Extended units are often meaningless above the form/strength level, because a product may have different forms and strengths and therefore a different type of unit. Eaches and units are most meaningful at the package level.

Provider Extended Units Average Price (DOL/PROV/EUAP). This is the average purchase price of a tablet, capsule, milliliter, or other extended unit in the specified time period. It is meaningful only at the package level.

Package Size (PCK-SIZ). Package size refers to the number of individual units contained in the selling package of a particular product type. The meaning of "units" varies, depending on the form of the product.

- Tablets and capsules are shown as a single-package unit. For example, a bottle containing 500 capsules has a package size of 1. (The actual number of capsules in the bottle is measured by package volume, rather than package size.)
- Injectable products usually have package sizes greater than one. For example, a 10-pack of injectable vials has a package size of 10, and a dozen bottles of cough syrup has a package size of 12.

Product (PRD). This element includes the drugs or vitamins manufactured and sold by pharmaceutical companies. You can select a product by either a numeric code or the product name.

Product Age (PRD-AGE). Product age is the number of years the product has been on the market, based on its initial appearance in the sales audits.

Product Form 1 - 3 (FRM1, FRM2, FRM3). Product Form refers to the physical dosage form of a drug, such as oral or injectable. This system consists of three levels, with each successive level containing more detail about the product form. For example, Product Form 1 = O contains all orals, Product Form 2 = OL contains all oral liquids, and Product Form 3 = OLS contains all oral liquids in syrup form. You can review a list of form codes using the Dataview Market Definition function. To include different levels of product form in your database, select each level for which you want to see totals.

Product Strength (STR). Most products are available in different potencies or strengths. For example, a product may be offered in both a 250-mg tablet and a 500-mg capsule.

Product Year (PRD-YEAR). This is the year the product was first introduced into the market.

RX Status (RXSTATUS). Use this element if you want to include prescription status in your database or report. RX Status is most meaningful when used to limit Product or a USC to data having a particular prescription status. RX Status can be either *Legend* (prescription required) or *Non-Legend* (no prescription required).

Three-Letter Form Code 1 - 3 (TLC1, TLC2, TLC3). This is the application form for classifying a product. Product form encompasses two classification systems—Product Form and Three-Letter Form Code. Both systems consist of three levels, with each successive level containing more detail about the product form. For example, TLC1=D contains all systemic oral liquids, TLC2=DC contains oral drops, and TLC3=DCB contains long-acting oral drops. In general, Three-Letter Form Codes provide a finer breakdown of Product Form. You can review a list of Three-Letter Codes using the Dataview Market Definition function.

Provider Historical Price (DOL/PROV/HP). This is the average price of a particular package within a specified time period. It is calculated by dividing dollars by units. Historical price is printed to two decimal places. For example, 14.48 means a package price of $14.48. Historical price is most meaningful at the package level.

Provider Kilograms (KG/PROV). This measure reports the chemical weight of quantities purchased. You must have Molecule, Chemical Family, or Chemical Sub-Family in the database contents to obtain kilogram weight. Weights are reported in metric measures, using the following weight symbols:

A	-	Thousand Tons	Z	-	1,018 Units
T	-	Ton	Y	-	1,015 Units
K	-	Kilogram	U	-	1,012 Units
G	-	Gram	V	-	109 Units
M	-	Milligram	S	-	106 Units
X	-	Microgram	E	-	1,000 Units

Examples: 4T3 = 4.3 metric tons or 4 metric tons + 300 kilograms
24K9 = 24.9 kilograms or 24 kilograms + 900 grams

Provider Units (UN/PROV). This measure represents the number of individual shipping packages purchased by non-federal hospitals, federal facilities, long-term care facilities, clinics, and HMOs in a specific time period. Units are most meaningful at the package level, since packages and their subunits contain different quantities of extended units.

Special Considerations

How Provider Perspective Relates to Factory Sales Figures

There are several reasons why analysts may encounter difficulty in attempting to match IMS estimates against factory sales:

- In many cases, it is difficult for companies to ascertain what portion of factory sales are made to the specific channels covered in Provider Perspective.
- Timing of transactions is rarely comparable. Factory sales may be recorded in December, while hospital purchase of the same items may not occur until February.
- Translation of factory sales dollars to hospital acquisition dollar levels is imprecise.

Submitter : Ms. Mary Ellen Kleiman **Date:** 12/05/2007

Organization : National Association of Chain Drug Stores

Category : Pharmacist

Issue Areas/Comments

GENERAL

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The National Association of Chain Drug Stores (NACDS) submits the attached November 13, 2007 report by Stephen W. Schondelmeyer, Pharm.D., Ph.D., FAPHA (with exhibits) regarding Average Manufacturer Price and Federal Upper Limits for agency consideration. Due to its size, it will be submitted in multiple submissions of PDF files (more then the 4 originally thought). See Attachments. [FOURTH OF SIX]

Submitter : **Ms. Mary Ellen Kleiman** **Date: 12/05/2007**

Organization : **National Association of Chain Drug Stores**

Category : **Pharmacist**

Issue Areas/Comments

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CMS-2238-FC3-9-Attach-1.PDF

#9

Protecting Rural Beneficiaries
with a
Medicare Prescription Drug Benefit

The Whole Package: Protecting Rural Beneficiaries with a Medicare Prescription Drug Benefit

Few would argue against providing Medicare beneficiaries with a prescription drug benefit. It is, quite simply, something they deserve. Indeed, given the increasing cost of prescription drugs, the increasing numbers of elderly, and the increasing role of pharmaceutical care in maintaining health, a prescription drug benefit is an absolute necessity. It is, however, not enough.

Critical as a drug benefit is, it is only part of the package. *Insuring* drugs without also *ensuring* accessible, high-quality, and affordable pharmaceutical care (the whole package) will not protect the health and well-being of our citizens. In fact, it could harm them. Therefore, any Medicare prescription drug benefit should include provisions that protect the access of all beneficiaries — rural and urban — to local pharmaceutical care.

In keeping with its mission *to improve the health of rural Americans through appropriate and equitable health care services,* the National Rural Health Association convened a meeting of experts in rural pharmacy in January 2003 to discuss the rural implications of a Medicare prescription drug benefit and offer suggestions on how best to design a benefit so as to protect rural beneficiaries — to ensure that they not just get the pharmaceuticals, but that they have local access to pharmaceutical care. This report synthesizes the findings and recommendations of those experts. Their consensus: Unless a benefit is designed with rural beneficiaries in mind, great damage could be done — damage that would be irreversible.

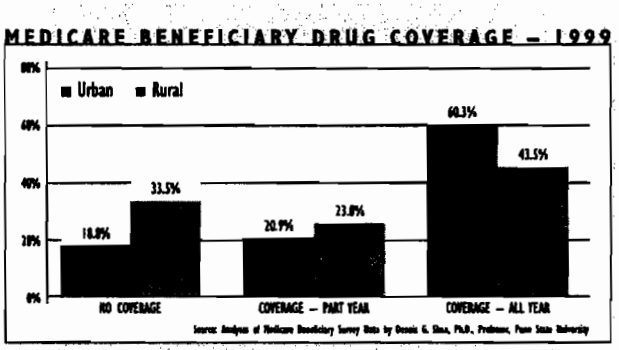
Failure to consider the unique features of the rural health care system in the design of a drug benefit could wreak havoc on rural pharmacies and the communities they serve. Any Medicare prescription drug benefit should include provisions that protect rural beneficiaries' access to local pharmaceutical care.

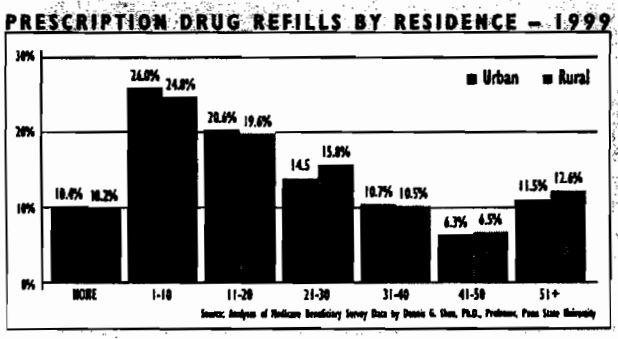
Indeed, such damage has happened in the past. In 1983, Medicare moved to an inpatient prospective payment system. By 1991, 193 rural hospitals had closed their doors, unable to survive under a pricing system based largely on an urban environment.[1] By 1998, 438 rural hospitals had closed, despite years of adjusting the payment formulas to "mitigate" the damage.[2]

Creation of a prescription drug benefit that fails to consider the unique features of the rural health care system could well wreak similar havoc on rural pharmacies and the communities they serve, ultimately harming the very people a drug benefit is meant to help.

Pharmaceutical Care: The Whole Package

The importance of prescription drugs to health care cannot be overstated. And their importance is only increasing. In 1950, 367 million outpatient prescriptions were written nationwide. Today, the number is close to three billion. Measured in number of prescriptions per person per year, Americans' usage went from 2.4 to 11. The elderly — who comprise the vast majority of Medicare beneficiaries — average 25-30 prescriptions per person per year.





With that phenomenal increase in pharmaceutical usage comes a rise in the need for pharmaceutical care. To illustrate that point, consider that studies show when a person is on nine or more prescription drugs, the likelihood of an adverse drug reaction is 100 percent. Just as the importance of prescription drugs to health care cannot be overstated, the importance of pharmaceutical care cannot be overstated.

[1] Trends in Rural Hospital Closure: *1988-1991. Office of the Inspector General, U.S. Department of Health and Human Services, July, 1993.*

[2] Rural Health in the United States, *Thomas C. Ricketts, III (ed.). New York, Oxford Press, 1999.*

So, what exactly is pharmaceutical care?

Contrary to popular opinion, pharmaceutical care is far more than the filling and dispensing of prescriptions. Rather, it is a critical component of the overall health care system, as important to patient health as any other component. Pharmaceutical care encompasses

- **Patient advice.** Pharmacists advise patients in any number of ways: how to take a prescription medication, whether the medication will affect or be affected by other medications, what over-the-counter treatments to take for various conditions, and in some cases, when to seek additional medical care.
- **Clinical service.** Depending on the setting, pharmacists provide patients with any number of clinical services, ranging from diagnostic testing to treatment.
- **Case management.** In order to protect patients' health and see to it that they get the best treatment, pharmacists regularly consult with physicians about patients' pharmaceutical needs — alerting physicians about potential drug interactions, offering suggestions for alternative treatments, and clarifying prescription orders.
- **Benefits management.** In the same vein, pharmacists also consult with insurance companies on behalf of patients — seeking coverage for a particular drug and correcting wrongly rejected claims.

Although they are often forgotten or taken for granted, pharmacists are a critical part of any health care system. Without them, the system will falter and ultimately fail, endangering patient health and well-being.

Rural Beneficiaries: Underinsured, Underserved

The percentages of rural Americans who are older and sicker are greater than those of urban Americans. Average wages in rural America are lower. Lack of health insurance is, depending on the measure, also a relatively greater problem in rural America. A greater proportion of rural Americans also lack access to adequate health care. The story is much the same with respect to Medicare beneficiaries and prescription drugs.

Medicare beneficiaries who live in our nation's rural areas enjoy prescription drug coverage at a far lower rate than do beneficiaries who live in urban areas. Depending on the measure, the gap between rural and urban beneficiaries with coverage was, in 1999, anywhere from seven percentage points to 17 percentage points.

That fact notwithstanding, data on prescription drug refills by residence show that rural beneficiaries age 51 and older obtain more refills than their urban counterparts. As a result of all these factors, 14 percent of rural beneficiaries in 1999 spent more than 10 percent of their income out of pocket on prescription drugs. Only eight percent of urban beneficiaries did so.

Rural Pharmacies: Critical Care, Critical Condition

While pharmacists and the care they provide are a critical component in any health care system, in some rural places underserved by doctors, clinics, and hospitals, they are the entire system. Indeed, studies have found that pharmacists are more widely distributed across rural areas than primary care doctors — often thought to be the mainstay of rural health care. Yet, according to a 1996 study by the American Pharmaceutical Association, 25 percent of the nation's population lives in rural America but only 12 percent of its pharmacists practice there. This, of course, comes on top of shortages of other health care providers and facilities in rural America — further weakening the health care system serving a quarter of our nation's citizens.

Reasons for the dramatic rural shortage include the obstacles to setting up shop in areas that can be remote, isolated, and contain higher percentages of low-income clientele. On top of that are the rising workload that pharmacists shoulder and the relative lack of help in rural areas.

According to the National Association of Chain Drug Stores, pharmacists in retail pharmacies alone filled three billion prescriptions last year — up 50 percent from 1990. The association's data also show that four out of five patients who visit a doctor leave with a prescription.

On the surface, such numbers would seem only to benefit pharmacists. In fact, the rise in prescriptions is a mixed blessing. A study of rural pharmacies in Minnesota, North Dakota, and South Dakota found that more than half of the pharmacists surveyed had difficulty obtaining relief coverage for vacations and time off. Indeed, some rural pharmacists report working 12 or more hours a day (20 percent of it on the phone dealing with third-party payer issues). Obviously, the chance for error increases under such conditions.

Precarious as the state of rural pharmacy is, the situation is getting worse. Pharmacies, particularly small, independent pharmacies — 70 percent of which are located in communities of 50,000 or less — face a long list of pressures:

- **Price takers.** Rural pharmacies are essentially price takers. Pharmacist after pharmacist reports being unable to negotiate prices with pharmaceutical suppliers. Rather, they are typically presented with a contract and pricing scheme and given a few days to take it or leave it. Not surprisingly, such arrangements favor the suppli-

ers and not the pharmacists. As evidence, consider that the average pharmacy makes only a one to two percent profit margin.

- **Small margins/low volumes.** The relatively small sales of a rural pharmacy mean that "making up on volume" for the small profit margin is all but impossible. Indeed, research shows that just to be viable, a pharmacy needs to serve a population of 4,500 people. In many areas, maintaining volume, let alone increasing it, is difficult enough.
- **Mail order.** Mail-order (including Internet) pharmaceutical sales are making the challenge of maintaining volume even harder. According to the Institute for Local Self Reliance, sales at mail-order pharmacies grew 24 percent in 2000 and accounted for some 15 percent of all prescription spending. Because mail-order suppliers deal in vast quantities, they can negotiate lower wholesale prices. And because they maintain no brick and mortar outlets, their overhead is much lower than retail pharmacists. As a result, mail-order suppliers can sell drugs at lower prices. On top of that, some third-party payers steer — some would say coerce — customers into using mail-order rather than local pharmacies. In some instances, pharmacy benefit managers even own the mail-order suppliers they steer customers to — a clear conflict of interest.
- **Age.** The majority of pharmacists in rural areas are approaching retirement age. The decline of pharmacy graduates coupled with the other obstacles to rural pharmacy mean that many will not be replaced.
- **Medicaid.** Some states are seeking to curtail their Medicaid expenditures by reducing even further the low profit margins pharmacies currently make. This is particularly hard on rural pharmacies since they have a higher percentage of Medicaid business than do urban areas (save for some inner city areas).

As a result of these and other pressures, 13 percent of independent pharmacies operated at a loss in 2001; 28 percent earned zero to only two percent profit. Together, these 41 percent of independent pharmacies are vulnerable and in danger of failing. Yet, despite it all, the rural pharmacies still above water continue to provide affordable, accessible, high-quality care. "Rural" does not mean "second-rate." We should never let it become so.

"Rural" does not mean "second-rate." We should never let it become so.

Losing Health Care and More

If rural pharmacies fail, they will leave a void in their communities' health care systems, economies, and civic capacities — a void that once created, will not easily be filled.

With or without a local pharmacy, most people will be able to get the drugs they need via mailorder. What they cannot get from the postman, however, is pharmaceutical care — the whole package. The postman will not be able to advise them, consult with their doctors, and represent their interests to benefits managers. And in rural America, driving to another pharmacy still in business to get that care might mean driving 30, 50, or even 100 miles.

In addition to losing health care, communities will lose local businesses that create, on average, 1.2 to 1.6 jobs for every job at the pharmacy and generate 1.2 to 1.6 dollars for every dollar of salary paid at the pharmacy. Finally, they will lose the civic capacity that a highly educated medical professional concerned with the wellbeing of his or her community adds to that community. In small rural towns and cities such losses can be devastating.

Ensuring Pharmaceutical Care in a Medicare Drug Benefit Plan

Medicare, because of its sheer size, can either ensure the future of pharmaceutical care as it insures prescription drugs, or it can make it virtually impossible for rural pharmacies to survive. It is, as one pharmacist put it, the light at the end of the tunnel. Whether that light represents hope or a speeding locomotive depends upon the design of the Medicare prescription drug benefit.

What will it take to ensure that a Medicare prescription drug benefit is not a speeding locomotive resulting in catastrophic losses to beneficiaries and their communities? What will it take to see to it that the benefit provides not just the drug, but also the whole package of pharmaceutical care?

A report by the Rural Policy Research Institute's Rural Health Panel lays out five key elements. Each has important implications for protecting rural beneficiaries' access to the whole package of pharmaceutical care.[3]

- **Equity.** The Medicare program should maintain equity vis-à-vis benefits and costs among its beneficiaries, who should neither be disadvantaged nor advantaged merely because of where they live.
- **Access.** The Medicare program should ensure that beneficiaries have reasonable access to all medical services, including having essential services within a reasonable distance/time of their residence and being able to afford medically necessary services.

[3] *An Assessment of Proposals for a Medicare Outpatient Prescription Drug Benefit: The Rural Perspective, Rural Policy Research Institute Rural Health Panel, January 9, 2003.*

- **Costs.** The Medicare program should include mechanisms to make the costs affordable, both to beneficiaries and to the taxpayers financing the program.
- **Quality.** The Medicare program should promote the highest attainable quality of care for all beneficiaries, defined in terms of health outcomes for beneficiaries.
- **Choices.** The Medicare program should ensure that all beneficiaries have comparable choices available to them — between both health care plans and health care providers.

As the Congress and Administration consider proposals to add a Medicare prescription drug benefit, they need to consider those five key criteria and build in protections for rural beneficiaries. Specifically, Congress and the Administration should consider the following recommendations.

- Rural areas are different than urban areas. Their unique characteristics present unique challenges in the design and delivery of any prescription drug benefit. Therefore, the plan should
  - Grant the Secretary of the U. S. Department of Health and Human Services the authority to recognize special circumstances that affect rural areas.
- Beneficiaries — rural and urban — need access to medications in emergency situations and access to the informational services provided by local pharmacists. Mail-order prescription services cannot provide either of these. Access to pharmaceutical care must be a key consideration. Therefore, a Medicare prescription drug plan should
  - Not rely solely on mail-order pharmacy services; it should also allow for walk-in services.
- The unique characteristics of rural America mean that a plan based solely on competition will not work there and will result in rural beneficiaries being underserved. Therefore, a Medicare prescription drug plan should
  - Not rely only on a private plan such as Medicare + Choice to be the sole vehicle for a prescription drug benefit. The government should also offer a base (default) plan in which it will assume an acceptable amount of risk so that the basic (default) plan of prescription drug coverage will be affordable to all Medicare beneficiaries with no other plan options.
  - Ensure that providers and deliverers of care are separate from those who enroll and educate beneficiaries. The government or a third-party contractor should provide consumers with objective information (including transparent information on pricing) about enrollment options. This is critically important in rural areas given the limited number of options that will likely be available.
  - Consider whether independent rural pharmacies or networks of independent rural pharmacies might be able to take on the role of a pharmacy benefit manager for rural communities.
- Rural beneficiaries are more likely to be served by community-based pharmacies that operate on a small volume and profit margin. Any move to cut costs by reducing the dispensing fees for rural pharmacists could be devastating to their economic viability. The potential loss of the local pharmacist would have a negative impact on quality of care for rural Medicare beneficiaries since they would not have access to medication management — a key need for a population that tends to take multiple medications and, therefore, needs to understand the impact of drug interactions. The plan should
  - Not seek to cut costs by reducing the dispensing fees for pharmacists.
  - Use consistent national pricing regardless of the geography or volume of the purchaser, and make that pricing transparent.
  - Develop ways to protect rural pharmacies that serve as a sole or critical point of contact for their community.
  - Create an administrative add-on for low-volume rural pharmacies.
  - Include "any willing provider" protection so that pharmacists in rural areas, including those serving Native American and Alaskan communities, are not bypassed by pharmacy benefit managers.
- The addition of a Medicare prescription drug benefit will dramatically change the scope of the health care delivery system across the health care system. The increase in utilization will create a greater need for pharmacist services to counsel beneficiaries and evaluate multiple drug interactions. This is particularly important in rural communities not served by a physician and where the pharmacist may be the only health care provider. Therefore, Congress and the Administration should consider a demonstration program to allow pharmacists in rural areas to expand their scope of services to recognize the new challenges of serving beneficiaries. This would require the following changes:
  - Pharmacists should be recognized as Medicare providers (with "provider status") who serve patients' drug-related needs as a part of the medical team in rural communities.

PARTICIPANTS AT THE RURAL PHARMACY ISSUES MEETING

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- The payment system should include Certified Pharmacy Technician codes for pharmaceutical care, case management, and appropriate counseling activities.
- All participating pharmacies in a Medicare prescription drug benefit should be able to dispense 90-day supplies. That would put them on a levelplaying field with mail-order services.
- Any new benefit should include a provision that places high-risk and high-cost patients (of which there are many in rural areas) in pharmacy case management programs with appropriate compensation.

- As Congress and the Administration implement a new Medicare prescription drug benefit, they will need to evaluate and assess the impacts of it. Therefore, they should
  - Require pharmacy benefit managers and any contractors providing services to report utilization and cost data with sufficient geographic identifiers and demographics to evaluate rural policy and impact issues.
  - Grant the Administration the authority and funding to conduct research on the impact of the program on rural pharmacy patients.

Given the importance of pharmaceutical care to the health and well-being of Medicare beneficiaries, simply insuring prescription drugs is not enough. A Medicare prescription drug benefit plan must also ensure that the full range of local pharmaceutical care — the whole package — is available, accessible, and affordable to all Medicare beneficiaries, both rural and urban. Anything less would do great harm to countless beneficiaries and the communities in which they live.

On January 15-16, 2003, the National Rural Health Association and the Federal Office of Rural Health Policy convened a Rural Pharmacy Issues meeting. Participants included pharmacists, researchers, and policymakers. The focus of the discussion: ensuring that a Medicare prescription drug benefit recognizes the unique situation of rural pharmaceutical care and its importance to the health and well-being of rural beneficiaries. This report is a synthesis of that discussion.

For more information about the meeting or rural pharmacy issues, please contact:

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Alexandria, VA 22314
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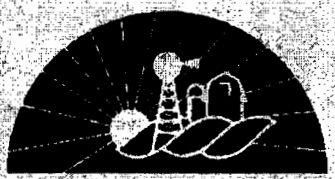
www.NRHArural.org

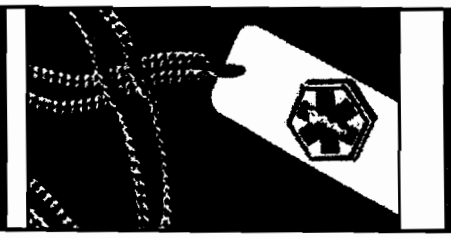


NATIONAL RURAL HEALTH ASSOCIATION

One West Armour Blvd, Suite 203
Kansas City, Missouri 64111-2087
www.NRHArural.org
(816) 756-3140

Exhibit 11

Rural Pharmacy Preservation Act
Minnesota Pharmacists Association, 2005



RURAL PHARMACY PRESERVATION ACT

ACCESS TO PHARMACISTS in rural Minnesota is nearing a crisis point. Pharmacies and pharmacists not only provide drug therapy and health care guidance regarding medications to patients coming into their pharmacy, they also serve local nursing homes, hospitals and other entities by providing medication reviews for patients, and ordering and delivering medications.

Rural pharmacy is fragile in today's environment due to increasing costs of doing business and continuous cuts to pharmacy reimbursement in both the public and private sectors. The result is many rural Minnesotans are loosing access to medications and the knowledge of a pharmacist. Incorporation of a rural pharmacy planning and transition grant program and rural loan forgiveness provides support to initiatives that preserve access to Pharmacy services for rural Minnesotans and assists rural communities in attracting pharmacists.

- A study of 126 rural communities with only one community pharmacy in Minnesota revealed that the 216,000 patients within these community's limits, would have to travel, on average, 22 miles to a neighboring community to receive medications. Not having access to a pharmacists or a pharmacy is also an issue for rural primary care clinics, health systems and rural communities.

- Minnesota loses 38 pharmacies per year: 10-12 of those community pharmacies are not replaced. From July 2004 to February 2005, Minnesota lost 22 pharmacies.

MAINTAINING LOCAL ACCESS TO MEDICATIONS AND THE KNOWLEDGE OF A PHARMACIST

- Through the grant program hospitals, clinics,' pharmacies and communities can collaborate and explore options to maintain local access to medications and the skills of a pharmacist. This grant program for pharmacy is needed to keep up with and reverse pharmacy closures and loss of pharmacists in rural areas.

- The grant program will be funded by excess licensure fees paid by pharmacists, pharmacies and wholesalers and collected by the Board of Pharmacy. Since the Board's budget has remained at a fixed rate and the fees brought in from licensures have increased, excess revenues have been swept into the state's special revenue fund. The excess fees will be dedicated to the grant program, which will be administered by the Minnesota Department of Health. The initiative will help pharmacy sustain pharmacy.

- In addition, rural pharmacist loan forgiveness is another incentive to attract new graduates to the rural areas that are in need of a pharmacist. The current rural loan-forgiveness program, funded by the provider tax and wholesale drug distributor tax incurred by pharmacies, encourages students graduating from the health care professions to practice in rural areas. However, this program currently does not include pharmacists. With the growing pharmacist shortage in rural areas it is necessary to add pharmacists into the program.

MINNESOTA PHARMACISTS ASSOCIATION • 1935 West County Road B-2, Suite 450 • Roseville, MN 55113

651-697-1771 Metro • 800-451-8449 MN • Fax: 651-697-1776 • liz@mpha.org • Abbie@mpha.org

Exhibit 12

U.S. Medicaid Drug Expenditures:
Estimated DRA Payment Cuts Due to AMP-Based FULs

Exhibit 12. U.S. Medicaid Drug Expenditures: Estimated DRA Payment Cuts Due to AMP-Based FULs

A	B	C	D	E	F	G	H	I	J	K	L	M
Year	Total Outpatient Rx Expenditures ($ expenditures)	Total Outpatient Less Mail Order Rx Expenditures[1] ($ expenditures)	Medicaid Outpatient Rx Exp. as % of Total Outpt. Rx $	Medicaid Outpatient Rx Expenditures[2,3] ($ expenditures)	Annual % Change in Medicaid $ ($ expend)	Medicaid FUL Rx $[4] Exp. as % of Medicaid Rx $	Medicaid FUL Rx Expenditures ($ expenditures)	CMS Estimate of Payment Cuts Due to FULs ($ redution)	DRA FUL Payment Cuts: as % of U.S. Outpt. Rx Exp	DRA FUL Payment Cuts: as % of Medicaid Rx Exp	DRA FUL Payment Cuts: as % of FUL Rx Exp	Payment Cut per Retail Pharmacy[6] ($ reduction)
	IMS Health	= B x .80	= E / B	Wolters Kluwer		CMS estimate	= E x G	CMS estimate	= I / B	= I / E	= I / H	= I / # of pharmacies
2000	$ 129,595,251,178	$ 103,676,200,942	13.0%	$ 16,881,347,748		8.3%	*$ 1,401,151,863*					
2001	$ 137,829,264,412	$ 110,263,411,530	13.5%	$ 18,542,227,429	9.8%	8.3%	*$ 1,539,004,877*					
2002	$ 146,061,775,774	$ 116,849,420,619	13.8%	$ 20,203,107,109	9.0%	8.3%	*$ 1,676,857,890*					
2003	$ 182,464,329,981	$ 145,971,463,985	14.0%	$ 25,453,966,351	26.0%	8.3%	*$ 2,112,679,207*					
2004	$ 195,842,406,186	$ 156,673,924,949	15.3%	$ 29,952,591,287	17.7%	8.3%	*$ 2,486,065,075*					
2005	$ 237,915,908,588	$ 190,332,726,870	13.5%	$ 32,150,827,883	7.3%	8.3%	*$ 2,668,518,714*					
2006	$ 257,977,458,909	$ 206,381,967,127	7.6%	$ 19,583,290,150	-39.1%	8.3%	*$ 1,625,413,082*					
2007	*$ 270,876,331,854*	*$ 216,701,065,484*	7.6%	*$ 20,562,454,658*	*5.0%*	8.7%	*$ 1,792,017,923*	$ 795,000,000	0.3%	3.9%	44.4%	$ 13,961
2008	*$ 284,420,148,447*	*$ 227,536,118,758*	7.6%	*$ 21,590,577,390*	*5.0%*	9.2%	*$ 1,976,699,761*	$ 1,285,000,000	0.5%	6.0%	65.0%	$ 22,565
2009	*$ 298,641,155,870*	*$ 238,912,924,696*	7.6%	*$ 22,670,106,260*	*5.0%*	9.6%	*$ 2,178,208,986*	$ 1,840,000,000	0.6%	8.1%	84.5%	$ 32,311
2010	*$ 313,573,213,663*	*$ 250,858,570,930*	7.6%	*$ 23,803,611,573*	*5.0%*	10.1%	*$ 2,401,475,407*	$ 1,980,000,000	0.6%	8.3%	82.4%	$ 34,770
2011	*$ 329,251,874,346*	*$ 263,401,499,477*	7.6%	*$ 24,993,792,152*	*5.0%*	10.6%	*$ 2,647,626,636*	$ 2,140,000,000	0.6%	8.6%	80.8%	$ 37,579
2007-11	$ 1,496,782,724,180	$ 1,197,410,179,344	7.6%	$ 113,620,542,032		9.7%	$ 10,995,028,713	$ 8,040,000,000	0.5%	7.1%	73.1%	
2008-11	$ 1,225,886,392,326	$ 980,709,113,861	7.6%	$ 93,058,087,375		9.9%	$ 9,203,010,790	$ 7,245,000,000	0.6%	7.8%	78.7%	
												# of retail pharmacies *56,946*

Sources:

[1] Adjusted to remove mail order prescriptions based on the fact that in 2006 mail order was about 20% of the outpatient prescription market according to IMS Health.

[2] Pharmaceutical Benefits Under State Medical Assistance Programs, 2005/2006, National Pharmaceutical Council, 2006

[3] Wolters Kluwer Health Pharmaceutical Source Audit Suite, data accessed 6/21/06 as reported in NACDS, The Chain Industry Profile, 2007, pp. 67-68; and annual volumes for 2000 to 2006.

[4] Federal Register, Vol. 72, No. 136, 42 CFR Part 447, Medicaid Program; Prescription Drugs, Final Rule, July 17, 2007, p. 39236.

[5] Federal Register, Vol. 72, No. 136, 42 CFR Part 447, Medicaid Program; Prescription Drugs, Final Rule, July 17, 2007, p. 39230-31.

[6] IMS Health reports the number of retail pharmacies as 56,946 for 2006 as found in in NACDS, The Chain Industry Profile, 2007, p. 15.

Exhibit 9

DDD™ Annual Class-of-Trade Analysis 2003
IM Health

The 2003 DDD Annual Class-of-Trade Analysis examines the 10 channels of business across the retail and non-retail pharmaceutical market. It provides statistics relative to market share, growth and overall trends for the past seven years. The Analysis also highlights and reports prescription sales as tracked by IMS Retail Method-of-Payment™.

The dollars used in the Class-of-Trade Analysis (unless otherwise stated) are based on *wholesale acquisition cost (WAC)* – those set by each pharmaceutical manufacturer. These prices do not reflect rebates, discounts or charge backs. Direct sales, as reflected in this analysis, are only for those manufacturers who participate in and provide direct sales data to IMS.

As part of IMS's Sales Force Effectiveness offerings, DDD is the industry's premier source of pharmaceutical sales intelligence. Tracking subnational, direct and indirect sales information for pharmaceutical products across all retail and non-retail classes of trade — DDD provides comprehensive insight and accurate assessment of pharmaceutical product sales.

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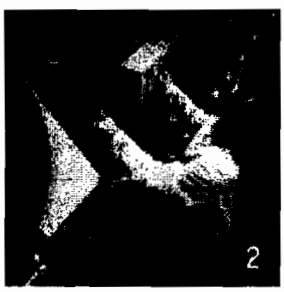

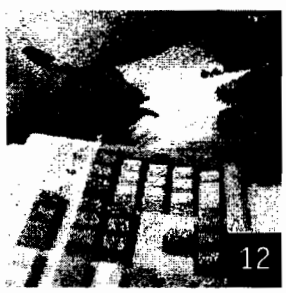

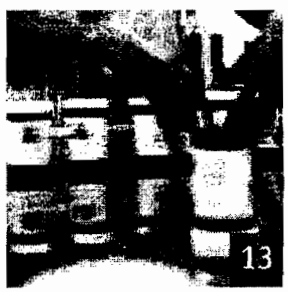

SUMMARY

Driven by consumer demand, the pharmaceutical industry reached annual sales of $233 billion in 2003. Fueled by strong sales across the top 10 therapy classes and the introduction of 21 new molecular entities (up from 17 in 2002), the industry overall grew at 8.8 percent. While this growth rate is slower than previous years, it is most telling considering the multitude of environmental factors influencing the U.S. market.

As in the recent past, the pharmaceutical industry is under the constant scrutiny of the government, media and the general public with politicians, health plans, and employers implementing new strategies to curtail drug spend. Further impacting growth is the reimportation of pharmaceutical products from Canada. Increasingly, brand products are moving to over-the-counter (OTC) status. And, switching from branded to generic products continues (growing by 9.2 percent on a total dispensed prescription basis in 2003).

The U.S. economy, tenuous at best, and marred by an unemployment rate of six percent (the highest it's been since 1995), also affected overall drug sales. Due to lack of disposable income, consumer polls indicate that patients are opting for non-compliance with recommended therapy treatments, including, cutting doses and ignoring prescription orders altogether.

In 2003, in spite of the many environmental factors and a slowed overall growth rate across the ten classes of trade, several channels faired well. Chain pharmacies and hospitals, the leaders within the retail and non-retail channels respectively, both achieved market share growth in 2003 – this after experiencing a decline in the previous year. Chain stores led all channels with a 28.3 percent market share, followed by hospitals with a 15.3 percent share, and mail service now up to 14.9 percent. This is good news for the chains and hospitals whose market share growth has fluctuated in recent years. As for mail service, while its growth rate has slowed somewhat, down from an average of 26% over the previous four years, its market share increase remains impressive.

Once again, based on DDD dollars, mass merchandisers and healthcare plans had negative growth rates and associated decreases in market share. This holds true for the miscellaneous channel as well, whose market share dropped by a full one percent.