

In Re Neurontin Marketing and Sales Practices Litigation, MDL Docket No. 1629

EXPERT REPORT OF KIMBERLY P. McDONOUGH

I, Kimberly P. McDonough, hereby state, under penalty of perjury, that the foregoing is true and correct.

1. QUALIFICATIONS

I am President of Advanced Pharmacy Concepts, an independent pharmacy benefit consulting and audit firm that provides services to employers, health plans, and government agencies regarding the administration of pharmacy benefits and implementation of clinical benefit programs. Advanced Pharmacy Concepts employs 32 individuals devoted entirely to the assessment of pharmacy benefit programs, drug pricing, and clinical utilization. Over the past five years, we have provided services to over 40 commercial and state government clients with total pharmacy expenditures in excess of four billion dollars. Advanced Pharmacy Concepts is the sole contractor to the Centers for Medicare and Medicaid Services (“CMS”) as the compliance auditor of the Medicare Part D, Part C, and PACE programs.

I served as a member and/or chairperson for committees of the American Pharmaceutical Association (“APhA”), the Academy of Managed Care Pharmacy (“AMCP”), and the Pharmacy Quality Alliance (“PQA”). I am a member and have served on the Board of Directors for the Rhode Island Pharmacist Association. I served as the Chairperson for the State of Rhode Island’s Drug Use Review Board from 1992 until 2000. I authored a chapter regarding the PBM industry in the recently published *Handbook of Pharmaceutical Public Policy*, and serve on the Advisory Board for the *Prescription Drug Benefit Cost and Plan Design Report*, published annually by the Pharmacy Benefit Management Institute.

I am a graduate of the Purdue University School of Pharmacy with a Doctor of Pharmacy Degree. I am currently licensed as a registered pharmacist in the states of Michigan and Rhode Island. I have previously been employed as a Director of Pharmacy in several hospitals and as Vice President of Pharmacy Operations for a regional hospital pharmacy service corporation. I have been employed as a Clinical Pharmacist for Harvard Community Health Plan, a regional health maintenance organization located in New England. I served as Director of Clinical Operations and Director of Product Development for MIM Health Plans, a national pharmacy benefit management company. In addition to these positions, I provided long-term care consulting services to local nursing homes and dispensed medications in community pharmacies.

I served on pharmacy and therapeutics committees (“P&T Committees”) for all of my previous employers in the hospital and managed care sector. These positions have included representation on the P&T Committee of Harvard Community Health Plan and on the P&T Committee for a coalition of health plans in the TennCare Medicaid Program, including BlueCross BlueShield of Tennessee, HealthNet, Access Med Plus, TLC Health Plan and Phoenix Health Plan.

Working as a subcontractor to a national firm, I served as a subject matter expert to the Centers for Medicare Services (“CMS”) regarding commercial pharmacy benefit practices and the use of drug management tools during the planning and implementation of the Medicare Part D program. I supervised the preliminary review of all drug management tools being used by Part D Plan Sponsors, including a review of individual

plan formularies, prior authorization criteria, and use of step therapy and tiers within the Plans' benefit programs.

I have been directly involved in a number of formulary and drug management activities involving a wide range of therapeutic classes. In this capacity, I conducted medical literature research in preparation for the P&T Committee meetings, developed clinical monographs describing the drugs or drug classes being reviewed, researched medical treatment standards, provided review of internal utilization patterns for the applicable medications, developed clinical coverage guidelines for selected medications, and led clinical discussions regarding the products under review. Examples of drug classes for which I provided review include cardiovascular agents, anti-infective products, HIV therapies, non-steroidal anti-inflammatory agents and anti-ulcer agents, among others.

A complete summary of my professional experience, presentations and publications is outlined in my resume, which is enclosed as Exhibit A.

2. SCOPE OF WORK

In this matter, I have been retained on behalf of Plaintiffs to provide testimony explaining the basic contours of the health insurance industry as they relate to the provision of pharmacy benefits to insured individuals and to identify the various drug management tools available to the managed health care industry as these pertain to the coverage of medications. I have also been asked to discuss the application of these drug management tools to the antiepileptic drug Neurontin, and to opine as to whether the application of these tools to Neurontin is practical.

My report is based on my professional experiences as a clinician and administrator in the health insurance and PBM industries, my review of relevant industry

publications, as well as the experience and knowledge that I have gained over the past eleven years as a consultant to TPPs, providers, and government agencies. The materials I rely on are cited in this report or identified in the attached Exhibit B.

3. PRIOR TESTIMONY

I have testified as an expert in deposition in the following cases: *Duramed Pharmaceuticals, Inc. vs. Wyeth-Ayerst, Inc.* Civil Action No. C-1-00-735, *J.B.D.L Corp. d/b/a Beckett Apothecary, et al. vs. Wyeth-Ayerst, Inc.* Civil Action No. C-1-01-704, and *CVS Meridien, Inc. and Rite Aid Corp vs. Wyeth-Ayerst, Inc.* Civil Action No. C-1-03-781. Each of these cases was filed in the United States District Court for the Southern District of Ohio. I have written an Expert report and provided a video tutorial in *New England Carpenters, et al vs. First DataBank, Inc and McKesson Corporation*, Civil Action No. 1:05-CV-11148-PBS, filed in the District Court of Massachusetts. I am being compensated at the rate of three hundred dollars (\$300) per hour for my services.

4. SUMMARY OF OPINIONS

TPPs and PBMs use a variety of different tools to assist in the management of drug utilization within their benefit programs. Examples of drug management techniques include formulary limitations, claim edit controls and prior authorization. However, these tools are limited by clinical and practical considerations that have a significant bearing on coverage of Neurontin by TPPs.

- The techniques available to TPPs and PBMs to control drug utilization are not well suited to a drug like Neurontin. Neurontin is FDA-approved for the treatment of epilepsy, a serious disease that is difficult to manage and for which treatment options are limited. TPPs and PBMs must assure that

epileptic patients have access to this therapy without creating barriers to care.

- TPPs and PBMs are unable to use the pharmacy point-of-service claim processing system to limit coverage of Neurontin to FDA-approved indications. Physicians and other prescribers are not required to include the patient's diagnosis on the prescription, and pharmacists do not have access to this information when they submit drug claims to the TPP or PBM.
- TPPs and PBMs are typically unwilling to require a prior authorization for Neurontin. Doing so would create significant disruption to providers and patients when Neurontin is prescribed and use for the treatment of epilepsy and other FDA-approved conditions.
- With limited resources, TPPs and PBMs focus drug management on drug therapies and diseases that are more costly to the plan, more prevalent or offer greater opportunities for quality improvement and reporting.
- All TPPs and PBMs are subject to the limitations and constraints described above.
- Pfizer¹ actively sought information from TPPs and PBMs about coverage of Neurontin. As a result of these efforts, Pfizer understood that TPPs and PBMs were unlikely, and often unable, to implement any drug management efforts that would restrict access to Neurontin for off-label uses.

5. PHARMACY BENEFIT PROGRAMS AND PLAYERS

¹ Unless otherwise specified, a reference to Pfizer applies to Pfizer, Parke-Davis and/or Warner Lambert

Pharmacy benefit programs are a common component of the health care benefit offered to insured individuals. Third party payors (“TPPs”) and pharmacy benefit managers (“PBMs”) provide and administer pharmacy benefit programs to individuals and process pharmacy claims using a uniform electronic claim transaction process that is standardized throughout the United States.

5.1. Third Party Payers

TPPs refers to those entities, other than government agencies, that pay the vast majority of the purchase price of medications on behalf of a group of beneficiaries. TPPs include health insurance plans, as well as Taft-Hartley union health and welfare funds and self-funded employers with active and/or retiree benefit programs. Each is discussed briefly below.

Health Insurance Plans

Health insurance plans provide medical and pharmacy benefits to a wide range of organizations nationally, including employers, state and local governments and Medicaid programs.² The structure and scope of benefits that are offered to employers and beneficiaries vary widely within these plans. Generally, however, health plan structures are as follows:

- **Indemnity Plans:** The health plan serves as a processor for medical claims, but engages in few, if any, negotiated efforts to manage individual health care costs. Indemnity programs were common in the past, but are rarely requested in the current healthcare market. If pharmacy benefits are offered, they are provided under a supplemental pharmacy benefit.

² The terms “health plans” and “managed care organizations” or “MCOs” are used interchangeably throughout this report

- Preferred Provider Organizations: The plan negotiates with a network of hospitals and physicians for discounted rates. Patients are encouraged to use these contracted providers, either through a mandate in their benefit or by requiring a larger out-of-pocket expenditure when patients used the services of non-participating (non-PAR) providers. Pharmacy benefits are frequently offered as an optional rider to employers groups, but these programs tend to be very loosely managed with open formularies and a wide network of participating pharmacies. By far, the largest number of insurers in the United States follow some variation of this business model, and most people in the United States are covered by this model.
- Health Maintenance Organizations: The plan contracts with a limited number of provider groups and hospitals to provide health services for their patients. In some HMO's, physicians and other health professionals may be employees of the HMO. In general, prescription benefits are part of the comprehensive package that is provided as a health benefit by these organizations, and are not an optional product. Generally, HMOs manage pharmacy benefits more tightly. The number of employees enrolling in HMO plans varies considerably by locality, with the largest portion of these plans being located in the Western United States.

There are many health plans nationally, including most large health plans, that provide a combination of the above models as a portion of their health benefit programs. Furthermore, these programs may be offered through an insured arrangement, where the health plan is liable for expenses incurred, or through an administrative services only

(“ASO”) agreement, in which the employer is self funded, but the health plan administers the benefit program.

Taft-Hartley Union Health and Welfare Plans

Taft-Hartley Union Health and Welfare Plans are organizations established for the purpose of negotiating and administering health benefits on behalf of local unions, their members and other eligible beneficiaries. These organizations typically use the combined purchasing power of their member unions to secure discounts and favorable rates for the purchase of health and pharmacy benefits. While medical benefits are often secured through national or regional health insurance companies, pharmacy benefits may be secured through a health insurance plan or directly from a PBM as a stand-alone benefit product. Formularies are often utilized by these organizations; however, due to the collective bargained nature of union benefit, most pharmacy benefits are fairly liberal with few restrictions.

Self-Funded Employers

Rather than purchasing insured health benefits for employees and their dependents, many employers opt to self-fund their benefit programs. Self-funding frees the employer to negotiate pricing of services and to customize the scope of benefits offered to employees. While some employers negotiate the prices of services directly with vendors, other employers, particularly small sized organizations will use the combined purchasing leverage of a collective of employers, using the services of a third party administrator (“TPA”) or a purchasing coalition. As with Union Health and Welfare Funds, self-funded employers may obtain pharmacy benefits through a health insurance plan or as a carve-out benefit directly from a PBM.

5.2. Pharmacy Benefit Managers

PBMs are organizations that provide services to TPPs for the purpose of providing pharmacy benefits. Rather than processing their own pharmacy claims, most health plans contract with a PBM for this purpose. Likewise, some employers choose to contract directly with a PBM for the management of their pharmacy benefit, rather than acquiring pharmacy benefits through a health plan.

There are more than 55 PBMs currently operating in the United States and the range of services provided by these individual companies is substantially similar.³ All PBMs provide point-of-service claim processing services as described below. In addition, PBMs may contract with retail pharmacies, provide mail order pharmacy services, negotiate rebates with drug manufacturers, develop formularies, and conduct drug utilization review activities.

5.3. Electronic Claim Processing

Historically, pharmacy benefits were provided as a supplement to major medical insurance that was offered by employers. Patients would submit receipts for their drug purchases to their major medical insurance carrier and, if the annual deductible was met, the insurer would reimburse the patient for a percentage of the prescription cost.

During the 1990's, with the evolution of point-of-service ("POS") claim capabilities, insurers and Medicaid programs embraced new electronic technology, eliminating the need for processing of paper receipts, dramatically improving process efficiencies and reducing out-of-pocket costs to the patient. Because POS pharmacy claim technology is standardized in the United States and its territories, all pharmacy

³ Compilation from the following resources: PBMI.com, the Pharmacy Benefit Management Institute Web site; www.PCMA.org, the Pharmaceutical Care Management Web Site; *Managed Care Rx Report*

claims are processed in a substantially similar manner, allowing individual access to pharmaceutical coverage across the nation, regardless of the location of the individual's benefit sponsor.

Pharmacy claims are processed electronically in accordance with standards that have been established by the National Council for Prescription Drugs Programs, Inc. ("NCPDP"). NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization that creates and promotes standards for the transfer of data within the pharmacy sectors of the health care industry.⁴ Factors that are addressed within the claim standards include telecommunication procedures for claim submission, standards for fields that are maintained in the claim transaction process, and unit standards for quantities that are dispensed.⁵ NCPDP claim transaction standards were adopted as the required format for pharmacy claim transactions under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").⁶ NCPDP also provides guidelines for the processing of pharmaceutical rebates, the format of prescription cards that are issued to beneficiaries, enrollment processes, procedures for the implementation of prior authorization requirements, and professional services implementation.

Electronic data interchanges ("EDIs") serve to route the pharmacy claim from the pharmacy, where the claim is generated, to the appropriate payer.^{7, 8} This process is completed in the same manner as many forms of electronic claim transmission for credit card and banking procedures through direct managed network connection options, frame

and Directory, Hospital Pharmacist Report Medical Economics, Inc. Montvale, NJ 1997, PBM02 Company Directory, Managed Healthcare Executive, March 2002.

4 <http://www.ncdp.org>

5 *NCPDP Basic Guide To Standards*, National Council for Prescription Drug Programs, 9240 East Raintree Drive, Scottsdale, AZ 85260, May 2005.

6 45 C.F.R. Parts 160-64.

7 <http://www.webmdenvoy.com/pages/pharmacies/pharm.html>

8 <http://www.ndchealth.com/pharmacy/pharmacy.htm>

relay and Virtual Private Network (“VPN”) technology.⁹ Once routed to the TPP or the TPP’s PBM, the claim adjudicates against the claim processing system, and is evaluated for a number of edits including the eligibility status of the individual, coverage of the applicable drug, assignment of any prescription edits or messages, determination of the individual’s copay, co-insurance or deductible, and designation of the approved payment amount.

Unlike medical claim transactions which are often processed after the delivery of care, pharmacy claim transactions are completed in nanoseconds, permitting POS transactions in the pharmacy. This POS technology can be used to transmit eligibility verification, information about drug interactions, and drug coverage limitations to a pharmacist before the prescription is adjudicated. However, edits that prevent the transmission and acceptance of a claim, such as a prior authorization requirement, can disrupt the patient’s access to drug therapy if used indiscriminately. For this reason, most organizations limit claim restrictions to refill timeliness (refill-too-soon), quantity restrictions (30-days’ supply) or age restrictions for selected medications. The use of electronic restrictions is largely affected by the standard fields that are populated during the claim transaction process.

Virtually all pharmacy claim processing systems and PBM claim technology have been compliant with the NCPDP standards for many years, long preceding the adoption of NCPDP guidelines as the national standard by HIPAA. This standardization was essential in order to assure that pharmacies were able process pharmacy claims electrically to any TPP or its PBM vendor. The result of the claim standards is that the

⁹ <http://www.ernetwork.com/Connect.aspx>

information available through the claim processing system to TPPs and PBMs is essentially identical nationwide.

6. DRUG UTILIZATION MANAGEMENT TECHNIQUES

There exist a number of programs or tools available to TPPs and PBMs to manage drug utilization within the insured population. The primary tools available for this purpose are formulary placement after review by the appropriate P&T Committee, cost sharing, claim edits and prior authorization. These are discussed below. The practicality of a TPP or PBM using these tools in an attempt to limit Neurontin's use for off-label (non-FDA approved) indications is also discussed.

6.1. P&T Committee

A P&T Committee is an entity established by some TPPs and all PBMs for the purpose of evaluating products that are being considered for formulary placement and developing programs to promote appropriate utilization of pharmaceuticals.¹⁰ The use of P&T Committees is a requirement for health plan accreditation and is widely used and accepted as the basis for decisions related to a TPP or PBM's formulary. P&T Committees are an established component of health care delivery throughout the TPP sector, including at PBMs, health plans, and government agencies.

The typical P&T Committee meets periodically throughout the year, often bi-monthly or once per calendar quarter. When considering drugs in a therapeutic class or new products for consideration on the formulary, P&T members are provided with relevant clinical information about the product, often in the form of a formulary packet. The information included in this packet is often derived from published medical

¹⁰ American Society of Health-System Pharmacists, *ASHP Statement on the Pharmacy and Therapeutics Committee*

literature, manufacturer-supplied materials, comments from FDA proceedings (including approval status), and the TPP or PBM's drug utilization experience. The P&T packet is intended to help committee members as they decide which products to include or exclude from formularies and when considering drug management options. Committee members also rely on their own clinical experience.

It is important to understand the P&T Committee performs no independent clinical research or laboratory analysis. P&T Committees make recommendations as to which drugs should be included or excluded from formulary. They also provide guidance and approval regarding the use of any tools, such as quantity limits or prior authorization, used in managing the insurance coverage of a specific drug or class of drugs. P&T Committee members do not control prescribing nor do they prevent or mandate the prescribing of any drug for a specific condition.

In my experience as the coordinator for P&T Committees for health plans and at a PBM, the identity of the P&T Committee membership is highly sought by pharmaceutical companies, including Pfizer. Because the purpose of drug marketing is to influence prescribing habits, drug makers like Pfizer have perceived that direct marketing to P&T Committee members could benefit their drug products during the formulary evaluation process. In my experience, pharmaceutical companies, including Pfizer and Parke Davis, are anxious to know the schedule adopted by the P&T Committee for review of their products. Using this information, they aggressively seek opportunities to promote their products to P&T Committee members immediately prior to these review dates.

P&T Committee members are often invited to participate in “marketing advisory meetings” and other informational sessions sponsored by manufacturers, including Pfizer and Parke Davis, during which information about products is disseminated. While these sessions can provide valid clinical information about a product, to the extent that information provided by pharmaceutical companies is incorrect or misleading, such information can influence the members of the P&T Committee as they consider formulary initiatives.

6.2. Formularies

The formulary is a list of medications that have been selected for the purpose of encouraging high quality and cost-effective prescribing of pharmaceuticals within a patient population. Formularies are segmented by the therapeutic uses of the drugs, often in accordance with established drug classifications systems such as the American Hospital Formulary Service (“AHFS”) or the British Formulary Service. Recently, the U.S Pharmacopeia established a formulary classification system that is used by many Medicare Part D programs. First DataBank® and Medispan® also maintain proprietary drug classification systems used in the claim processing system. In all of these systems, Neurontin is classified as an anti-epileptic medication.

Pharmacy benefits are offered under an open or closed formulary system. Under an open formulary system, all medications in the covered drug classes are paid for by the health plan or employer, regardless of formulary status.¹¹ The health plan or employer may utilize a variety of formulary management activities to encourage use of formulary drugs. Under a closed formulary system, only formulary medications are covered by the health plan. If a patient receives a prescription for a non-formulary medication, the

patient pays the full price of the medication or must obtain a prior authorization for the medication from the health plan to obtain coverage for the product. The use of closed formularies has been generally limited, particularly among TPP benefit programs, and has declined in use as more TPPs adopt tiered benefit programs, described more fully below.

In addition to the formulary, TPPs may limit coverage of some classes of medication based on the conditions being treated. For example, many TPPs exclude drugs for hair growth, cosmetic products and obesity treatments from standard benefit programs. In contrast, TPPs rarely adopt coverage limitations for drug categories, such as oncologics, anti-convulsants, and ant-retroviral therapy that are used to treat serious diseases. In fact, universal coverage of these products is mandated under Medicare Part D benefits and by some state regulations. The rationale for drug coverage in these categories is that the diseases are very serious and difficult to treat. TPPs typically try to give prescribers and patients access to all available medications with minimal disruption to care.

TPPs can utilize their formularies to promote compliance with national treatment guidelines, to discourage undocumented or non-medical uses of drug therapies, and to educate prescribers regarding the cost-effectiveness of drug treatment options; however, their ability to effectively do so is subject to practical limitations discussed below.

The development of the formulary, and of formulary management initiatives, is conducted under the direction of the TPP's P&T Committee¹¹ or under the P&T Committee of the PBM that is used by the TPP. The use of the P&T Committee for this

¹¹ Express Scripts, *White Paper: Formulary Management* June 2006.

¹² *Ibid*

purpose is meant to assure that the formulary is clinically sound, is sufficiently robust to meet the medical needs of the population being served, and is not unduly burdensome to providers and patients when accessing care.

Because Neurontin is indicated for the treatment of epilepsy, a disease that is very serious and sometimes difficult to treat, it has been widely accepted in a preferred position on most TPP formularies. Furthermore, the clinical options available for the treatment of seizures are limited and the medications indicated for this purpose are quite different in their mode of action, technical uses, and adverse effect profile. A wide range of products is essential for adequate management of this devastating malady. In my experience working with TPPs and their P&T Committees, these organizations are very hesitant to create any barriers that would prevent access to effective products for patients suffering from seizures.

Documents I have reviewed from Pfizer reflect that, because of its status as an antiepileptic medication, Neurontin enjoyed very wide formulary acceptance:

- A January 12, 1998, Parke-Davis Managed Care Business Plan states:
“Availability on formulary is virtually 100%. Anti-convulsant products currently fall below the radar screen for formulary and utilization controls.”¹³
- An August 2001 market research survey of pharmacy and medical directors from 25 HMOs revealed that 100% of these health plans included Neurontin on the formulary without restrictions or prior authorization requirements.¹⁴
- Pfizer’s internal HMO Opportunity Reports dated 2nd quarter 2001, show that, nationwide, only 1.8% of plans excluded Neurontin from formulary.

¹³ WLC_FRANKLIN_0000180522

Furthermore, when the product was included on formulary, only 1.1% of plans placed any restrictions or controls on Neurontin.¹⁵

- An April 15, 2002 market research report, conducted by Health Strategies Group (HSG) on behalf of Pfizer, concluded “Short Term: Neurontin Will Retain Board Formulary Access.”¹⁶ Among the key findings in this report was that Neurontin would not be re-reviewed by P&T Committees should it receive the neuropathic pain indications from the FDA.¹⁷
- A July 2002 document prepared by HSG summarized TPP attitudes toward Neurontin stating “[c]ustomers do not want to restrict access to epilepsy products.”¹⁸

6.2.1. The Formulary Review and Selection Process

The decision whether or not to place a given pharmaceutical product on a drug formulary is first and foremost a clinical decision. The health plan’s P&T Committee will review the FDA approved clinical indications for the product or products in question and FDA comments associated with the approval of the products. The P&T Committee relies on published studies that evaluate product efficacy, safety and, when available, directly compare the product to other agents in the appropriate therapeutic category or with comparable clinical uses. Manufacturers often submit a formulary dossier about products for use by the P&T Committee during the drug review process.¹⁹ The P&T

¹⁴ Pfizer_AFannon_003135, conducted for Pfizer by Market Measures Interactive, LLC, a division of NOP World.

¹⁵ Pfizer_SDoft_0069882

¹⁶ Pfizer_SADoft_0049850

¹⁷ *Ibid*

¹⁸ Pfizer_CGrogan_0006249 “Pfizer Neuropathic Panel Advisory Boards: Top-Line Findings and Summary”

¹⁹ *AMCP's formulary resource used widely by health plans.*

<http://www.modernmedicine.com/modernmedicine/Modern+Medicine+Conference+News>, Apr 18, 2008

Committee will also review any existing utilization of the product, or of comparable products, by health plan members. The P&T Committee's evaluation is limited to a review of published medical information, such as clinical studies published in peer-reviewed articles and the formulary dossier provided by the manufacturer, and drug utilization. The P&T Committee does not engage in primary research and cannot detect instances in which information about a drug may have been suppressed by a manufacturer, is unpublished, or is inaccurately represented in the medical literature or other information provided by the manufacturer.

6.2.2. Cost Sharing and Drug Tiers

TPPs use cost-sharing as a tool when promoting cost-effective utilization of pharmaceuticals. TPPs typically achieve member cost-sharing through three different methods²⁰:

- ▶ Deductibles in which the patient pays his or her entire prescription cost until a specific dollar amount has been paid out of pocket;
- ▶ Coinsurance, or percentage copayment, specifies the percentage of the prescription cost that the members pays for each prescription; or
- ▶ Copayments, fixed dollars amounts that members pay for each prescription.

Plans can have a single copayment or co-insurance regardless of the drug type or use a tiered design that allows for different payment amounts for different types of drugs (e.g. generics and brands). Plans may also combine the use of deductibles, copayments and co-insurance within their benefit programs.

Of the various cost-sharing designs used by TPPs, tiered benefits have been widely accepted for many years,²¹ and accounted for over 80% of benefit programs

offered in 2006.²² Formularies are often tied to tiered benefits to encourage utilization of lower cost products, particularly for brand and generic medications; however, tiered benefits are not typically used to discourage off-label utilization of medications. Prior to 2000, the most common benefit design was one in which there was a copay for generic products, with a higher copay for branded products regardless of formulary status (a two-tier copay system). By 2002 over 50% of all employers utilized incentive formularies, where the lowest copay was charged for generic medications, and higher copays were required for second-tier and third-tier medications.²³ The actual copay that is charged to patients varies with the benefit plan and has increased over the past several years.

In the typical three-tiered formulary, a low copay is charged for generic products, a modest copay is applied to preferred brand medications, while the highest copayment levels are required for brand medications for which a generic equivalent is available and for non-preferred brand medications. Other benefit plans that are utilized within the insurance industry include four- and five-tier benefits, co-insurance (where the patient typically pays a flat percentage of the cost of the drug), and programs with annual and maximum deductibles. Some TPP plan benefits assign unique copays to very expensive biotechnology products for cost sharing purposes.

Cost-sharing is often aligned with the TPP's formulary in an effort to promote the use of low-cost products and to maximize rebates and discounts on medications, particularly for those drugs which are clinically comparable. For example, proton pump inhibitors ("PPIs"), medications used for the treatment of heartburn, are widely

²⁰ Express Scripts *Pharmacy Benefit Guide*, Feb 2003.

²¹ Express Scripts *Pharmacy Benefit Guide*, 2003. pg 49.

²² *Prescription Drug Benefit Cost and Plan Design Report*, The Pharmacy Benefit Management Institute, Tempe, AZ, 2007 edition, pg 2.

²³ Caremark, *2004 Trend Report*, pg. 7.

considered to be clinically equivalent. Examples of PPIs include Prilosec, Nexium, Acifex, and Prevacid. While all of these products are very effective, the cost of the products can differ significantly. Prilosec is available in generic form and as an over-the-counter medication. Many P&T Committees have adopted programs to promote generic Prilosec (omeprazole) as a first line agent, with minimal cost-sharing. Because the remaining products are clinically similar, the P&T Committee may consider product cost and rebates offered by manufacturers when selecting a preferred brand product for the formulary. Preferred products are often subject to a moderate cost-sharing, while non-preferred agents are subject to higher cost-sharing.

In my experience working with many TPPs and PBMs, Neurontin has been widely accepted as a preferred agent and is subject to modest cost sharing requirements. From a practical perspective, a TPP would gain little financial advantage in designating Neurontin as a non-preferred agent and assessing a higher copayment. Because Neurontin utilization is low in comparison with many other drugs, the overall financial savings to the pharmacy program would be minimal compared to the impact that can be achieved by managing utilization of other drugs. More importantly, a higher copayment for Neurontin may result in reduced patient compliance. If this were the case, the cost of managing a single, preventable seizure could far out-weigh any product cost savings attained from a higher copayment.

Pfizer's experience working with TPPs supports my observations:

- An August, 2001, report of a survey regarding Neurontin coverage, conducted with medical executives from 25 HMOs, revealed "Neurontin

[is] covered on the second tier at nearly all of them.”²⁴ One respondent indicated “Dilantin, Neurontin, Tegretol, Topamax, and Trileptal are second tier. Those are all AEDs. They are basically put on formulary as anti-epileptics: as certain ones must be used and are the best for the patient, they all end up on tier two.”²⁵

- A June 24, 2002, market research report prepared for Pfizer acknowledged the fact that few plans had placed Neurontin on the third tier of their formulary.²⁶

6.2.3. Claim Edits

Claim edits are an effective, inexpensive tool that can be used by TPPs to manage drug utilization. The claim edit uses the POS claim adjudication technology to establish a limit or coverage “rule” for a particular drug product, limiting drug coverage at the time of dispensing. The edit must be limited to parameters that are readily identified at the time of prescription claim adjudication and transmitted in the claim adjudication process. For example,

- Days’ supply: TPPs often limit the number of doses dispensed by a retail pharmacy to a 30-day supply or 100 units, whichever is greater.
- Age: TPPs may limit the use of acne medications to individuals under the age of 18. Because date of birth is a required field in the claim database, an age edit can be easily applied to selected medications and claims so that medications are readily processed for eligible individuals.

²⁴ Pfizer_AFannon_0003134, conducted by Market Measures Interactive, LLC

²⁵ Pfizer_SDoft_0051016

²⁶ Pfizer_CGrogan_0002399 “report titled: *Pfizer Neuropathic Pain Management: HMO and Long-Term Care Advisory Board* conducted by Health Strategies Group on behalf of Pfizer.

- Quantity limits: Quantity limits may be used when a drug is intended to be covered under the pharmacy benefit, but the coverage is limited. For example, some TPPs may elect to limit medications that are lifestyle in nature, such as Viagra, to a select number of tablets per month.

NDC blocks, another form of claim edit, are used to prevent the processing of drug categories that are not covered under the TPP's pharmacy benefit. For example, many TPPs exclude over-the-counter products (i.e. non-legend or non-prescription medicines), fertility agents, and cosmetic agents from coverage.²⁷ NDC blocks are applied to these categories to prevent the inadvertent processing of these claims.

Step therapy edits, yet another form of claim edit, are used by TPPs to encourage the use of a comparable, but lower cost medication prior to the coverage of a higher cost product. Step therapy edits are commonly employed in Medicare benefit programs and have been increasingly adopted by TPPs. The step edit is administered through the electronic POS system which uses prescription history as a basis for the adjudication of a drug. For example, a TPP might require that a patient use generic Claritin ("loratadine") prior to covering the branded, therapeutically similar antihistamine, Zyrtec. Because these products are very safe and have comparable levels of efficacy, use of the low-cost product first is considered acceptable. In this example, a claim for Zyrtec will be covered at a specified copayment level if there is prior evidence of loratadine therapy in the patient's claim history. If the prior therapy does not exist, the patient may be charged a high copay level or a prior authorization may be required for coverage of the drug therapy.

²⁷ *The Wyeth Ayerst Prescription Drug Benefit Cost and Plan Design Survey Report*, The Pharmacy Benefit Management Institute, Inc., Tempe, AZ, 2000 edition.

Claim edits are not suitable for limitations that restrict the use of a drug to a specific clinical indication (such as an off-label use) because the diagnosis for which the drug has been prescribed is not maintained in the pharmacy data processing system. While the NCPDP claim processing standards include a field for diagnosis, physicians are not required to, and typically do not, include a diagnosis with the drug prescription. Efforts to mandate inclusion of the diagnosis on the prescription, a process that would require legislative action in each state, have been resisted by providers out of concerns for patient privacy. Quite simply, without crucial diagnosis information, a TPP or its PBM simply cannot differentiate the reasons for which a drug is prescribed using the claim processing system.

6.2.4. Prior Authorizations (“PAs”)

Prior authorization is a drug management tool that is used when the drug coverage process requires information that cannot be readily obtained through the claim processing system. Such criteria may include diagnosis, laboratory values or other clinical parameters. For example, a health plan may wish to cover growth hormone for deficiency states or Turner’s Syndrome, but would wish to exclude the product when it is being prescribed to enhance athletic performance. When a prior authorization is applied, the claim is rejected at the pharmacy and the pharmacist is notified that the prescriber must contact the TPP or the TPP’s PBM to obtain approval for coverage, much in the same manner that pre-certification is required for the use of certain health care services.

The prior authorization process can be disruptive to care and is expensive to administer. In my recent experience, the cost charged by a PBM to administer prior authorizations can exceed \$40 per PA request and additional operational costs are

incurred by both the TPP and the provider to support the prior authorization process. Equally important, there is frequently great resistance to the prior authorization process by patients and their physicians, as well as from drug manufacturers. Often times, physicians view prior authorization as a threat to their diagnostic and treatment authority and pharmaceutical companies believe prior authorization keeps their products from patients who might benefit from them.²⁸ Indiscriminate use of prior authorization requirements can result in physician backlash and adversely influence member satisfaction with a health plan. For these reasons, the use of this tool is often limited to drugs that are very expensive and for drugs that have a high potential for inappropriate or non-medical uses. In 2006, a PBMI study found that prior authorization was applied most frequently to experimental agents, human growth hormones, injectable medications, and infertility therapies, as well as to lifestyle or cosmetic drug uses (erectile dysfunction, weight loss, hair growth).²⁹

As was previously described, TPPs and their PBMs do not have access to diagnosis as a component of the claim transaction through the POS system. Because it is impossible to know the reason for which Neurontin was being prescribed when a claim is processed, a prior authorization would be necessary if the TPP's coverage of Neurontin were limited to FDA-approved diagnoses.

Prior authorization has rarely been used for the management of Neurontin. Any prior authorization intended to restrict the use of Neurontin to FDA-approved indications would create a significant barrier to care for those patients with seizure disorders. The efficacy of seizure therapy is highly dependent on patient compliance and consistent drug

²⁸ Reisman, D. Drug Benefit Trends, 12(10):22,24, 2000

levels. A prior authorization typically requires 24 to 72 hours for processing. If the patient does not plan for this delay, medication doses may be missed, which may result in an increased potential for seizure activity, particularly for patients with refractory seizure disorder. In my experience, TPPs do not implement pharmacy programs that may adversely impact patient care, especially for serious disorders such as epilepsy.

My opinions are consistent with the comments that were shared with Pfizer through its marketing assessments.

- In an August 2002, survey of 25 HMOs, not one was using prior authorization for the management of Neurontin.³⁰
- When asked about restrictions on Neurontin to prevent coverage for pain, a Pharmacy Director from a health plan indicated “we have not placed any restrictions in the [anti-epileptic] class or area. We are afraid that without optimum treatment, patients suffer. They can lose their jobs and drivers licenses, along with driving health care costs up because every time they have a convulsion, they undoubtedly go to the emergency room. As far as putting restrictions on Neurontin for that, it would seem inappropriate, given the fact that patients who legitimately use it for the anticonvulsant properties would be hampered in their therapy.”³¹
- According to another respondent “[O]ur company has a care coordination philosophy which essentially means they have taken off their requirements

²⁹ *The Prescription Drug Benefit Cost and Plan Design Survey Report*, The Pharmacy Benefit Management Institute, Tempe, AZ, 2007 edition, pg 28.

³⁰ Pfizer_AFannon_0003135, Survey conducted by Market Measures Interactive on behalf of Pfizer.

³¹ Pfizer_SDoft_0051028

for prior authorization. They want to have a more member-friendly, physician-friendly process, so that they do not stand in the way of that relationship. There are just a few products that have a PA on them, but they would be benefit driven: in other words, Retin-A would require prior auth just to prevent use for cosmetic purposes. In the area of neuropathic pain, that situation does not present itself, so there are no restrictions on these agents that are on formulary at all in terms of appropriate use.”³²

- An April 15, 2002 marketing summary report, researchers working on behalf of Pfizer recognize that “customers do not want to restrict access to epilepsy products”³³ and “plans want easy access to anticonvulsants for epilepsy patients.”³⁴
- A July 2002 report prepared by HSG indicated plans “are unwilling to manage neuropathic pain because they perceive the chances of success are low.”³⁵ According to HSG “Plans still categorize Neurontin as an anticonvulsant and are hesitant to restrict therapies for difficult-to-manage epilepsy patients.”³⁶

6.2.5. Drug Utilization Review

Drug utilization review (“DUR”), by definition, is a retrospective review of drug utilization patterns. This tool is commonly used to review pharmacy use trends and identify opportunities for improvement, or to provide insight to the Pharmacy &

³² Pfizer_SDoft_0051008

³³ Pfizer_SDoft_0049846

³⁴ Pfizer_SDoft_0049850

³⁵ Pfizer_CGrogan_0006249 “Top Line” findings from the Pfizer Neuropathic Panel Advisory Boards

³⁶ Pfizer_SDoft_0049846

Therapeutics Committee as formulary management decisions are considered. In these capacities, the DUR process is quite valuable for informational purposes and can help a TPP prioritize its future drug intervention activities.

Less frequently, DUR has been used to identify prescribing patterns that may be suggestive of a problem with corresponding outreach to and feedback from a provider. Because this process is conducted long after the dispensing, and presumed use, of the medication, it is not an effective tool for prospective management of drug utilization, but can be useful when identifying patterns of prescribing or drug dispensing that suggest misuse or fraud by patients, providers or members.

6.2.6. Disease management

Disease management refers to a coordinated program to address the comprehensive diagnosis and treatment of a specific disease or condition. These programs address a broad range of health issues associated with patient care, including the use of diagnostic tools, drug therapies and non-drug therapies. Disease management efforts are often focused at high cost illnesses that result in frequent, but preventable use of health resources, including hospitalization and emergency rooms use. Examples of common programs include diabetes and asthma disease management. Some TPPs also assign case managers to those patients with complicated or high risk illnesses that are likely to require extensive use of health care resources and have a prolonged period of recovery. Universally, the focus on disease management is to provide access to the appropriate levels of care efficiently to avoid disease exacerbation and the development of complications that may result from the illness. Access to and compliance with appropriate drug therapy is a frequent component of many disease management programs.

In my experience, TPPs select diseases for management when the cost of the disease is high and intervention has a reasonable likelihood of a successful outcome - meaning the program has a significant chance of achieving the desired goal of the program. Program goals may include reducing the frequency of disease exacerbation, preventing complications or adverse events from care, or minimizing waste or avoidable health care expenditures, among others. For example, in my prior experience at a health plan, asthma and substance abuse were identified as driving factors for emergency room visits. When selecting an intervention program, the health plan opted for an asthma management program because of the strong belief that we could achieve a successful outcome for our efforts: improving compliance with asthma drug treatment standards and reducing emergency room visits for acute exacerbations of asthma. Although reducing substance abuse is equally important, the likelihood of success was viewed as lower.

During advisory board sessions with employer/union health plans, managed care plans, PBMs and long-term care plans conducted in late 2001 and early 2002, Pfizer focused on the use of Neurontin as a component of a disease management program for neuropathic pain. In summary, the feedback of the participants is consistent with my personal experience. Health plans were unwilling “to tackle management of an area where the chances of success are low.”³⁷

Disease management programs are designed to provide a comprehensive approach to the diagnosis and treatment of a specific disease state, usually in accordance with national treatment standards. Although drug therapy is addressed in a disease management program, it is not the focus of the program. For example, a disease program specific to the diagnosis and treatment of epilepsy would serve no purpose in managing

Neurontin use for the treatment of neuropathic pain. Because Neurontin was promoted and used for many medical indications, both approved and not-approved by the FDA, managing the drug through disease management would require many disease management programs, a process that would be impractical and costly.

6.2.7. Other Drug Management Tools

TPPs use a variety of other tools, including academic detailing, face-to-face pharmacy consultation, and prescriber profiling, when managing pharmacy benefits. These tools are useful for educational outreach when the number of providers and the geographic region of the TPP are limited and the health plan is a primary source of patients to these providers in their particular region. For example, an HMO with a closed provider panel³⁸ and limited number of contracted health care facilities (for example, Network Health, a Massachusetts HMO, provides most of its medical care through community health centers in Boston) may find academic detailing to be efficient and effective in disseminating drug information. However, because most of the TPP market is not concentrated enough to use these tools, these programs are very expensive to administer and are not practical as a routine drug management activity. Correspondingly, these tools are adopted by less than 10% of TPPs.³⁹

7. MANAGEMENT OF NEURONTIN

Although TPPs have a variety of tools that can be used to manage drug costs and promote high quality prescribing and utilization of pharmaceuticals, these tools are not

³⁷ Pfizer_SDoft_0049847

³⁸ A closed provider panel describes a health plan that limits member health coverage a limited number of providers, often employees of the HMO or a limited network contracted with the HMO.

³⁹ *The Prescription Drug Benefit Cost and Plan Design Survey Report*, The Pharmacy Benefit Management Institute, Tempe, AZ, 2007 edition, pg. 30

suitable for managing utilization of Neurontin for off-label indications. Consequently, most TPPs included Neurontin on their formularies with few, if any limitations, and at modest copayment levels.

7.1. TPPs nationwide included Neurontin on their formulary

Because Neurontin is indicated for the treatment of seizure disorders, the product is widely accepted and is readily available without restrictions on most TPP formularies nationally.⁴⁰

7.2. TPPs and their PBMs cannot limit claims for Neurontin based on the diagnosis for which it is prescribed

TPPs and PBMs are unable to identify off-label uses of Neurontin from the POS pharmacy claim transaction. The diagnosis for which a drug is prescribed is not required on a prescription and pharmacies do not have access to diagnostic information at the time a claim is adjudicated. As a result, a diagnosis code is not included as a component of typical claim transactions and is unknown to the TPP or PBM. An HMO respondent to a Pfizer-sponsored survey indicated “[b]ecause we do not have a true ability to determine the diagnosis, we err on the side of conservatism. Without a true line to diagnosis, we cannot tell what the drug is being used for.”⁴¹

7.3. TPPs and PBMs have limited motivation to address off-label uses of Neurontin

While the cost of Neurontin was not insignificant to health plans, when setting priorities for drug interventions, other medication costs and opportunities are more compelling. With limited resources to implement drug management programs, TPPs and PBMs prioritize the areas of clinical focus on those therapeutic classes with the highest

⁴⁰ Pfizer_SDoft_0064400

⁴¹ Pfizer_SDoft_0051063, conducted by Medical Market Interactive, LLC.

medical or pharmacy expenditures, on very high cost, often injectable, medications that have a limited range of medical uses, or products with high potential for serious toxicity.

From the documents that I have seen, Pfizer was well aware of the limitations faced by TPPs and PBMs in their coverage of Neurontin. In 2001 and 2002, and possibly at other times, Pfizer commissioned a series of Advisory Board meetings to assess TPP and PBM attitudes toward formulary placement and the management of Neurontin.⁴²

These meetings were coordinated by Health Strategies Group (HSG) a health care market research company. The meetings were conducted by representatives from HSG and by Pfizer personnel, including Pfizer's Medical Director.⁴³ The agenda of these meetings was to provide an overview of neuropathic pain, discuss the treatment of neuropathic pain using Neurontin, and discuss formulary management strategies, including an assessment of the likelihood that a TPP or PBM might implement formulary limitations or management tools to restrict Neurontin use to its approved indications, a process that would limit Pfizer's success in marketing Neurontin. Individuals who attended these meetings included executives, including Medical and Pharmacy Directors, from TPPs and PBMs.⁴⁴

As Pfizer learned repeatedly from the Advisory Board meetings TPPs and their PBMs cannot readily identify circumstances in which Neurontin is prescribed for off-label indications. This limitation essentially prevented TPPs from limiting Neurontin coverage to FDA-approved uses. Comments from reports of the Advisory Board sessions highlight this fact:

⁴² Pfizer_CGrogan_0006145; Pfizer_RGlanzman_0167341

⁴³ Pfizer_RGlanzman_0167341

⁴⁴ Pfizer_CCrogan_0006153

- “The key to a PBM’s ability to manage use of Neurontin for pain is identifying and segmenting pain patients from epilepsy patients, which PBMs currently cannot do.”⁴⁵
- “We do not promote the appropriate use of agents by disease state. Part of the reason for that is the limits on reporting. There is no way for us to track specific ICD-9 codes at the physician office level when they are prescribing a particular agent.”⁴⁶

Pfizer also commissioned Market Measures Interactive, a health research firm, to assess TPP attitudes toward the treatment of neuropathic pain and to assess the willingness of TPPs to restrict coverage of Neurontin.⁴⁷ This research was conducted using voice-response technology via the telephone. Interviewees included pharmacy and medical directors from national or large health plans. From this research, Pfizer learned that TPPs and PBMs were unlikely to focus drug management efforts on Neurontin, preferring instead to use their limited resources to address more pressing concerns. This fact is demonstrated repeatedly by comments from individuals and in the summary statements provided by Market Measures Interactive as described in the statements below:

- “Neuropathic pain is not considered a significant part of the overall pharmacy budget and is therefore not closely monitored by most of them.”⁴⁸

⁴⁵ Pfizer_CGrogan_0006251

⁴⁶ Pfizer_SDoft_0051008

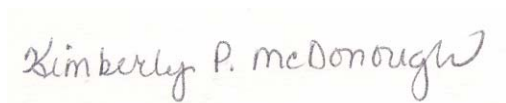
⁴⁷ Pfizer_AFnanon_0003115

⁴⁸ Pfizer_AFannon_0003123

- “Although this is an important area, it does not have the significance of other chronic diseases such as congestive heart failure, diabetes, asthma, hypertension, etc.”⁴⁹
- “The cost of Neurontin is overshadowed by the cost of other pain drugs.”⁵⁰
- “The pain is not worth the effort.”⁵¹

A report of these sessions summarized the representations of individuals from TPPs and PBMs very efficiently: “Prescription benefit management organizations, and their clients, have limited resources and must focus utilization management resources on priority disease states.”⁵²

I reserve the right to supplement this report and amend my opinions upon review of further information.



Kimberly P. McDonough

August 1, 2008

Date

⁴⁹ Pfizer_AFannon_0003123

⁵⁰ Pfizer_CGrogan_0005994

⁵¹ Pfizer_CGrogan_0005995

⁵² Pfizer_SDoft_0022366

EXHIBIT A

- Served as TQM facilitator for corporate quality improvement activities.

Pharmacy Systems, Inc.

1986 – 1990

- Vice President 1987-1990
- Director of Pharmacy 1986-1987

White County Memorial Hospital

1982-1986

Accomplishments

Administrative

- Founder, and current President, of a successful corporation providing clinical support and pharmacy audit services to employers, managed care organizations, and physician practice organizations.
- Twenty-five years of administrative experience, at a Director level or higher, in a variety of pharmacy venues including managed care, hospital, and long term care. Direct employee supervision for fifteen of these years with responsibilities that included clinical activities, provider support, drug utilization analysis and management, and quality assurance.
- 2007 Small Business Association Entrepreneur of the Year for the State of Rhode Island, awarded by the U.S. Small Business Association
- 2006 Rhode Island Minority Business Enterprise of the Year presented by Governor Carcieri and the Rhode Island Economic Development Corporation
- Management of pharmacy expenditures in Medicaid, Medicare and commercial populations for managed care insurers, employers, and physician practice management organizations.
- Testified on healthcare issues before hearings on behalf of U.S. Representatives of Congress, state legislative oversight committees, other state administrative organizations, and professional organizations.
- Served as Chair of the Rhode Island Drug Use Review Board, Chairman of Legislative Committee for AMCP, and committee member for AMCP, APhA and Member and Board of Directors for Rhode Island Pharmacists Association.

Managed Care Experience

- Developed, from baseline, the clinical pharmacy programs within managed care organizations, including establishment of policies and procedures, formulary analysis and process, and clinical outcome measuring of programs.
- Designed and implemented multiple pharmacy and provider based clinical management programs, including clinical treatment guidelines, pharmacy based asthma management programs, and clinical management of long term care patients
- Designed and participated in evaluation of PBM and specialty pharmacy industries, ranging from RFP development and evaluation of bid responses, auditing of services,

contracting support, pharmacy network evaluation, 340B contract and class of trade pharmacy assessments

- Extensive publications and presentations, nationally and regionally, with focus on clinical management medication use in patients, outcomes of clinical programs, and bridging roles of healthcare providers to enhance clinical management of patients.

Medicare Experience

- Served as a primary consultant to the Centers for Medicare and Medicaid services in the development of the Medicare part D drug benefit and discount card programs
- Conducted review of formularies and bid submissions for the initial roll-out of the Medicare Part D program
- Served as the project director under Advanced Pharmacy Concepts' sole source contract with CMS for the compliance audit of Medicare Part D, Part C and PACE programs
- Trained as a MEDIC contractor for fraud and abuse oversight of Medicare Part D programs.

Marketing

- Developed and organized clinical products options for corporate marketing efforts of several healthcare organizations, including operational organization of product offerings, development of marketing materials, and providing clinical support and training to the marketing department.
- Instrumental in the initial marketing efforts to support the initial public offering through the Security and Exchange Commission for MIM Corporation.
- Actively participated in major marketing initiatives in public and private corporations, providing personal clinical support and follow

Appointments

- Board Member, Rhode Island Pharmacist Association
June 2003 to June 2007
- Chairman, Continuing Education Committee, Rhode Island Pharmacist Association,
June 2007 to present
- Adjunct Assoc. Professor of Clinical Pharmacy, University of Rhode Island,
Kingston, Rhode Island 1991 to present
- Rhode Island Drug Use Review Board
1993 to 1999, Chairperson 1995 to 1999.
- Academy of Managed Care Pharmacy
Alexandria, VA,
Legislative Committee
Member 1995 to 1999
Vice Chairperson 1997 - 1998.

- Chairperson 1998 - 1999.
Strategic Marketing Committee
- Chairperson 2000 – 2001
Vice Chairperson 1999 – 2000
- Managed Care Model Development Committee
Facilitator 1999 – 2002.
- Quality Task Force
Member August 2007 to present
- American Pharmaceutical Association- Washington, DC.
Member, Strategic and Tactical Committee 1995 to 1999.

Awards Received

- 2007 Small Business Association Entrepreneur of the Year for the State of Rhode Island, awarded by the U.S. Small Business Association
- 2006 Rhode Island Minority Business Enterprise of the Year presented by Governor Carcieri and the Rhode Island Economic Development Corporation
- Recipient of Harvard Community Health Plan’s Diamond Award for outstanding services in establishing cost effective management of pharmacy benefits for members.
- Recipient of the 1999 Baxter Laboratories/National Pharmacy Technician Board award for Innovations in Pharmaceutical Care.
- Recipient of 2003 Elan Pharmaceuticals Innovative Pharmacy Practice Award from the Rhode Island Pharmacists Association

Presentations

- Regulatory changes affecting pharmaceutical pricing presented to Associated Pharmacies, Inc, Savannah, GA April 12, 2008.
- Emerging Standards for Improving Patient Safety, presented at the Pharmacy Benefit Management Institute, Scottsdale, AZ, February 28, 2008.
- NCQA/APC Activities: Measure Specification Development & Pilot Test Results, presented to the Pharmacy Quality Alliance, Washington, DC, Nov. 30, 2007
- Regulatory changes affecting pharmaceutical pricing and prescription fulfillment presented to the Northeast Pharmacy Services Corporation, Groton, CT, Nov. 8, 2007.
- Pharmacy Quality Alliance Initiatives: Measuring Performance in 2008 & Beyond, presented to the National Association of Community Drug Stores, Boston, MA, August 12, 2007.
- Pharmacy Quality Metrics, presented at the Academy of Managed Care Pharmacy Meeting, Boston, MA, October, 6, 2006

- Essentials of Benefit Design and Drug Mix Management, presented at the Pharmacy Benefit Management Institute, Scottsdale, AZ, April 26, 2006.
- Medicare Part D Quality Measures Update, presented at the Academy of Managed Care Pharmacy Meeting, Seattle, WA, April 6, 2006.
- Opportunities to Implement Quality Measures in Managed Care Pharmacy, presented at the Academy of Managed Care Pharmacy Regional Meeting, Scottsdale, AZ, Feb 23, 2006.
- Countdown to Medicare Part D: Essential Information for the Pharmacist, presented to the New Hampshire Pharmacy Association, Manchester, NH, December 11, 2005.
- Countdown to Medicare Part D: Essential Information for the Pharmacist, presented to the Northeast Pharmacy Services Corporation, Groton, CT, Nov. 11, 2005.
- Countdown to Medicare Part D: Essential Information for the Pharmacist presented to the Vermont Pharmacy Association, Montpelier, VT, October 23,, 2005.
- Overview of Pharmacy Benefit Operations and Drug Pricing, presented at the Toyota Motor Manufacturing Suppliers Conference, Lexington, KY, Jan. 14, 2005.
- Overview of the Medicare Prescription Drug Act, presented to the Rhode Island Pharmacist Association Spring Seminar, Warwick, RI, May 26, 2004.
- Escalating Drug Spending – Management of Care and Costs, presented and moderated panel discussions at the National Medical Health Care Congress, Washington, DC, May 7, 2004.
- Ramification of Consolidation in the PBM Industry, presented at the Pharmacy Benefit Management Institute Annual Conference, Scottsdale, AZ, April 26, 2004.
- Overview of the Medicare Prescription Drug Act, presented to Associated Pharmacies, Inc. annual meeting, Savannah, GA, April 16, 2004.
- Agree or Disagree: Health plans are making progress in Their Specialty Pharmacy Spend, presented at the Academy of Managed Care Pharmacy meeting, San Francisco, CA, April 3, 2004.
- Effective Management Strategies for Specialty Pharmacy, presented at the IQPC Specialty Pharmacy Conference, Chicago, IL, March 16, 2004.

- What You Should Know about Prescription Drug Costs, presented to the BlueCross BlueShield of Vermont Users Conference, Burlington, VT, November 18, 2003.
- Using Consistent Methodologies to Streamline and Improve Claim Processing Methodologies, presented to the IIR Specialty Pharmacy Conference, Dallas, TX, October 28, 2003.
- Specialty Drug Coverage: Different Approaches to Manage Costs, presented at The Academy of Managed Care Pharmacy meeting, Montreal, QB, Canada, October 16, 2003.
- Re-defining the Pharmacy Benefit, Schering Consumer Driven Health Care Conference, Laguna Niguel, CA, March 15, 2002.
- Accountability in Prescriptions Benefits, presented in cooperation with the Healthcare Web Summit, February 19, 2002
- The Changing Healthcare Environment and its Impact on Pharmacy Revenues, presented at the Northeast Pharmacy Services Corporation Annual Seminar, Mystic, CT, Nov. 8, 2002.
- Monitoring PBM Performance and Auditing the Pharmacy benefit, presented at the National Managed Health Care Congress, Atlanta, GA, March 12, 2001.
- Orientation to Academic Detailing, presented to United Health Care Pharmacy Management Team, Minneapolis, MN, October 19, 1998.
- Building an Academic Detailing Program, presented at the Academy of Managed Care Pharmacy Meeting, Chicago, IL, October 7, 1998.
- Merging Pharmacy and Medical Data for Outcome Measures, presented to the Ohio Health Association, annual meeting, Columbus, OH, September 29, 1998.
- Healthcare Access in South America: City, Rural Areas and Jungle, presented to the Rhode Island Pharmacists Association, annual meeting, Falmouth, MA, June 28, 1998.
- U.S. Healthcare, Policy and Lifestyle, presented to numerous Rotary Clubs, Minas Gerais, Brazil, April 11 through May 16, 1998.
- Academic Detailing Primer, presented at the Academy of Managed Care Pharmacy Meeting, Seattle Washington, October 31, 1997.
- Expanding the Role of the Community Pharmacist, presented to the Northeast

- Pharmacy Services Corporation annual meeting, Ledyard, CT, Nov. 20, 1996.
- Evaluating Pharmacy Benefit Management Services, presented to the Ohio HMO Association, Columbus, Ohio, November 11, 1996.
 - Carving Out Pharmacy Formulary and Utilization Management, presented to the Eastern Medicaid Pharmacy Administrators Conference, Sandwich, MA, October 8, 1996.
 - Evolving Role of Pharmacy, presented at the Rhode Island Society of Hospital Pharmacists' meeting, Newport, RI, October 18, 1996.
 - Current Trends in Managed Care, presented at the Annual Preceptor Conference, University of Rhode Island College of Pharmacy, Kingston, RI, June 12, 1996.
 - Navigating the payment minefield: How pharmacists are getting paid for services, presented at the Annual Meeting, American Pharmaceutical Association, Nashville, TN, March 12, 1996.
 - Tenn Care Formulary and Network Management, presented to the Tennessee Formulary Oversight Committee, Nashville, TN, November, 1995.
 - Managing Drug Utilization and Quality of Pharmaceutical Services, presented at the University of Tennessee, School of Pharmacy, Memphis, TN, November 22, 1995.
 - Healthcare: The Tennessee Experiment, presented to the Philadelphia Area Managed Care Pharmacists Forum, Philadelphia, PA, October 1995.
 - The Pharmacist's Role in Smoking Cessation Counseling, presented to the Massachusetts Pharmaceutical Association, Worcester, Massachusetts, March, 1995.
 - The Pharmacist's Role in Smoking Cessation Counseling, presented at the Massachusetts Pharmaceutical Association MidYear Clinical Meeting, Westborough, Massachusetts, February, 1995.
 - Assessing and Managing the Outcomes of Anxiolytic Therapy, presented at the monthly pharmacy continuing education program, Mercer University, Atlanta, GA., November 22, 1994.
 - Utilizing TQM Principles in a Managed Care Setting, presented at the National Managed Health Care Congress, New York, New York, September 1994.
 - The Pharmacist's Role in Smoking Cessation Counseling, presented to the

Massachusetts Pharmaceutical Association Annual meeting, Sturbridge, Massachusetts, June, 1994.

- The Pharmacist's Role in Smoking Cessation Counseling, presented to the Massachusetts Pharmaceutical Association, Westport, Massachusetts, June 1994.
- New Concepts in Drug Utilization Review, presented at the Spring Continuing Education Seminar, University of Rhode Island, Newport, Rhode Island, March 1993
- Selection of Agents in the Treatment of Hypertension, presented at the Dunnington Nurses Pharmacy Symposium, Boston, Massachusetts, November 19, 1992
- Treatment of Hypertension, presented at the Northeast Federal Pharmacists Educational Symposium, Boston, Massachusetts, November 18, 1992
- Treatment of Hypertension, presented at the Federal Pharmacists' Fall Educational Seminar, West Point Military Academy, West Point, New York, October 15, 1992
- Nicotine Patches, interviewed on Insite Educational Radio, Providence, Rhode Island, August 6, 1992
- Pain Management, presented to Hallworth House clinical staff, Providence, Rhode Island, August 3, 1992
- Antihypertensive Treatment in the Geriatric Population, presented at the Dunnington Clinical Pharmacy Group Meeting, Brockton, Massachusetts, June 4, 1992
- Conducting an ACE-inhibitor conversion program, presented in association with the American Society of Consultant Pharmacists' Clinical Midyear Meeting, Montreal, Ontario, Canada, November 1991
- Economic Impact of a Voluntary ACE-inhibitor Substitution Program in a Staff Model health Maintenance Organization, presented at the midyear clinical conference, American Society of Hospital Pharmacists, Las Vegas, Nevada, December 1990
- The Importance of Maintenance Therapy in the Management of Duodenal Ulcer Disease, presented at Harris Wholesale Pharmacy Education Seminar, Warwick, Rhode Island, May 23, 1990
- Selection and Utilization of Information, presented at the National Managed Health Care Congress, Washington, DC, April 1990

- OTC and Prescription Drug Use in the Elderly Population, presented at Rhode Island AARP meeting, Greenville, Rhode Island, March 13, 1990
- Guest speaker, Occupational Outlook 1988, Purdue University, West Lafayette, Indiana, March 1988
- Expanding Pharmacy Services with Limited Resources, presented to the Indiana Society of Hospital Pharmacists, Indianapolis, Indiana, July 13, 1985
- Implementation of a Standard Neonatal Hyperalimentation in a Community Hospital, presented at the Midwest Residency Conference, University of Nebraska Medical Center, Omaha, Nebraska, May 1982. Awarded 3rd place in nutritional division.

Publications

- McDonough, K. “Pharmacy Benefit Managers”, *Handbook of Pharmaceutical Public Policy*, Hayworth Pres, Inc. New York, 2007.
- McDonough, K.: *Summary of National Pharmacy Indicators*, Pharmacy Quality Council, American Pharmaceutical Association, Washington, DC, 1999.
- McDonough, K.: “Enalapril to Lisinopril: Economic Impact of A Voluntary ACE-inhibitor Substitution Program in a Staff Model Health Maintenance Organization”, *The Annals of Pharmacotherapy*, 26 (3), March 26, 1992, pg. 399-404
- McDonough, K.: Editor, *Pharmacy Update*, Pharmacy Systems, Inc., Quarterly Newsletter, 1989 to 1992
- McDonough, K.: *Technician Training Manual*, Pharmacy Systems, Inc., 1988
- McDonough, K., and Caress, T.: “Unit Dose Ophthalmic Products for Emergency Use”, *American Journal of Hospital Pharmacy*, vol. 41, no. 12, Dec. 1984
- McDonough, K., Cartwright, G., Bryant, B.: “Standardization of Hyperalimentation in a Neonatal Intensive Care Unit,” *American Journal of Intravenous Therapy and Clinical Nutrition*, vol. 10, no.1, Jan. 1983

EXHIBIT B

List of Documents Reviewed

1. Third Coordinated Amended Complaint filed November 2, 2006
2. Declaration of Gregory K. Bell, Ph.D. In Opposition to Plaintiff's Renewed Motion for Class Certification

Table of Pfizer Documents

1.	Pfizer_AFannon_0003115 – 39
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18.	Pfizer_SDoft_0050987 – 1079
19.	Pfizer_SDoft_0052466 – 541
20.	Pfizer_SDoft_0064383 – 437
21.	Pfizer_SDoft_0069865 – 82
22.	Pfizer_SPiron_0010471 – 622
23.	Pfizer_SPiron_0023653 – 83
24.	WLC_FRANKLIN_0000177768 – 77
25.	WLC_FRANKLIN_0000180515 – 36