

BEFORE
THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

PUBLIC HEARING ON REGULATIONS IMPLEMENTING THE PRESCRIPTION

DRUG MARKETING ACT, AS AMENDED

DOCKET NO. 92N-0297

TESTIMONY OF ANTHONY L. YOUNG

ON BEHALF OF THE PHARMACEUTICAL DISTRIBUTORS ASSOCIATION

My name is Anthony Young. I am a partner in the law firm Piper Marbury Rudnick & Wolfe LLP. I am General Counsel to the Pharmaceutical Distributors Association.

The Pharmaceutical Distributors Association is an association of licensed prescription drug wholesalers that are not "authorized distributors of record" for all of the pharmaceuticals that they distribute. Nonetheless, association members have an ongoing relationship with the manufacturers from which they purchase drugs on a regular basis. This association was formed to assure that the Prescription Drug Marketing Act, as amended ("PDMA"), is interpreted fairly and equitably and in a fashion that will not destroy the businesses of its members.

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The wholesale drug distribution system encompasses a variety of businesses. First, there are full line wholesalers that carry most if not all the prescription drugs distributed in this country. These full line wholesalers distribute to hospitals, health care plans, chain drug stores, grocery and department stores with pharmacies, pharmacy buying groups and other smaller wholesalers. Most of the pharmaceuticals they distribute are purchased directly from manufacturers.

Second, there are also many regional and specialty wholesalers that carry a very large line of pharmaceuticals but who do not buy most of their inventory directly from manufacturers. In this category, there is a species of wholesaler known as "secondary wholesalers." Finally, there are small wholesalers who service small areas. Their customers are clinics, physicians' offices, workplace dispensaries and veterinary offices. All wholesalers, large and small, are required under PDMA to be licensed under State law and all must maintain records of the purchases and sales that they make.

In the main, our association members are secondary wholesalers whose principal business is in the purchase and distribution of pharmaceuticals on an arbitrage basis. They try to buy drugs at prices lower than Average Wholesale Cost ("WAC") and they do their best to sell those drugs at a profit. They buy from manufacturers when deals are offered and prior to price increases. Sal Ricciardi of Purity Wholesale Grocers will tell you about arbitrage. This kind of arbitrage market exists because there is substantial vigorous competition in the pharmaceutical industry and price competition fosters arbitrage.

In the Federal Register notice of September 19, 2000 (65 Fed. Reg. 56480) the Food and Drug Administration propounded six questions pertaining to the wholesale distribution of prescription drugs. On behalf of the PDA, I am providing responses to these questions. I will not repeat the questions. In addition, I will provide testimony on other PDMA-related issues that are important to the association and to wholesale distributors.

1. How does the final rule, as published, affect the ability of unauthorized distributors to engage in drug distribution. What specific requirements would be difficult or impossible for unauthorized distributors to meet? Why?

Question No. 1: The final rule requires distributors who are not "authorized distributors of record" to provide their customer a history of all prior sales back to the manufacturer of the drug. As stated at the outset, the vast majority of prescription drugs first pass through one of the major full line wholesalers. These full line wholesalers are "authorized" distributors and they are not required under PDMA to provide a "pedigree" for the drugs they distribute, and they do not. They do not because it is not required and the costs to create pedigrees would be substantial. Therefore, a wholesaler who is not "authorized" who would buy from or through an "authorized" distributor will not be able lawfully to sell the drug because it will not be able to create a pedigree that goes any farther back than the full line "authorized" distributor.

There is no practical way for the not "authorized" distributor to obtain from the full line wholesaler the pedigree information required by the final rule. Of course, a wholesaler who is not "authorized" could offer to pay a premium to the full line

wholesaler for drugs with a sales history. Clearly, however, Congress never contemplated that PDMA would be a vehicle for wholesalers to sell the paperwork required to resell a drug.

It is our association's position that question no. 1 should be turned around. Why after twelve years of operating under FDA guidance that requires the sales history to go back only to the last "authorized distributor" has the FDA determined that the sales history should now go back to the manufacturer? No good and sufficient reason for this change has ever been articulated by the Administration. In our view, it is not required by the law and there is no demonstrated health or safety reason why this additional burden should be imposed on the wholesale drug distribution system.

I will not detail here FDA's 1988 guidance under which this industry has operated. Our comments of June 30, 2000 detail the association's position with respect to the guidance.

2. If the final rule diminished the ability of unauthorized distributors to engage in drug distribution, what effect would this have on the distribution system? What, if any, adverse public health consequences would result? What would be the economic costs to manufacturers, distributors (authorized and unauthorized), and consumers of drugs?

Question No. 2. Despite increasing concentration in the wholesale drug distribution business and the creeping entry into distribution by pharmaceutical companies themselves, secondary wholesalers continue to play an important role in the efficient distribution of pharmaceuticals.

The more than 4,000 secondary wholesalers nationwide also serve many small end users, such as nursing homes, medical and veterinary practices, clinics and dispensaries who are not and cannot be served by large, high volume distributors at an affordable price. These secondary distributors are severely threatened by the final rule. Indeed, many of these small secondary wholesalers had not even heard of PDMA until publicity about the final rule reached them. But don't be surprised that you don't see many small distributors here. They are keeping their heads down because they fear they will find themselves the subject of an enforcement action if they choose simply to stay in business despite this final rule. And there is another reason they are not here. They fear that their criticism of the final rule could lead to their being cut off by manufacturers from whom they now buy directly. If these small wholesalers go out of business, there will be a serious disruption of drug distribution to those they now serve.

Small wholesalers purchase through cooperative like organizations that buy from manufacturers and full line wholesalers. These cooperatives then fill the orders of the small wholesalers who serve doctors, clinics and others. If this system of distribution to small outlets is degraded by the final rule, it truly will threaten the health of the human and animal patients served by these small but important health care providers.

Given the number of small wholesalers, almost 4,000, and their important service to the health care delivery system, our association was surprised that pharmaceutical manufacturers are not supporting a change in the final rule back to the FDA guidance of the past twelve years. After all, manufacturers' drugs are being distributed by these wholesalers. And losing these distributors will disrupt the system.

With respect to economic costs, our association's position on the costs to small businesses and the analysis required for the final regulation to be lawfully promulgated is set forth in our June 30 comments.

Appended to this testimony are the reports of two economists retained by our association to provide opinions on the impact of the final rule. The authors are Bruce W. Hamilton, Ph.D., Professor of Economics at the Johns Hopkins University and economist, C. Daniel Mullins, Ph.D., Associate Professor at the University of Maryland School of Pharmacy. According to Professor Mullins, the economic impact of the final rule will result in the exit of secondary wholesalers from the marketplace and lower competition. The end result will be higher drug prices, higher insurance premiums, and enhanced ability to charge premium prices, and according to Dr. Mullins, the potential impact on rural areas could be devastating.

Drawing upon Dr. Mullins' conclusions, Dr. Hamilton applies standard Federal Trade Commission, Department of Justice antitrust analyses to conclude that concentration among distributors in regional and local markets potentially increases significantly. He details his analysis in his report.

3. If the act were amended by Congress to delete the requirement for provision of a drug pedigree by unauthorized distributors, would there be an increased risk of distribution of counterfeit, expired, adulterated, misbranded, or otherwise unsuitable drugs to consumers and patients?

Question No. 3. If the requirement for a drug pedigree were deleted by Congress, the risk that there may be adulterated pharmaceuticals distributed might

increase slightly. Under the current system, possible counterfeit drugs are found because they appear to be counterfeit to someone in the distribution system. And the drug pedigree is not the principal resource for tracing the history of a drug's distribution. The principal resource are the purchase and sales records of the distributors in the chain. However, the amendment cosponsored by over 30 Members of Congress, H.R. 4301, including Congressman John Dingell, PDMA's author, would retain the intent of the PDMA to provide accountability by replacing the paper trail requirement with a mandatory written certification by the unauthorized distributor that the drugs were first purchased by an authorized distributor. This written certification would be provided by unauthorized distributors to their customers just like the current pedigree, and would be subject to criminal penalty if it were falsified. Under current law and regulation, the FDA and state authorities could verify the accuracy of all written certifications during periodic inspections, and this information would be available to law enforcement, if necessary. The Congressional proposal maintains the integrity of the wholesale licensing and distribution standards created under the PDMA, but achieves this goal in a workable and more reasonable fashion than the FDA final rule. Thus, there would be virtually no real increase in risk to consumers and patients from the bill proposed by the Congress.

4. If the act were amended by Congress to require authorized distributors to provide a pedigree, what types of additional costs and burdens would they incur?

Question No. 4. Again, this question should be turned around, "What health and safety justification exists for such an amendment?" If this were done, "authorized"

distributors would be required to bear the costs of the inventory control systems that would be required to provide pedigrees for all the drugs that they sell. These costs would be a significant burden for an industry whose profit margins are already very small. To provide the pedigree information on drugs they have purchased, authorized distributors would have to physically separate and control drugs in their warehouses by the date they were purchased, further separated by lot number, dosage form and dosage amount. This would be a logistical nightmare because large full line distributors might purchase an amount of a given drug once a week from a manufacturer, and this amount might contain several lot numbers and/or dosage forms and amounts. Under the FDA's hypothetical question, each particular lot number and dosage form or amount would have to be kept separate from every other identical product in inventory, or purchased the next week. Under long standing FDA regulations, every distributor already maintains this information in its business records, which are subject to inspection by FDA and state authority. The difference is that distributors would be required to create a system of providing this sales history to their customers for the huge volumes of drugs entering and exiting their warehouses.

For the Administration to propose that Congress impose these burdens and their associated costs on the drug delivery system truly would be impolitic. Consumers and politicians are unanimous in their concerns about the high cost of pharmaceuticals. Americans already pay handsomely for the fact that we have an outstanding drug regulatory system and a patent system that rewards innovation and brings the fruits of that innovation to our health care system. We have high drug prices and we have the

best pharmaceuticals in the world. Any proposal to impose additional costs with no demonstrable increase in health or safety to consumers has no chance of serious consideration.

5. Could specific changes be made to the information that is required under 21 C.F.R. 203.50 to appear on a pedigree to make it more practical, from an authorized distributor's standpoint, to voluntarily provide a pedigree? Would use of a standardized government form be helpful?

Question No. 5. This question is also misguided. The Administration should be focusing on reducing the burdens of regulation on the drug distribution system, not increasing the burdens. As stated above, all distributors already maintain this detailed information in their business records under existing wholesale licensing regulations. The burden comes from establishing any system that requires "authorized distributors" to provide a pedigree. Reducing the specific information required or creating a new government form, would not materially alter this hugely burdensome and costly requirement.

6. If actual sales by a manufacturer to a distributor were used by FDA as the only criterion to determine whether an ongoing relationship exists between them (and as a result, whether the distributor is an authorized distributor of record), would it result in more distributors being authorized than if a written authorization agreement is required? What other types of criteria might be used by FDA to make this determination?

Question No. 6. If FDA were to return to the guidance of the last twelve years, that two transactions among a manufacturer and a distributor in a two year period

constitute an ongoing relationship, there would be no increase in the number of distributors who are authorized. The number would stay the same as it is now because such a return would maintain the status quo. It would not increase because it must be assumed that, after twelve years, those wishing to compete have entered the market and are doing so.

There is no good and sufficient reason why FDA should not maintain the status quo of its prior view of the law. Under the status quo, distributors must have records documenting the transactions with manufactures that they rely upon to support their "authorized" status. The requirement that this information be produced on inspection could be built into the final regulation.

The final rule interprets the term "ongoing relationship" to require a written contract between a manufacturer and a distributor as evidence that such a relationship exists. The final rule gives manufacturers the absolute authority to designate which companies, if any, are to be known as "authorized" distributors under PDMA. This rule would apply even if a distributor purchases drugs from the manufacturer on a weekly basis. Comments in the administrative record in this proceeding describe what happened after the FDA first proposed these regulations. Manufacturers did not renew contractual relationships with distributors with whom they had been doing business and, at the same time, continued to do business with.

Since manufacturers have been reducing the number of distributors to whom they sell directly over the last decade or more, it is logical to expect that manufacturers would further reduce the number of authorized distributors under FDA's final rule. The

other obvious result of the final rule is to give manufacturers further pricing power. There is a value in being an authorized distributor, and manufacturers would undoubtedly use the unilateral, unreviewable ability arbitrarily to designate companies as authorized distributors to extract a higher price from those distributors. Such higher prices would be passed on to consumers and taxpayers.

The FDA's proposal to detach the designation of a distributor as authorized from actual sales and transactions stands the statutory language, "ongoing relationship" on its head. An "ongoing relationship" can and does exist in the absence of a contract. This is why the FDA's initial guidance on this provision reasonably interpreted this term to mean two purchases by a distributor in a 24 month period. There is no logic or need for the FDA to use anything other than actual sales of drugs by a manufacturer to a distributor to determine authorized distributor status. Let the marketplace continue to determine who is authorized and who is not. Do not allow manufacturers to create artificial distinctions.

Why FDA has chosen to upset the status quo and give manufacturers more power over distributors than they now have is not apparent from the record of the past twelve years under PDMA. Competition in the pharmaceutical industry and in the wholesale distribution of pharmaceuticals has been settled at least since the amendments to PDMA in 1992. Upsetting that prior balance now can only lead to an increase in prices and a decrease in any vigorous price competition that does exist. There is no reason that an agency with no expertise in competition, and with no basis in

its health and safety regulation of pharmaceuticals, should be upsetting this mature market.

I enclose the Declaration of Steve Sims, our association's lobbyist. He was a staff person for Congressman Dingell, the author of PDMA and he was one of those involved in its drafting. Here is part of what Mr. Sims states in his Declaration:

5. As a professional staff member, I followed FDA's implementation of PDMA. In 1992 Congress amended PDMA to address issues that were viewed as not consistent with the intent of Congress. The principal issue had to do with the use of code numbers in-sales histories or "pedigrees." PDMA was amended to require that the names of those companies involved in prior transactions appear in pedigrees. As staff, we were aware that FDA guidance required a pedigree to go back to the manufacturer or the last authorized distributor. This was considered by me to be wholly consistent with the requirements of the PDMA as it was originally enacted and no change made in the 1992 amendments was intended to revise FDA's guidance on this issue.

* * *

It is my belief that the FDA's original guidance, which was that two sales in a two year period constituted an ongoing business relationship and that a non authorized distributor had only to trace the sales history of a drug product back to an authorized distributor, was consistent with the intent of the Congress in enacting the PDMA and that the FDA's Final Rule

definitions do not reflect either the reality of prescription drug distribution or Congressional intent.

I will now discuss the needs of our association regarding the timing of the Administration's decision on whether to return to the 1988 guidance or let the final rule stand.

Our members advise that under the present state of the record, a decision is needed by January 15, 2001. This is because they need from January 15 to October 1, 2001, to run out their inventories in an orderly, non-fire sale context. If, as requested in our Petition for Stay, the Administration interprets the final rule to apply to product first entering interstate commerce after October 1, 2001, then a decision by January 15, 2001 is not necessary. This issue could be resolved, we believe, through correspondence. A letter from the Administration to the association interpreting the final rule to apply to drugs first shipped after October 1, 2001 would suffice to address the January 15, 2001 concern. I will initiate that request by letter next week.

July 1, 2001 is our association's next important date. If there is no decision on the final rule by that date, our association will seek a judicial stay and review of the final rule. The reason for filing suit at that time is to give the Court a full opportunity to address the issues that we will raise. These are our members' businesses and they intend to protect them.

In the Federal Register notice staying the final rule and in the notice announcing this meeting, the FDA stated:

An unauthorized wholesale distributor that purchases a product from a manufacturer or authorized distributor of record without an identifying statement showing the prior sales of the drug could not provide an identifying statement to its purchasers and, therefore, could not conduct further wholesale transactions of the drug in compliance with § 203.50.

That statement alone should be enough to convince the FDA to return to its prior guidance. And we urge FDA to promptly do so.

Anthony L. Young
Piper Marbury Rudnick & Wolfe LLP
(202) 861-3882
anthony.young@piperrudnick.com



UNIVERSITY OF MARYLAND

October 18, 2000

Anthony L. Young
Piper, Marbury, Rudnick, & Wolfe, LLP
1200 Nineteenth Street, NW
Washington, DC 20036-2412

Dear Mr. Young:

As you requested, I have reviewed various materials related to the FDA's final regulation related to the Prescription Drug Marketing Act (hereafter referred to as PDMA). I find the final rules to be anti-competitive, harmful to small business owners, and potentially detrimental to the health and welfare of the American public. Following is a brief summary of specific concerns that I have regarding PDMA.

Many secondary wholesalers are likely to go out of business

While authorized distributors are encouraged to provide a drug origin statement, they are not required to do so under PDMA or the final rule. (Anti-)competitive forces would discourage authorized distributors from providing drug origin statements since failure to provide such documentation would limit the ability of smaller secondary wholesalers from conducting business as they currently do. In fact, there would be an economic incentive *not* to provide such statements. Since much of the business conducted by secondary wholesalers involves purchasing from and selling to authorized wholesalers, secondary wholesalers would literally be unable to conduct business in compliance with the final rules. This outcome would result in exit of secondary wholesalers from the market place and lower competition.

Those secondary wholesalers that remain will be disadvantaged when signing contracts

The final rule replaces the current policy regarding "authorized distributors" by requiring a signed contract between the manufacturer and the authorized distributor. With the added rules concerning drug origin statements, distributors will have an increased desire to become "authorized". Manufacturers, empowered by this new regulation, will be able to assert additional pressures on such distributors to enter into price or volume agreements, either directly or indirectly by waving the "carrot" of being authorized.

An added barrier to entry will produce added oligopoly power to the drug distribution chain
Americans typically pay a higher price for their prescription drugs than citizens of any other country in the world. There are a variety of reasons that contribute to these higher prices, including a high level of regulation and highly concentrated research & development and manufacturing systems for particular pharmaceutical agents. One of the forces that assists in keeping downward pressure on prices is the downstream purchasing power within the drug distribution system. Managed care purchasers, and the distributors that sell to them, are able to negotiate preferred pricing arrangements with manufacturers. If the revised PDMA regulations go into effect and the number of distributors decreases substantially, wholesalers will enjoy oligopoly power and will have less incentive to pass savings on to their customers. The end result of consolidation in the wholesale distribution system will be some or all of the following:

- ◆ higher drug prices
- ◆ higher insurance premiums
- ◆ greater ability of manufacturers to charge premium prices
- ◆ additional formulary restraints by managed care organizations*
- ◆ greater profits for larger wholesalers

Focus on most profitable markets could lead to reduced access and shortages in rural areas
In the midst of national debates concerning how to correct the inherent problem in Medicare, which limits seniors' access to prescription drugs, it seems counter-productive to implement policy that could introduce another barrier to access. Since many rural areas, many clinics, and many provider-dispensing offices are serviced principally by secondary distributors, a consolidation of the distributor market would likely reduce efficient servicing of these markets. These rural areas and underserved facilities would eventually be able to get needed drugs, but not necessarily in time for the patients. Patients in rural areas often travel a long distance for a physician visit. If they aren't able to fill their prescription the same day, they might not travel back "into town" the next day. In many instances, this can lead to considerable illness and hardship days or weeks later. For example, a patient with an acute infection who does not get an appropriate antibiotic may experience a considerable worsening of his/her health state and require a costly hospitalization.

In my current research, I am working with the Alpha One Foundation, a patient advocacy group that helps promote research related to a genetic illness called alpha 1-antitrypsin deficiency. As part of my research, I have analyzed data and spoken with actual patients who have been unable to gain consistent access to infusion therapy that literally saves their lives. Although my research focuses on the economic burden of reduced access, the emotional burden is quite apparent. I have spoken with fearful elderly individuals, heart broken parents, and individuals who have experienced bouts of depression due to the emotional stress of "not knowing" whether they will receive necessary treatments. The potential impact on a large number of individuals in

* Managed care organizations, faced with increasing drug prices and a more consolidated drug distribution industry, would likely respond by increasing restrictions on the numbers of drugs available on their formularies. This would be done in order to counteract the pressure on increased drug expenditure but would restrict patient access and could prove harmful to patients' health.

geographic areas that might not be covered under a consolidated distribution system could be devastating.

Discounts currently obtained by secondary wholesalers could vanish

Many secondary wholesale transactions involve the acquisition of drugs just before price increases go into effect. By strategically purchasing at a period in time prior to price increases, secondary wholesalers are able to pass along savings to downstream customers. This benefits patients directly through lower retail prices and indirectly through savings to managed care insurers that are reflected in lower premium increases. If secondary wholesalers exit the market place, these discounts would disappear, further contributing to higher drug costs and restricted access.

The impact of PDMA is more detrimental to small businesses

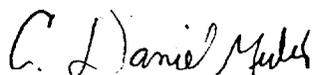
Since authorized distributors tend to be larger distributors, it is clear that the increased requirements under the final regulations will apply more frequently to smaller businesses. If all distributors were required to provide a drug origin statement, the added burden of additional paperwork would apply to all competitors and give no segment of competitors an advantage. The real burden stems from having to provide a drug origin statement when the previous distributor is not required to provide one.

Adding additional regulations upon existing regulations often leads to unintended consequences

The economics, policy, and medical literature is filled with research that documents the unintended consequences of policy reform measures. Many times the harmful impact of reform can be predicted in advance, but sometimes the detrimental effect it is not clear until after reform has been initiated. While the above statements detail several concerns about PDMA and its potential negative impact, it remains unclear exactly what the impact would be. At the same time, the current system seems to be working well and the FDA has established very effective safeguards for ensuring the quality of the drug distribution system. In the absence of problems with the current system, one question remains: If it isn't broken, why fix it?

I hope that the above assessment sheds some light on the discussion regarding the revised FDA rules under PDMA. If you have any questions concerning my comments, please do not hesitate to call me at 410-706-0879.

Very truly yours,



C. Daniel Mullins, PhD
Associate Professor, Pharmacoeconomics



C. Daniel Mullins, PhD | Pharmacy Administration Graduate Program

- Education
- Employment
- Awards
- Grants
- Publications
- Book Reviews
- Presentations
- Service Activities
- Journal Reviews
- Consulting

Education

- Ph.D. Economics, Duke University, 1994
- M.A. Economics, Duke University, 1991
- B.S. Economics, M.I.T., 1986

Employment

University of Maryland School of Pharmacy

Associate Professor/Graduate Program Director *July 1999 -present*

Assistant Professor *July 1995 -June 1999*

Research and teaching focuses on pharmacoeconomics, pharmaceutical/health outcomes research, pharmaceutical pricing, and economic analysis of the pharmaceutical industry. Teaching responsibilities include a graduate course on *Pharmaceutical Economics*, a PharmD course on *Context of Health Care* and lectures in *Drug Information* and *Principles of Study Design and Analysis*.

University of North Carolina School of Pharmacy

Assistant Professor/Director of Graduate Studies *July 1994 - July 1995*

Assistant Professor *July 1993 - July 1994*

CIBA-GEIGY Corporation

Public Policy Intern *Summer 1990*

John Hancock Insurance Co.

Marketing Analyst - Long Term Care *December 1988 to August 1989*

Marketing Analyst - Property & Casualty *January 1988 to December 1988*

Actuarial Analyst - Property & Casualty *June 1986 to January 1988*

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Awards

1998 Faculty Development Award in Pharmacoeconomics. Provides \$40,000/year for 2 years. Source: Pharmaceutical Research and Manufacturers of America (PhRMA).

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Grants

"Annotated Bibliography for Treatment of Congestive Heart Failure (CHF)." Source: USP; \$66,700 (Principal Investigator).

"Eplerenone CEA." Source: Searle 2000; \$347,300. (Principal Investigator).

"Impact of Pipeline Drugs on Future Pharmacy Costs." Source: HIAA/BCBS 2000; \$50,012 (Principal Investigator).

"Prescription Costs for Medicare Beneficiaries: What We Know and What We Need to Know." Source: DHHS, Assistant Secretary for Policy and Evaluation. Contract No. SA-00-0064 2000; \$24,598 (Co-Investigator; Principal Investigator=Bruce Stuart).

"Adult Medicaid Patients' Dental Visits in EDs." Source: AHCPR (1 R01 HS10129-01) 1999; \$139,853 (Co-Investigator; Principal Investigator=Len Cohen).

"Alpha 1-Antitrypsin Deficiency Cost of Illness Model." Source: Alpha One Foundation 1998; \$32,956 (Principal Investigator).

"Cost of IVIG Therapy for PIDDs by Site of Care." Source: Immune Deficiency Foundation 1998; \$16,100 (Principal Investigator).

"An Economic Analysis of Alternative Treatment Regimens for Acromegaly." Source: Novartis Pharmaceutical Corp. 1998; \$27,000 (Co-Investigator; Principal Investigator=Bruce Stuart).

"ZEBRA and EORTC Economic Evaluation." Source: Zeneca Pharmaceuticals 1998; \$15,000 (Principal Investigator).

"Abciximab Outcomes/Cost Analysis." Source: School of Pharmacy DRIF Award 1998; \$9,865 (Principal Investigator).

"Utilization and Cost of IVIG Therapy for PIDDs." Source: Immune Deficiency Foundation 1998; \$16,675 (Principal Investigator).

"Econometric Model of Annual Expenditures for Cancer." Source: School of Medicine DRIF Award 1998; \$15,000 (Co-Investigator; Principal Investigator=Sandra Brooks).

"Pharmacoeconomic Analysis of CAP Program." Source: Pharmacia & Upjohn (In conjunction with BCBS of MD, BCBS of the National Capital Area, MAMSI, and NYLCare) 1997; \$41,254 (Principal Investigator).

"Evaluation of Emergency Medical Systems (EMS) Triage of Elderly Trauma Patients." Source: UMAB Geriatrics and Gerontology Education and Research (GGEAR) Program 1997; \$25,000 (Co-Principal Investigator; Principal Investigator=Jane Scott).

"Pharmaceutical Research Monitoring Project." Sources: Merck, Novartis, Pfizer, Pharmacia-Upjohn, and Wyeth-Ayerst 1997; \$25,000/firm = \$125,000 (Principal Investigator on two; Co-Investigator on three).

"Update of Pharmacoeconomic Guidelines/Principle List." Source: Health Outcomes Work Group at PhRMA 1997; \$14,500 (Principal Investigator).

Unrestricted educational grant for development of economic models. Source: Wyeth-Ayerst Research 1996; \$15,000 (Principal Investigator).

"Cost-Benefit Analysis of the Community Health Worker Initiative." Source: UMAB Geriatrics and Gerontology Education and Research (GGEAR) Program 1996; \$19,499 (Principal Investigator).

"Pharmaceutical Care Outcomes in a Well-Elderly and Frail-Elderly Continuing Care Retirement Community Population Using Multiple Medications." Source: UMAB Geriatrics and Gerontology Education and Research (GGEAR) Program 1996; \$18,886 (Co-Principal Investigator; Principal Investigator=Maddie Feinberg).

"Medicaid Drug Rebates, Pharmaceutical Prices and Unintended Consequences of Health Policy Reform" Source: Duke University Center for Aging Studies/The Glaxo Award in Long Term Care Research (Doctoral Dissertation Grant) 1992; \$2,000.

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Publications

Brooks SE, Chen TT, Ghosh A, Mullins CD, Gardner JF, Baquet CR. Cervical Cancer Outcomes Analysis: Impact of Age, Race and Comorbid Illness on Hospitalizations for Invasive Carcinoma of the Cervix. *Gynecologic Oncology* 2000 (forthcoming).

Reed SO, Mullins CD, Magder LS. Cost Effectiveness of Abciximab During Routine Medical Practice. *Pharmacoeconomics* 2000 (forthcoming).

Luchette FA, Barrie PS, Oswanski MF, Spain DA, Mullins CD, Palumbo F, Pasquale MD. Practice Management Guidelines for Prophylactic Antibiotic Use in Tube Thoracostomy for Traumatic Hemopneumothorax. *The Journal of Trauma* 2000; 48 (4):753-7.

Luchette FA, Borzotta A, Croce MA, O'Neill PA, Whittmann DH, Mullins CD, Palumbo F, Pasquale MD. Practice Management Guidelines for Prophylactic Antibiotic Use in Penetrating Abdominal Trauma. *The Journal of Trauma* 2000; 48 (3):508-18.

Mullins CD. An Overview of Cancer Economics. *The American Journal of Managed Care* 1999; 5(6 suppl):S371-S376.

Amin SP, Mullins CD, Duncan BS and Blandford L. Comparison of the Costs of Treatment for Diabetes and Hypertension in an IPA Group Model HMO. *American Journal of Health Systems Pharmacy* 1999; 56(15):1515-20.

Weidle P, Bradley L, Gallina J, Mullins CD, Thorn D, and Siegel LP. Pharmaceutical Care Intervention Documentation Program (PCIDP) and Related Cost Savings in a University Hospital. *Hospital Pharmacy* 1999; 34(1):43-52.

Mullins CD and Ogilvie SD. Emerging Standardization in Pharmacoeconomics. *Clinical Therapeutics* 1998; 20(6):1194-1202.

Reed SD, Mullins CD, Roffman DS and Mays DA. Difficulties in applying clinical trial information to the practice setting: Case of a high-cost drug. *American Journal of Health Systems Pharmacy* 1998; 55(22):2409-14.

Mullins CD and Palumbo FB. Maintaining Public Assistance Data in the Managed Care Era. *SGIM (Society of General Internal Medicine) Forum* 1998; 21(3):5,10.

Mullins CD, Cooke CE, and Cooke JL. Applications of Pharmacoeconomics for Managed Care Pharmacy. *Journal of Managed Care Pharmacy* 1997; 3(6):720-726.

Grabowski HG and Mullins CD. Pharmacy Benefit Management, Cost-Effectiveness Analysis, and Drug Formulary Decisions. *Social Science & Medicine* 1997; 45(4):535-544.

Mullins CD, Morris LS, Perfetto EM and Ogilvie SD. Pharmacoeconomics of NSAIDs: Beyond Bleeds. *Journal of Managed Care Pharmacy* 1997; 3(4):425-430.

Palumbo FB and Mullins CD. Quality-of-care data from managed care organizations.

Letter to the editor. *New England Journal of Medicine* 1997; 336(6):443-444.

Mullins CD. Price and Welfare Implications of a Medicare Pharmaceutical Rebate. *New York Health Sciences Journal* 1996; 1(4):243-255.

Mullins CD. Most-Favored-Customer Protection and Medicaid Rebates under OBRA 1990. *Journal of Research in Pharmaceutical Economics* 1996; 7(3):49-63.

Mullins CD and Weisman ES. A Simplified Approach to Teaching Markov Models. *American Journal of Pharmaceutical Education* Spring 1996; 60(1):42-7.

Mullins CD, Baldwin R and Perfetto EM. What Are Outcomes? *Journal of the American Pharmaceutical Association* January 1996; NS36(1):39-49.

Mullins CD. Toward an Understanding of Pharmaceutical Pricing Strategies Through the Use of Simple Game Theoretic Models. *Journal of Research in Pharmaceutical Economics* 1995; 6(3):1-14. (Reprinted in Smith, MC, ed. *Studies in Pharmaceutical Economics*. New York: Pharmaceutical Products Press, 1996.)

Hartzema AG and Mullins CD. *Pharmaceutical Chartbook*. New York: Pharmaceutical Products Press, 1995.

Mullins CD. Combining the Principles of Epidemiology and Economics. *American Journal of Pharmaceutical Education* Winter 1994; 58[4]:427-430.

Mullins CD. Drug Firm-Mail-Order Mergers: Marriages of Convenience? *American Pharmacy* August 1994; NS34(8):38-42.

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Book Reviews

Mullins CD. *Review of Robert M. Sloane, et al.* *Introduction to Healthcare Delivery Organizations: Functions and Management, Fourth edition* in *American Journal of Pharmaceutical Education* Spring 2000; 64:106.

Mullins CD. *Review of Stuart O. Schweitzer* *Pharmaceutical Economics and Policy* in *American Journal of Pharmaceutical Education* Spring 1998; 62:104-5.

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Presentations

"Outcomes Research for Everyone Else: A Primer for the Non Outcomes Researcher" Tutorial at the DIA Annual Meeting, San Diego, CA, June 2000.

"From Good to Blockbuster: Successes in Outcomes Research" Session Chair at the DIA Annual Meeting, San Diego, CA, June 2000.

"Study Design Issues in Health Economics" Session Chair at the DIA Annual Meeting, San Diego, CA, June 2000.

"Cost-Effectiveness/Cost-Benefit Analyses (Session 2)" Session Chair at the ISPOR Annual Meeting, Arlington, VA, May 2000.

"Employer Cost of Diabetes" presented at the BMS Employer Diabetes Health Panel, Carlsbad, CA May 2000.

"The Impact of Pipeline Drugs on Pharmaceutical Expenditures" presented at the HIAA/BCBSA Pipeline Pharmaceuticals Symposium, Washington, DC, April 2000.

"The Impact of Pipeline Drugs on Pharmaceutical Expenditures" presented at the HIAA/BCBSA Pipeline Pharmaceuticals Symposium, New York, NY, April 2000.

"Outcomes Collected in Randomised Clinical Trials and Retrospective Database Studies" presented at the DIA EuroMeeting, Nice, France, March 2000.

"Estimates of the Indirect Cost of HIV and AIDS in the United Kingdom" (poster) presented at the DIA EuroMeeting, Edinburgh, Scotland, November 1999.

"Government's Role in Pharmaceutical Pricing" presented at the Drug Pricing Policy Forum, Kunming, China, October, 1999.

"Pharmaceutical Pricing and International Practice" presented at the Drug Pricing Policy Forum, Kunming, China, October, 1999.

"Cancer Screening in Maryland: A Review of the Cancer Insurance Study and Cost

Related Aspects" presented at the Maryland State Council on Cancer Control: Cancer Roundtable Meeting at Johns Hopkins School of Hygiene & Public Health, Baltimore, MD, October, 1999.

"Applied Pharmacoeconomics for Formulary Decision Making" presented at the 7th Annual ASCP Mid-Atlantic Conference, Cumberland, MD, August 1999.

"Outcomes Research for Everyone Else: A Primer for the Non Outcomes" Tutorial at the DIA Annual Meeting, Baltimore, MD, June 1999.

"Recent Successful Launches: The Role of Outcomes Research" Session Chair at the DIA Annual Meeting, Baltimore, MD, June 1999.

"Pharmacoeconomic Decision Making: Observations from the Real World" presented at the DIA Annual Meeting, Baltimore, MD, June 1999.

"Outcomes Data on Osteoporosis for Formulary Decisions" presented at the Lilly Centre for Women's Health Outcomes Symposium, Indianapolis, IN May 1999.

"Cost-of-Treatment vs. Cost-of-Illness Analysis" presented at The Wintergreen Conference V, Wintergreen, VA, May 1999.

"Pharmacoeconomic Evaluation of a Community Acquired Pneumonia Program" presented at the Academy of Managed Care Pharmacy's Annual Meeting, Minneapolis, MN, April 1999.

"Impact of Community Acquired Pneumonia (CAP) Guidelines on Treatment Costs" presented at the DIA's Pharmaceutical Outcomes Research: Past, Present and Future Workshop, Seattle, WA, April 1999.

"Alpha 1-Antitrypsin Deficiency Cost of Illness Analysis" presented at the American Thoracic Society Annual Meeting, San Diego, CA, April 1999.

"Cost-of-Treatment Models: Tools for Comparative Cost Analyses" (poster) presented at the PhRMA Foundation Annual Awardee Meeting, New York, NY, April 1999.

"Practical Overview of Pharmacoeconomic Research" presented at ASCP's Generating and Analyzing Data for Clinical and Business Applications Workshop, Seattle, WA, November 1998.

"Pharmacoeconomics - A Practical Approach" presented at the Maryland Society of Health-System Pharmacists 33rd Annual Seminar, Deep Creek Lake, MD, October 1998.

"Cost of Treatment vs. Cost of Illness Analysis: Managing Annual Budgets vs Projecting Lifetime Expenditures for your Patients" presented at the Zitter Group's 5th Annual Congress on Health Outcomes & Accountability, San Diego, CA, October 1998.

"Pharmacoeconomics/Outcomes Research Mini Course" presented at the Clínic Barcelona, Hospital Universitari, Barcelona, Spain, September 28 - October 4, 1998.

"Pharmacoeconomics/Outcomes Research" presented at the Regulatory Affairs Professional Society Conference on "International Clinical Trials," Newark, NJ, August 1998.

"International Pharmacoeconomics Guidelines: Areas of Consensus and Disagreement" presented at the Regulatory Affairs Professional Society Conference on "International Clinical Trials," Newark, NJ, August 1998.

"Outcomes Research for Everyone Else: A Primer for the Non Outcomes" Tutorial at the DIA Annual Meeting, Boston, MA, June 1998.

"Case Study: The Health Care System Focus" presented at Howard University's "Pharmacoeconomics, Clinical Outcomes and Patient Care Seminar" Greenbelt, MD, June 1998.

"Issues in Developing Economic Models for Managed Care: The Case of Osteoporosis Prevention" workshop presented at ISPOR's annual meeting, Philadelphia, PA, May 1998.

"Practical Overview of Pharmacoeconomics" presented at ASCP's "Data...Your Competitive Edge" Workshop, Baltimore, MD, April 1998.

"Decision Modeling in Pharmacoeconomics" presented as a roundtable discussion at the APhA Annual Meeting, Miami, FL, March 1998.

"Outcomes Research for Everyone Else...Introduction to the History, Jargon and Definitions" presented at the DIA Conference on Outcomes Research for the Non Outcomes Researcher, Baltimore, MD, March 1998.

"Pharmacoeconomic Guidelines: Areas of Consensus and Disagreement" presented at the ISPOR Conference on Pharmacoeconomics: Identifying the Issues, Crystal City, VA, February 1998.

"Pharmacoeconomics of NSAIDs: Beyond Bleeds" presented at the APhA Annual Meeting, Los Angeles, CA, March 1997.

"Economic Model of NSAID Use and Upper Gastrointestinal Symptoms" presented at the Association of Rheumatology Health Professionals National Scientific Meeting, Orlando, FL, October 1996.

"Outcomes Research Assessment" presented at a USP Mini-Symposium, Rockville, MD, July 1996.

"Strategic Drug Pricing in the Presence of Managed Care Competition" presented at The Wintergreen Conference IV, Wintergreen, VA, May 1996.

"Strategic Drug Pricing in the Presence of Managed Care Competition" presented at the Southern Economic Association Annual Meeting, New Orleans, LA, November 1995.

"Unintended Consequences of Medicaid Rebates" presented at the DIA Annual Meeting, Orlando, FL, June 1995.

"The Appropriate Setting for Measurements in Pharmacoeconomic Evaluations" presented at CePOR Conference, Chapel Hill, NC, April 1995.

"Medicaid Drug Rebates, Pharmaceutical Prices and Unintended Consequences of Health Policy Reform" presented at the Glaxo Career Development Awards Convocation, Durham, NC, March 1995.

"Medicaid Drug Rebates, Pharmaceutical Prices, and Unintended Consequences of OBRA 1990" presented at The Wintergreen Conference III, Wintergreen, VA, October 1994.

"The Interface of Methodologies from Epidemiology and Economics," presented at the American Association of Colleges of Pharmacy Annual Meeting, Albuquerque, NM, July 1994.

"Pharmaceutical Managed Care: A Penny Saved is a Penny Earned," poster presentation at the American Pharmaceutical Association Annual Meeting, Seattle, WA, March 1994.

"Most-Favored-Customer Protection and Medicaid Rebates under OBRA 1990," presented

at the Southern Economic Association Annual Meeting, New Orleans, LA, November 1993.

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Service Activities

UMB Faculty Affairs Committee 1999, 2000

UMMS Therapeutics Committee Member 1995 - present

UMB Faculty Senator 1997 - 1999

UMB Curriculum Committee 1996, 1997

UMB Assessment Focus Group 1995, 1996

UMMS Pharmacy-Industry Partnership Member 1995, 1996

UMMS Surgery Team Adjunct Member 1995

APHA Annual Meeting Abstract Reviewer 1997

AphA Annual Meeting Abstract Reviewer 1996, 1999

ASCP Pharmacoeconomic Fellowship Selection Panel 1996

Advisory Panel for ASCP Fleetwood Project 1995 - 1999

Board Member, Maryland Public Health Association 1996 – present

Treasurer, Maryland Public Health Association 1998 – 2000

NHLBI Reviewer 1997, 1998

Maryland Health Care Commission Hospital and Ambulatory Surgical Facility Report Card Steering Committee Member 2000

Journal Reviews

American Journal of Pharmaceutical Education, Reviewer 1997, 1998, 1999, 2000

American Journal of Managed Care, Reviewer 1999, 2000

Clinical Therapeutics, Editorial Board 2000

Health Affairs, Reviewer 1997, 1999, 2000

Health Services Research, Reviewer 1998

Journal of Health Politics, Policy and Law, Reviewer 1997

Journal of Pharmacy Teaching, Reviewer 1994, 1995, 2000

Journal of Research in Pharmaceutical Economics, Reviewer 1994, 1995

Medical Care, Supplemental Issue Reviewer 1995

PharmacoEconomics, Reviewer 1995, 1997, 1999

Science, Reviewer 2000

Value in Health, Editorial Board 1998, 1999, 2000

Consulting

Aventis

Bristol-Meyers Squibb

Clinical Pharmacy Associates

Eli Lilly

MEDTAP systems

PAREXEL

Pfizer Pharmaceuticals

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October 26, 2000

Anthony L. Young, Esq.
Piper Marbury Rudnick & Wolfe LLP
1200 – 19th Street, N.W.
Washington, D.C. 20036

Re: Impact of New PDMA Rules on the Pharmaceutical Distributor Markets

Dear Mr. Young:

I have reviewed the role of distributors in the pharmaceutical industry and the likely impact of the FDA's proposed rule changes on their roles. As discussed below, I believe the result of the rule changes will be less resale of pharmaceuticals, fewer distributors and ultimately higher prices. In assessing the likely impact, I observed that a number of manufacturers, three somewhat overlapping levels of distributors, and end-users characterize the pharmaceutical industry. These various participants, my observations, and my conclusions are set forth below.

Manufacturers:

Large pharmaceutical companies manufacture most drugs. Upon introduction, patents protect most drugs. When the patent expires, manufacturers face competition from generic drugs but frequently continue to retain some name-brand market power over generics.¹ The monopoly power attained by the pharmaceutical companies is the legal reward for the research that went into the creation of the patented drug, and under United States patent law the manufacturers are entitled to this reward for innovation.²

National, Mid-Level and Local Distributors:

There are three partially overlapping layers of distributors. First, there are the "Big 5" manufacturers, who operate nationally.³ They buy from the manufacturers. They sell much of their product directly to end-users (physicians, hospitals, nursing

¹ The name-brand drug generally sells at a premium over the generic, indicating the presence of some residual market power.

² Of course, it is well understood that a patent by itself is no guarantee of monopoly power. Monopoly power requires both barriers to entry (for example from patents) and a product demand curve which lies in part above the marginal cost curve.

homes and the like). But they also sell some product to smaller regional distributors and to a very large number of local distributors. These local distributors generally operate in very small geographic markets. The mid-level distributors sometimes buy from the manufacturers, and sometimes do not sell "down the chain," but rather to the Big 5. This occurs when the Big 5 can get better prices from the mid-level distributors than from the manufacturers.

End Users:

Pharmaceuticals are purchased by physicians, drugstores, hospitals, and other third parties who purchase drugs on behalf of patients, who of course are the real end users. But for all practical purposes, distributor sales to physicians, hospitals and so on constitute the end of the chain of distribution.

The Roles of Distributors:

In many markets, distributors play two quite distinct economic roles. The first is that suggested by the title – they distribute product from the manufacturer to the end user and provide services for both in the process. Manufacturers use distribution chains rather than selling direct because the distributors have expertise and contacts which they themselves lack. In this industry, it has been noted that "along with the delivery of pharmaceuticals, the wholesalers have a broad range of value-added services that they can provide to their dispensing customers. These services are often not provided by the manufacturer and would be difficult and costly for the dispenser (customer) to reproduce them."⁴

The second role of the network of distributors is that of arbitrageur. In any market in which the manufacturer has market power (a downward-sloping demand curve) there is the potential for substantial profits to arise from price discrimination. The standard textbook profit-maximizing monopolist charges a price above cost. But the market, even for a monopolist, restrains the price. If the price is raised too high, a small number of consumers will continue to buy the product but many others (too many others), who would have been willing to pay a somewhat lower price, opt out of the market.

³ The Big 5 are Cardinal Health, Inc., Bergen-Brunswick Corp., AmeriSource Health Corp., McKesson Corp. and Bindley Western Industries, Inc.

⁴ Memorandum Opinion, FTC v Cardinal Health, Inc., p. 6 (1998).

Of course, the monopolist (or any manufacturer with market power) would like to find a way to charge a high price to those relatively few who are willing to pay it, and to charge a lower but still profitable price to other consumers. In the extreme case, the manufacturer would like to tailor the price to fit the consumer, with consumer-specific prices ranging from high to low (down to pricing at cost or slightly above). If a monopolist is able to perfectly price discriminate – that is, to really charge the maximum price that every end-user is willing to pay, then he can earn approximately double the profit that he could earn by charging a single price to all customers.

From the manufacturer's perspective, price discrimination is frequently difficult to maintain because it opens the door to arbitrageurs. Distributors – unless they are somehow constrained from doing so – naturally undertake this arbitrageur's role.

Arbitrage:

Arbitrage is the art of buying low and selling high. An important fact to note is that arbitrage opportunities exist whenever the same product sells for different prices in different circumstances, but that arbitrageurs actually destroy arbitrage opportunities by their own actions. Clearly not everybody can buy low and sell high. Both the original seller and the original buyers will try to play off one arbitrageur against another. And in addition, as the seller's stock runs low he will raise his price. Correspondingly, as the buyer's demand is satisfied he will only offer a lower price.

The economic role of the arbitrageur, though not the role envisioned by the arbitrageur himself, is to enforce the **law of one price**. The law of one price states that in a freely functioning market, in which there are no artificial impediments to arbitrage, any given commodity must command only one price throughout the marketplace.

As the foregoing should make clear, if a manufacturer wants to engage in price discrimination, one of his first concerns is the elimination of arbitrage. In the parlance of distribution networks, the manufacturer must ensure that his distributors sell only to "target" customers. Frequently, manufacturers attempt to enforce exclusive territories (i.e., they attempt to prevent "transshipment"). Thus if a manufacturer finds it profitable to discriminate against one territory, he need not fear that his distributor in the favored territory will resell product and frustrate his effort to obtain the high price.

Environments in Which Price Discrimination Flourishes:

Successful price discrimination requires two ingredients: ability to identify end users with different willingness to pay, and ability to prevent end users or the distribution network from engaging in arbitrage. Probably the most effective environments for price discrimination are those in which it is physically impossible for the end user to resell the product. There is no resale market, no arbitrage, and a great deal of price discrimination in surgery and college education. There is also a great deal of price discrimination in airline tickets – not because it is physically impossible to resell tickets but because the airlines have succeeded in making it impossible for a ticket holder to resell all or part of his ticket. If tickets or legs of tickets could be resold on a secondary market, then airlines would be unable to charge a higher price for travelers (business travelers, with a high willingness to pay) premium prices if they do not stay over a Saturday night. If resale were possible (and there is no technical reason why it is not), then distributors would buy up low-priced tickets. They would “unroll” round-trip tickets into one-way legs and resell them. The Law of One Price would prevail.

In the case of pharmaceuticals there is no technical reason why they cannot be resold. However, if the manufacturers can control the resale market, they can prevent or greatly curtail the kind of reselling that would undermine price discrimination.

Arbitrage in the Pharmaceutical Distribution Industry:

I do not have data on the strength of arbitraging in the pharmaceutical industry. However, there is anecdotal evidence that it is prevalent. There are reported instances of lower-level distributors occasionally selling to the Big 5. This occurs despite the fact that the “natural” flow of drugs is from the manufacturer to the Big 5 and from the Big 5 either directly to the end user or to a lower-level distributor who in turn distributes to the end user. It is hard to imagine that these “upstream sales” are anything but arbitrage.

Furthermore, in an industry characterized by such a maze of distribution channels, with the Big 5 sometimes selling to wholesale distributors, sometimes to retail distributors, and sometimes direct to end users, one would expect healthy arbitrage.

Effect of the Rule Change on Arbitrage:

Perhaps even more than its effect on the number of small distributors, and the level of competition among retail distributors, is the effect of the proposed rule change on

arbitrage. The requirement that every transaction be documented with a pedigree all the way back to the manufacturer means that the manufacturers and the Big 5 have vastly increased control over the paths followed by drugs from manufacturer to end user. The Big 5 have already demonstrated this control by refusing to provide pedigrees or authorized distributorships to small distributors. As noted in more detail below, there is a District Court finding that local markets in this industry are "born to leak." This leakage, which will likely be greatly curtailed by the proposed rule change, is arbitrage in action.

Effect of the Rule Change on Value-Added Service:

The report of C. Daniel Mullins, Associate Professor of Pharmacoeconomics at the University of Maryland, documents anticipated changes in the number of viable distributors which will result from the proposed rule change.⁵ He goes on to discuss the probable economic consequences of that destruction of distributors. I wish to note that the effect on competition is likely to be even more deleterious than he indicated in his report.

At present there are numerous distributors, some operating nationally, some regionally and some just locally. In *FTC v Cardinal Health, et al*, the Court found that there is a national market for drug wholesaling. Whereas in some regions there are well-defined local markets (basically the western half of the United States where competition from regional and local distributors is less intense), the eastern half of the country is characterized by a sufficiently thick layer of regional distributors that local markets are not easily definable. The Government's expert testified, and the Court agreed, that local markets are "born to leak." Whereas distributors in the western half of the country may enjoy some local market power, distributors in the eastern half of the country apparently do not.

If the proposed rules force the closure of a sufficiently large number of regional and local distributors, then it is reasonable to anticipate that the multistate (largely east of the Mississippi) market would be transformed into a set of autonomous local markets. Instead of X distributors competing against one another throughout the eastern United States, we may end up in a setting where one or two regional/local distributors serve each local area. To take a hypothetical, suppose that the rule change reduces the number of

⁵ Dr. Mullins' report does not provide a precise estimate of the number of distributors which will be forced to exit the industry, but he clearly demonstrates that there will be a major effect on smaller distributors.

distributors from 40 to 10.⁶ If the distributors are of equal size, and if they all compete throughout the region, the HHI is raised from 250 to 1000.⁷

But now suppose, reasonably, that the rule change not only reduces the number of distributors from 40 to 10, but also greatly curtails transshipment of pharmaceuticals. The Eastern United States is transformed from a single regional market to many local markets. Although these markets were "born to leak," the proposed rule has stopped or at least greatly curtailed the leaking. Suppose for example that many or all of the surviving regional distributors concentrate in only 1/3 of the region's local markets. Secure in the knowledge that the new rules have stifled transshipment of drugs, the distributors recognize that they have local monopoly power. If three subnational distributors now serve each local market, the local HHI will have risen all the way from 250 to 3333. The reason is that the rule change not only directly reduces the number of distributors, but it also potentially increases the autonomy of local markets. In one of the antitrust defendant's favorite phrases, it "brings order to the marketplace."

Of course, the very likely effect of isolating local markets and reducing the number of distributors is to raise prices. This effect is different from, but related to, the effect described earlier – that of facilitating price discrimination. On both counts, the proposed rule change is likely to have a seriously deleterious effect on the price of pharmaceuticals and the level of service end-users will receive.

Sincerely,

Bruce W. Hamilton, Ph.D.
Professor of Economics

⁶ I emphasize that these numbers are illustrative. I have not performed a detailed econometric analysis to determine the exact pre and post rule-change market shares.

⁷ Market concentration is a function of the number of firms in a market and their respective market shares. As an aid to the interpretation of market data, the FTC and DOJ use the Herfindahl-Hirschman Index ("HHI") of market concentration. The HHI is calculated by summing the squares of the individual market shares of all the participants. FTC/DOJ Horizontal Merger Guidelines, § 1.5.



Bruce W. Hamilton Professor of Economics

bruce.hamilton@jhu.edu

Office: Mergenthaler Room 441

Phone: (410) 516-7613

Fax: (410) 516-7600

Postal Address:

Dept of Economics

Johns Hopkins University

3400 N. Charles St.

Baltimore, MD 21218

Office Hours: Tue, Wed, Fri 7:30 - 10:30

Bruce Hamilton came to Johns Hopkins as an Assistant Professor in 1973, one year after obtaining his Ph.D. from Princeton University. Since that time he has spent his entire career at Hopkins, with the exception of a one-semester Sabbatical leave at Bilkent University in Ankara, Turkey. He was made Professor of Economics in July 1983, and served as Acting Chair during spring term, 1993-94. He then served as Department Chair from July, 1985 through June, 1992.

Dr. Hamilton is an applied microeconomist. Until approximately 1985, virtually all of his research was in the broad field of urban economics, with specialties in urban public finance and urban transportation. His work during the 1970s on the Tiebout Hypothesis led to a resurgence in professional interest in the workings of local public economies.

Subsequently, Dr. Hamilton's research has been more eclectic. He has recently published a paper on the economics of professional sports stadia, with emphasis on the new stadia in Baltimore. He has a working paper on the causes of the recent (two-decade) dramatic rise in automobile longevity. This work shows that essentially all of the longevity improvement is unrelated to any improvements in the inherent durability of cars themselves.

More recently he has used a food-demand function and the PSID data set to estimate the annual bias in the Consumer Price Index, separately for whites and blacks. As this method has very limited data requirements, he is currently determining whether the technique might fruitfully be applied to the measurement of inflation in other countries, including developing countries whose data are poor.

Dr. Hamilton teaches the Elements of Microeconomics course in the undergraduate curriculum, as well as an upper-level seminar on the Economics of Antitrust (jointly taught with antitrust attorney Robert Levy). In the Ph.D. program he teaches the first course in the Microeconomic Theory sequence.

Curriculum Vitae

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UNITED STATES OF AMERICA

BEFORE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

PHARMACEUTICAL DISTRIBUTORS ASSOCIATION

DECLARATION OF STEVE SIMS

1. My name is Stephen Sims. I am a self-employed lobbyist and I represent the Pharmaceutical Distributors Association. When the PDMA was enacted I was a Special Assistant to the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives. Between July 10, 1985, when I presented staff testimony before the Subcommittee, and the April 1988 signing of the Prescription Drug Marketing Act by then President Ronald Reagan, the Subcommittee on Oversight and Investigations held eight days of hearings, issued two staff reports and one Subcommittee Report on problems with the integrity of the distribution system for prescription drugs in the United States. I led the Subcommittee's investigation and was deeply involved in the drafting and passage of the PDMA. I make this Declaration as an individual and not on behalf of the Subcommittee or the Committee. I make this Declaration based on my best recollection of the events that occurred from 1985 to 1992 with respect to the investigations regarding the distribution of prescription drug samples and the reimportation and the wholesale distribution of prescription drugs and the enactment in 1988 and 1992 of the Prescription Drug Marketing Act and its amendments (PDMA).

2. In my position as professional staff member, I was one of the staff persons principally involved in drafting of PDMA. The intent of the Subcommittee and the Committee as I recall it was to regulate the distribution of prescription drug samples, bar the reimportation of prescription drugs, license all prescription drug wholesalers and require a paper trail to accompany prescription drugs distributed by wholesalers who were not manufacturer-authorized distributors.

3. I have read the Food and Drug Administration's December 1999 final regulations implementing the PDMA. These regulations have two requirements which I firmly believe go beyond what I recall to be the intent of the Congress and those who were involved with the legislation in 1988 and in 1992.

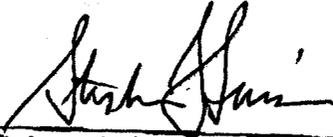
4. The final regulations require a prescription drug reseller to disclose all transactions back to the purchase of the drug from the manufacturer. In PDMA, Congress was careful to exempt manufacturer-authorized wholesalers from the requirement of providing their customers with a history of prior sales. The requirement applies only to those distributors who are not authorized by the manufacturer. Since most prescription drugs then were first purchased by manufacturer-authorized distributors, it was never intended that resellers be required to look back through these distributors to the manufacturer.

5. As a professional staff member, I followed FDA's implementation of PDMA. In 1992 Congress amended PDMA to address issues that were viewed as not consistent with the intent of Congress. The principal issue had to do with the use of code numbers in sales histories or "pedigrees." PDMA was amended to require that the names of those companies involved in prior transactions appear in pedigrees. As staff, we were aware that FDA guidance required a pedigree to go back to the manufacturer or the last authorized distributor. This was considered by me to be wholly consistent with the requirements of the PDMA as it was originally enacted and no change made in the 1992 amendments was intended to revise FDA's guidance on this issue.

6. One of the primary objectives of the PDMA was to prevent the introduction into commerce of drugs that were counterfeit or of unknown quality. This is why the statute divided drug wholesalers into two categories, those who purchased directly from manufacturers and those who did not. Because the PDMA required all resellers to be licensed by the states in which they did business and to meet minimum standards for the storage, handling and recordkeeping of the drugs they bought and resold, the Congress was not concerned about the quality of the pharmaceuticals sold directly by manufacturers to licensed wholesalers. Indeed, the PDMA exempted such purchases by "authorized" wholesalers, defined as companies that had "an on going business relationship" with manufacturers, from the pedigree requirement. The pedigree only pertained to purchases subsequent to direct sales by manufacturers to distributors, and was designed to identify sources of product that might be dangerous, such as adulterated drug samples, stolen merchandise, counterfeits or domestically manufactured goods that were exported, stored in unknown conditions and then reimported. And the Congress did not limit resales by secondary wholesalers, but only sought through the pedigree to identify the true origin of the products so that the reseller industry could, in effect, police itself. It is my belief that the FDA's original guidance, which was that two sales in a two year period constituted an ongoing business

relationship and that a non authorized distributor had only to trace the sales history of a drug product back to an authorized distributor, was consistent with the intent of the Congress in enacting the PDMA and that the FDA's Final Rule definitions do not reflect either the reality of prescription drug distribution or Congressional intent.

I declare under penalty of perjury that the foregoing is true and correct.



Stephen Sims

Washington, D.C.

October 13, 2000