The Honorable Duane Mutch
State Capitol
600 East Boulevard Avenue
Bismarck, North Dakota 58505-0360

Re: House Bill No. 1332 – Regulation of Pharmacy Benefit Management

Dear Mr. Chairman:

I write to you to express my concerns regarding the Federal Trade Commission staff's letter of March 8 about North Dakota House Bill No. 1332 which is now before the Senate and your committee. As a former government enforcement official with years of experience in enforcing antitrust and consumer protection laws, I believe the proposed statute is a refined and carefully constructed approach to the numerous consumer protection problems posed by Pharmacy Benefit Managers ("PBMs"). The FTC staff's comments may be based on economic theory, but they miss the mark because they ignore the economic realities of the North Dakota marketplace and the legitimate problems addressed by the proposed legislation.

I was the Policy Director of the Bureau of Competition of the Federal Trade Commission from 1998 to 2001, and attorney advisor to then-Chairman Robert Pitofsky from 1995-1997. In these positions, I was actively involved in the Commission's advocacy program and regularly advised state and federal legislators on proposed legislation.[1] This advocacy role can be valuable where it is based on empiricism, careful industry-specific studies and enforcement actions. However, where the Commission or any other Washington-regulator provides advice that lacks an empirical foundation or ignores the unique nature of specific markets, those comments have frequently and appropriately been rejected by state legislatures.

PBMs pose a myriad of difficult consumer protection and competition problems. I know this first hand as a former enforcement official and as a private practitioner advising both PBMs and pharmacies. At the FTC, I helped spur the initial PBM enforcement actions against the Merck-Medco and Lilly-PCS PBM mergers and other investigations of anticompetitive PBM conduct. Through its orders in those cases the FTC attempted to provide a greater level of transparency to enable covered entities to get a fair deal. Unfortunately, as described below, those efforts were not successful as demonstrated by the large number of government and private enforcement actions challenging anticompetitive and fraudulent conduct by PBMs.

As a private practitioner, I regularly counsel participants in the pharmaceutical marketplace including manufacturers, PBMs, and pharmacies about how to comply with the competition and consumer protection laws and other regulations. As in most markets, most participants attempt to comply with the letter of the law. But frequently federal statutes may fall

[1] In private practice I have, and continue, to advise state legislatures and attorneys general offices on health care competition and consumer protection issues including the need for states to regulate PBMs.

short and provide limited protections. In these situations, state legislation is appropriate. That is why numerous state legislatures are considering and enacting PBM regulations.

I write to you as counsel for the North Dakota Pharmacists Association (NDPhA). As the professional society representing all pharmacists in the state of North Dakota, the objectives of the NDPhA are to: (1) advocate the role of the pharmacist as an essential provider of healthcare; (2) support pharmacists in providing optimal pharmaceutical care; and (3) improve pharmacists' services and delivery of products needed by health care consumers. NDPhA stands fully behind House Bill No. 1332. It addresses much needed reform to the operation of PBMs, helps deter fraudulent and anticompetitive conduct and makes their activity much more transparent.

Through my work with NDPhA I have learned about the unique marketplace for the delivery of pharmaceuticals in North Dakota. Because there are less than 200 pharmacies in a geographically disperse state with few metropolitan areas the pharmacy market is very unconcentrated. In contrast, the PBM market is dominated by a single firm. Pharmacies operate on very low margins and rely increasingly on insurance plans for revenue. The elimination of even a small number of pharmacies can significantly harm North Dakota consumers who, in many instances, already travel significant distances to secure their drugs. That is why the state has enacted patient freedom of choice legislation to assure a diverse set of providers in the market and to protect otherwise underserved localities. *See* N.D. Cent. Code 26.1-36-12.2.

The FTC staff's letter of March 8, 2005 to Senator Richard Brown fails to recognize the nature of the North Dakota market or the legitimate reasons for the proposed legislation.[2] While I respect the views of my former colleagues, I believe their comments on North Dakota's pending PBM legislation are not based on empirical study, ignore the significant problems of fraud and deception in the market and fail to recognize the unique nature of the North Dakota market. Most, if not all, of their viewpoints in the March 8 letter are based upon a theoretical analysis which is not keyed to the PBM market and certainly not North Dakota.

Attached is testimony that I recently gave before the National Legislative Alliance on Prescription Dug Prices ("NLARX"), a bipartisan alliance of state legislators in over a dozen states.[3] The purpose of the NLARX is to facilitate efforts by states to control prescription drug prices. My testimony outlines in detail the numerous state and federal enforcement actions and private consumer protection and fraud cases taken against PBMs. I know of no other market in which there has been such a significant amount of prominent enforcement actions. Many of these actions are led by a multi-state coalition of state attorneys general. Simply put, throughout the United States numerous states are devoting considerable resources to combating fraudulent and anticompetitive conduct by PBMs.

Despite this growing body of hard evidence as to the anticompetitive, fraudulent, and deceptive practices of PBMs, the FTC has remained silent. They have not initiated any significant investigations nor have they joined in any of the state or federal investigations.

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[2] This is not surprising since I believe the staff failed to speak with any of the proponents of the proposed legislation.

[3] I have also attached two other articles that discuss the need for reform of the PBM market.

The Growing Body of Evidence as to the Anticompetitive Practices of PBMs

While the Department of Justice and multiple states Attorneys General Offices have several investigations and significant enforcement actions against PBMs, the FTC has remained on the sideline. Although your committee may be aware of some of these actions, allow me to summarize the most prominent case. On April 26, 2004, the United States, 20 state attorneys generals, and the defendants Merck & Co., Inc., Merck-Medco Managed Care, L.L.C., and Medco Health Solutions, Inc. (together referred to as "Medco"), agreed to a settlement of claims for injunctive relief and violations of unfair trade practice laws.[4] The complaint attacked a wide variety of fraudulent and deceptive conduct by Medco, documenting at length Medco's efforts to prefer higher priced drugs, engage in unwarranted and harmful "therapeutic interchange" and fail to pass on payments to the covered entities.

For this fraudulent and deceptive conduct the states secured $20 million in damages, $6.6 million in fees and costs, and about $2.5 million in restitution to patients who incurred expenses related to drug switching between a set of cholesterol controlling drugs. As important is injunctive relief.

This settlement prohibits Medco from soliciting drug switches when:

- The net drug cost of the proposed drug exceeds the cost of the prescribed drug;
- The prescribed drug has a generic equivalent and the proposed drug does not;
- The switch is made to avoid competition from generic drugs; or
- The switch is made more often than once in two years within a therapeutic class of drugs for any patient.

The settlement requires Medco to:

- Disclose to prescribers and patients the minimum or actual cost savings for health plans and the difference in co-payments made by patients;
- Disclose to prescribers and patients Medco's financial incentives for certain drug switches;
- Disclose to prescribers material differences in side effects between prescribed drugs and proposed drugs;
- Reimburse patients for out-of-pocket costs for drug switch-related health care costs and notify patients and prescribers that such reimbursement is available;
- Obtain express, verifiable authorization from the prescriber for all drug switches;
- Inform patients that they may decline the drug switch and receive the initially prescribed drug;
- Monitor the effects of drug switches on the health of patients; and
- Adopt the American Pharmacists Association code of ethics and principles of practice for pharmaceutical care for employees at its mail order and call center pharmacies.

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[4] Consolidated Case No. 00-cv-737; U.S. District Court for the Eastern District of Pennsylvania. The United States and the following state Attorneys Generals joined in the settlement: Arizona, California, Connecticut, Delaware, Florida, Illinois, Iowa, Louisiana, Maine, Maryland, Massachusetts, Nevada, New York, North Carolina, Oregon, Pennsylvania, Texas, Vermont, Virginia, and Washington.

This case and its settlement was a significant step forward in holding PBMs accountable for their actions, making their activities more transparent, and ensuring that consumers are protected. Further enforcement actions are expected as investigations by over 20 attorneys general continue.[5] For your review and consideration, I attach an index of recent federal and state enforcement actions. To the best of my knowledge, the FTC has not commented on any of these legal actions. Not surprisingly then, the FTC staff's letter relies upon general theoretical reports and studies, and makes no reference to the growing landslide of enforcement actions that states are undertaking against PBMs.

Comments on House Bill No. 1332's Provisions Relating to Contracting with Retail Pharmacies and Restrictions on Certain Drug Substitutes

House Bill No. 1332 is a modest, carefully refined effort to protect consumers in the state. The FTC staff argues that House Bill No. 1332 would limit PBM's freedom in contracting with retail pharmacies and prohibit certain drug substitutions. As detailed below, the FTC staff is mistaken on both counts.

A. Restrictions on Contracting with Pharmacies

In order to assure that consumers receive the full range of benefits from their pharmaceutical plans, the legislation prohibits certain forms of price discrimination among pharmacies. The concerns addressed by the proposed legislation are legitimate. Some PBMs refuse to permit pharmacies to dispense 90-day prescriptions, enabling only mail order pharmacies to dispense long-term prescriptions.

The FTC staff appears to suggest that such price discrimination is efficient, but provides no empirical basis for why that is true, for PBMs generally or PBMs in North Dakota. The FTC staff seems to suggest that the ability to price discriminate will improve "negotiating leverage" by the PBMs against the pharmacies, but there is no reason to believe that the PBMs can not secure whatever price they want for access under the current environment. The FTC staff also seems to assume that pharmacies have some choice as to which programs to participate in or the reimbursement level. But this assumption is belied by the reality of the market. Retail pharmacies in North Dakota are given contracts on a take it or leave it basis with little or no room for negotiation.

As a general matter price discrimination may be harmful, especially when used by a dominant firm to raise entry barriers and harm competition (and that certainly is a possibility in this market). On the other hand, if preventing price discrimination was anticompetitive, as suggested by the FTC staff's comments, then one would expect that the FTC could cite specific enforcement actions against that type of conduct.

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[5] One should not expect that the Merck enforcement action, or other future enforcement actions will completely solve the competitive and consumer protection problems in the market. These actions are time-consuming and costly and solve only the symptoms of the problem. Legislation may the only effective tool to deal with these issues.

The FTC staff also seems to suggest that mail order is less expensive than securing drugs through retail pharmacies. It relies on two dated studies of the issue. More recent studies and articles suggest that consumers may pay more for drugs through mail order or that PBMs favor more expensive drugs through their mail order operations.[6] Mail order might not be less expensive in North Dakota if that market is dominated by a single provider. Moreover, even if that was true that mail order was less expensive the State could appropriately make the judgment that the access, choice, and service provided by retail pharmacies are more important than price.

There are legitimate reasons for the State of North Dakota to seek to prevent these types of price discrimination. North Dakota is a sparsely populated state where consumers may have to travel significant distances to a pharmacy. It is legitimate and sound public policy for the state to adopt a law that facilitates access to a large number of pharmacies and this access may be more important than the ability to negotiate lower prices for pharmacy services. This may be one reason why the state has adopted a statute guaranteeing freedom of choice for pharmacy participation in managed care plans. *See* N.D. Cent. Code 26.1-36-12.2. Certain types of price discrimination could force numerous small town pharmacies out of business. In turn that would create a severe diminution in service for many North Dakota consumers living in rural areas.

B. Prohibitions on Certain Drug Substitutions

I disagree with the FTC staff's claim that House Bill No. 1332 may limit a PBM's ability to effect certain drug substitutions. House Bill No. 1332 specifically identifies the circumstances when drug substitution is allowed, including the option to get a less expensive generic drug in place of a more expensive brand name, and when the substitution is confirmed by a physician to be in the best medical interest of the patient. This provides additional and important safeguards for consumers not already codified under N.D. Cent. Code 19-02.1-14.1(3). Contrary to the FTC's broad claim (unsupported by any empirical evidence) that the language of the bill would make safe and cost-reducing drug substitutions less common, and could increase the cost of pharmaceuticals, the outcome of this section of the bill will insure that the doctor and patient will control any drug substitution, not the PBM. The consumer will still have a choice, and the consumer and his/her doctor will have the final say in whether to allow for a drug substitution.

This is as it should be. The record provided by the numerous enforcement actions either completed or underway indicate that PBMs have engaged in the practice of switching patients' medication to earn financial rewards. This improper drug interchange/substitution has taken place via PBM practice which: (1) induce physicians to switch patient medications by providing misleading, false or incomplete information that subverted patient care to profit motives; and, (2) secretly increase the cost of drugs provided to beneficiaries by knowingly interchanging patients' medications to prevent them from taking advantage of soon to be released available generic drugs. The language of House Bill No. 1332 ensures that PBMs will not be allowed to subvert the intent of a physician in his/her care for a patient, but it does allow substitution for lower-priced generic or therapeutically equivalent drugs once a PBM requests such a substitution. In other words, the physician will have the final say in providing medication to the patient, not the

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[6] Barbara Martinez, "Generic Drugs By Mail Can Be a Raw Deal," Wall Street Journal, Feb.15, 2005 (Page B1).

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PBM. This is an important step forward and an important guard against abusive PBM practices in the area of drug substitution.

Finally, the FTC staff's concern over the definition of "therapeutically equivalent" drugs may no longer be relevant. It is my understanding that this issue was resolved in the other chamber of this Assembly. During the hearings held by the House, the Pharmaceutical Research & Manufacture's of America (PhRMA) noted the possibility for confusion. An amendment was proposed and accepted by the House which corrected this portion of House Bill No. 1332. This provision of the bill is important as it will provide the oversight to complement what is already in North Dakota's statute which guides the prescriptions made by doctors and prescription dispensing by pharmacists

Reasons Why the FTC Staff's Comments are not Relevant to this Legislation

Let me briefly provide several reasons why the FTC's comments are off the mark.

- **The FTC Staff's comments ignore the problems being addressed by the legislation.** As noted above the two provisions seek to address central problems of potentially fraudulent or misleading conduct by PBMs. For example, there have been allegations that PBMs discriminate in providing mail order and ultimately mail order provides higher priced drugs. In addition, there have been allegations that PBMs engage in therapeutic substitution which ultimately leads to the use of higher priced drugs. The proposed legislation seems to be a narrow and refined effort to address both of these problems. It is notable that the FTC's comments do not even acknowledge the existence of these problems. That is not surprising because the FTC unlike several state attorneys general have declined to even investigate these issues.

- **There is inadequate empirical basis to support their arguments.** Rather than relying on investigations or enforcement actions, the FTC staff relies on their healthcare hearings and one merger investigation. The FTC did address PBMs in their healthcare hearings, but those hearings addressed solely the issue of transparency and not the issues of price discrimination, therapeutic interchange, or the fraudulent or deceptive conduct engaged in by PBMs. The FTC staff also mentions an investigation of a merger of two of the largest national PBMs. However, the fact that the FTC might have concluded in the course of that investigation that there was vigorous competition does not suggest whether these firms could engage in deceptive or fraudulent conduct or whether regulation was unnecessary

- **The comments ignore the realities of the North Dakota market.** The FTC staff's criticism of House Bill No. 1332 is based on an inaccurate understanding of the market in North Dakota. Rather than investigate the market prior to providing comments, or basing those comments on the nature of competition in North Dakota, the FTC staff recites facts from a merger investigation that the market is robustly competitive with over 60 PBMs. In fact, in North Dakota a single firm has over 70% of the market. When North Dakota state employees group, the

North Dakota Public Employees Retirement System sent a Request for Proposals, only one PBM participated. The North Dakota market is not vigorously competitive. Moreover, there has been relatively little entry into the North Dakota PBM market. The comments appear to assume that if pharmacies are unhappy with the terms or conditions of a proposed contract with a PBM there are several other PBMs they can turn to. Again, that is simply not the case in North Dakota.

- **The FTC staff ignores the impact of this type of legislation in other states.** For example, in South Dakota similar legislation has led to a savings of over $2 million a year for the state employees' plan.

The FTC staff's position is inconsistent with current marketplace realities (especially those of the North Dakota market) and lacks a sound empirical foundation. The proposed legislation may lead to a more equitable and desirable combination of choice, cost control and quality in the delivery of pharmaceuticals. Moreover there are significant competition and consumer protection problems addressed by this legislation which deserves serious consideration.

I appreciate the opportunity to provide these comments. Please contact me if I can be of assistance.

Sincerely,

David A. Balto

DAB/jeb