John E. Calfee

American Enterprise Institute

1150 17th St., NW, Washington, D.C.

tel: 202-862-7175 -- fax: 202-862-7177 -- email: calfeej@aei.org

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Public Hearings on

"H.R. 4489, the FEHBP Prescription

Drug Integrity, Transparency, and Cost Savings Act,"

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I would like to thank the Subcommittee for inviting me to testify in these hearings on H.R. 4489, "The FEHBP Prescription Drug Integrity, Transparency, and Cost Savings Act. I am a Resident Scholar at the American Enterprise Institute for Public Policy Research, where I have conducted research on pharmaceutical and health care markets. I have also occasionally consulted for firms in the pharmaceutical and related industries. The views I present are my own, not those of any organization including the American Enterprise Institute, which does not take institutional positions on specific legislation, litigation, or regulatory proceedings.

H.R. 4489 focuses on a specific market: prescription drug coverage for federal employees. The legislation would impose a wide variety of restrictions, controls, and mandates,

most of them involving the operations of pharmacy benefit managers (PBMs) in the FEHBP drug benefit. The legislation's most important provisions fall into several categories:

- (1) *Cross-ownership:* PBMs that own retail pharmacies, or are owned by a retail pharmacy or a pharmaceutical manufacturer, or are owned by a health plan that would earn a profit from the PBM's FEHBP business, would be prohibited from FEHBP.
- (2) Financial transparency: New transparency rules would be applied to financial relationships among PBMs, health plans, drug manufacturers, retail pharmacies, and patients. PBMs would also be required to supply the Office of Personnel Management (OPM) with detailed information on their contracts with health plans.
- (3) *PBM price controls:* PBMs would be required to turn over to health plans practically all rebates and other monies received from pharmaceutical firms. PBMs could not reimburse pharmacies less than the amount they receive from health plans. OPM would set the maximum dispensing fee paid to retail pharmacies. In addition, PBMs could not require pharmacies to participate in other networks organized by the PBM.
- (4) *Drug price controls:* Health plans would be prohibited from reimbursing PBMs more than the Average Manufacturer Price (AMP) for drugs; while manufacturers would be required to provide AMP data to OPM.
- (5) *Prescription drug substitution controls:* New restrictions or disclosures would be required in connection with prescription drug "substitutions" arranged by PBMs.
- (6) Restrictions on the use of prescription drug data for marketing purposes: PBMs could not sell utilitzation and claims data without OPM approval.

H.R. 4489 would disrupt long-standing practices in the FEHBP drug benefit. Essentially the same practices are common in the Medicare Part D drug benefit and throughout most of the much larger private sector. In all these markets, health plans, payers, pharmacies, and PBMs have been free to negotiate a nearly infinite variety of arrangements. The proposal to upend these practices in the FEHBP drug benefit raises three questions. First, is there a basis for thinking that the current system works badly? Second, would this legislation succeed in the

difficult task of improving upon such a complex system without generating offsetting adverse consequences? The third question is about the potential effects on pharmaceutical R&D if H.R. 4489 succeeds in its obvious goal of reducing drug prices and therefore limiting the returns to drug development.

Does Competition Work Badly for the FEHBP Drug Benefit?

H.R. 4489 largely rests upon two assumptions. One, addressed here, is that competition works poorly in the drug benefit portion of FEHBP, particularly in connection with the operations of PBMs. The second assumption, addressed in the next section, is that H.R. 4489 would improve the FEHBP drug benefit without causing offsetting adverse consequences.

Competition in the PBM sector is vigorous and multi-faceted. It arises directly from the many services offered by PBMs. Prominent among those services is the assembling of dense networks of retail pharmacies; the operation of mail-order pharmacies; the handling of prescription drug insurance claims; the construction of formularies to determine which drugs are covered in various circumstances; the design and administration of "disease management" plans to deal with chronic medical conditions; the dissemination of information to physicians and patients in conjunction with formularies, disease management, and other matters; the design and use of copayment schedules and other tools to control costs, especially the use of generics; the design and administration of tools to address drug interactions and treatment compliance; and the collection and analysis of massive databases.

Most of these activities invite competition. Three large national PBMs compete more or less everywhere. They are typically joined by dozens of regional or specialty firms. Several large health insurance firms, such as WellPoint, Aetna, and Cigna, operate their own PBMs (FTC 2005, p. iii). Large retail pharmacies, such as Walgreens and RxAmerica, have long operated PBMs (FTC 2005, p. iii). Some retail pharmacies, including Wal-Mart and Walgreens, sometimes bypass PBMs completely by negotiating directly with employers and health plans to provide many services normally provided by stand-alone PBMs (*Wall Street Journal*, May 4, 2009). Large employers have also experimented with working directly with drug manufacturers and pharmacies while also contracting for high levels of transparency; notable examples include Caterpillar, Perdue, and the University of Michigan (*Wall Street Journal*, Dec. 29, 2006).

Finally, drug manufacturers can also bypass PBMs and deal directly with health plans, pharmacies, and doctors.

Thus PBMs compete with each other and with retail pharmacies, large health plans, large employers, and even pharmaceutical manufacturers. As documented in the 2005 FTC report (which examined hundreds of contracts in effect for years 2002 and 2003), the result is a highly diverse set of arrangements. The basic tool is freely negotiated contracts. Some contracts provide for much of what would be required by H.R. 4489, such as pass-through of payments from drug manufacturers, and transparency on payments or on spreads between reimbursements levels. Other contracts conform to the usual view of this market, with health plans concerned mainly with bottom-line results – such as what they actually pay for drugs rather than the details of intervening arrangements and transactions – while leaving it up to PBMs to work out the best deals they can. Basic market discipline is provided by the simple fact that unsatisfied parties, including health plans and employers, can seek alternative terms from competing PBMs and other entities more or less annually.

These circumstances make it unlikely that PBMs have been able to distort drug benefit markets substantially and inappropriately in their favor. Much evidence bears this out. The 2005 FTC staff report explored potential conflicts of interest arising from PBM ownership of mail-order pharmacies (or mail-order ownership by firms that own PBMs). Specifically, the FTC looked for discernable effects on drug prices; on dispensing generic vs. branded drugs; on switching patients from lower-priced to high-priced drugs; on the use and pricing of repackaged drugs (which were rarely used at all); and especially on various indicators of the strength of competition generally in the FEHBP drug benefit. In the course of their work, FTC staff looked into virtually every aspect of PBM operations, based partly on the analysis of a large body of proprietary data for years 2002 and 2003.

In essentially every case, the FTC found little evidence of favoritism or "self-dealing." Total drug prices were actually lower at PBM-owned mail-order pharmacies than at non-PBM-owned ones (FTC 2005, p. vi). Financial agreements between PBMs and manufacturers reflected the dynamics of competition in the relevant drug class; they rarely extended to other brands sold by the same manufacturer (p. ix). (Such product-by-product pricing in the face of competition is typical of many markets involving "channels" or intermediaries; see Coughlin, et al. 2001, p. 360 ff. and citations therein). Agreements on formulary and market share payments

were typically devised in a manner that incentivized PBMs to control health plan's costs, with little regard to whether the PBM was large or small, insurer-owned or retailer-owned, and so on (p. ix). The size and ownership of PBMs had little effect on generic dispensing rates, with the most noticeable disparities apparently explained by such factors as copayment structure, physicians' tendencies to specify "dispense as written," and the occasional PBM's ability to negotiate a brand price below the corresponding generic price (p. x-xi). Switching of patients from one brand to another was extremely rare for all kinds of PBMs (p. xii).

In general, the deeper the FTC probed into the operations of PBMs and related entities, the more reassuring were the results. This was largely attributed to complex, robust, far-reaching, negotiation-driven competition. Reports from other federal agencies, while far less detailed and more reliant upon secondary literature rather than original data analysis, have reached largely consistent conclusions. Among these are three reports from the Congressional Budget Office (CBO 2007a, 2007b, and 2008) and two from the Government Accountability Office (GAO 2003 and 2009). The 2003 GAO report, for example, found that FEHBP enrollees paid the lowest prices for 30-subscriptions when purchasing through PBM-owned mail-order pharmacies.

Is H.R. 4489 Likely to Improve the FEHBP drug benefit?

H.R. 4489 would greatly narrow the choices available to health plans and other market participants. Given the complexity of the FEHBP drug benefit market and the freedom with which sophisticated parties can negotiate nearly any arrangement they desire, a natural question is whether H.R. 4489 is likely to improve the market by preventing health plans from doing what they would sometimes prefer to do. Unfortunately, the main interventions proposed in H.R. 4489 are more likely to burden FEHBP drug beneficiaries than to help them.

The plan to force transparency upon drug price negotiations and other financial relationships raises two problems. One is that in the PBM market, many prices involve bundles rather than a single clearly defined item. This is typical of intermediaries or channels (i.e., "middlemen") in many if not most large markets, such as grocery retailing. Often, what appears to be a price for a specific product also includes various services (delivery, carrying charges, etc.) which are not separately priced (Coughlin, et al. 2001; Monroe 2003, p. 409-421). The

same is true of rebates, which are also common in channels (cf. Coughlin, et al. 2001, p. 241, on grocery retailing). As the FTC staff notes in its 2005 report, seemingly simple data on drug reimbursement levels may reflect the inclusion of certain services (p. vii-viii). Any attempt to make prices transparent will therefore require delving deeply into the operations of health plans and others. The second problem with mandated transparence is that economic reasoning strongly indicates that price transparency would invite price-matching by other firms, the prospect of which would eliminate the advantages that manufacturers and PBMs could gain from negotiating discounts. This would undermine incentives to engage in price discounting in the first place (e.g., FTC Sept. 7, 2004).

Also inimical to competition, including competitive discounting, would be a requirement for PBMs to pass through essentially all rebates and other monies received from pharmaceutical manufacturers. This would leave little incentive for PBMs to negotiate rebates – which amount to price discounts – and would essentially turn that task over to health plans and others, who may be far less effective.

Explicit price controls, which rarely do good in non-monopoly markets, are unlikely to provide benefits in the PBM sector of FEHBP. H.R. 4489 would prohibit PBMs from negotiating a "spread" between what they pay for drugs and reimbursement levels to pharmacies. This would discourage PBMs from seeking to reduce dispensing fees or seeking lower prices from drug manufacturers, both of which normally reduce health care costs. In addition, the enforcement of this provision would provoke excessive market intervention in order to disentangle the various services that are often bundled with the provision of drugs to pharmacies (see FTC 2005, p. vii-viii, on pricing and bundling). (Disputes over fees and prices are endemic in channels; see Coughlin, et al. 2001, and Iyer and Villas-Boas 2003). On the other hand, H.R. 4489's provision for OPM to set a maximum dispensing fee paid to pharmacies would require OPM to unravel the true costs of drug dispensing (along with bundled ancillary services) and then set a ceiling without disrupting the entire prescription drug distribution system. There is no reason to think this would reduce costs or improve access.

The ownership restrictions that would be imposed by H.R. 4489, particularly the effective prohibition on retail pharmacy-owned PBMs, would limit competition and reduce efficiency by depriving the market of the advantages of "vertical integration." In a market as competitive as that for the services provided by PBMs, there are compelling theoretical and empirical reasons to

think that vertical integration is far more likely to reduce prices than to increase them (FTC 2005, p. v-vi). This is partly due to the efficiencies that motivate vertical integration in the first place, and also to the ability of vertically integrated organizations to avoid the "double marginalization" that increase prices unduly as products pass through unnecessary levels of independent firms.

In adding new regulations to the design and operation of drug formularies, again, there is little reason to expect H.R. 4489 to bring improvements for patients. Formularies are typically designed by independent pharmacology experts in consultation with health plans and payers. When therapeutic efficacy is involved, as when encouraging patients to move from one cholesterol-reducing drug to another, the primary tool is differential co-payments and appeals to physicians, leaving physicians and patients free to make decisions. State laws largely prevent more aggressive measures. Little evidence has emerged of problematic formularies designed by PBMs. In its Sept. 7, 2004 letter, the FTC staff emphasized that unwise restrictions on PBMs could discourage useful, cost-saving drug substitutions.

Finally, there is the matter of PBM sales of utilization and claim data without OPM approval. Should OPM balk at such sales – as seems likely, simply because the drafters of H.R. 4489 took the trouble to include this provision in the bill – the probable effect would be to inhibit useful activities including better targeting of drugs and information about drugs.

H.R. 4489 and Pharmaceutical R&D

One apparent goal of H.R. 4489 is to reduce the prices paid to drug manufacturers. Health plans would be prohibited from reimbursing more than average manufacturer prices (AMP). AMPs are based on economy-wide sales prices, not just those in FEHBP. Whatever the intention effects of the AMP provision, H.R. 4489 would probably fail to reduce overall drug prices because manufacturers would probably respond by adjusting prices throughout the market. This is clear from experience with "best-price" regulation in Medicaid, where the net effect of forcing a gap between Medicaid and non-Medicaid drug prices was to increase non-Medicaid prices (Morton 1997).

Nonetheless, by controlling the relationship among prices in different markets, H.R. 4489 would invite scrutiny of drug prices from the perspective of OPM. That agency is likely to be far

more interested in reducing drug prices than in motivating the development of new drugs or new uses for existing drugs. I am unaware of any evidence that American branded drug prices are too high and therefore induce too much R&D. With price controls being prevalent in all other advanced economies, the U.S. market is the only large market in which largely unregulated competition among pharmaceutical buyers and sellers shapes and rewards drug development. The fact that H.R. 4489 tends to upset that situation is cause for worry.

Conclusions

H.R. 4489 contains many provisions that would inhibit rather than enhance basic functions in the FEHBP drug benefit. Restrictions on cross-ownership between PBMs and retail pharmacies, health plans, and drug manufacturers would reduce efficiency without providing tangible benefits in terms of health care costs or patient welfare. Broad transparency requirements would inhibit competition to reduce drug costs, again without providing significant benefits. Finally, controls over pricing by PBMs, pharmacies, and health plans would bring detailed intervention by OPM, would disrupt many of the most efficient arrangements now prevailing in the FEHBP drug benefit market, could easily raise costs, and would open the door to the suppression of formerly market-based drug prices and therefore threaten R&D incentives.

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