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April 12, 2013

Senator Rosalyn H. Baker
Hawaii State Capitol, Rm. 230
415 South Beretania St.
Honolulu, HI 96813

Representative Della Au Belatti
Hawaii State Capitol, Rm. 331
415 South Beretania St.
Honolulu, HI 96813

Re: House Bill 65

Dear Senator Baker and Representative Belatti,

I write in support of House Bill 65 ("Bill" or "HB-65") which will allow beneficiaries of a prescription drug benefit plan the choice to purchase prescription drugs from a mail order pharmacy or a local retail pharmacy. This Bill would preserve patient choice and thereby protect the important competition among pharmacies that leads to improved service at decreased costs. Below we provide brief background on pharmacy benefit managers (PBMs), address the importance of the Bill, how it encourages greater competition among pharmacies, and enhances the welfare of consumers. We then address the ERISA issue and explain why the legislation is not preempted by ERISA.

I write to you based on my experience of over a quarter century as an antitrust and consumer protection attorney, and as a former antitrust enforcer with the Antitrust Division of the Department of Justice and The Federal Trade Commission (FTC). At the FTC, I was the Policy Director and attorney advisor to Chairman Robert Pitofsky. I helped bring some of the first antitrust cases against PBMs and have testified before Congress, regulators, and state legislatures on PBM competition. I have testified before Congress four times and before ten state legislatures on PBM reform issues and have served as an expert witness for the State of Maine on PBM regulation.[1]

Background

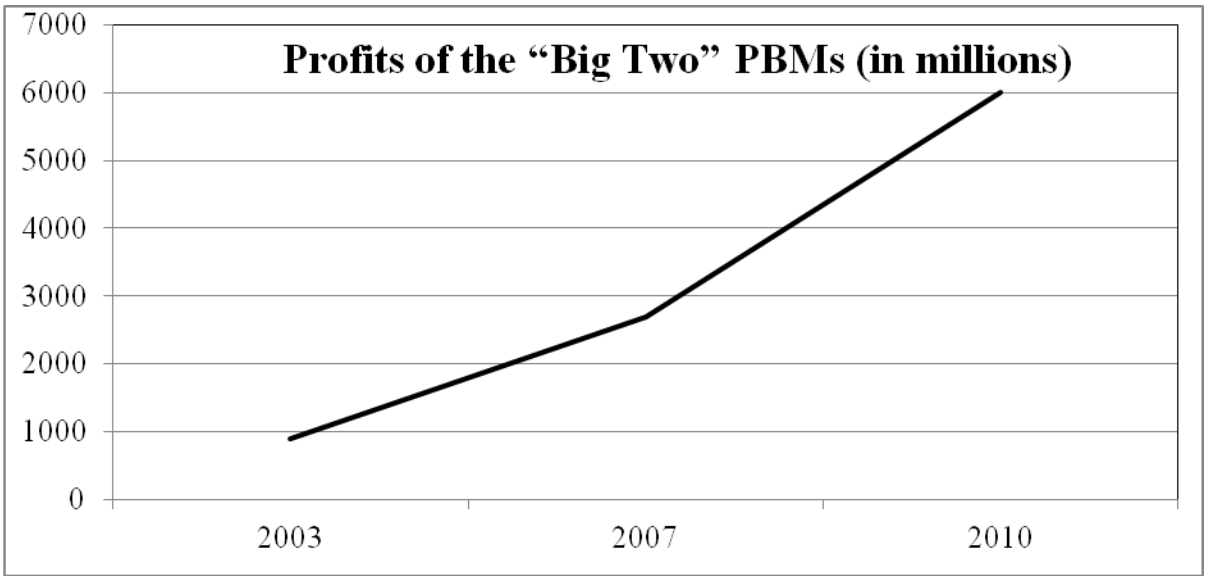
Pharmacy Benefit Managers are one of the most problematic, least regulated and least understood aspects of the healthcare delivery system. Over 80% of pharmaceuticals in the United States are purchased through PBM networks. PBMs serve as intermediaries between health plans, pharmaceutical manufacturers and pharmacies, and PBMs establish networks for consumers to receive reimbursement for drugs. Although the primary function of a PBM

[1] *See* David Balto, Advocacy and Testimony, available at http://www.dcantitrustlaw.com/index.php?id=9.

initially was simply to create networks and process pharmaceutical claims, these entities have exploited the lack of transparency and created conflicts of interest which have significantly distorted competition, reduced choices for consumers and ultimately increased the cost of drugs.

One of the key conflicts of interest is when a PBM owns its own mail order operations. When a PBM is integrated in this fashion it no longer serves as an honest broker, seeking the lowest cost of dispensing or the lowest cost of drugs. That is why PBMs that own mail order dispense a smaller proportion of generic drugs than community pharmacies. Ultimately the lower generic substitution rate leads to higher costs for consumers and health plans.

The PBM market is dominated by two PBMs, ESI/Medco and CVS Caremark who together control over 80% of the market for large health plans. Because the two largest PBMs' operations are clouded in secrecy and are replete with significant conflicts of interest, PBMs have effectively increased the cost of drugs over the past several years and have seen their profits skyrocket from $900 million a year to over $7 billion a year at the expense of payors and consumers. Much of the rise in the cost comes from PBMs' use of mandatory mail order.



HB-65 encourages greater competition among pharmacies and enhances consumer welfare

HB-65 enhances competition by providing consumers greater choice and the ability to use their community pharmacy. Setting aside the cost to the health plan, community pharmacies are preferable in several respects. Community pharmacies offer health care counseling for consumers, and in inner city or rural areas a community pharmacist may be the closest and most accessible health care provider. Mail order may be a risky proposition in some inner city neighborhoods. Numerous drugs, especially those that need special handling or counseling are delivered more effectively in a face-to-face interaction with a pharmacist. Forcing consumers into "mandatory" mail order clearly reduces consumer choice and deprives consumers of the services they often need.

This Bill will be a significant spur to competition by putting mail order and community pharmacies on a level playing field. By protecting the ultimate consumer's ability to utilize their pharmacy of choice, this Bill would force mail order companies to compete with retail pharmacies on cost and quality of service. This competition for patients represents an important level of rivalry among pharmacy businesses that will result in improved service for the patients of both mail order and retail pharmacies.

HB-65 preserves a patient's ability to choose their own provider, which is a basic concept of competition. The Bill clearly enhances consumer welfare by protecting patient choice and increasing access to what the individual consumer deems as proper pharmacy care. It further increases convenience by enabling consumers to receive pharmacy service from a broader array of providers. Moreover, by forcing mail order businesses to directly compete with the service provided by retail pharmacies, consumers will benefit from improved pharmacy services and decreased costs.

HB-65 will also benefit health plans. Currently health plans often pay more for mandatory mail order programs for two reasons. First, mandatory mail order programs compared to retail pharmacies are less effective at generic substitution and have higher cost generics. [2] Second, there is far more medication waste from mandatory mail order programs than from retail pharmacy.

ERISA will not preempt this Bill

The Employee Retirement Income Security Act ("ERISA") covers most employee benefit plans, including health plans, and provides detailed standards under the goal of uniformity to protect employee pension plans from fraud and mismanagement.[3] As a result, generally ERISA can preempt state laws that "relate to any employee benefit plan."[4] ERISA does however have a savings clause that saves from preemption state laws governing the "business of insurance" so long as the State's law is "limited to entities within the insurance industry" (e.g., limited to entities such as insurance companies).[5]

Similar bills to HB-65, proscribing mandatory mail order, have been passed in New York and Pennsylvania. These laws took the ERISA preemption issue into consideration when they were drafted and enacted into law, and neither is preempted, nor have they been challenged by ERISA. These bills both seek to regulate health insurance policies which provide coverage for

[2] Norman V. Carroll, *A Comparison of the Costs of Dispensing Prescriptions through Retail and Mail Order Pharmacies: Final Report to the NCPA Foundation*, Virginia Commonwealth University (Feb. 2013).
[3] 29 U.S.C. § 1001, *et seq*.
[4] 29 U.S.C. § 1144(a).
[5] 29 U.S.C. § 1144(b)(2)(A).

prescription drugs.[6] Under the insurance regulation savings clause, states can regulate the terms and conditions of health insurance, for example, the benefits in an insurance policy or the rules under which the health insurance market must operate. Moreover, the federal courts have narrowed the broad interpretation of ERISA preemption of state laws and have expressed reluctance to find state laws preempted by ERISA. *See, e.g., N.Y. State Conf. of Blue Cross and Blue Shield Plans v. Travelers Inc. Co*., 514 U.S. 645 (1995).

HB-65 will not be preempted by ERISA for a number of reasons. First, the provisions of this Bill only have an indirect impact on ERISA plans. The Bill merely provides that plans allow beneficiaries the option to choose to obtain prescription drugs through the mail or at a retail pharmacy. The Bill does not preclude the uniform administrative practice or provisions of an interstate prescription drug benefit package; the Bill does not place on plans restrictions on the amount to which prescription drugs are covered; the Bill does not mandate coverage of a particular drug; the Bill does not create any new mandated benefit plans must provide; and the Bill does not provide for a plan beneficiary to use an out of network provider. The Bill simply allows the consumer to choose which pharmacy in their network they would like to use. The Supreme Court has held that such indirect impact on an ERISA covered plan is insufficient to "relate to" plans for the purposes of ERISA exemption. *See Travelers Inc. Co. 514 U.S. at 654*.

Second, the Bill's regulation of "prescription drug plan[s]" clearly falls into the ERISA savings clause. The definition of "prescription drug plan" is an insurance plan that includes coverage for prescription drugs. As the Supreme Court has explained this unambiguously is a governance of the "business of insurance" limited to entities that are insurance companies. *See KY Ass'n. of Health Plans, Inc. v. Miller*, 538 U.S. 329, 342 (2003) (A state law "regulates insurance" if it is "specifically directed toward entities engaged in insurance.").

Finally, PBMs are not ERISA-covered entities. HB-65 also purports to regulate pharmacy benefit managers. PBMs are not ERISA-covered entities, and therefore are not subject to ERISA preemption. PBMs can potentially be regulated under ERISA as a fiduciary to an employee benefit plan,[7] however HB-65 does not require PBMs to act as fiduciaries; and with the exception of a Maine statute,[8] PBMs have not been found to be fiduciaries under ERISA. *See e.g., Glanton v. AdvancePCS Inc.,* 465 F.3d 1123 (9th Cir. 2005); *Bickley v. Caremark RX, Inc.,* 461 F.3d 1325 (11th Cir. 2006); *Central States SE & SW Areas Health and Welfare Fund v. Merck-Medco Managed Care, LLC*, 433 F.3d 181 (2d Cir. 2005).

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[6] The New York bill specifically exempts a "policy that is the result of a collective bargaining agreement between an employer and a recognized or certified employee organization" (i.e. self-insured plans) because self-insured plans are not exempt under ERISA.

[7] 29 U.S.C. § 1104(a)(1) (discusses duties of third-party fiduciaries).

[8] Despite the fact that PBMs are required to be fiduciaries under Maine law ("PBM Act"), the First Circuit Court of Appeals found that the PBM Act did not have a connection with ERISA plans because it does not interfere with the national, uniform administration of ERISA-covered plans. *Pharmaceutical Care Management Ass'n. v. Rowe*, 429 F.3d 294 (1st Cir. 2005). Moreover, the First Circuit found the PBM Act to not be preempted under ERISA because the requirements in the law do not restrict the freedom of employers to structure and administer their plans in Maine in the same manner as employees elsewhere. *Id.* at 303.

Thus, we strongly believe the legislation raises no ERISA issue and would survive any legal challenge under ERISA.

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HB-65 will protect the patient's ability to choose their pharmacy provider, and thereby allow competitive forces to better control cost and quality in the delivery of pharmaceuticals. The Bill will broaden access to pharmaceutical services and increase the welfare of all Hawaii residents. Furthermore, as drafted, there is no ERISA preemption issue. HB-65 is limited in its influence on ERISA plans such that its provisions will not related to plans for the purposes of preemption. Further, the entities the Bill regulates either fall into the ERISA savings clause and do not risk federal preemption, or are not ERISA-covered entities, and therefore not subject to ERISA preemption.

I strongly support HB-65 and urge that it be signed into law.

Sincerely,

David A. Balto