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Expert Opinion

Pharmacy benefit design: Johnson & Johnson lawsuit ushers in new 'duty of prudence' standard

Regardless of its outcome, this class action will dramatically change pharmacy benefit management and the standard of care to which management will be held on benefit design.

By **Jonathan E. Levitt, Esq.** & By **Dae Y. Lee, Pharm.D., Esq., CPBS** | March 12, 2024 at 07:36 AM

A groundbreaking lawsuit was filed on February 5, 2024, by a class of Johnson & Johnson (JNJ) employees against JNJ and the Pension & Benefits Committee, as well as the committee members (collectively, the "trustees"). Regardless of

its outcome, this class action will dramatically change pharmacy benefit management and the standard of care to which management will be held on benefit design.
Large employers looking to avoid copycat employee class actions have an urgent need to exercise prudence and diligently audit their pharmacy benefit managers (PBMs). The Employee Retirement Income Security Act (ERISA) establishes that health care plans, including prescription drug benefits and trustees owe employees a fiduciary duty of "loyalty" and "prudence" in managing pharmacy benefit design. This duty extends to deciding what drugs get placed on formulary and what drugs are excluded from formulary, and understanding rebates and amounts paid to employee benefit consultants.

The JNJ class action alleges that trustees mismanaged employee prescription drug benefits by selecting the wrong PBM, the wrong benefit consultants, by failing to collect all rebates and through formulary mismanagement. It is now a "sue or be sued" atmosphere in the pharmacy benefits industry. Plans can audit and potentially file suit against their PBM, or they can fail to audit, and get sued by employees. Trustees permitting the "status quo" of opaque operations of PBMs will no longer meet the standard of care.

A wake-up call for plan sponsors

The class action complaint lodged against JNJ shines the spotlight on very specific and disturbing drug pricing practices. The company allegedly paid over $10,000 for a medication readily available on the market for $50. Plaintiff's counsel wisely spotlighted drugs that are not rebated; thus, the plan trustees likely cannot answer the complaint by alleging that rebates brought the net price down to the cash price.

Another focal point is the relationship between JNJ, its PBM, Express Scripts, Inc. (ESI), and JNJ's benefits consultant, Aon. The complaint alleges that Aon had undisclosed financial motivations and conflicts of interest in recommending ESI.

While JNJ is likely to file a motion to dismiss, plan trustees should carefully watch the court's analysis of the fiduciary duty and duty of prudence owed by plan trustees. Although the duty of prudence owed in each case is context-specific, in the investment context, plan sponsors are obligated to monitor investment options and remove imprudent ones, such as "higher priced" funds "when materially identically lower priced" funds were available. *Tibble v. Edison Int'l*, 575 U.S. 523, 523 (2015). Exploring a lack of prudence, the lawsuit claims JNJ's committee failed to adequately consider non-traditional PBMs and neglected to conduct periodic requests for proposal (RFPs) that might have

identified more cost-effective, pass-through pricing models. This alleged breach of fiduciary duty potentially led to higher costs for plan participants, driven by PBM spread pricing, rebate retention and other PBM profit motives. Another duty of prudence will involve contract negotiation. The complaint alleges JNJ breached its duty of prudence by selecting the wrong PBM, failing to negotiate favorable PBM contract pricing terms and allowing the self-interested PBM to develop the plan's formulary. For example, JNJ and trustees allegedly selected ESI to be theplan's PBM without a formal RFP for various services including, without limitation, drug prices, formulary management, pharmacy networks, and administrative services. In doing so, the class action alleges that JNJ and trustees allowed ESI to take full control of the formulary that resulted in significant spread in prescription drug reimbursement. Plans should consider whether the duty of prudence is adequately honored by allowing the PBM to prioritize more expensive drugs over generics, potentially at the expense of plan participants.

The duty of prudence extends to all contract terms, including what pharmacy the plan allows the PBM to select. The complaint alleges that JNJ permitted ESI to steer plan participants towards more expensive options at ESI's wholly owned specialty pharmacy. Plans should consider the duty of prudence when deciding whether to use alternative vendors offering lower-cost solutions, compared to the PBM-owned specialty pharmacy.

This benefit design class action is a harbinger of a trend against plan sponsors and trustees that failed to honor their duty of prudence. The Consolidated Appropriations Act (CAA) has clarified the plans' fiduciary duties to monitor their PBMs and brokers. Plans must ensure that any compensation paid, directly or indirectly, to PBMs and consultants, is reasonable and justifiable.

Fiduciary duty: twin obligations of loyalty and prudence

The fiduciary duty has two components: Trustees and plans must act with a duty of both loyalty and prudence when handling plan assets. The duty of loyalty requires fiduciaries to act solely in the interest of plan participants and beneficiaries. Concurrently, the duty of prudence mandates the exercise of care, skill, prudence, and diligence in the management and administration of the plan. The class action alleges that JNJ failed to meet these obligations when it came to negotiating and managing the PBM relationship and pharmacy benefit plan design. JNJ allegedly allowed ESI to retain rebates, engage in spread pricing, and design formularies that significantly inflated costs for plan participants.

Conflicted brokers and consultants in the trustees' fiduciary obligations

The JNJ class action requires plans to look more carefully at employee benefits consultant relationships. Honoring the duty of prudence requires careful vetting of brokers for potential conflicts of interest. The case of Osceola School District against its broker, Gallagher, is another ongoing consultant litigation. In JNJ, the plaintiff alleges that Aon had a significant conflict of interest. Aon was compensated by ESI for steering JNJ's plan towards ESI as the PBM. The class raised concerns about the impartiality of Aon's recommendation, pointing to a breach of fiduciary duty in the selection process. ERISA requires plan fiduciaries to obtain written disclosure of all direct and indirect compensation that a service provider, such as a broker or PBM, receives while servicing the plan. The plaintiff contends that JNJ failed to recognize or address this conflict of interest.

Similarly, the Osceola School District's settlement with its broker, Gallagher, over undisclosed payments from insurance carriers, underscores the need for transparency and due diligence. Conflicts of interest can lead to plan recommendations that may not align with the best interests of plan sponsors and their beneficiaries, breaching the fiduciary duty of loyalty.

JNJ and Osceola School District are cautionary tales that emphasize the importance of scrutinizing agreements between plans and brokers. To protect the interests of plan participants and comply with fiduciary duties, plan sponsors must demand transparency on broker compensation and search for potential conflicts of interest. Fulfilling this diligence as to broker compensation is essential for plan sponsors to honor the duty of prudence, safeguard against conflicts, and avoid employee class actions. It is also worth noting that conflicted brokers and consultants set up coalitions to place additional limits on plan sponsors' ability to access information about their drug costs and their ability to analyze claims data.

Expanding the discourse: beyond compliance

While adherence to fiduciary duties is critical, a deeper issue plagues the PBM landscape: the opacity resulting from vertical integration among PBMs, insurance carriers, specialty pharmacies and rebate aggregators. This complexity exacerbates the challenges plan sponsors face. Vertical integration, the process where companies within the same supply chain merge or are owned by a single entity, has become a defining characteristic of the PBM industry. Consolidation causes the clear potential for conflicts of interest, lack of transparency, and adversely impacts pharmacy benefit design.

When PBMs, insurers, rebate aggregators and pharmacies are under the same umbrella, the competition is stifled, and the incentive to prioritize patient care and cost efficiency can diminish. This environment necessitates a proactive approach from plan sponsors, demanding greater disclosure and clarity in their dealings with PBMs and other health care providers. For example, the lawsuit filed by Ohio's Attorney General against Express Scripts and Prime Therapeutics, alongside five other PBMs, underscores the gravity of these concerns. The legal action alleges that these companies engaged in practices that artificially inflated drug prices and deprived consumers of cheaper drug options, highlighting the dire need for regulatory scrutiny and reform within the industry. Such practices not only undermine the fiduciary duties of plan sponsors, but also the broader goal of accessible and affordable healthcare. Pictured below is the current vertically-integrated PBM landscape.

Plans must audit PBMs and rebate aggregators

For self-funded employers, the urgency to audit PBMs has never been greater. Effective PBM audits uncover hidden fees, rebate discrepancies, formulary design flaws, and spread pricing practices that inflate plan costs. More importantly, audits satisfy the fiduciary duty of prudence, demonstrating a commitment to managing plan assets responsibly and in the best interest of participants.

Pharmacy benefit design is fraught with challenges that require vigilant oversight and proactive management. The JNJ lawsuit underscores the potential legal and financial ramifications of failing to adequately audit PBMs and vet brokers.

Conducting thorough audits of PBMs should no longer be seen as optional, but rather an essential component of the duty of prudence. Moving forward, best practices to ensure compliance with the twin duties of loyalty and prudence will likely include, at a minimum, that the plan sponsor: (i) demand transparency about compensation and any potential conflicts of interest, and (ii) retain industry experts to navigate the complexities of PBM contracts and management. Leveraging legal insights can empower plan sponsors to make informed decisions and implement best practices in plan administration.

Conclusion

Recent employee class action lawsuits require plan sponsors to rethink their pharmacy benefit design. Plans must honor the fiduciary duty of "prudence" by auditing their PBM and employee benefit consultants. The JNJ class action is a critical reminder of the importance of fiduciary duties in employee benefits plans. By taking decisive steps to audit PBMs, vet brokers, and ensure compliance with fiduciary obligations, plan sponsors can protect themselves from liability and safeguard the interests of their plan participants.

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