Lewandowski v. Johnson & Johnson

Chapter One: The Beginning of a New Era

Prescription Drug Fiduciary and Document Claims Are Here to Stay
Time to Study, Learn, Prevent and Succeed

This lawsuit is a game changer. Just like the 401(k) retirement plan fee cases brought more than twenty years ago, this lawsuit has real impact. Regardless of its outcome, the claims against Johnson & Johnson ("J&J") in the proposed class action litigation brought by Ann Lewandowski, have generated industry wide focus and concerns regarding group health and prescription drug plan strategies, approaches and compliance. This lawsuit puts a spotlight on the fundamental principles of ERISA fiduciary responsibility and plan document compliance on all health and prescription drug plans.

Many important questions are being asked. Did the J&J internal fiduciary Committee get it wrong? Are these claims legitimate? Would J&J allow its covered persons to have to pay such huge amounts for drugs when lower cost options are available? Does J&J not have a compliant prescription drug plan document and summary plan description?

Motivated by the lawsuit's claims, plan sponsors, benefits brokers, advisors and consultants are now working to assess the claims and to reexamine and focus their efforts on understanding the merits of the claims, the impact of these claims on health and prescription drug plans, and how the claims affect what each of them does, every day.

Naturally, a number of industry professionals have written commentary on this lawsuit. Candidly, many commentators have *completely missed* some very important elements of the claims, the nature of the claims, and what may actually be missing from the claims. Notably, those of us with experience on both sides of the proverbial ERISA aisle – the retirement plan as well as the group benefit plan sides, immediately see the parallels of these ERISA fiduciary claims to those that continue to impact the retirement plan community. We immediately think about the nature of the allegations, and how they likely will be pursued by the Plaintiff, and how they likely will be defended by the J&J Defendants.

This begins a series of writings, in which we will examine the nature of the allegations, how Plaintiff will and does pursue such claims, and how the J&J Defendants may and do defend against them. And, as the case proceeds, we will comment on those efforts, not just to report on them, but to analyze the impact of this case upon our plan sponsors, brokers and other industry players.

Within this effort, we will not take sides. True learning here is essential. To do that effectively, we will approach our evaluations in a balanced way with the primary goal of assessing the impact of the ERISA fiduciary rules on the group health and pharmacy benefit plan industry, the critically important and noted plan documentation challenges, and the other features of this lawsuit that will serve to benefit the industry as a whole.

The Lawsuit Basics

A study of this lawsuit, the parties and the claims begins with the basics. On February 5, 2024, Ann Lewandowski, a participant and covered person under what is described as the Group Health Benefits Plan of Johnson and Johnson and Affiliated Cos., sued J&J and an administrative

Committee, its individual members, including members of management, in a 75-page class action lawsuit. (*Lewandowski v. Johnson & Johnson,* D.N.J., No. 1:24-cv-00671). Plaintiff alleges various breaches of ERISA fiduciary duties best summarized at a high level as gross mismanagement of prescription drug benefits. These prescription drug benefits are provided under medical plans sponsored by J&J (the "J&J Rx Plan"). Noting that J&J is also a pharmaceutical manufacturer, Plaintiff alleges that mismanagement led to millions of dollars in higher payments, higher premiums, higher deductibles, higher co-insurance, and more.

Notably, a Complaint, which is the starting point of a lawsuit, has certain requirements. First, the Plaintiff must have standing – or the right to bring the claim. Federal law is particular about this concept, which is actually derived from Article III of the U.S. Constitution. Next, if there is standing, Plaintiff must satisfy something referred to as the "notice pleading rules." The lawsuit does not have to contain every single assertion of fact, or every allegation or point of proof. It has to be sufficient to raise facts that demonstrate some type of violation of law, and under federal constitutional requirements, it must have resulted in some harm or damage. In response to a lawsuit, the J&J Defendants must file an Answer, or they can move to dismiss the case in its entirety. A motion to dismiss will happen here, and we will include that part of the case in our study.

Unpacking the allegations is no simple task. And, we will not address every claim in detail in this first Chapter. Over time, we will address many of the allegations and related concepts. To start, we will provide an overview of the claims. In general, the lawsuit claims assert that J&J, through its committee and individuals as ERISA fiduciaries, failed to:

- Exercise required fiduciary prudence before selecting a PBM;
- Exercise required fiduciary prudence in agreeing to make its ERISA plans and beneficiaries pay unreasonable prices for prescription drugs;
- Exercise required fiduciary prudence in agreeing to contract terms with its PBM that needlessly allows the PBM to enrich itself at the expense of the company's ERISA plans and their beneficiaries (including the failures to monitor the drug formularies, supervise conflicted third parties, or to conduct an adequate review);
- Properly carve out their specialty-drug program from their broader contract with the PBM;
- Protect plan assets and beneficiaries' interests (by failing to steer beneficiaries to lower cost options);
- Actively manage and oversee key aspects of the company's prescription-drug program; and
- Failed to provide the ERISA required plan document and summary plan description upon request.

No Plan Document/Summary Plan Description?

A critical error would be to trivialize the allegation that J&J failed to produce the ERISA required Plan Document (ERISA §402) and Summary Plan Description ("SPD")(ERISA §102). A properly constructed Plan Document/SPD is not only legally required, but essential to the overall operation, management and delivery of prescription drug benefits. Besides, a cogent Claims Procedure (ERISA §503) might have allowed the Defendants to address certain of the claims before the lawsuit in an administrative process. The commonly provided prescription drug schedules of benefits and related flyers and hand-outs just don't cut it, especially when plan design calls for the management of prescription drug use and costs. Properly tuned documentation creates

the rules to manage the various aspects of solid prescription drug benefit designs and includes formulary designations, step therapies, drug exclusions, specialty protocols, other exclusions and restrictions, carve outs, potential patient advocacy and alternate funding (a whole other topic), networks, supply rules, generic drug access and more.

Is it true that J&J does not have a Plan Document/SPD for the J&J Rx Plan? Perhaps, but not likely. But, even if it does, the failure to produce such documents comes with a potential penalty of up to $110/day per violation (ERISA §502(c)). If Plaintiffs can generate multiple unmet requests on this point, with more than 130,000 employees, that theoretically adds up.

It is possible that J&J does not and did not have a full or complete Plan Document/SPD and that J&J used grossly inadequate hand-out types of documentation. Why? Because, unlike group health insurers, PBMs have just not been in the plan document business. This is a huge gap in the industry that is potentially exposed by this lawsuit. There are virtually no third party resources for self-funded plans to obtain a separate Prescription Drug Plan Document/SPD, except for ERISA lawyers, which is an expensive but capable resource, and **EZ ERISA,** at www.ezerisaplan.com, an existing compliance website that fortuitously launched a complete Doc*Smart* Rx Product last summer. (For full disclosure, this author created this compliance resource website some ten years ago).

If J&J does not actually have a fully compliant Plan Document/SPD, everything that J&J would like to enforce and manage regarding the J&J Rx Plan is subject to challenge and may be completely unenforceable.

So, **Lesson 1** is to make sure that if you use a separate PBM for your Prescription Drug Plan, make sure you have a fully compliant, complete Prescription Drug Benefit Plan Document and SPD.

What is Missing in the Fiduciary Claims?

Questions arise from the lawsuit that compel consideration of the ERISA fiduciary roles and responsibilities. How is the selection of a PBM an ERISA fiduciary function? Are all acts by the J&J Committee and its members subject to the ERISA fiduciary standards? Are actions by the PBM subject to the ERISA fiduciary rules? These questions are critically important in the evaluation of the claims, and in our learning about what we do to ensure that in the group health and prescription drug benefit space, we are complying with the ERISA standards.

Importantly, there appear to be concepts that relate to the existence of an ERISA fiduciary relationship and fiduciary functions that are not stated concisely in the lawsuit. Critically important to Plaintiff's claims regarding the selection of PBM Express Scripts, is that the selection of an ERISA fiduciary is a fiduciary process. That begs the question as to whether Express Scripts is a fiduciary relative to the prescription drug benefit plan.

The threshold fact to determine fiduciary status is that Express Scripts must perform ERISA fiduciary functions for the J&J Rx Plan to make the selection of Express Scripts a fiduciary determination by the Committee. This determination begins with an assessment of the roles and responsibilities of Express Scripts as the PBM.

Notably, there are functions that relate to ERISA plans that are non-fiduciary functions that may be performed by the plan sponsor or third parties. Non-fiduciary functions include the

sponsor's right to establish a plan of benefits and determine the rules and plan design for such a plan. Non-fiduciary functions also include ministerial acts. These often include basic calculations, which for prescription drug plans, includes, for example, the amount of a deductible or co-pay that applies to a prescription, or determining if a particular supply line is in-network or out-of-network.

There are other functions that refer or relate to the exercise of any discretionary authority or discretionary control respecting management of such prescription drug plan, or the exercise of any authority or control over the disposition of the J&J Rx Plan assets. Similar in concept to the third-party administrator that administers a self-funded group health plan, a PBM acts to administer prescription drug benefits. When a PBM has such discretionary responsibility or authority in the administration of an ERISA plan, the PBM is an ERISA fiduciary. For example, the approval of the payment of a prescription drug for a covered person is a fiduciary function. A PBM often controls and moves the plan's money to pay for a claim, which is the control over a plan asset and, again, a fiduciary function. The determination of medical necessity is generally a fiduciary function. Claims processing determinations and appeals are fiduciary functions.

So, under ERISA, *the selection of an ERISA fiduciary is a fiduciary function*. In this case, the selection of Express Scripts as a PBM will likely be determined to be a fiduciary function, even though all of the activities of Express Scripts are not fiduciary in nature.

It is alleged repeatedly that Defendants breached their fiduciary duty in the selection of Express Scripts as the PBM. Plaintiff repeatedly alleges that the PBM is in conflict and engages in tactics that harm the participants, and that are designed to enrich the PBM. Specifically, Plaintiff alleges that "Defendants failed to engage in a prudent and reasoned decision-making process before agreeing to a PBM contract that requires the Plans and their beneficiaries to pay Express Scripts …prices." (Compliant at ¶132.)

Caution is warranted, because not all of the activities in regard to the J&J Rx Plan design, or the conduct of the PBM are within the scope of fiduciary duties. The broad allegations about the pricing structures and a failure to use bargaining power and consider other strategies for the delivery of prescription drug benefits, requires a separate evaluation as to whether they are fiduciary functions. But, for this purpose, the threshold is met. The selection of Express Scripts is a fiduciary decision, to the extent that Express Scripts is providing fiduciary services.

So, there is learning from the alleged wrongdoing in this regard. We can consider how group benefits brokers, consultants and advisors evaluate prescription drug managers, PBMs and others. We can evaluate how we focus that effort to not only serve to meet the ERISA required functions, but also to build and maintain ERISA prescription drug plans that work for our participants and that manage and control cost reasonably.

In many cases, unlike what is alleged in the lawsuit, group insurance brokers are looking to alternative methods and functions. The lawsuit alleges a failure to negotiate contracts. Contract negotiation and market evaluations are commonly done by many brokers and other consultants. Buying power based upon a group insurance broker's customer base, or the employ of group purchasing organizations, are examples of how brokers employ buying power in negotiations. Assessment and evaluation of the deliverables, including drug categories, the application of formularies and related strategies, clinical evaluation of utilization, the consideration of other resources, bolt-on providers, and other alternative providers, is done by group insurance brokers as part of their work to assist employers in the efforts to deliver prescription drug benefits. Time will tell what J&J did here.

Fundamentally, ERISA fiduciary rules are not about the answer. The fiduciary standards do not also require that the participants be offered or given the lowest priced product or services. The standard mandates a process whereby the fiduciary engages in prudence and diligence, under the circumstances then prevailing to evaluate the role of a PBM fiduciary, as others would in the exercise of such a determination. So, many of the suggestions of alternatives made in the lawsuit might have been appropriate for consideration. But there is no fiduciary mandate in this regard. That said, if it can be shown that after a reasonable, prudent, and diligent process, Express Scripts was still selected, then the fiduciary standards may have been satisfied.

Of course, the opposite is also true. If a PBM was selected based upon a haphazard, limited, or deficient process, then, the consequences that flow from such a potential failure expose the selecting fiduciaries to liability.

It will be very interesting to see what facts are demonstrated regarding the process and evaluations conducted by Aon, the broker for the J&J Rx Plan. In the meantime, many brokers and consultants continue to do their good work to evaluate plans and programs of benefits, access buying power when appropriate, negotiate over pricing, services, and availability, and work to achieve the goals and objectives of the employer client appropriate for such circumstance.

As such, many group benefits brokers are already assisting their clients in fulfilling their fiduciary responsibility relative to the selection of a PBM fiduciary for the delivery of group prescription drug benefits. And, of course, a compliant prescription drug benefit Plan Document/SPD.

Up next: The letter writing campaign to the Judge about a Motion to Dismiss

Coming soon: Is formulary selection, and access points for generic and specialty drugs a fiduciary function subject to the ERISA fiduciary rules, or plan design function?

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