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### ERISA Health Plan Lawsuits: Why Should We Care?

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A recently filed lawsuit against Johnson & Johnson can serve as an example to use when advocating for patients who have insurance through their employers that can potentially hurt them physically and financially. When your patient has an employer-funded health insurance plan where the employer directly pays for all medical costs — called an ERISA plan for the federal law that governs employee benefit plans, the Employee Retirement Income Security Act — there are certain accountability, fairness, and fiduciary responsibilities that the employers must meet. These so-called ERISA plans do not have to follow state utilization management legislation that addresses harmful changes in insurers' formularies and other policies, so when the plans are not properly overseen and do not mandate the delivery of proper care at the lowest cost, both the patient and employer may be losing out.

The J&J lawsuit serves as a bellwether warning to self-insured employers to demand transparency from their third-party administrators so as not to (knowingly or unknowingly) breach their fiduciary duty to their health plans and employees. These duties include ensuring reasonable plan costs as well as acting in the best interest of their employees. There were multiple complaints in the lawsuit by a J&J employee, stating that she paid a much higher price for her multiple sclerosis drug through the plan than the price she eventually found at a lower cost pharmacy. The allegations state that J&J failed to show prudence in its selection of a pharmacy benefit manager (PBM). In addition, the company failed to negotiate better drug pricing terms, and the design of the drug plan steered patients to the PBM specialty pharmacy, resulting in higher prices for the employees. All of these led to higher drug costs and premiums for employees, which, according to the lawsuit, is a breach of J&J's fiduciary duties.

# Why Should Rheumatologists Care About This?

With all insurance plans, it feels as though we are dealing with obstacles every day that keep us from giving the excellent rheumatologic care that our patients deserve. Self-insured employers now account for over 50% of commercial health plans, and as rheumatologists caring for the employees of these companies, we can use those

transparency, accountability, and fiduciary responsibilities of the employer to ensure that our patients are getting the proper care at the lowest cost.

Not only is the J&J lawsuit a warning to self-insured employers, but a reminder to rheumatologists to be on the lookout for drug pricing issues and formulary construction that leads to higher pricing for employees and the plan. For example, make note if your patient is forced to fail a much higher priced self-injectable biologic before using a much lower cost infusible medication. Or if the plan mandates the use of the much higher priced adalimumab biosimilars over the lower priced biosimilars or even the highest priced JAK inhibitor over the lowest priced one. Let's not forget mandated white bagging, which is often much more expensive to the plan than the buy-and-bill model through a rheumatologist's office.

Recently, we have been able to help rheumatology practices get exemptions from white-bagging mandates that large self-insured employers often have in their plan documents. We have been able to show that the cost of obtaining the medication through specialty pharmacy (SP) is much higher than through the buy-and-bill model. Mandating that the plan spend more money on SP drugs, as opposed to allowing the rheumatologist to buy and bill, could easily be interpreted as a breach of fiduciary duty on the part of the employer by mandating a higher cost model.

### **CSRO Payer Issue Response Team**

I have written about the Coalition of State Rheumatology Organizations (CSRO)'s Payer Issue Response Team (PIRT) in the past. Rheumatologists around the country can send to PIRT any problems that they are having with payers. A recent PIRT submission involved a white-bagging mandate for an employee of a very large international Fortune 500 company. This particular example is important because of the response by the VP of Global Benefits for this company. Express Scripts is the administrator of pharmacy benefits for this company. The rheumatologist was told that he could not buy and bill for an infusible medicine but would have to obtain the drug through Express Scripts' SP. He then asked Express Scripts for the SP medication's cost to the health plan in order to compare the SP price versus what the buy-and-bill model would cost this company. Express Scripts would not respond to this simple transparency question; often, PBMs claim that this is proprietary information.

I was able to speak with the company's VP of Global Benefits regarding this issue. First of all, he stated that his company was not mandating white bagging. I explained to him that the plan documents had white bagging as the only option for acquisition of provider-administered drugs. A rheumatologist would have to apply for an exemption to buy and bill, and in this case, it was denied. This is essentially a mandate.

I gave the VP of Global Benefits an example of another large Fortune 500 company (UPS) that spent over \$30,000 per year more on an infusible medication when obtained through

SP than what it cost them under a buy-and-bill model. I had hoped that this example would impress upon the VP the importance of transparency in pricing and claims to prevent his company from unknowingly costing the health plan more and its being construed as a breach of fiduciary duty. It was explained to me by the VP of Global Benefits that his company is part of the National Drug Purchasers Coalition and they trust Express Scripts to do the right thing for them. As they say, "You can lead a horse to water, but can't make it drink."

#### Liability of a Plan That Physically Harms an Employee?

A slightly different example of a self-insured employer, presumably unknowingly, allowing its third-party administrator to mishandle the care of an employee was recently brought to me by a rheumatologist in North Carolina. She takes care of an employee who has rheumatoid arthritis with severe interstitial lung disease (ILD). The employee's pulmonary status was stabilized on several courses of Rituxan (reference product of rituximab). Recently, BlueCross BlueShield of North Carolina, the third-party administrator of this employer's plan, mandated a switch to a biosimilar of rituximab for the treatment of the ILD. The rheumatologist appealed the nonmedical switch but gave the patient the biosimilar so as not to delay care. Her patient's condition is now deteriorating with progression of the ILD, and she once again has asked for an exemption to use Rituxan, which had initially stabilized the patient. Her staff told her that the BCBSNC rep said that the patient would have to have a life-threatening infusion reaction (and present the bill for the ambulance) before they would approve a return to the reference product. An employer that knowingly or unknowingly allows a third-party administrator to act in such a way as to endanger the life of an employee could be considered to be breaching its fiduciary duty. (Disclaimer: I am not an attorney — merely a rheumatologist with common sense. Nor am I making any qualitative statement about biosimilars.)

We now have a lawsuit to which you can refer when advocating for our patients who are employed by large, self-insured employers. It is unfortunate that it is not the third-party administrators or PBMs that can be sued, as they are generally not the fiduciaries for the plan. It is the unsuspecting employers who "trust" their brokers/consultants and the third-party administrators to do the right thing. Please continue to <u>send us your payer issues</u>. And if your patient works for a self-insured employer, I will continue to remind the CEO, CFO, and chief compliance officer that an employer with an ERISA health plan can potentially face legal action if the health plan's actions or decisions cause harm to an employee's health — physically or in the wallet.

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