END, HIERSEMAN AND CRAIN, L.L.C.

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CUKER LAW FIRM, L.L.C.

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IN THE FEDERAL DISTRICT COURT OF THE EASTERN DISTRICT OF WISCONSIN

SHANON SCHMIDTKNECHT individually and WILLIAM SCHMIDTKNECHT individually and as Special Administrator of the Estate of COLE SCHMIDTKNECHT W10520 Tipperary Road Poynette, WI 53955

Plaintiffs,

v.

OPTUMRX, INC. 2300 Main Street Irvine, CA 92614

and

CIVIL ACTION

DOCKET NO:

COMPLAINT IN CIVIL ACTION

JURY TRIAL DEMANDED

WALGREENS BOOTS ALLIANCE, INC. 108 Wilmot Road Deerfield, IL 60015

and

WALGREENS PHARMACY 729 W. Northland Avenue Appleton, WI 54914

Defendants.

CIVIL ACTION COMPLAINT

Plaintiffs, Shanon Schmidtknecht, individually, and William Schmidtknecht, individually and as Special Administrator of the Estate of Cole Schmidtknecht, by and through their undersigned attorneys, hereby demand damages of the Defendants, in a sum in excess of the local arbitration limits, exclusive of interest, costs, and damages for prejudgment delay, upon the causes of action set forth below.

PARTIES

- 1. Plaintiff Shanon Schmidtknecht is an adult citizen of the State of Wisconsin, residing therein at W10520 Tipperary Road, Poynette, Wisconsin 53955.
- 2. Plaintiff William Schmidtknecht is an adult citizen of the State of Wisconsin, residing therein at W10520 Tipperary Road, Poynette, Wisconsin 53955.
 - 3. Cole Schmidtknecht was born on March 18, 2001, and died on January 21, 2024.
- 4. Cole Schmidtknecht was an adult citizen of the State of Wisconsin, who formerly resided therein at 1426 West Weiland Lane, Appleton, Wisconsin 54914.
- 5. William Schmidtknecht was appointed as the Special Administrator of the Estate of Cole Schmidtknecht by the Circuit Court of Outagamie County, Wisconsin, on January 6, 2025.

- 6. Defendant OptumRx, Inc. is a corporation incorporated in the state of California with its corporate headquarters located at 2300 Main Street, Irvine, California 92614.
 - 7. Defendant OptumRx, Inc. will be referred to herein as "OptumRx."
- 8. Defendant Walgreens Boots Alliance, Inc. is a corporation incorporated in the state of Delaware with its principal place of business and headquarters at 108 Wilmot Road, Deerfield, Illinois 60015.
- 9. Defendant Walgreens Boots Alliance, Inc. does business as Walgreens Pharmacy at retail pharmacy locations across the country.
- 10. One such Walgreens retail pharmacy is located at 729 West Northland Avenue, Appleton, Wisconsin 54914.
- 11. Defendant Walgreens Boots Alliance, Inc. and Walgreens Pharmacy will be collectively referred to herein as "Walgreens Defendants."

JURISDICTION AND VENUE

- 12. Federal jurisdiction in this action is predicated upon diversity of citizenship under statutory authority of 28 U.S.C. § 1332. The amount in controversy exceeds \$75,000.00.
- 13. For purposes of diversity under 28 U.S.C. § 1332, Plaintiffs are citizens of the State of Wisconsin, Defendant OptumRx is a citizen of the State of California, and Walgreens Defendants are citizens of the States of Delaware and Illinois.
- 14. Venue is proper in the Eastern District of Wisconsin pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this District with respect to the civil action in question.

OPERATIVE FACTS

THE OLIGOPOLY OF PHARMACY BENEFIT MANAGERS

- 15. In the modern U.S. healthcare system, Pharmacy Benefit Managers (hereinafter "PBMs") are entities that act as middlemen between health insurers, prescription drug companies, and pharmacies.
- 16. The nation's three largest PBMs oversee the fulfillment of over 79% of drug prescriptions in the United States, belonging to over 200 million Americans.
- 17. One of these three giant PBMs is United Health Group's subsidiary, OptumRx. OptumRx services claims for over 66 million people nationwide. Their market share has been steadily rising over the past decade as the industry has consolidated into a powerful oligopoly.
- 18. PBMs artificially drive up healthcare costs for Americans in a myriad of ways, such as forcing patients to fill prescriptions for more expensive drugs even when cheaper alternatives exist for the same conditions and setting artificial requirements that patients go on so-called "step-up" regimens, where they are required to try more expensive drugs for a certain period of time dictated by the PBM, before they are permitted to receive the medication their doctor chose.
- 19. To make matters worse, research shows that a significant portion of Americans do not have emergency savings and cannot afford an unexpected expense of over \$400. One study found that 27% of adults have no emergency savings at all.

¹ See PR NEWSWIRE, 37% of Americans can't afford an emergency expense over \$400, according to Empower research, https://www.prnewswire.com/news-releases/37-of-americans-cant-afford-an-emergency-expense-over-400-according-to-empower-research-302187157.html; CNBC, Personal Finance

44% of Americans can't now an unexpected \$1,000 expense from savings, https://www.cnbc.com/2024/01/24/man

^{44%} of Americans can't pay an unexpected \$1,000 expense from savings, https://www.cnbc.com/2024/01/24/many-americans-cannot-pay-for-an-unexpected-1000-expense-heres-why.html

² See BANKRATE, Bankrate's 2024 Annual Emergency Savings Report, https://www.bankrate.com/banking/savings/emergency-savings-report/

20. According to an interim staff report released in July of 2024 by the Federal Trade Commission as part of the agency's ongoing investigation into the growing and consolidating PBM industry, the FTC stated that PBMs "wield enormous power and influence over patients' access to drugs and the prices they pay. This can have dire consequences for Americans, with nearly three in ten surveyed Americans reporting rationing or even skipping doses of their prescribed medicines due to high costs."

PBMS DICTATE PATIENTS' MEDICATIONS BASED ON THEIR OWN FINANCIAL INTERESTS

- 21. Advair Diskus is a brand name for a corticosteroid inhaler that is used to prevent and control symptoms of asthma.
- 22. As the fall of 2023 approached, OptumRx changed its formulary of covered drugs for the coming year and determined that it would no longer cover Advair Diskus.
- 23. Nor would OptumRx cover Advair Diskus's generic equivalents, such as fluticasone propionate/salmeterol.
- 24. Instead, OptumRx would only cover Advair HFA or Breo Ellipta, two newer brand drugs, whose manufacturer had paid OptumRx substantial kickbacks (euphemistically called "rebates" and/or "compensation") in exchange for their favorable placement on OptumRx's updated formulary, while excluding Advair Diskus and its generic equivalents.
- 25. This practice of requiring patients to change their medications so that the PBM can collect kickbacks from the drug manufacturer is called "non-medical switching" because the choice of medication is dictated by the PBM's financial interests, not the best medical interests of patients.
- 26. Under OptumRx's updated 2024 formulary, a patient with a prescription for Advair Diskus, or a generic alternative, could only have that prescription filled if the patient

obtained a "Prior Authorization," which required the prescribing physician to specifically ask

OptumRx to cover the medication in advance, and for OptumRx to specially approve the

medication before the prescription was filled.

27. According to OptumRx's Provider Manual, when a Prior Authorization is required, the patient or their physician and/or pharmacist must go through the following steps before the drug can be dispensed:

Prior Authorization (PA) Process Key Steps:

- The Member's Prescriber or Member's appointed/authorized representative can submit a PA request.
- If the request and the provided information falls within established guidelines, the request will be approved.
- If the request and provided information falls outside the established guidelines, a Pharmacist reviews the request and contacts the prescriber if additional information is required.
- If required by state law, the request will be reviewed by a medical director before issuing the final decision.
- Additionally, where required by law, the Prescriber is offered the opportunity for a peer-to-peer consultation prior to the issuance of an adverse medical necessity determination.

Once the request is approved or denied, our PA system will automatically generate a written correspondence to both the Member and Prescriber.

- 28. Also according to OptumRx's Provider Manual, even "urgent cases have a turnaround time of seventy-two (72) hours for commercial Benefit Plans, from receipt of request to review the case."
- 29. Similar to the Prior Authorization process is Step Therapy, which requires a patient to first take a "preferred" drug of OptumRx's choosing for a dictated period of time, before they can take the drug prescribed by that patient's doctor.
- 30. In this case, OptumRx required that patients prescribed Advair Diskus undergo Step Therapy and try preferred drugs from manufacturers that had provided kickbacks, such as

Advair HFA, Breo Ellipta or Symbicor first, before they could refill their doctors' prescriptions for Advair Diskus.

- 31. OptumRx could have structured its formulary to allow existing patients taking Advair Diskus to continue refilling their prescriptions without difficulty, and only require Step Therapy and/or Prior authorization for new prescriptions of Advair Diskus ("new cases only").
- 32. OptumRx chose not to do so, because applying the new, non-medical criteria to existing patients would generate far more money in kickbacks to OptumRx.
- 33. OptumRx also could have left the generic equivalent of Advair Diskus on the formulary, while excluding the brand version.
- 34. Under Wisconsin law, pharmacists have discretion to substitute a brand prescription with its generic equivalent, without prescriber approval, unless otherwise specified in the prescription.
- 35. A pharmacist, however, cannot substitute one brand for another without prescriber approval.
- 36. OptumRx also dictates the prices charged for drugs to the pharmacy providers in its network and specifies that failing to charge the price OptumRx dictates, or charging for non-covered ingredients, may subject the pharmacy to termination from OptumRx's network, which would deprive the pharmacy of a significant portion (approximately 20%) of their business.
- 37. An OptumRx publication presented the following alternatives to patients who immediately needed a drug that requires a prior authorization:

Getting a short-term supply

If you must take a medication that requires prior authorization right away, there are two options that may work for you. First, ask your doctor if a sample is available. Or, check with your pharmacy to request a short-term supply of 5 days or less. Keep in mind, you

will be responsible for the full cost at that time. If the prior authorization request is approved, then your pharmacist can fill the rest of your prescription.

If you see your medication listed, we encourage you to talk with your doctor about your treatment and medication options. If you have questions about the PA process, call the phone number on your member ID card.

- 38. Neither of these options were viable for patients taking Advair Diskus because first, Advair Diskus was a mature drug which had been on the market for many years, so the manufacturer no longer made free samples available, and second, Advair Diskus is an inhaler, which is not available in a five-day supply.
- 39. According to OptumRx's own Provider Manual, Prior Authorizations should only be required for drugs which may not be medically necessary, such as to:

prevent coverage of select products that have potential for use that is typically outside the scope of the pharmacy or medical benefit (e.g., prescribed for treatment of conditions for which there is insufficient clinical evidence supporting safe and/or effective use); use for conditions which are not covered by the Plan (e.g., cosmetic use, or conditions excluded by the Plan); or use in situations where quantity or duration of treatment exceeds those defined as safe and effective in clinical compendia, treatment guidelines or supported through published and/or consulted expert opinion (e.g., OptumRx National P&T Committee).

- 40. None of these criteria applied to Advair Diskus or its generic equivalents, which are safe and effective for asthma, and fall well within the scope of the pharmacy benefit.
- 41. Because Prior Authorizations can deprive patients of needed medications, the standard of care in the PBM industry, and statutory law in many states including Wisconsin, mandates that PBMs advise patients in advance of formulary changes that will adversely affect their ability to access their existing medications, whether that is by increasing the patient's cost or excluding coverage altogether.
 - 42. Indeed, OptumRx's own website tells prescribing physicians that:

During formulary cycle updates, OptumRx reaches out to impacted patients with the information they need, including suggested covered alternative medications. We're here to support you and your patients through this process. (emphasis original)

and

Certain states require OptumRx to communicate prior authorization changes before the effective date. Flyers are sent to members to outline the drugs affected by prior authorization, quantity limits, and step therapy based on benefit plan designs. Please review each document for more details.

- 43. One of those "certain states" is Wisconsin, which puts certain restrictions on a PBM's authority to require prior authorization.
- 44. First, Wisconsin law requires at least thirty (30) days advance notice of any formulary change that removes a drug from their formulary or places it on a higher (i.e. more expensive) tier, to give enrollees the chance to request an exception to the formulary change. Wis. Stat. § 632.861(4).
- 45. Next, Wisconsin Law requires that any Step Therapy protocol imposed by a PBM like OptumRx be based on "clinical review criteria that are based on clinical practice guidelines that are derived from peer-review publications, evidence-based research, and widely accepted medical practice. If such clinical practice guidelines are unavailable, the insurer, pharmacy benefit manager, or utilization review organization shall derive clinical review criteria from peer-reviewed publications, evidence-based research, and widely accepted medical practice." WIS. STAT. § 632.866 (2)(a).
- 46. There is no legitimate peer-reviewed publication or evidence-based research that supports switching a patient whose asthma is well-controlled by Advair Diskus to a different medication.

- 47. To the contrary, peer reviewed literature establishes that this kind of non-medical switching is associated with adverse medical outcomes.
- 48. The same Wisconsin statute further requires that "[a]n insurer, Pharmacy Benefit Manager, or utilization review organization shall describe on its internet site the process and criteria used for selecting and evaluating clinical practice guidelines [] to develop step therapy protocols." WIS. STAT. § 632.866 (2)(c).

COLE SCHIMDTKNECHT IS DENIED HIS MEDICATION

- 49. Twenty-two-year-old Cole Schmidtknecht had a medical history of chronic asthma, stemming from infancy.
- 50. Cole managed his asthma with daily preventative doses of Advair Diskus. Advair Diskus and its generic equivalents had safely and effectively treated Cole's asthma for more than a decade.
- 51. Beginning in March 2023, Cole was employed by Kriete Truck Center Green Bay [hereinafter "Kriete Trucking"], located at 2090 Mid Valley Drive, De Pere, Wisconsin 54115, where he earned a modest hourly wage.
 - 52. Like most Americans, Cole received his health insurance from his employer.
- 53. At Kriete Trucking, he was on a self-insured plan that was administered by United Health.
- 54. Under this United Health plan, OptumRx was the PBM for Cole's prescription medications.
- 55. Cole's prescription had historically been covered by his insurance. Under the United Health-OptumRx Plan in 2023, Cole's asthma medication, Advair Diskus, was covered

and would cost no more than about \$66.86, even during the deductible phase of coverage, or about \$35 during the covered phase.

- 56. On January 10, 2024, Cole went to his local OptumRx-Walgreens pharmacy, Store # 12693, located at 729 West Northland Avenue, Appleton, Wisconsin 54914, expecting to fill his usual prescription for his Advair Diskus inhaler, as prescribed by his physician.
- 57. At the pharmacy, Cole was advised by the Walgreens Defendants that his medication was no longer covered by his insurance and that his Advair Diskus preventative inhaler would cost him \$539.19 out of pocket.
- 58. Despite the clear requirements under Wisconsin law, OptumRx never provided Cole with thirty (30) days' notice that his Advair Diskus, nor its generic equivalents, would not be covered by his insurance in 2024.
- 59. As a result, he did not have the opportunity to ask for an exception to the OptumRx's re-classification of the medication under its formulary that suddenly made his normal medication prohibitively expensive.
- 60. Also contrary to requirements under Wisconsin law, OptumRx did not describe its process and criteria for selecting and evaluating step therapy protocols on the internet before requiring Cole to switch medications for no medical reason.
- 61. According to a statement by OptumRx, in this scenario, the Walgreens pharmacist should have contacted Cole's prescribing physician about three other "clinically-appropriate alternatives available at a Tier-1 [more affordable] Co-pay: "Premium Drug Exclusion: Drug Not Covered; -Contact prescriber; Use Advair HFA; Breo Ellipta; Symbicort."
 - 62. Walgreens Defendants did not follow these instructions.

- 63. Walgreens Defendants never provided Cole with any more affordable workarounds to obtain his usual inhaler for his chronic asthma.
- 64. Walgreens Defendants did not offer Cole a generic alternative to Advair Diskus and further told Cole that there were no cheaper alternatives or generic medications available.
- 65. Walgreens Defendants did not contact OptumRx to request an exception to the reclassification on Cole's behalf.
- 66. Likewise, Walgreens Defendants did not contact Cole's prescribing physician to ask them to request an exception on Cole's behalf.
- 67. Walgreens Defendants did not provide Cole with a free or discounted Advair Diskus inhaler for him to use until he was able to contact his physician or United Health.
- 68. In fact, Walgreens Defendants did not take any steps to attempt to help Cole obtain the medication that he relied upon to control his asthma.
- 69. Because Cole could not afford this unexpected expense of \$539.19, he left the Walgreens without filling his prescription.
- 70. By removing Advair Diskus and its generic equivalents from its formulary, OptumRx caused Cole to leave the pharmacy without the necessary asthma medication his physician prescribed.
- 71. By removing Advair Diskus and its generic equivalents from its formulary without giving Cole thirty days' notice to request an exception, OptumRx caused Cole to leave the pharmacy without the necessary asthma medication his physician prescribed.
- 72. By requiring a Prior Authorization for the prescription for Advair Diskus and its generic equivalents, OptumRx caused Cole to leave the pharmacy without the necessary asthma medication his physician prescribed.

- 73. By requiring a Cole undergo a step-up regimen before he could fill his prescription for Advair Diskus and its generic equivalents, OptumRx caused Cole to leave the pharmacy without the necessary asthma medication his physician prescribed.
- 74. OptumRx knew or should have known that Cole would be forced to leave the Walgreens pharmacy without his life-sustaining medication while he awaited OptumRx's approval, which would take at least seventy-two (72) hours.
- 75. Over the next five days, Cole repeatedly struggled to breathe, relying solely on his old "rescue" (emergency) inhaler to limit his symptoms, because he did not have a preventative inhaler designed for daily use.
- 76. On January 15, 2024, five days after visiting the OptumRx-Walgreens pharmacy, Cole had a severe asthma attack and began to asphyxiate.
- 77. His roommate, Mitchell Huiting, immediately drove him to the Emergency Room at ThedaCare Regional Medical Center-Appleton, located at 1818 North Meade Street, Appleton, Wisconsin 54911.
- 78. Cole became unresponsive and pulseless in the car, about two minutes before they arrived.
- 79. When he presented to the ER, practitioners recorded that Cole was unconscious, pulseless, and appeared blue.
- 80. Emergency medical staff immediately gave Cole two rounds of epinephrin and performed two rounds of Cardiopulmonary Resuscitation, lasting over four minutes, to try to get him to regain consciousness.
 - 81. Despite their best efforts, Cole never woke up again.

- 82. Cole remained in the Intensive Care Unit on a ventilator for six days, until doctors finally informed his parents, William and Shanon Schmidtknecht, that he was beyond help.
- 83. On January 21, 2024, Cole's parents agreed to withdraw life supporting care and Cole was pronounced dead.
- 84. The immediate cause of death listed on his death certificate was *status* asthmaticus.
 - 85. As a result of these events, Cole suffered the following injuries and damages:
 - a. Severe asthma attack;
 - b. Asphyxiation;
 - c. Shortness of breath;
 - d. Traumatic brain injury;
 - e. Altered level of consciousness;
 - f. Starvation of oxygen;
 - g. Hypoxia;
 - h. Hypothermia;
 - i. Panic;
 - j. Pain and suffering;
 - k. Emotional distress;
 - 1. Mental anguish;
 - m. Loss of life's pleasures;
 - n. Loss of earnings; and
 - o. Death.

- 86. As a result of Cole Schmidtknecht's death, Plaintiffs Shanon Schmidtknecht, and Bill Schmidtknecht, and the Estate of Cole Schmidtknecht suffered the following damages:
 - a. lost earnings of Cole Schmidtknecht between the time of his injury and his death;
 - b. Cole Schmidtknecht's total estimated future earning power less his cost of personal maintenance;
 - c. pain and suffering endured by Cole Schmidtknecht prior to his death, including, but not limited to, physical pain and suffering, mental pain and suffering, mental suffering, loss of life's pleasures, disfigurement, and humiliation;
 - d. medical expenses;
 - e. funeral, and burial expenses;
 - f. monetary support Cole Schmidtknecht would have provided during his lifetime, the value of services provided or which could have been expected to have been performed in the future by Cole Schmidtknecht, and all pecuniary losses suffered as a result of Cole Schmidtknecht's death;
 - g. Individual plaintiffs Shanon Schmidtknecht and William Schmidtknecht lost the society and companionship of their son, Cole Schmidtknecht;
 - h. other serious and severe injuries, the exact nature of which are unknown to Plaintiff at this time; and
 - i. all damages available under Wisconsin law.

COUNT I: NEGLIGENCE

Plaintiffs v. Defendant OptumRx, Inc.

- 87. The preceding paragraphs are incorporated by reference as though fully set forth herein.
- 88. At all relevant times, Defendant OptumRx engaged in the business of providing and managing the pharmacy benefits to millions of people, including Cole Schmidtknecht.

- 89. Defendant OptumRx had a duty to not artificially inflate prescription drug prices for medications such as Advair Diskus for insured patients, including Cole Schmidtknecht, making them so unaffordable that patients could not obtain the medications their physicians prescribed.
- 90. Defendant OptumRx had a duty to inform asthmatic patients, including Cole Schmidtknecht, who were previously taking and who had been continuously prescribed Advair Diskus, of their decision to reschedule the medication and the impact this decision would have on pricing, so patients could request an exception to the rescheduling by the PBM.
- 91. Defendant OptumRx failed to exercise reasonable care in that they knew, or should have known, of the unreasonable risks of harm resulting from:
 - a. Failing to ensure that asthma patients, including Cole Schmidtknecht, had access to Advair Diskus, or its generic equivalent, as prescribed by their physician;
 - b. Failing to notify Cole Schmidtknecht that the medication that he had been relying on for years would be dramatically increasing in price;
 - c. Failing to give at least thirty (30) days advance notice to asthmatic patients, including Cole Schmidtknecht, that the medication that he had been relying on for years would no longer be covered, so that they could request an exception before their next refill;
 - d. Failing to afford an exception to Cole Schmidtknecht to OptumRx's re-scheduling of Advair Diskus to a not covered drug, despite his long history of taking, relying on, and benefitting from Advair Diskus without any negative side effects;
 - e. Forcing patients, including Cole Schmidtknecht, who had historically taken Advair Diskus to switch to another asthma medication for no sound medical reason, in violation of the standards expressed in Optum's own Provider Manual; See, e.g., para. 43 *supra*.
 - f. Forcing patients, including Cole Schmidtknecht, who had historically taken Advair Diskus to adhere to a step-up regimen on another medication for no sound medical reason and without supporting peer-reviewed medical literature;
 - g. Failing to provide retail pharmacies, including Walgreens, with information to provide to patients who were impacted by their rescheduling of Advair Diskus to a not covered drug, so that they could obtain an alternative medication;

- h. Failing to provide the Walgreens pharmacy located at 729 West Northland Avenue, Appleton, with information and/or means necessary to make sure that patients, including Cole Schmidtknecht, who were adversely impacted by the formulary change, would receive a covered alternative medication before these patients left the pharmacy; and
- i. Failing to provide employees at the Walgreens pharmacy located at 729 West Northland Avenue, Appleton, Wisconsin 54914 with information to provide Cole Schmidtknecht with regarding the impacts of the re-scheduling of Advair Diskus to a not covered drug, so that he could obtain an alternative medication.
- 92. Defendant OptumRx failed to exercise reasonable care in that they knew, or should have known, of the unreasonable risks of harm to asthmatic patients, including Cole Schmidtknecht, which would result from their failing to provide access to Advair Diskus or its generic alternatives.
- 93. As a direct and proximate result of the acts and omissions of Defendant OptumRx, Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, suffered the injuries described above.
- 94. The negligence of Defendant OptumRx and its employees, agents, ostensible agents, shareholders, officers, directors, and/or managing agents, as set forth above, was a direct and proximate cause of the injuries and damages suffered by Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht.

WHEREFORE, Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, respectfully demand judgment against Defendants, jointly and severally, for sums in excess of the local arbitration limits, exclusive of pre-judgment, post-judgment interest, and costs.

COUNT II: NEGLIGENCE

Plaintiffs v. Walgreens Defendants

- 95. The preceding paragraphs are incorporated by reference as though fully set forth herein.
- 96. At all relevant times, Walgreens Defendants engaged in the business of providing prescription medications to pharmacy patients.
- 97. Walgreens Defendants had a duty to provide medications such as Advair Diskus to patients, including Cole Schmidtknecht, as their physicians prescribed, or if their prescribed medication was not covered by their health insurance, exercise reasonable care to provide affordable alternative options to patients, including Cole Schmidtknecht, at the point of service.
- 98. Walgreens Defendants had a duty to inform asthmatic patients who were previously taking and had been continuously prescribed Advair Diskus, including Cole Schmidtknecht, of OptumRx's decision to reschedule the medication and the impact this decision had on pricing, and work to find alternative ways for patients, including Cole Schmidtknecht, to fill their prescriptions.
- 99. Walgreens Defendants failed to exercise reasonable care in that they knew, or should have known, of the unreasonable risks of harm resulting from:
 - a. Failing to seek OptumRx's approval to fill the prescription;
 - b. Failing to seek OptumRx's approval to fill the prescription with the generic equivalent;
 - c. Failing to immediately request a Prior Authorization from OptumRx on an urgent basis;
 - d. Failing to immediately contact Cole's prescribing physician to request a new prescription to a covered medication on an urgent basis;
 - e. Failing to immediately contact Cole's prescribing physician so they could immediately request a Prior Authorization from OptumRx on an urgent basis;

- f. Failing to provide an emergency supply of Advair Diskus or its generic equivalent to Cole Schmidtknecht;
- g. Failing to provide an emergency supply of one of the covered asthma medications to Cole Schmidtknecht for him to rely on while the Prior Authorization was pending;
- h. Failing to inform Cole that these requests had been made and that his medication would become available to him at an affordable price in 72 hours;
- i. Failing to adequately train staff around how to perform services to ensure patients were advised of all the options open to them and received necessary pharmacy services;
- j. Failing to provide adequate staffing and resources to its retail pharmacy locations to ensure patients were advised of all the options open to them and received necessary pharmacy services; and
- k. Failing to take corrective actions to ensure patients received necessary medical services and were advised of all the options open to them following multiple indications that pharmacists were under-trained, and pharmacies were under-staffed and under-resourced, and therefore could not ensure patients received necessary pharmacy services and were advised of all the options open to them.
- 100. Instead of taking any of these steps, Walgreens Defendants simply told Cole that his medication would cost \$539.19.
- 101. This price was unconscionably high, and well above Walgreens Defendants' acquisition cost for this drug.
- 102. Walgreens Defendants had a duty to notify asthmatic patients, including Cole Schmidtknecht, who were previously taking and had been continuously prescribed Advair Diskus, of OptumRx's decision to reschedule the medication and the impact this decision had on pricing, and work to find alternative ways for patients, including Cole Schmidtknecht, to fill their prescriptions.

- 103. Walgreens Defendants failed to exercise reasonable care in that they knew, or should have known, of the unreasonable risk of harm to asthmatic patients, including Cole Schmidtknecht, that would result from their failing to provide him with Advair Diskus or a medically equivalent alternative medication at an affordable price at the point of service.
- 104. As a direct and proximate result of the acts and omissions of Walgreens Defendants, Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, suffered the injuries and damages as set forth above.
- 105. The negligence of Walgreens Defendants and its employees, agents, ostensible agents, shareholders, officers, directors, and/or managing agents, as set forth above, was a direct and proximate cause of the injuries and damages suffered by Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht.

WHEREFORE, Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, respectfully demand judgment against Defendants, jointly and severally, for sums in excess of the local arbitration limits, exclusive of pre-judgment, post-judgment interest, and costs.

COUNT III: NEGLIGENCE PER SE VIOLATION OF THREE WISCONSIN STATUTES ESTABLISHING A STANDARD OF CARE FOR PBMS

Plaintiffs v. Defendant OptumRx, Inc.

- 106. The preceding paragraphs are incorporated by reference as though fully set forth herein.
- 107. At all relevant times, Cole Schmidtknecht was an enrollee as defined by WIS. STAT. § 632.861(1)(b).

- 108. Defendant OptumRx's treatment of Cole Schmidtknecht violated three different Wisconsin statutes: Wis. STAT. § 632.861(3), Wis. STAT. § 632.861(4) and Wis. STAT. § 632.866 (2)(a).
- 109. Under WIS. STAT. § 632.861(3), a PBM shall "not require an enrollee to pay at the point of sale for a covered prescription drug an amount that is greater than the lowest of all of the following amounts:
 - (a) The cost-sharing amount for the prescription drug for the enrollee under the policy or plan.
 - (b) The amount a person would pay for the prescription drug if the enrollee purchased the prescription drug at the dispensing pharmacy without using any health plan or health insurance coverage.

WIS. STAT. § 632.861(3)

- 110. Defendant OptumRx required Cole Schmidtknecht to pay \$539.19 at the point of sale for Advair Diskus.
- 111. The \$539.19 for Advair Diskus is an amount greater than the lowest amount of both the cost-sharing amount under the policy/plan and the amount that a person would pay if the enrollee purchased the Advair Diskus at the dispensing pharmacy without using any health plan or health insurance coverage, in violation of Section 632.861(1)(b).
- 112. Wisconsin law also requires at least thirty (30) days advance notice of any formulary change that removes a drug from the formulary or places it on a higher (more expensive) tier, and simultaneously inform the enrollees like Cole of the procedure for the enrollee to request an exception to the formulary change. WIS. STAT. § 632.861(4).
- 113. On January 1, 2024, Defendant OptumRx changed Advair Diskus from a covered drug to an excluded drug that would only be covered if the patient obtained Prior Authorization or went through step therapy.

- 114. Defendant OptumRx failed to provide Cole Schmidtknecht with thirty (30) days' advanced written notice of the formulary change that removed Advair Diskus from the formulary policy/plan or that reassigned Advair Diskus to a benefit tier for the policy or plan that has a higher deductible, copayment, or coinsurance.
- 115. Defendant OptumRx did not provide Cole Schmidtknecht with information on the procedure to request an exception to the Advair Diskus formulary change.
- 116. At all relevant times, Cole Schmidtknecht was using Advair Diskus when thirty (30) days' advanced written notice was required.
- 117. Wisconsin Law also required that any step therapy protocol Defendant OptumRx imposed be based on "clinical review criteria that are based on clinical practice guidelines that are derived from peer-review publications, evidence-based research, and widely accepted medical practice. If such clinical practice guidelines are unavailable, the insurer, pharmacy benefit manager, or utilization review organization shall derive clinical review criteria from peer-reviewed publications, evidence-based research, and widely accepted medical practice." WIS. STAT. § 632.866 (2)(a).
- 118. At all relevant times, Defendant OptumRx failed to use clinical review criteria based on clinical practice guidelines derived from peer-review publications, evidence-based research, or widely accepted medical practice when it established its step therapy protocol for Advair Diskus.
- 119. At all relevant times, Defendant OptumRx failed to continually update the clinical review criteria based on an update to the clinical practice guidelines or a review of new evidence and research and newly developed treatments.

- 120. Defendant OptumRx had an obligation not to violate State law in providing prescription medications to Plaintiffs' decedent, Cole Schmidtknecht.
- 121. Defendant OptumRx failed to comply with State law in managing pharmacy benefits for Plaintiffs' decedent, Cole Schmidtknecht, including, but not limited to, WIS. STAT. §§ 632.861(3) -(4) and 632.866(2).
- 122. WIS. STAT. §§ 632.861(3)-(4) and 632.866(2) are safety statutes enacted to protect patients taking prescription drugs.
- 123. Cole Schmidtknecht was in the class that WIS. STAT. §§ 632.861(3)-(4) and 632.866(2) were enacted to protect.
- 124. The legislative intent in passing WIS. STAT. §§ 632.861(3) -(4) and 632.866(2) as part of the 2021 Wisconsin Act was to protect consumers and increase transparency and accountability in prescription drug pricing.
- 125. As a direct and proximate result of the acts and omissions of Defendant OptumRx, Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, suffered the injuries and damages as set forth above.

WHEREFORE, Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, respectfully demand judgment against Defendants, jointly and severally, for sums in excess of the local arbitration limits, exclusive of pre-judgment, post-judgment interest, and costs.

COUNT IV: PUNITIVE DAMAGES

Plaintiffs v. Defendant OptumRx, Inc.

126. The preceding paragraphs are incorporated by reference as though fully set forth herein.

- 127. OptumRx intentionally disregarded the rights of Plaintiffs' decedent, Cole Schmidtknecht, and similarly situated individuals when it violated State laws.
- 128. OptumRx was aware that the result or consequence of serious injury or death was substantially certain to occur when it violated State law and acted in intentional disregard of that serious injury or death.
- 129. At all relevant times, OptumRx's conduct was grievous and outrageous, and evinced such a degree of intentional disregard of the rights of Cole Schmidtknecht and similarly situated individuals as to warrant punitive damages.
- 130. OptumRx's grievous and outrageous conduct caused the harms and injuries suffered by Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, as set forth above, warranting punitive damages.

COUNT V: PUNITIVE DAMAGES

Plaintiffs v. Walgreens Defendants

- 131. The preceding paragraphs are incorporated by reference as though fully set forth herein.
- 132. Walgreens Defendants intentionally disregarded the rights of Plaintiffs' decedent, Cole Schmidtknecht, and similarly situated individuals when it violated State laws.
- 133. Walgreens Defendants were aware that the result or consequence of serious injury or death was substantially certain to occur when they violated State law and acted in intentional disregard of that serious injury or death.
- 134. At all relevant times, Walgreens Defendants' conduct was grievous and outrageous, and evinced such a degree of intentional disregard of the rights of Cole Schmidtknecht and similarly situated individuals as to warrant punitive damages.

135. Walgreens Defendants' grievous and outrageous conduct caused the harms and injuries suffered by Plaintiffs, Shanon Schmidtknecht, William Schmidtknecht, and the Estate of Cole Schmidtknecht, as set forth above, warranting punitive damages.

FIRST CAUSE OF ACTION: WRONGFUL DEATH ACTION

Plaintiffs Shanon Schmidtknecht and William Schmidtknecht individually v. All Defendants

- 136. The preceding paragraphs are incorporated by reference as though fully set forth herein.
- 137. Plaintiffs, Shanon Schmidtknecht, individually, and William Schmidtknecht, individually, bring this action under and by virtue of WIS. STAT. § 895.04.
- 138. As a result of the acts and omissions of all Defendants, Cole Schmidtknecht died on January 21, 2024.
- 139. As a result of the acts and omissions of all Defendants, Plaintiffs, Shanon Schmidtknecht, individually, and William Schmidtknecht, individually, suffered harms and losses which are compensable pursuant to Wis. Stat. § 895.04.

WHEREFORE, Plaintiffs, Shanon Schmidtknecht, individually, and William Schmidtknecht, individually, respectfully demand judgment against Defendants, jointly and severally, for sums in excess of the local arbitration limits, exclusive of pre-judgment, post-judgment interest, and costs.

SECOND CAUSE OF ACTION: CLAIM OF THE ESTATE OF COLE SCHMIDTKNECHT

Plaintiffs v. All Defendants

140. The preceding paragraphs are incorporated by reference as though fully set forth herein.

141. Cole Schmidtknecht died on January 21, 2024.

142. As a result of the acts and omissions of all Defendants, Cole Schmidtknecht was

caused grave injuries and death resulting in the entitlement to damages by the Estate of Cole

Schmidtknecht, deceased.

143. Plaintiffs, Shanon Schmidtknecht, individually, and William Schmidtknecht,

individually and as Special Administrator of the Estate of Cole Schmidtknecht, bring this action

on behalf of the Estate of Cole Schmidtknecht, deceased, and claims the full measure of damages

compensable under Wisconsin law.

WHEREFORE, Plaintiffs respectfully demand judgment against Defendants, jointly and

severally, for sums in excess of the local arbitration limits, exclusive of pre-judgment, post-

By:

judgement interest, and costs.

Respectfully submitted,

Date: 01/21/25

Michael A. Trunk, Esquire

Helen A. Lawless, Esquire

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