Supreme Judicial Court

FOR THE COMMONWEALTH OF MASSACHUSETTS

No. SJC-12409

CARMEN CORREA,
ADMINISTRATRIX OF THE ESTATE OF YARUSHKA RIVERA,
PLAINTIFF-APPELLANT,

v.

ANDREAS P. SCHOECK,
NEW ENGLAND NEUROLOGICAL ASSOCIATES, P.C.,
AND WALGREENS EASTERN CO., INC.,
DEFENDANTS-APPELLEES.

AMICUS CURIAE BRIEF FOR
THE AMERICAN ASSOCIATION OF JUSTICE and
THE MASSACHUSETTS ACADEMY OF TRIAL ATTORNEYS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES:

REGULATIONS:

RULES:

STATUTES:

OTHER AUTHORITIES:

STATEMENT OF THE AMICI CURIAE

The American Association for Justice (AAJ) and the Massachusetts Academy of Trial Attorneys (Academy), offer this filing in response to this Court's solicitation of briefing on the question of whether a pharmacy owes a duty of care to its customer to notify that customer's physician that an insurer will not pay for her prescription medication without prior authorization.

AAJ is a national voluntary bar association whose trial-lawyer members primarily represent plaintiffs in personal injury, workers' compensation, civil rights, and in other civil actions. Many AAJ members practice in Massachusetts.

The Academy is a voluntary, non-profit, state-wide professional association of attorneys in the Commonwealth. The Academy's purpose is to uphold and defend the Constitutions of the United States and the Commonwealth of Massachusetts; to promote the administration of justice; to uphold the honor of the legal profession; to apply the knowledge and experience of its members so as to promote the public good; to reform the law where justice so requires; to advance the cause of those who seek redress for injury

to person or property; steadfastly to resist efforts to curtail the rights of injured individuals; and to help them enforce their rights through the courts and other tribunals in all areas of law. The Academy has been actively addressing various areas of the law in the courts and the Legislature of the Commonwealth since 1975.

The amici urge the Court to recognize the duty of reasonable care that a pharmacy owes to its customer to notify her physician that her insurer will not pay for her prescription medication without prior authorization.

ISSUE PRESENTED

Courts in this Commonwealth and elsewhere recognize that, when a pharmacist has special knowledge that a prescription may cause harm or death to a particular patient, that pharmacist has a duty to take action to avoid that harm. Here, the Superior Court failed to recognize that duty when it exonerated a pharmacy, even though its pharmacists repeatedly failed to inform a physician that it could not fill a prescription the physician wrote, depriving the plaintiff's daughter of life-sustaining medication and

leading to her death. Did the Superior Court err in failing to recognize that duty?

STATEMENT OF THE CASE

Andreas P. Schoeck, M.D. (Dr. Schoeck) had prescribed Topamax, a medication that prevents life-threatening seizures, for Plaintiff-Appellant's decedent, Yarushka Rivera (Ms. Rivera). See Correa v. Schoeck, Mass. Super. Ct., No. 12-cv-4164, slip op. at 2 (Dec. 27, 2016). But when Ms. Rivera's family tried to fill that prescription at Walgreens Pharmacy (Walgreens), the pharmacist learned that Ms. Rivera's insurer, MassHealth, would not pay for the prescription unless her physician obtained prior authorization. Id.

Prior authorization requirements for prescription drugs are a commonplace, and Walgreens has a procedure in place for handling them: a Walgreens pharmacist sends a fax to the prescribing physician, asking the physician to obtain prior authorization from the patient's insurer; if the physician does not respond, a Walgreens pharmacist will call the doctor to follow up. A.I. 19, 69-71; A.II. 9-10, 13-14, 22, 28, 34, 46-47, 50-51, 53-55, 91, 94-98. In Ms. Rivera's case,

Walgreens never contacted Dr. Schoeck, A.I. 54, 58-60, 189; A.II. 76-77, 172-73, even though Walgreens's pharmacists promised Ms. Rivera's family at least seven different times that they would. A.I. 68-71.

Even though Walgreens's pharmacists knew Ms. Rivera could not obtain her medication without prior authorization from her insurer, id., even though Walgreens knew Dr. Schoeck had not completed the necessary prior authorization paperwork, and even though Walgreens knew (or reasonably should have known) that Ms. Rivera could suffer a fatal seizure without Topamax, see A.II. 41-42, 60-63, 70, 98-99, Walgreens pharmacists did not call Dr. Schoeck. See Appellant's Br. at 18-20. Ms. Rivera never got a refill of her life-saving medication. She suffered a fatal seizure while waiting for Walgreens to call Dr. Schoeck. A.II. 110.

On October 12, 2012, Carmen Correa, Ms. Rivera's mother, sued Walgreens and others for wrongful death. See Appellant's Br. at 10. The Superior Court granted summary judgment in favor of Walgreens. See Correa, supra at 1-2. Mrs. Correa moved for reconsideration, arguing in relevant part that the court erred by failing to recognize that Walgreens owed a duty of

care to Ms. Rivera because it had "specific knowledge" that Ms. Rivera's inability to obtain Topamax without prior authorization subjected her to "an increased danger." Id. at 11.

The Superior Court refused to revise its summary judgment order. Id. at 13. The court relied solely on a single sentence in Cottam v. CVS Pharmacy, 436 Mass. 316 (2002), in which this Court determined that a pharmacy "has no duty to warn a customer of potential side effects" of a drug, so long as the pharmacy has "no specific knowledge of an increased danger" to that "specific customer." Id. at 323. The Superior Court acknowledged, as has this Court, that pharmacies may be held liable in other circumstances.[1] Correa, supra at 11-12.

The Superior Court's only analysis of whether Walgreens owed Ms. Rivera a duty of care that obliged it to call Dr. Schoeck about the need for prior

[1] For example, pharmacists could be held liable for "filling a prescription for what the pharmacist knew to be a lethal dose," "failing to warn the customer" that "two prescriptions . . . adversely interact" with one another," and "failing to warn" a known alcoholic that his medication had an "adverse interaction with alcohol." Cottam, 436 Mass. at 323.

authorization appeared in two footnotes.[2] See id. at 12 n.3, 13 n.5.

First, the court brushed aside analogous authority holding that a pharmacist "has a duty to . . . notify a prescribing doctor of [a] customer-specific risk," finding that case "distinguishable." Id. at 12 n.3, citing Klasch v. Walgreen Co., 127 Nev. 832, 838, 840 (2011). The court offered only a non-sequitur rationale for its rejection of Klasch: "only [a] prescribing physician could [obtain] prior authorization." Id.

Second, the court acknowledged that it must recognize a duty where "existing social values, customs, and considerations of policy" counseled in favor of a duty. Id. at 13 n.5. But the court did not analyze whether "social values, customs, [or] considerations of policy" would favor a pharmacist's placing a simple phone call to a doctor when doing so could save a customer's life. Instead, the court re-characterized Mrs. Correa's grievance against

[2] The body of the court's opinion focused on whether Walgreens should have known that the dosage for another of Ms. Rivera's prescriptions was too low. Id.

Walgreens as a complaint that the pharmacy "fail[ed] to provide a customer with her prescription after the customer's insurer denies coverage and the customer is unable to pay," and implied that imposing liability in that circumstance would constitute an "onerous burden." Id. The Superior Court did not address whether requiring a pharmacist to make a phone call that could save a patient's life was "onerous."

The Superior Court directed entry of a partial final judgment in favor of Walgreens, pursuant to Massachusetts Rule of Civil Procedure 54(b). Id. at 17. This appeal followed.

ARGUMENT

This Court has recognized the general common-law principle that "'a defendant owes a duty of care to all persons who are foreseeably endangered by his conduct, with respect to all risks which make the conduct unreasonably dangerous.'" Jupin v. Kask, 447 Mass. 141, 147 (2006), quoting Tarasoff v. Regents of Univ. of Cal., 17 Cal.3d 425, 434–35, 131 Cal. Rptr. 14, 551 P.2d 334 (1976). See also Remy v. MacDonald, 440 Mass. 675, 677 (2004) ("As a general principle of tort law, every actor has a duty to exercise

reasonable care to avoid physical harm to others"). But "[t]he concept of 'duty' . . . 'is not sacrosanct in itself.'" Luoni v. Berube, 431 Mass. 721, 735 (2000), quoting W.L. Prosser & W.P. Keaton, Torts § 53, at 358-59 (5th ed. 1984). That is, "a duty finds its 'source in existing social values and customs.'" Mullins v. Pine Manor College, 389 Mass. 47, 51 (1983). See also Luoni, 431 Mass. at 735 (existence of duty "is an expression of the sum total of . . . considerations of policy which lead the law to say that the plaintiff is entitled to protection" (internal citations omitted). "Notions about what should be foreseen, in other words, are very much interwoven with our feelings about" what is "fair and just." Whittaker v. Saraceno, 418 Mass. 196, 198 (1994).

"'No better general statement can be made than that the courts will find a duty where, in general, reasonable persons would recognize it and agree that it exists.'" Luoni, 431 Mass. at 735, quoting Prosser & Keaton. The question for this Court, therefore, is whether reasonable people would recognize that a pharmacist should act to protect a patient from the

foreseeable harm that could follow if the patient were deprived of a life-saving medication.

I. Courts in this Commonwealth and around the country have recognized that a pharmacist has a duty of care where, as here, he or she knows of a "specific risk" to a "particular customer."

The Superior Court did not consider any of these policy rationales, or weigh the social customs or expectations. Instead, it rested its refusal to require the Walgreens pharmacists to alert a physician about a specific risk to a specific patient on an overbroad reading of Cottam. In doing so, the Superior Court both glossed over the limited reach of Cottam and overlooked the teachings of other courts in both Massachusetts and other jurisdictions.

A. The holding in Cottam does not exonerate a pharmacist for all wrongs, as at least one Massachusetts court has acknowledged.

Cottam held only that--under this Court's adoption of the "learned intermediary doctrine"--doctors, not pharmacies, have a duty to educate patients about a drug's side effects. Cottam, 436 Mass. at 322. As the Superior Court has recognized, however, this Court confined its holding to situations in which "the pharmacist has no specific knowledge of

an increased danger to a particular customer" (emphasis added). Id. at 323.

Brienze v. Casserly, Mass. Super. Ct., No. 01-1655-C (Dec. 19, 2003) neatly articulated the point at which Cottam's limited exemption of a pharmacist's duty of care to customers ends. Brienze, supra. That point is the moment at which the pharmacist gains specific knowledge of an increased risk to a particular customer. Id. In other words, the rule in Cottam is wholly concerned with general risk; Cottam does not speak to known specific risks.

Brienze acknowledged that "[i]t is true that '[b]ecause the physician is the appropriate person to perform the duty of warning a patient of the possible side effects of prescription drugs,' a pharmacist has no general duty to warn." Id., quoting Cottam, 436 Mass. at 322. But the Cottam Court "did not declare that pharmacists have absolutely no duty" (emphasis added). Id. The Brienze court explained that Cottam stood only for the proposition that, "'where the pharmacist has no specific knowledge of an increased danger to a particular customer, the pharmacist has no duty to warn of potential side effects.'" Brienze, supra, quoting Cottam, 436 Mass. at 322-23.

The Brienze court adhered to Cottam's distinction, declining to balloon the learned intermediary defense to exonerate all wrongs by a pharmacy or pharmacist. Id. ("Therefore, the duty imposed in this case is not within the scope of the learned intermediary doctrine carved out by Cottam"). Applying Cottam, so limited, to the facts before it, the Brienze court concluded that Cottam "does not eliminate a pharmacist's duty to warn a particular customer of the potentially adverse interaction of two drugs which the pharmacist knows the customer is taking." Id.

Cottam itself supports imposing a duty on pharmacists who have specific knowledge about a particular patient. This Court grounded its reasoning for imposing "a duty to warn their patients of . . . side effects" on physicians on their "superior knowledge of the patient's medical history and unique condition" and on the fact that they are therefore "in a better position" to decide which "side effects they determine are necessary and relevant." Cottam, 436 Mass. at 321-23.

Having made clear that it was grounding the rule on the difference between the specific knowledge

available to the physician and the general knowledge available to the pharmacist, the Cottam Court left open the door to the situation here, where the pharmacist held specific knowledge regarding danger to a particular customer. It acknowledged cases in which "the pharmacist failed to act on specific knowledge that he or she possessed regarding danger to a particular customer," but declined to "address cases such as these" at that time (emphasis added). Cottam, 436 Mass. at 322-23. In other words, this Court distinguished, rather than rejected, this persuasive authority, leaving for another day the issue of whether Massachusetts will follow those courts in imposing a duty on pharmacists sitting on specific knowledge regarding increased danger to a particular patient's health.

That day has come: before this Court is a case in which a pharmacy knew of "specific risk" to a "particular customer," and yet did nothing. In this case, the pharmacist had specific knowledge that a particular customer was at increased risk of catastrophic medical consequences if she did not timely receive the prior authorization and the life-saving prescription. That specific knowledge

triggered an obligation to follow up with the physician about the need for immediate prior authorization.

B. Courts around the country recognize that a pharmacist has a specific duty to act where he or she has knowledge of an increased danger to a particular customer.

Courts around the country have "imposed a duty on pharmacies that goes beyond merely filling prescriptions accurately." Cottam, 436 Mass. at 322. Many of those courts recognize the same distinction that Brienze finds in Cottam: while there is no general duty to warn of broadly applicable side effects, pharmacists "owe their customers a duty beyond accurately filling prescriptions" when there are "additional factors, such as known contraindications, that would alert a reasonably prudent pharmacist to a potential problem." Morgan v. Wal-Mart Stores, Inc., 30 S.W.3d 455, 466 (Tex. Ct. App. 2000).

For example, courts have recognized that pharmacists must inform doctors when a particular prescription is potentially fatal. The Missouri Court of Appeals acknowledged that a pharmacy could be liable for filling a prescription for a lethal dose of

narcotics, because pharmacists "are in the best position to contact the prescribing physician, to alert the physician about the dose and any contraindications relating to other prescriptions the customer may be taking as identified by the pharmacy records, and to verify that the physician intended such a dose for a particular patient." Horner v. Spalitto, 1 S.W.3d 519, 523-24 (Mo. Ct. App. 1999) (reversing summary judgment). Imposing such a duty "should increase the overall quality of health care." Id. The Pennsylvania Superior Court held a pharmacy responsible for failing to notify the customer's physician of obvious inadequacies on the face of a prescription that could lead to a patient taking a fatal dose of the medication. Riff v. Morgan Pharmacy, 353 Pa. Super. 21, 29-30 (1986) (affirming verdict against pharmacy). See also Pittman v. Upjohn Co., 890 S.W.2d 425, 435 (Tenn. 1994) (holding pharmacist owed duty to warn customer of "unavoidably unsafe drug" where "no warning had been given by the physician" but affirming summary judgment where decedent not customer of pharmacy).

Courts have held that a pharmacist may have a duty to warn the customer when multiple prescriptions

may negatively interact, and that question of fact precludes summary judgment. See, e.g., Lasley v. Shrake's Country Club Pharmacy, Inc., 179 Ariz. 583, 588 (1994) (reversing dismissal of allegations that pharmacist failed "to advise a customer of the addictive nature of a drug, to warn of the hazards of ingesting two or more drugs that adversely interact with one another, and to discuss with the physician the addictive nature of a prescribed drug and the dangers of long-term prescription of the drug"); Dooley v. Everett, 805 S.W.2d 380, 385-86 (Tenn. Ct. App. 1990) ("whether the duty to warn of potential drug interaction is included within the pharmacist's duty to his customer is a disputed issue of fact preventing the granting of summary judgment"); Kenneth R. Baker, The OBRA 90 Mandate And Its Developing Impact On The Pharmacist's Standard Of Care, 44 Drake L. Rev. 503, 509-10 (1996) ("The significance of Dooley lies in its shift from focusing on a pharmacist's duties to focusing on the standard of practice of pharmacy--thus shifting from a legal to a factual analysis").

Other courts have held that a pharmacist may have a duty to warn physicians or customers where a

prescription may pose a risk in light of a customer's unique medical history. This includes instances where the pharmacist learns that "a pharmacist has personal knowledge that a customer is taking medication more quickly than prescribed" and "that the customer may have developed an addiction to the drug or that the customer is improperly disposing of the drug," Hooks SuperX, Inc. v. McLaughlin, 642 N.E.2d 514, 518-19 (Ind. 1994), or where a pharmacist "knew [that the customer] was alcoholic and knew, or should have known, that the prescribed drugs were contraindicated" for alcoholics, Hand v. Krakowski, 89 A.D.2d 650, 651, 453 N.Y.S. 2d 121, 122-23 (1982). "Clearly, under these circumstances, the dispensing druggist may have had a duty to warn [the customer] of the grave danger involved and to inquire of the prescribing doctors if such drugs should not be discontinued." Hand, 89 A.D.2d at 651, 453 N.Y.S.2d at 123.

While these fact patterns are varied, each follows a common logical thread. In each case, the pharmacist knew something specific about a particular customer's prescription, and was in a position to prevent harm to the customer. In such circumstances,

it is right to require that pharmacist do something more than blindly hand out pills.

Circumstances like those at issue here, in which a pharmacist learns that a specific prescription requires prior authorization, follow that same thread. When a pharmacist tries to submit a prescription requiring prior authorization to a customer's insurer for payment, the insurer will tell the pharmacist, not the doctor, that the pharmacist cannot fill the prescription without prior authorization. At that point, the pharmacist uniquely possesses knowledge critical to the health and safety of a patient: knowledge that a patient cannot receive her life-saving medication without further action by the doctor.

II. Society depends on pharmacists to safeguard patients' health and life, and to augment patient care.

Pharmacists are not automatons who unquestioningly fill vials with pills by rote; they are professionals. Pharmacists are "integral members of [a] health care team[.]" Morris, Not Your Father's Pharmacist, 78 N.C. Med. J. 164 (2017). See also Adams & Blouin, The Role of the Pharmacist in Health Care: Expanding and Evolving, 78 N.C. Med. J. 165,

165 (2017) (noting pharmacists have "evolved" into "a critical partner in the provision of care").

Society's view of pharmacists has evolved since the days when pharmacists were seen as merely "responsible for . . . distributing a medication." Adams & Blouin, supra at 165. See also Albanese & Rouse, Scope of Contemporary Pharmacy Practice: Roles, Responsibilities, and Functions of Pharmacists and Pharmacy Technicians, Council on Credentialing in Pharmacy (2009), available at http://pharmacycredentialing.org/Contemporary_Pharmacy_Practice.pdf (last viewed Jan. 1, 2018) ("Contemporary pharmacy practice reflects an evolving paradigm from one in which the pharmacist primarily supervises medication distribution and counsels patients, to a more expanded and team-based clinical role providing patient-centered medication therapy management, health improvement, and disease prevention services").

Pharmacists are charged with "engaging in health systems management," working side-by-side with physicians to provide life-saving care to patients. National Governors Association, The Expanding Role of Pharmacists in a Transformed Health Care System

(2015), available at https://www.nga.org/files/live/sites/NGA/files/pdf/2015/1501TheExpandingRoleOfPharmacists.pdf (last viewed Jan. 1, 2018). This is particularly true in the modern environment in which "demanding new practice and payment models," such as prior authorization, "are required to further optimize care and outcomes." Adams & Blouin, supra at 165-66.[3] That is why at least one professional organization of pharmacists has recognized that pharmacists are obligated to "ensure that the prior authorization process is administered in the most efficient manner possible." Academy of Managed Care Pharmacy, Prior Authorization (2012), available at http://www.amcp.org/prior_authorization/ (last viewed Jan. 1, 2018).

[3] Massachusetts itself recognizes the integral role of the pharmacist as a clearinghouse for information about a patient's medications, and charges the pharmacist with the obligation to "take appropriate measures to ensure the proper care of [a] patient"--"which may include consultation with the prescribing practitioner"--where, as here, there is "any significant change in drug, dose, or directions." 247 Code Mass. Regs. § 9.07(2)(a)-(b) (2014) (Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments) (See Addendum 2).

A. Federal and state policy favor expediting availability of drugs subject to prior authorization restrictions.

"Prior authorization policies require a physician or a plan enrollee to obtain the insurer's advance approval before the insurer will cover the cost of certain treatments and medications." Worthy, McClughen, & Kulkarni, Now or Never: The Urgent Need for Action Against Unfair Coverage Denials for Quality Health Care, 48 Loy. U. Chi. L.J. 1041, 1064 (2017).

Although prior authorization procedures arose initially to control hospital costs in the 1960's, the practice quickly spread to prescription drug costs, as prescription drugs became an increasingly important--and expensive--element of American health care. Jessica Behrendsen, A Brief History of How We Got to Electronic Prior Authorization (2017), available at https://www.covermymeds.com/main/insights/articles/2017-12-01-a-brief-history-of-how-we-got-to-electronic-prior-authorization/ (last viewed Jan. 2, 2018). See also Ford, Congressional Research Service, Medicaid: Reimbursement for Outpatient Prescription Drugs, CRS-15 (Mar. 7, 1991) (between 1982 and 1988, prescription drug costs "increased at an average annual rate of 9.5

percent . . . more than any other component of the health care sector").

As costs increased, Medicare and Medicaid played an increasingly important role in protecting access to needed medications. The laws and regulations governing those programs carefully balanced the need to keep costs down through prior authorization restrictions with access to medication. In the Omnibus Budget Reconciliation Act of 1990, 104 Stat. 1388-143, Congress granted the states broad discretion to adopt prior authorization requirements for coverage of nearly all prescription drugs under their Medicaid programs. The only statutory limitation on this discretion is the requirement that the state plan commissioner respond to prior authorization requests within 24 hours. 42 U.S.C. § 1396r-8(d)(5). (See Addendum 1).

The courts have balanced the same interests. Although the Supreme Court has upheld a state's right to impose prior authorization restrictions on the majority of prescription medications, it cautioned that Maine's efforts to keep costs down must be "consistent with . . . the best interests of the recipients." Pharm. Research & Mfrs. of Am. v. Walsh,

538 U.S. 644, 665 (2003). The Court made clear that a state's prior authorization requirement would violate the very purpose of the program and could not be upheld "if it severely curtailed Medicaid recipients' access to prescription drugs." Id.

There can be no clearer or firmer statement of the "existing social values" that should inform this Court's decision: the policy underlying Medicaid programs, like MassHealth, supports imposing a legal duty on pharmacies to act to ensure that doctors are notified of MassHealth prior authorization requirements, because such a duty would ensure that customers can obtain the medications prescribed by their doctors.

B. Consumers expect pharmacists to address prior authorization issues.

As pharmacists' roles have expanded beyond dispensing pills, pharmacists are now entrusted with navigating the coverage requirements of a large number of private insurers, as well as Medicare and state Medicaid programs. Although this may sound onerous, pharmacists--even at small retail pharmacies--have at their fingertips extensive databases and sophisticated software that catalogue, report, and allow pharmacists

to respond to insurer requirements. See Selzler, Electronic PA: What Is It and How Does It Work? (2016), available at http://blog.computer-rx.com/electronic-pa-what-is-it-and-how-does-it-work (last viewed Jan. 2, 2018).

Given this superior access to insurance information, society has come to expect pharmacists to communicate an insurer's prior authorization requirements to the prescribing physician. See, e.g., Selzler, supra ("Traditionally, prior authorizations are obtained by the pharmacist . . . The pharmacy must contact the prescriber and fax over the required information"). Information about pharmacies' history of handling prior authorizations is ubiquitous. See, e.g., Gasbarro, My pharmacist says he needs "prior authorization"—what's that all about? Consumer Affairs (Apr. 6, 2015), available at https://www.consumeraffairs.com/news/my-pharmacist-says-he-needs-prior-authorization-whats-that-all-about-040615.html (last viewed Jan. 2, 2018) ("Generally, the pharmacy will contact the doctor who prescribed the medicine and let him know that [the patient's] medicine requires a PA"); Health Markets, Prior Authorization for Prescription Drugs: All You

Need To Know (2016), available at https://www.healthmarkets.com/resources/health-insurance/prior-authorization-for-prescription-drugs/ (last viewed Jan. 2, 2018) ("First, your pharmacy will contact whoever prescribed the medication. They will let the physician know the insurance company required a prior authorization"); Poquette, Why Do Some Prescriptions Require Prior Authorization? Pharmacy Times (Aug. 8, 2016), available at http://www.pharmacytimes.com/contributor/jason-poquette/2016/08/why-do-some-prescriptions-require-prior-authorization?p=2 (last viewed Jan. 2, 2018) ("Some pharmacies will call the prescriber, while others will fax a form. Some will use online services developed exclusively for the purpose of dealing with prescriptions requiring PAs. The best processes also keep the pharmacy involved so the prescription isn't just abandoned").

Given the federal policy favoring speedy access to medications requiring prior authorization, the professional obligations imposed on Massachusetts pharmacists, and broad consumer expectations, it would be neither unfair nor unforeseeable for this Court to

oblige pharmacists to contact physicians about prior authorizations.

C. A reasonable pharmacist could foresee that a patient like Ms. Rivera would suffer serious, perhaps fatal harm, unless that pharmacist informed the patient's physician that an insurer would not pay for a prescription absent prior authorization.

The harm to Ms. Rivera caused by Walgreens's failure to inform Dr. Schoeck of MassHealth's prior authorization restriction was foreseeable. Dr. Schoeck prescribed Topamax to prevent seizures caused by epilepsy. Correa, supra at 2. Walgreens knew that Ms. Rivera could die without that medication. A.II 42, 60-63, 70. Walgreens also knew that Ms. Rivera could not receive the medication unless Dr. Schoeck obtained prior authorization from MassHealth. Id.

Walgreens did not deny Ms. Rivera the medication outright; it would have sold the medication to her, at full cost. But the reality for many patients, and certainly for Medicaid enrollees like Ms. Rivera, is that medication is functionally inaccessible unless Medicaid pays for it.

As one commentator has pointed out, the cost of prescription drugs has threatened access to needed medications for many Americans. "Three in ten adults

(29%) say they have not filled a prescription because of the cost in the last two years" (citation omitted). Paula Tironi, Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs, 19 Annals Health L. 311, 317 (2010). "[N]early a quarter" have "cut pills in half or skipped doses in order to make a medication last longer." Id. The more medications a patient takes, or the lower the patient's income, the more common problems with prescription affordability become. Id.

Put bluntly, Medicaid enrollees such as Ms. Rivera by definition face likely deprivation of life-saving medications if their doctor does not know to obtain prior authorization. Indeed, "[e]ven a short-term delay in access to medications for conditions such as HIV, cancer, and seizures poses a serious risk to the health and safety of plan enrollees, including permanent damage or death." Worthy, et al., supra at 1065 (emphasis added). That risk can be eliminated or minimized with a simple telephone call from a pharmacist to a doctor to start the prior authorization process. This Court should tell pharmacists that they must make that potentially life-saving call.

CONCLUSION

The amici urge this Court to recognize the duty of reasonable care that a pharmacy owes to its customer to notify her physician that her insurer will not pay for her prescription medication without prior authorization.

Respectfully submitted,

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ADDENDUM

ADDENDUM
TABLE OF CONTENTS

ADDENDUM 1

42 U.S.C. § 1396r–8(d). Payment for covered outpatient drugs.

(d) Limitations on coverage of drugs

(1) Permissible restrictions

(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

(ii) the drug is contained in the list referred to in paragraph (2);

(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) of this section or in effect pursuant to subsection (a)(4) of this section; or

(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

(2) List of drugs subject to restriction

The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) Agents when used for anorexia, weight loss, or weight gain.

(B) Agents when used to promote fertility.

(C) Agents when used for cosmetic purposes or hair growth.

(D) Agents when used for the symptomatic relief of cough and colds.

(E) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

(F) Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1396d(bb)(2)(A) of this title, agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(G) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

(H) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

(I), (J) Repealed. Pub.L. 111-148, Title II, § 2502(a)(1)(A), Mar. 23, 2010, 124 Stat. 310

(K) Redesignated (H)

(3) Update of drug listings

The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

(4) Requirements for formularies

A State may establish a formulary if the formulary meets the following requirements:

(A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of

the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3) of this section).

(B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) of this section (other than any drug excluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6) of this section), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) Requirements of prior authorization programs

A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial

participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6) of this section) only if the system providing for such approval--

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) Other permissible restrictions

A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this chapter.

(7) Non-excludable drugs

The following drugs or classes of drugs, or their medical uses, shall not be excluded from coverage:

(A) Agents when used to promote smoking cessation, including agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

(B) Barbiturates.

(C) Benzodiazepines.

ADDENDUM 2

247 Code Mass. Regs. § 9.07 (2014)

9.07: Maintaining Patient Records, Conducting a Prospective Drug Utilization Review and Patient

Counseling

The purpose of 247 CMR 9.07 is to enhance the public health and welfare by requiring that pharmacists offer consultation to patients regarding their prescriptions in order to promote optimum therapeutic outcomes, avoid patient injury and reduce medication errors.

(1) Patient Records.

(a) A pharmacist or pharmacist's designee shall maintain a confidential record for all patients for whom prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the pharmacist to identify previously dispensed drugs at the time the prescription is presented for dispensing. The pharmacist or pharmacist's designee shall make a reasonable effort to obtain, record and maintain the following information:

1. name, address, telephone number, date of birth or age, and gender of the patient for whom the prescription is intended;

2. individual history, including known drug allergies and drug reactions;

3. a comprehensive list of medications and relevant devices dispensed by the pharmacy;

and

4. the pharmacist's comments relevant to the patient's drug therapy.

(b) A pharmacist shall maintain the patient's record for a period of not less than 12 months from the date of the last entry in the profile record, except as otherwise required by state and federal law. This record may be computerized.

(2) Prospective Drug Utilization Review.

(a) A pharmacist shall conduct a prospective drug utilization review ("DUR") before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. This DUR may include a review of the patient record and each new prescription presented for dispensing, for the purpose of promoting therapeutic appropriateness, by making a reasonable effort to identify the following:

1. over-utilization or under-utilization;

2. therapeutic duplication;

3. drug-disease contraindication;

4. drug-drug interaction;

5. incorrect drug dosage or duration of drug treatment;

6. drug-allergy interactions;

7. clinical abuse or misuse; and

8. any significant change in drug, dose or directions.

(b) Upon identifying any of the above, the pharmacist shall take appropriate measures to ensure the proper care of the patient which may include consultation with the prescribing practitioner and/or direct consultation with the patient.

(c) The review shall be based upon current standards which may include the following:

1. The American Hospital Formulary Service Drug Information;

2. the United States Pharmacopoeia Drug Information;

3. the American Medication Association Drug Evaluations; and

4. other peer-reviewed medical literature.

(3) Patient Counseling.

(a) The pharmacist or pharmacist's designee shall offer the services of the pharmacist to discuss, with all persons presenting new prescriptions, issues that in the pharmacist's professional judgment are deemed to be significant for the health and safety of the patient.

(b) The pharmacist's designee shall be an individual appropriately trained to make the offer to counsel and under the direct supervision of the pharmacist.

(c) A sign of not less than 11 inches in height by 14 inches in width shall be posted in a conspicuous place, adjacent to the area where prescriptions are dispensed, informing customers of their rights, pursuant to 247 CMR 9.07 and to M.G.L. c. 94C, § 21A, to counseling by a pharmacist where their prescription was filled. Said sign shall read, in letters not less than ½ inch in height: "Dear patients, you have the right to know about the proper use of your medication and its effects. If you need more information please ask the pharmacist."

(d) When the offer to counsel is accepted, the pharmacist shall provide such information which, in the pharmacist's professional judgment, is necessary for the patient to understand the proper use of the patient's prescription which may include the following:

1. Name and description of the medication;

2. dosage form, dosage, route of administration and duration of therapy;

3. special directions and instructions for preparation, administration and use by the patient;

4. common severe side and adverse effects or interactions and therapeutic contraindications or precautions with legend and non-legend medications which the pharmacist deems relevant;

5. techniques for self-monitoring drug therapy;

6. proper storage;

7. prescription refill information; and

8. action to be taken in the event of a missed dose or adverse reaction.

(e) The offer to counsel shall be made to the patient, or the person acting on behalf of the patient when confidentiality can be maintained, either by face to face communication or telephone. If the patient does not pick up the prescription at a pharmacy or the offer is not made by telephone then the offer must be made in writing. This offer must provide a tollfree telephone service to facilitate communication between such person and the pharmacist and must state the following: "Dear patient, you have the right to know about the proper use of your medication and its effects. If you need more information please ask the pharmacist". Printed material containing information on the drug may accompany this written offer to counsel provided the patient is informed that said information is not comprehensive and that the patient should call for further information if needed.

(f) Counseling must be made by a pharmacist, or a pharmacy intern under the direct supervision of the pharmacist if deemed appropriate by the pharmacist.

(g) Counseling must be available at all times when a pharmacy is open for business.

(h) The provisions of 247 CMR 9.07 shall apply to pharmacists who directly dispense medications to outpatients and patients being discharged from hospitals, institutions and clinics.

(i) The provisions of 247 CMR 9.07 shall not apply to any drug dispensed to an inpatient at a hospital, nursing home or any other setting where medication is administered by an authorized individual, except to the extent required by the Federal Health Care Financing Administration pursuant to the provisions of 42 USC 1396r-8.

RULE 16 CERTIFICATION

I, Thomas R. Murphy, hereby certify that the Brief herein complies with the rules of court that pertain to the filing of briefs, including, but not limited to: Mass. R. App. P. 16(a)(6); Mass. R. App. P. 16(e); Mass. R. App. P. 16(f); Mass. R. App. P. 18; and Mass. R. App. P. 20.

/s/ Thomas R. Murphy

Thomas R. Murphy