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On a muggy evening, Wendy Dolin was walking her dog a month after the bewildering suicide of her husband, the former Reed Smith partner Stewart Dolin, when a friend accompanying her uttered a strange word suggesting an explanation: akathisia. Looking up the condition online that night in 2010, Dolin was stunned by how closely its symptoms of intense restlessness and anxiety seemed to match her husband's puzzling behavior in the days before he took his life by jumping on the tracks of an O'Hare airport-bound Blue Line train in Chicago.


Stewart Dolin

The name of the condition, more familiar to neuropsychiatry professionals and pharmaceutical injury lawyers than to Wendy Dolin, a licensed clinical social worker in Illinois, shone to her through the fog of an inexplicable act by a man she had known for 42 years. He had seemed his usual self until just days before the incident, she said, when he had begun taking paroxetine, the generic version of the antidepressant Paxil.

He became so distressed soon after going on the medication that he pled to her one night that week in July: “I don't get it, Wendy. I still feel so anxious,” she recalled.

After poring over internet search results about lawsuits that alleged that akathisia was a known side effect of Paxil, which belongs to a class of antidepressants called selective serotonin reuptake inhibitors, Dolin decided on a seemingly improbable course of action. She would sue the drugmakers responsible for the manufacturing and labeling of Paxil, a drug whose generic version her husband had taken for only six days before his death.

“I’d got home that night and Googled akathisia, Paxil, and suicide, and lo and behold, all this information pops up,” Dolin said, referring to search results of papers published in psychiatry journals and litigation summaries on law firm websites.

"It was completely clear — all of us were looking through our emails and notes from him and there was no clue, nothing, that it could have been something else," she said.

Baum Hedlund Aristei & Goldman PC, a small personal injury firm based in Los Angeles, had been litigating wrongful death and injury suits involving suicides and suicide attempts related to antidepressants for about 20 years when Dolin contacted it in 2010 to take on her mission. Nearly two years later, the firm filed her negligence and wrongful death suit against Mylan Inc., the Netherlands-based generic-drug maker that manufactured the drug her husband was taking, and GlaxoSmithKline, which sold the drug’s branded versions and devised its labels, as the U.S. Food and Drug Administration requires.

> The idea that in this country, so many people take generics and that they have no legal recourse, it’s just unthinkable.
>
> — Wendy Dolin

The timing of her suit was inopportune for a plaintiff alleging an injury from a generic drug. The U.S. Supreme Court had just issued a landmark decision in 2011 in Pliva v. Mensing that shielded generic-drug makers from claims about their labeling of drug side effects and contraindications because FDA rules require them to follow the same warning language of their branded counterparts. Meanwhile, dozens of courts around the country were taking cues from a 1994 decision by the Fourth Circuit in Foster v. American Home Products Corp., which had found that although branded-drug makers are responsible for the labeling of their products, they don’t have a duty to warn patients taking generic versions of their drug.

The mountain of unfavorable case law had threatened to nip Dolin’s suit in its early pleading stages. Instead, she prevailed through multiple summary judgment motions by GSK — although the Mensing decision did jettison Mylan from her suit — as her lawyers strategized to counter the difficult precedent and found a willing ear in the Illinois federal judge overseeing the suit, James Zagel. Guided by the handful of courts before him to find branded-drug makers could be held liable under other tort theories besides strict product liability, he issued a surprising endorsement of Baum Hedlund’s arguments in the Dolin case, finding in February 2014 that GSK could be held liable for common law negligence claims.

Judge Zagel found that, unlike some other states, Illinois common law did not compel him to treat all claims stemming from a product injury as product liability claims.

“The injury here did indeed occur in connection with a product. And GSK manufactures products,” he wrote in his ruling. “Yet Plaintiff has not brought suit against GSK for tortious conduct committed strictly

as a manufacturer of products. And, though GSK implicitly urges to the contrary, I see no reason why all suits brought against GSK must be brought against GSK qua manufacturer."

Under his watch, the case is set to proceed to a monthlong trial in January, and it will be the first to involve a suicide allegedly caused by a generic antidepressant, and the first to test whether a jury would actually hold a branded-drug maker liable for a generic-drug injury. Many of the earlier suits filed over suicides allegedly linked to generic antidepressants have either settled or been dismissed.

Wendy Dolin with her husband Stewart on a 2007 vacation in Aspen, Colorado.

If Dolin prevails, the stakes will be high for generic-drug patients across the country. Her attorneys believe it would likely set the stage for the Seventh Circuit to address the issue for the first time in the event of a GSK appeal. In that scenario, the question before the court would be whether branded-drug makers can be held liable for injuries caused by generic-equivalent drugs that they did not themselves make. If the Seventh Circuit were to answer the question differently from the few other federal appeals courts that have done so — the Fourth and Sixth circuits have ruled against the idea that a branded-drug maker could be liable for a generic-drug injury — the suit could very well wend its way up to the nation's highest court.

"The idea that in this country, so many people take generics and that they have no legal recourse, it's just unthinkable," Dolin said. "I'd love this case to be the one that says, 'This is no longer acceptable.'"

The Paradox of Litigating Over Generics

Generic drugs account for roughly 80 percent of all prescription drugs dispensed in the U.S., according to the FDA. Their prevalence is due in part to their cost, which can be as low as a tenth of the price of their branded equivalent. In 2010, the use of generic drugs saved the U.S. health care system roughly $158

billion, according to an estimate by the generic-drug trade group the Generic Pharmaceutical Association, which the FDA cites on its website.

Those savings often interact with state laws in ways that ensure the widespread use of generics. A number of states have laws that encourage pharmacists to choose cheaper equivalents to a brand name prescription, unless a prescribing doctor includes explicit instructions not to do so. Such is the case in Illinois, where state pharmaceutical laws actually require such a substitution unless a doctor has advised against it. Some of the few courts that have sided with plaintiffs in generic-drug injury cases have also highlighted this conundrum for generic-drug plaintiffs.

The Alabama Supreme Court, the highest state court in the country to address the issue of whether a branded-drug maker can be held liable for a generic-drug injury — and one of the few to answer it in the affirmative — emphasized those implications in a 2014 ruling.

"Additionally, many insurance plans are structured to promote the use of generic drugs," the court wrote in the decision. Dolin's own health insurance plan covers only generics, she said. The Alabama Supreme Court ruling, however, which came in the then-groundbreaking case Weeks v. Wyeth, has since been negated by a 2015 law by the state Legislature that rejects the notion that a branded-drug maker can be held liable for a generic drug.

The unique position of generics has a relatively recent history. The Federal Food Drug and Cosmetics Act once required all drugmakers to show that their drugs were safe and properly labeled before the agency would approve them. Then the 1984 Hatch-Waxman amendments to the FDCA sought to simplify the process for generic-drug makers, in order to expand affordable treatment options for patients. The amendments allowed generic-drug makers to sidestep requirements to conduct clinical trials to show the drugs' safety and effectiveness, but it required them to show that they have followed the formulation and labeling of branded counterparts that have already undergone such trials.

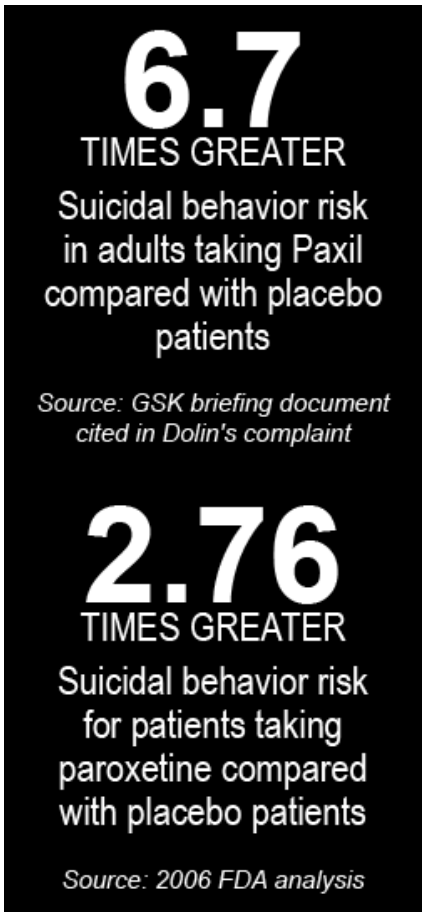
Consumer advocates believe that such requirements have created a significant gap in protecting patients for injuries they may have sustained because of inadequate warnings, while protecting generic-drug makers from most liability claims involving their products. Public Citizen, the consumer advocacy group that petitioned the FDA in 2011 for the agency to allow generics to independently go about making changes to their labels, holds that view.

"A majority of prescriptions are filled with generic drugs because it makes health care more affordable, but when the drug doesn't have adequate warnings on it, then physicians and patients can't make proper decisions," said Allison Zieve, the director of Public Citizen's litigation group.

“Brand name manufacturers are required to update their labeling when they become aware of new information of drug risks, but once a generic is on the market, the market share for the branded version drops very quickly, and the brand name often stops selling the drug altogether,” she said. “There’s nobody under the current regime monitoring the drug to make sure that labels are updated.”

But the U.S. Supreme Court cited the Hatch-Waxman Act in cementing the protections for generic-drug makers in its 2011 Mensing decision. That case involved claims by Gladys Mensing and Julie Demahy, plaintiffs from Minnesota and Louisiana, respectively, that their long-term use of a generic version of the heartburn drug Reglan sold by drugmakers including Pliva caused them to develop tardive dyskinesia, a neurological condition that causes involuntary movements such as uncontrollable twitching or blinking.

The court found in its ruling that generic-drug makers cannot satisfy state law requirements to strengthen their warnings when they are already required by federal law to match branded-drug labels.



In 2013, the Supreme Court expanded these protections further in Mutual Pharmaceutical Co. Inc. v. Karen Bartlett, largely blocking design defect claims by citing, among other factors, “Congress’ decision to regulate the manufacture and sale of generic drugs in a way that reduces their cost to patients but leaves generic-drug manufacturers incapable of modifying either the drugs’ compositions or their warnings.”

The Dolin Litigation

It was around the time of this flurry of major precedent against generic-drug plaintiffs in the courtroom that Brent Wisner of Baum Hedlund, then an associate at the firm in its San Francisco office, took on Dolin’s suit in 2012, his first case as a practicing attorney.

The suit faced hurdles not only because of the Mensing decision and the eventual Bartlett decision but also because of the sweeping influence of the Fourth Circuit’s Foster ruling, which had barred just the type of allegations that Dolin was making, he said.

Dolin’s suit claimed her husband had killed himself after exhibiting uncharacteristically high anxiety within days of taking generic Paxil, which had been prescribed to him by his family doctor and friend of 20 years, Dr. Martin Sachman. GSK’s warning label, which the generic version’s maker, Mylan, was required to follow, had misled patients and doctors, she claimed. It did not sufficiently warn that akathisia, which according to her complaint is marked by “profound inner restlessness and agitation,” could give rise to suicidal tendencies, she said. GSK has argued that the 2010 labels for Paxil contained warnings about akathisia that said the condition was “most likely to occur during the first few weeks of treatment.” Dolin insists that GSK did not connect the dots clearly enough between akathisia and suicide or sufficiently note the incidence of such risks in adults.

PRESCRIBING INFORMATION

PAXIL®
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Suicidality and Antidepressant Drugs

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of PAXIL or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. PAXIL is not approved for use in pediatric patients. (See WARNINGS: Clinical Worsening and Suicide Risk, PRECAUTIONS: Information for Patients, and PRECAUTIONS: Pediatric Use.)

Her suit also claimed that although GSK apparently knew of a statistically significant risk of suicidal behavior in adults taking the medication — roughly 6.7 times higher compared with patients on a placebo — the drug's label concealed that risk by claiming that "the suicidality risk did not extend past the age of 24." GSK has said that this language was ordered by the FDA as part of its warnings on all SSRIs that "short term studies" of antidepressants did not show such risks of suicidal behavior.

The Fourth Circuit's ruling in the Foster case involved the death of a six-week-old infant who had been given a generic version of a colic medication called Promethazine Syrup Plain. The appeals court squarely rejected the notion that a brand-name pharmaceutical could be held liable for negligent misrepresentation claims in that instance. But in the pre-Mensing era of that ruling, the court had found that generic drugs were responsible for their own labeling, emphasizing the benefits they enjoyed because of the Hatch-Waxman amendments allowing them to circumvent expensive clinical trials.

> I had a lot of people telling me I had no chance to prevail.
>
> — Brent Wisner, Wendy Dolin's attorney

"Name brand manufacturers undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information," the panel wrote. "Generic manufacturers avoid these expenses by duplicating successful pioneer drugs and their labels."

At the time Wisner prepared to fight motions by Mylan and GSK challenging the viability of Dolin's case, some 70 other courts had more or less adopted the Fourth Circuit's view in Foster, according to court documents.

"Coming out of law school you want to deal with complicated legal issues," said Wisner, who had just graduated with his law degree from the Georgetown University Law Center in 2010. "But I had a lot of people telling me I had no chance to prevail."

So he hatched a plan. Anticipating that Mylan and GSK would seek to quickly dispose of his claims, he approached them in February 2013 with a calculated compromise. He would agree to put discovery on hold while the parties addressed questions of whether Dolin's claims were preempted or not viable, but in exchange, Mylan and GSK would have to file their motions challenging her claims roughly at the same time.

That way, Wisner reasoned, he could address both defendants' motions in a single opposition, creating a path for the judge to issue a cohesive response addressing the arguments of both defendants in the same opinion. Mylan filed its motion to dismiss in August 2012, citing the Mensing ruling. GSK followed suit with its summary judgment motion in January 2013, arguing that there was "virtual unanimity" among the numerous courts to consider this question and that they had rejected the kind of misrepresentation theories that Dolin was advancing. The drugmaker also argued that Illinois product liability laws require claims related to injuries caused by a product be brought against the company that actually manufactured it.

"Regardless of how plaintiff couches her claims, they are all barred under Illinois law because GSK did not manufacture, distribute or sell the immediate-release paroxetine that allegedly caused Mr. Dolin's death," it argued. "Without this fundamental predicate, Plaintiff cannot establish the necessary elements of her claims."

Wisner believed his approach could nudge Judge Zagel to make a more comprehensive analysis about whether case and state laws truly end up leaving most generics plaintiffs with no legal recourse for alleged injuries.

"I wanted him to be ruling on the ability of my client to get any sort of justice," Wisner said. "My thinking was, when you consider both of these issues together — innovator and generic immunity — it is easy to see how unfair the law has become."

Judge Zagel took the cue and found in his now-renowned ruling in February 2014 that Illinois law doesn't call for common law negligence claims to be treated like product liability claims just because the suit involves a product and an alleged injury it caused.

"GSK vigorously contends that the design and warning label are not in themselves 'products,'" Judge Zagel wrote. "[But] GSK has not shown why Plaintiff should be precluded from claiming at common law that GSK, independent of its capacity as a manufacturer of one particular iteration of paroxetine, was negligent in connection with its responsibility for these 'non-products,' and that this negligence contributed to her injury."

The ruling was a breakthrough for Dolin, too. "The phone rings [that day], and Brent [Wisner] says, 'I think you just sorta made history here,'" she said.

The Trial

The Dolin trial is set to boil down to a few crucial questions for the jury, foremost of which is whether the drug Paxil, which the FDA first approved in 1992, causes suicidal tendencies in adults. Dolin's experts, who are expected to testify on this issue of general causation, have so far withstood GSK's challenges.

Among them is Dr. Joseph Glenmullen, a psychiatry professor at the Harvard Medical School who has written two books about antidepressant side effects. In a 2007 report to Baum Hedlund, unsealed in a different case over Paxil in Kansas state court, Glenmullen argued that GSK's own data to the FDA in 1989 showed a substantial increase in risk of suicidal tendencies in patients on Paxil compared to those on placebo pills but that the drugmaker underreported or downplayed such risks to regulators.

It was only in 2006 that the company acknowledged in a so-called Dear Health Care Provider letter, which is meant to inform doctors of updated safety information, that Paxil could increase the risk of suicidal tendencies in certain patients by about six times as compared with a placebo, according to his report. That year, GSK modified its label to warn that it had found Paxil posed a "statistically significant" increase in the frequency of suicidal behavior in adult patients with major depressive disorder. This language made way for the FDA's classwide labeling for all SSRIs the following year that would update all black box warnings — the agency's most serious safety warnings — on the drug. The classwide label would warn patients and consumers only about increased suicidal tendencies among young patients aged 18 to 24.

In 2011, Wendy Dolin founded a nonprofit dedicated to spreading awareness of akathisia titled MISSD, shorthand for "the Medication-Induced Suicide Prevention and Education Foundation in Memory of Stewart Dolin."

Glenmullen's report, along with a similar one that followed the same year by the British drug safety regulator finding GSK knew of such risks in adolescent patients since 1998, prompted Iowa Republican Senator Chuck Grassley to urge the FDA in June 2008 to determine if the drugmaker had suppressed any safety information when it sought approval for the drug.

Glenmullen has maintained his position in the Dolin case, in which he has testified that taking paroxetine was a "proximate cause" in Stewart Dolin's suicide. GSK sought to exclude his testimony in September, arguing that Glenmullen had not shown any idea linking Paxil to suicides, only to suicide attempts, which the drugmaker argued was not an adequate substitute.

Judge Zagel denied such motions in November, finding that Dolin's experts had offered "reliable" testimony.

Dolin's experts also include Dr. David Healy, a psychiatry professor at the University of Wales in England. Healy, who has worked as an expert witness for Baum Hedlund for years in lawsuits involving antidepressants, has stated in the case so far that GSK's own labeling documents from 2006, including letters to physicians, had acknowledged that "the frequency of suicidal behavior was higher in patients treated with paroxetine compared with placebo … this difference is statistically significant."

If the jury agrees on that question of general causation, it would then have to decide whether GSK adequately warned of the risk. If it decides the warnings were insufficient, the jury would then have to consider whether the failure to warn led to the suicide — that is, whether better warnings would have led Dr. Martin Sachman to prescribe a different treatment.

Baum Hedlund has also enlisted former FDA physician David Ross to testify on the regulatory history between GSK and the FDA and what data the drugmaker shared with the agency.

One of the key points of contention is whether GSK did its thorough due diligence to make sure its labels contained warnings specific to Paxil's potentially increased risk for suicidal tendencies — the FDA's own analysis found a 2.76 times higher risk for patients taking paroxetine.

Although GSK had asked the FDA about adding Paxil-specific warnings to the agency's classwide warnings in 2007 in order to alert doctors and patients about the drug's potential to cause suicidal tendencies in adults, it did not follow through with the agency's invitation to ask for a formal meeting to discuss that change, Dolin has argued.

GSK has dismissed this argument as mere "conjecture about a meeting that did not take place," countering that it had submitted two different sets of documents to the FDA under its Changes Being Effected program, which allows branded-drug makers to update their labels based on new information. Each time, GSK said, it sought to retain warnings specific to Paxil on its label, but it received a rejection by the agency, according to its filings.

Defense attorneys believe GSK's argument could offer an important window for the drugmaker to persuade the jury that even if it had actually called for such a meeting, the FDA would likely not have approved it.

"Both Judge Zagel and Dolin have said here, 'You could have had that meeting, so you haven't exhausted all your options to show that the FDA couldn't be convinced otherwise," said Henninger Bullock of Mayer Brown LLP, who has represented branded-drug makers in similar suits. "But GSK can say: 'Well, we tried, and the FDA told me twice already that I couldn't modify the classwide label, so to request a meeting would be futile.'"

A spokeswoman for the FDA declined to comment on pending litigation.

Besides experts, Dolin and her two adult children with Stewart are expected to testify, along with Sachman, who said at deposition last year that he didn't know of the drug's risks and if he had he would never have prescribed it to his best friend, Wisner said.

Wendy Dolin may be questioned at trial over the circumstances surrounding her husband's death. "I knew my husband, and I don't even consider it a suicide anymore," she said.

GSK, which has taken a whopping 30 depositions in the case over a one-and-a-half-year period, has designated more than two dozen witnesses, including company witnesses and about nine experts.

"GSK is not responsible for Mr. Dolin's death and we've submitted our position in filings to the court," spokeswoman Jenni Ligday told Law360 in a statement.

Dolin herself may be grilled on the specifics of her husband's mental state and activities leading up to his death. Some salient details of his final hours stand out to her as especially convincing evidence that he did not plan his suicide in a state of anxiety over long-simmering work-related problems, as GSK has argued.

The drugmaker had argued that Stewart Dolin had experienced work-related anxiety and depression for years, according to a heavily redacted segment of its summary judgment motion in October.

Shortly before his bizarre and tragic visit to the subway station, he had had lunch with an accountant at the Rivers Restaurant near his office in the Chicago Loop. There, he had ordered a chicken salad, requesting the dressing on the side, Wendy recalled, remarking ruefully, "You had the dressing on the side an hour before you [supposedly] planned to die?"

"I knew my husband, and I don't even consider it a suicide anymore," Dolin said. "I consider it a fatal drug reaction."

Sindhu Sundar is a feature writer at Law360. Follow her on Twitter.