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Speed, high volume can trigger mistakes

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The prescription called for Inderal to control a little boy's tremors. A Walgreens pharmacy instead gave him Methitest, a steroid usually prescribed for older males. Five-year-old Trey Jones took the wrong medication for two months and began showing signs of early puberty. How do mistakes like this happen?



Family photo of Trey Jones

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Five-year-old took wrong medication for two months



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Enlarge By H. Darr-Beiser, USA TODAY

Benjamin Goldberg, 6, reads with his father, Richard. Benjamin was sickened by too-strong dosages of amoxicillin from a pharmacy in 2001.

By Kevin McCoy and Erik Brady, USA TODAY

When Tabitha Jones picked up her stepson's medicine at a Walgreens store near Nashville in 2004, she had no way to know the pharmacy was so busy that its manager had asked for more staffing months earlier to "decrease the pharmacist's stress."

RX FOR ERRORS

TODAY'S REPORT: Many lawsuits against pharmacies settled in silence | **Minimizing risks:** 9 steps you can take | Pharmacist counseling helps



GRAPHIC: How prescriptions are filled, how mistakes are made, and what pharmacies are doing to prevent them

DAY 1: Speed, volume can trigger mistakes | **Debate:** Corporate policies can cause errors, retired pharmacist says | They actually help, current pharmacist says

DAY 2: One pharmacy's fatal mistake; hear woman's story of her late husband | Drugstore chains rely on pharmacy technicians

She also had no idea the drug Walgreens gave her that day was a steroid never intended for children and not the blood pressure drug prescribed to treat Trey Jones' hand tremors and hyperactivity. Walgreens refilled the prescription four times, eventually at double the adult dosage, before the error was caught. The 5-year-old not only went into premature puberty but also erupted in rages.

Trey's parents sued Walgreens, fearing the steroid could stunt the boy's growth or cause liver damage. "We don't know what could happen later on down the road," his father, Robert Jones Jr., said in a 2006 pretrial deposition.

Pharmacy chains say they've spent billions of dollars on safety technology and other improvements that have cut their prescription-error rates to a fraction of 1%. As aging baby boomers and other Americans increasingly rely on prescription drugs, an Auburn University pharmacy study in 2003 projected the odds of getting a prescription with a serious, health-threatening error at about 1 in 1,000. That could amount to 3.7 million such errors a year, based on 2006 national prescription volume.

A USA TODAY investigation found evidence that corporate policies — such as allowing or encouraging pharmacists to fill hundreds of prescriptions daily and rewarding fast work — can contribute to errors like the one that befell Trey Jones.

CORPORATE POLICIES CAN FOSTER ERRORS: "There is a correlation between workload and errors," retired pharmacist says.

CORPORATE POLICIES REDUCE ERRORS: Recent advances have made "the pharmacist much more accurate," current pharmacist says.

The investigation reviewed policies and alleged errors at rivals Walgreens (WAG) and CVS (CVS), the nation's two largest drugstore chains, which fill nearly one-third of all retail prescriptions nationwide. It included a review of scores of lawsuits, as well as pharmacy board disciplinary actions in 10 states. Some common factors emerged:

•**Too many prescriptions, too few pharmacists.** Some stores fill so many prescriptions that pharmacists work long shifts with few breaks. In the case of Benjamin Goldberg, a North Carolina baby whose parents were given an antibiotic with instructions for five times the prescribed dosage, the state pharmacy board reprimanded a CVS pharmacy for filling prescriptions "at such a rate as to pose a danger to the public health or safety."

INTERACTIVE GRAPHIC

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TRACKING PHARMACY ERRORS

There are no comprehensive counts of prescription errors. Many go undetected or unreported. No federal agency tracks them.

On the state level, where pharmacy boards monitor pharmacies and pharmacists, only North Carolina requires that all significant errors be reported.

Academic studies offer rough estimates of the incidence of errors.

A pharmacy that fills 250 prescriptions a day makes about four errors daily, according to a study published in 2003 by Auburn University researchers. They examined one day's worth at 50 pharmacies in six cities.

A 2001 survey of more than 2,800 pharmacists by Texas Tech researchers found 34% suggested at least one of their patients per week was at risk for a mistake.

When pharmacy owners are required to produce error data in lawsuits, they typically do so under confidentiality orders, says Barry Furrow, a law professor at Drexel University.

The last known time Walgreens produced such data without a protective order was in the mid-1990s.

The data showed 6,147 incidents for the wrong drug, wrong dosage or wrong instructions over two years. It also showed 223 drug-error lawsuits.

Walgreens says the totals equal an error rate of "22-thousandths of 1%."

Walgreens was ordered to produce similar data in the Trey Jones case, but the court granted a motion that barred public disclosure.

By Erik Brady and Kevin McCoy

- **An emphasis on speed.** American consumers expect fast pharmacy service, and the chains try to meet that expectation. Walgreens guidelines obtained by USA TODAY say pharmacists need as little as two minutes to fill a prescription. That doesn't leave enough time to counsel patients about a new prescription, says William Kennedy, a former Walgreens pharmacist and union leader.

CVS monitors whether pharmacists meet goals for filling prescriptions by promised times and ensuring phones are answered swiftly. The Institute for Safe Medication Practices urged CVS to review whether the policies place "speed above safety" after a Massachusetts investigation substantiated 62 drug errors or other concerns.

- **A reliance on technicians.** Walgreens and CVS rely on lower-paid, lesser-trained technicians to help pharmacists by processing and packaging prescriptions. Although pharmacists by law must verify that each medication contains the right drug, dosage and directions, they don't always catch technicians' errors. In Jacksonville, roofing contractor Terry Paul Smith died of a methadone overdose in 2001 about 36 hours after getting a prescription for which a dosage error by a Walgreens technician went unnoticed by a pharmacist.

- **Pharmacist incentive awards.** At Walgreens, bonuses paid to pharmacists and pharmacy managers are based in part on increases in prescription volume. Until this year, CVS partly based pharmacists' bonuses on their success in meeting company goals for filling prescriptions by the times promised to patients and for ensuring phones are answered promptly.

- **Counseling gaps.** All but two states require pharmacies to offer face-to-face counseling to most customers who pick up new prescriptions. But state records show CVS was cited at least once by the North Carolina Board of Pharmacy for failing to offer or provide counseling, and Walgreens was disciplined at least five times since 2002 for similar infractions in Oregon.

Walgreens provided a demonstration of the high-tech safety systems used in the chain's pharmacies but declined to make executives available for USA TODAY interviews. In written responses, the chain said it has spent nearly \$1 billion in the last 10 years on safety training and technology. "That investment shows how seriously we take our responsibility to be error-free," Walgreens said, adding that its goal "is to take out the possibility of human error as much as possible and have a zero error rate."

CVS also provided a demonstration of its computer and safety

WORKLOADS, STAFFING PRESSURES WORRY MANY PHARMACISTS

systems. Papatya Tankut, CVS' vice president for pharmacy professional affairs, said in an interview that improvements have cut errors to "a small fraction of 1%," a rate she said is "continuing to decline."

Daniel Hussar, a pharmacy professor at the University of the Sciences in Philadelphia, offers a more critical view. He says staffing policies have made pharmacy chains stressful workplaces. "The emphasis on speed is counterproductive. It's an invitation for error," says Hussar, editor of *The Pharmacist Activist*, an online newsletter.

The Trey Jones case

Trey Jones ate three meals a day like a typical 5-year-old until he started taking Methitest, a synthetic hormone for older males whose bodies aren't producing enough testosterone. Afterward, he "would eat a plate full of food and come back and get seconds, and 10 minutes later, he would want thirds," his father, Robert, said in his deposition. The boy's wall-kicking rages made it difficult for him to focus on schoolwork. "You couldn't tell him to do anything," his father said.

Trey's hands continued to shake, so his doctor doubled the initial 10-milligram dose of Inderal. Walgreens again misfilled the prescription, this time with a higher dosage of the steroid. Trey began experiencing genital pain, his father said.

When Walgreens caught the error, the pharmacist told Tabitha Jones only to contact Trey's doctor, court records show. Trey's parents halted the steroid use soon afterward. Trey, now 8, gets regular growth and liver tests. Natasha Leibel, a Columbia University pediatric endocrinologist not involved with the case, says steroid use by a child "could, in theory, ... compromise adult height." Liver disease is a rarer effect of long-term use, she says.

Trey's parents filed a complaint with the Tennessee pharmacy board and sued Walgreens. Robert Jones knew the challenges would be hard but says keeping drug errors "from happening to someone else" was reason enough to fight.

Pretrial discovery in the Jones case showed the Springfield, Tenn., pharmacy where the errors began was busy: Trey's prescription was among 477 filled by two pharmacists on Sept. 30, 2004.

Months earlier, pharmacy manager Jill Brown had written in an internal report that the store had surpassed its goal of

averaging 350 prescriptions a day and "could use a third pharmacist to ... decrease the pharmacist's stress." But she said in a pretrial deposition that Walgreens guidelines say a store must average 550 prescriptions a day to get a third pharmacist.

David Work, a former North Carolina Board of Pharmacy executive director tapped as an expert witness by the Jones family, wrote in a report filed in court that the store's prescription volume and staffing represented "a breach of Walgreens' (safety) obligation."

In its responses to USA TODAY, Walgreens said, "Errors don't occur more often at a busy pharmacy than a slow pharmacy."

Philip Burgess, national director of pharmacy affairs for Walgreens, testified in a 2007 deposition for a different case that he saw no link between pharmacist workload and errors. He said mistakes were "more related to lack of focus."

Both Walgreens and CVS have cited a University of Cincinnati study that found workload was just one factor in drug errors. The study, partly funded by the National Association of Chain Drug Stores, found pharmacists were most at risk for mistakes when less busy, or during a drop in drug volume. The study examined 36 chain pharmacy sites.

U.S. District Court Judge Aleta Trauger, who presided over the Jones case, saw it differently. "Although the defendant denies that there is any connection between number of prescriptions processed per day and mistakes, common sense and at least one purported expert argue in favor of the opposite conclusion," she wrote in a 2007 pretrial ruling. Trauger said she would let a jury decide whether the prescription volume amounted to recklessness, a finding that could have exposed Walgreens to punitive damages.

But the case never went to trial. Walgreens acknowledged in a pretrial conference last March that it had violated the standard of care owed to Trey. The parties reached a late-December settlement that includes a confidentiality order barring Walgreens and Trey's family and attorneys from discussing the financial terms and other details.

Tennessee's pharmacy board conducted its own investigation. In 2005, it imposed a \$500 fine on Walgreens pharmacist Avani Sindhal for violating state rules that require pharmacists to keep health and safety as their top concern. She said in a 2006 deposition that she thought Trey's prescription called for the steroid. Sindhal, who still works for Walgreens, also said she didn't recall seeing Trey's birth date on the prescription.

Catastrophic consequences

Most prescription errors don't cause major health problems, but the outcomes occasionally can be catastrophic. Walgreens has lost three trials involving deaths caused by drug mistakes since September 2006. Verdicts in the cases totaled more than \$61 million.

The cases include the 2002 death of Eric Warren, a 31-year-old Arizona high school wrestling coach. He died from an interaction between Tramadol and methadone, painkillers dispensed at different times by a Walgreens pharmacy in Flagstaff, Ariz. A jury awarded his family \$6 million in October after hearing evidence that Walgreens pharmacist Al Salembier neither warned Warren about the potential drug interaction nor double-checked the second prescription with his doctor. Walgreens is appealing the case.

In August, a Florida jury awarded \$25.8 million to the family of Beth Hippely, 42, a mother of three who died in 2002 after Walgreens mistakenly gave her a blood thinner 10 times stronger than prescribed. The chain is seeking a new trial.

Walgreens also faced a Florida trial last year over the 2001 death of Smith, the Jacksonville roofing contractor who received a methadone prescription with incorrect dosage instructions. But the chain reached a confidential settlement with Smith's family in December.

Prescription volume is rising nationwide. The 3.7 billion prescriptions filled in 2006 represented a 12% increase from 2002, according to data from IMS Health, a pharmaceutical and health care consultant.

But the number of pharmacists — about 240,000 nationwide, including about 110,000 in chain drugstores — hasn't kept pace. Parts of 42 states were identified as pharmacist shortage areas in a 2007 survey by the National Association of Chain Drug Stores.

Some pharmacists say the busy working conditions that have resulted raise the risk of errors. "It isn't uncommon to walk in for your shift at 8 a.m. and find 100 scripts (prescriptions) ... to fill before you even get started. Imagine the pressure," says Kennedy, the retired Walgreens pharmacist from Illinois and former head of a union for Walgreens pharmacists. "There is a correlation between workload and errors. ... I can tell you that from my own experience."

Walgreens said Kennedy, who retired in 2006, isn't current on today's pharmacy conditions.

After a Walgreens pharmacist in Bullhead City, Ariz., mistakenly dispensed a heart drug instead of a pancreas medicine to David Morris in 2004, the state pharmacy board questioned whether the store had sufficient staffing. "Our current pharmacists feel we are constantly understaffed when we are asked to keep within our 'budget,'" Pamela Huntoon, the pharmacy manager, wrote, state records show. Morris' wife caught the error before any harm occurred.

"No pharmacist ever has to fill a single prescription more during the workday than they feel is safe," Walgreens told USA TODAY.

There are few standards within the industry for determining how much volume is too much.

The North Carolina Board of Pharmacy, the only state board that requires all major drug errors to be reported, has a rule of thumb: It weighs workload when it investigates mistakes at any pharmacy that filled more than 150 prescriptions per pharmacist per day. Those that fill more than 150 don't automatically violate state rules. But the board has questioned or reprimanded about 12 pharmacies since 2002 for letting pharmacists work at rates that could "pose a danger to the public health or safety," state records show.

James DeVita, CVS' director of quality assurance, says that before taking action, the board should assess other factors, including whether a pharmacy has technology that lets it handle higher volumes safely.

Baby would 'writhe in pain'

Typical of the North Carolina reprimand cases was the 2001 injury of 16-day-old Benjamin Goldberg. Born prematurely, he had an infection that required hospital care with intravenous antibiotics, says his father, Richard Goldberg, an assistant professor of biomedical engineering at the University of North Carolina.

After 10 days, Goldberg and his wife, Edie Kahn, an occupational therapist, brought Benjamin home with a prescription for oral amoxicillin, a common antibiotic. They filled the prescription at a CVS pharmacy. "We noticed just a lot of discomfort from that first dose. He cried for many hours," says Goldberg. And he would "writhe in pain" after new doses, says Kahn.

Checking with the hospital after two days, Goldberg says he learned Benjamin's dosage was "way over what he should be getting." The dosage on the CVS label was five times what had been prescribed.

Although the infant suffered no lasting injuries, Goldberg complained to the state pharmacy board. The panel found that CVS pharmacist David Rogers and a second pharmacist dispensed more than 400 prescriptions on the date of the error. The board reprimanded Rogers and CVS for filling prescriptions at a dangerous rate.

Work, the state board's executive director at the time of the Goldberg case, says error risk increases with high workload. He likens the danger to a tachometer warning: "You can run that car up past that red line for a while. But sooner or later, you know bad things are going to happen."

CVS said it could not discuss the Goldberg case for privacy reasons.

Tying pay to volume

USA TODAY found Walgreens and CVS have policies that seem to stress speed in filling prescriptions.

Walgreens' budget guidelines for work hours, never previously publicized, say a pharmacist at a typical store might have as little as two minutes to verify the accuracy of a drug, its dosage and directions.

"That's not enough. They allow no time for counseling" patients about their medications, checking the work of technicians and fulfilling other duties, says Kennedy.

"We have never dictated the time a pharmacist spends on a prescription," Walgreens said. "Pharmacists are licensed professionals; we expect them to exercise good professional judgment." Stores may adjust the guidelines "as needed," the chain said.

Kennedy challenges that assertion: "Walgreens corporate (executives) will tell you ... that there is no pressure to increase speed, and that pharmacists are supposed to use their professional judgment and go at a pace where they're not going to make errors. ... What filters down to middle management is completely opposite. They're in the stores pushing the volumes."

CVS tracks how often its pharmacists meet three corporate goals: no more than a 15-minute wait for most patients who opt to wait in a store while prescriptions are filled, filling prescriptions promised to other patients on time, and ensuring that phones are answered within 20 seconds. Computer screens highlight prescriptions for in-store patients in yellow. For other patients, computers mark in red those prescriptions that aren't ready when promised.

CVS says it historically based a small percentage of pharmacist bonuses on how well the goals were met. The incentives came into question when a 2005-06 Massachusetts Board of Pharmacy investigation substantiated 62 of 80 complaints of errors and other concerns against CVS.

In a settlement, CVS agreed to have the Institute for Safe Medication Practices review the chain's pharmacy practices in Massachusetts for two years. The institute recommended that CVS "examine (the) appropriateness of current elements of (the) pharmacist incentive plan" and eliminate practices that "create pressures that place

speed above safety."

Michael Cohen, president of the institute, says the policies were questioned out of concern pharmacists would feel "they were getting incentivized ... or disincentivized" if the goals weren't met.

DeVita, CVS' quality-assurance director, says the phone-answering goal was instituted as a courtesy for patients and doctors. Tankut, the chain's pharmacy vice president, says the policy for in-store patients was designed to ensure the fastest reasonable service time for those with urgent medical needs, such as newly discharged hospital patients.

Saying the system helps pharmacists prioritize their work, Tankut adds, "We never compromise safety for speed." She also says pharmacists can extend waits if a pharmacy is busy. "It is not necessary or required for the pharmacy staff to work faster," Tankut says.

Starting in January, CVS dropped the measures from the incentive plan used to decide pharmacist bonuses, although the chain still tracks the goals. CVS spokesman Michael DeAngelis says the move wasn't a direct response to the safety institute.

Walgreens pharmacy managers are eligible for a bonus up to 10% of their income based in part on prescription-volume increases, James Schmid, national director of pharmacy operations for Walgreens, said in a 2003 deposition.

Burgess, in a 2007 deposition, was asked whether bonus decisions should take into account drug errors. He disagreed, saying, "Errors, as unfortunate as they are, are human errors."

Walgreens said, "It's inconceivable that a health care professional making more than \$100,000 a year would jeopardize their license to practice in order to influence their bonus by a few hundred dollars."

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