# Major U.S. pharmacy chains promise safety improvements

In response to the Tribune tests, some of the nation's largest pharmacy chains said they would take significant steps to improve patient safety.

#### **CVS**

CVS said it will change its policies and computer system to require pharmacists to call the prescribing doctor or warn the patient when a serious drug interaction is flagged. Those changes will apply to the chain's 30,000 pharmacists at its 9,600 drugstores.

Currently, CVS allows pharmacists to override computer alerts if they review the warning and accompanying medical literature and conclude the prescription is appropriate. In the future, the system will not allow pharmacies to dispense certain flagged medications unless the pharmacists document in the computer that they have called the doctor or counseled the patient.

CVS said its pharmacists will undergo a comprehensive training and certification program on the new rule, to be implemented early next year. The rule will apply to other safety issues, such as drug-allergy interactions, duplicative therapies and orders involving unusually high or low doses, later in the year.

To reduce "alert fatigue," CVS said it will work with its database providers to streamline alerts to help ensure that pharmacists are presented the most important warnings.

In addition, CVS said it will change its approach to the "offer to counsel." Throughout the industry, pharmacists often address a legal requirement that pharmacies must offer to counsel patients by having staff ask customers at checkout, "Do you have any questions for the pharmacist today?" or sometimes simply, "Any questions?" CVS said it will require a more robust and explanatory communication.

CVS said the new wording has not been finalized but that the company's 50,000 technicians will be trained in the new policy.

## Walgreens

Walgreens said it will provide additional training on drug interactions for its 27,000 pharmacists at its 8,175 U.S. drugstores, including the 222 pharmacies in the New York metropolitan area under the Duane Reade banner. A pharmacy staff meeting on drug interactions will be held chainwide.

To give pharmacists more time to help patients, Walgreens said it is accelerating efforts to move administrative tasks out of stores and to a centralized office.

Walgreens also said it has notified staffers of relevant policies and procedures, including that pharmacists should always counsel patients on new prescriptions.

### Wal-Mart

Wal-Mart said it will update and improve its pharmacy alert system. Once that process is completed, the company's pharmacy operating manual will be amended accordingly, and Wal-Mart's 16,000 pharmacists at 4,500 stores will be required to undergo computer-based training on the changes.

The company also said it will send a notification to all of its pharmacists reminding them of best practices in terms of identifying drug interactions and warning patients. Wal-Mart said it will reinforce that pharmacists should counsel all patients filling new prescriptions.

### Kmart

Kmart said it is reviewing its policies, computer systems and training programs relevant to its 528 pharmacies.

The company said it is also studying whether to bolster the way it approaches the "offer to counsel" and whether to require new customers to fill out medication forms to help staff detect drug interactions.



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TRIBUNE WATCHDOG UPDATE DANGEROUS DOSES

## Tougher laws for pharmacies urged

Durbin joins regulators, calls for safer drug pairing policies after Tribune tests

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The minimum staffing levels 
for pharmacies to address 
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U.S. Sen. Dick Durbin, in
response to the findings,
called for new nationwide
policies to protect consumers from drug combinations.
"It's hard for me to believe that, in this age of
computers and software, we



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#### TOM SKILLING'S FORECAST



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By Karin Laub and Edith M. Lederer





Monday, December 19, 2016

TRIBUNE WATCHDOG DANGEROUS DOSES

# Tougher laws for pharmacies urged

Durbin joins regulators, calls for safer drug pairing policies after Tribune tests

## By Ray Long and Sam Roe

Citing a Tribune investigation into dangerous drug interactions, the head of the nation's top association of pharmacy regulators is urging states to enact tough laws to require pharmacists to counsel patients when they pick up medications.

"Counseling has to occur," said Carmen Catizone, executive director of the National Association of Boards of Pharmacy.

He said he wants states to publicly disclose pharmacy medication errors. In addition, he said, authorities should examine whether to set minimum staffing levels for pharmacies to address workload issues.

The Tribune investigation, published online Thursday and in the print edition Sunday, found that Chicago-area pharmacies frequently dispense dangerous drug combinations without warning patients. Of the 255 drugstores tested by the newspaper, 52 percent sold risky drug pairs without mentioning the potentially harmful or even fatal interactions.

U.S. Sen. Dick Durbin, in response to the findings, called for new nationwide policies to protect consumers from drug combinations.

"It's hard for me to believe that, in this age of computers and software, we would still be dealing with such a fundamentally dangerous issue," Durbin said in an interview. "You would think that, at this point, with records being kept and the vast amount of knowledge on these drugs, the pharmacists could wave off prescriptions that are dangerous to customers."

He asked: "Where's the safety for the consumer?"

Drug interactions, in which one drug alters the effect of another, have been a major public health problem for years, but little progress has been made in reducing the risks.

The Tribune testing represents the largest and most comprehensive study of its kind. In response to the findings, three of America's biggest pharmacy chains — CVS, Walgreens and Wal-Mart — said they would take steps to improve patient safety at stores nationwide. The changes would cover 22,000 drugstores and involve additional training for 123,000 pharmacists and technicians.

State laws on when pharmacists must counsel patients vary across the country. In Illinois, pharmacies are required to provide patients with an "offer to counsel" on all prescriptions. Pharmacies often address this requirement by having staff ask customers at checkout, "Do you have any questions for the pharmacist today?" or



E. JASON WAMBSGANS/CHICAGO TRIBUNE

A Tribune study surveyed pharmacies' responses to prescriptions for five drug combinations that could harm patients.

sometimes simply, "Any questions?"

Catizone said he would like to see all states require pharmacists to actually provide — not just offer — counseling about first-time medications and changes of doses

CVS, the nation's largest pharmacy chain by store count, said it would change its approach to the "offer to counsel" in light of the Tribune tests. The company said it will require a more robust and explanatory communication between staff and patients. Once the wording is finalized, CVS' 50,000 technicians will be trained in the new policy, the company said.

CVS had the highest failure rate of any chain in the Tribune tests, dispensing the medications with no warning 63 percent of the time.

Catizone said his association, composed of state regulatory agencies, would help provide advice in response to Durbin's call for action. The association influences state policy through the development of national standards, which can provide a framework for new legislation.

When pharmacies find out about a medication error, Catizone said, they should be required to report the instance to their state board of pharmacy. Once a state investigation is complete, he said, the reports should be publicly released.

Pharmacies sometimes have to fill hundreds of prescriptions in a single shift, and pharmacists have fought to increase staffing levels because of the workload.

Catizone's group previously has called on states to prohibit, restrict or regulate company policies that measure the speed of pharmacists' work. In light of the Tribune's findings, Catizone said the question of minimum staffing levels should be explored.

Durbin, the Senate's second-highest-ranking Democrat, also is pressing for answers.

He sent letters to industry groups representing independent and chain stores, asking them to explain what they are doing to reduce patient risk of drug interactions. Contacted by the Tribune, the groups, the Illinois Pharmacists Association and the National Community Pharmacists Association, said they will develop responses to Durbin's letter.

At the federal level, Durbin is urging the federal Centers for Disease Control and Prevention to determine how common it is for pharmacists not to warn about drug interactions. In a letter to the CDC, he asked the agency to establish concrete steps to ensure the safety of consumers and to issue guidelines to state boards of pharmacy and private industry groups.

He wrote that he is "deeply concerned by what appears to be an underlying problem of misplaced emphasis on quick service over patient safety."

Durbin urged the CDC to examine how software can be better used to alert pharmacists to the risks of drug interactions. He also asked the agency to examine how company metrics that track prescriptions, workload and customer wait-time might affect patient safety and pharmacy error.



TUESDAY, DECEMBER 20, 2016

Breaking news at chicagotribune.com

TRIBUNE WATCHDOG UPDATE DANGEROUS DOSES

## Rauner wants drug interaction solutions

Governor tells agencies to find how to hold wrongdoers accountable

BY RAY LONG AND SAM ROE | Chicago Tribune

Tribune investigation that found pharmacists failed half of the time to warn can bout dangerous drug interactions.

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by reporters sold risky drug pairs without men-tioning the potential for harmful or even fatal inter-actions. "The Tribune's investi-



Opponents lose bid

## 12 killed as truck rams market

48 hurt at German

By Kirsten Grieshaber Associated Press

BERLIN — A tr rammed into a crow Christmas market in cer Berlin on Monday ever killing at least 12 people injuring 48, some of t



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Tom Skilling's forecast High 30 Low 24 Chicago Weather Center: Complete forecast on back page of A+E section 169th year No. 355 © Chicago Tribune 14,0455 00001





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# Chicago Tribune

Tuesday, December 20, 2016

TRIBUNE WATCHDOG DANGEROUS DOSES

# Rauner wants drug interaction solutions

Covernor tells agencies to find how to hold

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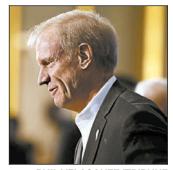
Constructions described by the described pharma of the time to warn about dangerous drug interactions.

? CALL 1-800-TRIBUTHE Republican governor's move came as the longtime Democratic chair of ANG NEWS AT CHIC Illinois House health-care committee began crafting legislation Monday to set min-

imum staffing levels at pharmacies to prevent pharmacists from racing through prescriptions like an "assembly line."

The newspaper, in stories published online Thursday and in print Sunday, found that 52 percent of 255 pharmacies tested by reporters sold risky drug pairs without mentioning the potential for harmful or even fatal interactions.

"The Tribune's investigation revealed a troubling potential that some pharmacists are not complying with state law," Rauner's office said in a statement. "The governor has asked state agencies to investigate what additional action, if any, could be taken either administratively or through legislation to hold wrongdoers accountable and protect public health."



PHIL VELASQUEZ/TRIBUNE Gov. Bruce Rauner wants agencies to study improving pharmacy practices.

Drug interactions, in which one drug alters the effect of another, have been a major public health problem for years, but little progress has been made in reducing the risks.

Rep. Mary Flowers, D-Chicago, called for the minimum staffing levels as part of a multipronged bill she hopes will overhaul how pharmacies, the last line of defense for patients seeking safe medications, handle prescriptions.

The Tribune report "really opened my eyes, and I'm sure it has opened up a lot





PHIL VELASQUEZ/CHICAGO TRIBUNE

Rep. Mary Flowers, D-Chicago, wants to set minimum staffing levels at pharmacies to prevent filling prescriptions like an "assembly line."

line number for patients to call if a pharmacist failed to catch a bad drug interaction or if a pharmacist fails to tell a patient about the potential for a major drug interaction. Flowers said she wants to study whether standards are strong enough for pharmacy technicians in Illinois.

The Tribune testing represents the largest and most comprehensive study of its kind. In response to the findings, three of America's biggest pharmacy chains — CVS, Walgreens and Wal-Mart — said they would take steps to improve patient safety at stores nationwide. In the Tribune tests, CVS failed 63 percent of the time, Wal-Mart 43 percent of the time and Walgreens 30 percent of the time.

Flowers said she feared the speed required for pharmacists to keep up with their workloads may cause "repercussions."

"Just like a person speeding up and down the highway, sooner or later there's going to be crash," she said. "They're moving way too fast."

In Illinois, pharmacists who detect a serious interaction are supposed to contact the prescribing doctor to see if the order is correct or if an alternative therapy is available, according to the Illinois Department of Financial and Professional Regulation. Pharmacists then should alert the patient.

But in the Tribune tests, many pharmacies dispensed dangerous drug pairs without speaking to the tester about the potential interaction or attempting to contact the doctor.

Illinois law also requires pharmacies to conduct several drug safety checks on prescriptions, including whether the dose is reasonable and whether the medication might interact with other drugs the patient is taking. Yet the Tribune found that pharmacists rarely asked what other medications testers were using.

And though Illinois requires pharmacies to "offer to counsel" patients on all prescriptions, pharmacists throughout the industry often address this requirement by having technicians ask patients at checkout, "Do you have any questions for the pharmacist today?" or sometimes simply, "Any questions?" Some states require actual counseling, at least on a first-time medication.

Rep. Lou Lang, D-Skokie, said he has met with union members who have expressed concerns about the number of hours pharmacists are often required to

work and that they wanted to cut hours in order to minimize the chances of errors.

"We want to make sure that people that are filling prescriptions are well-rested and well-treated and not filling prescriptions at a time that they are doing so to the detriment of public safety," Lang said. "For instance, we don't allow pilots to fly more than a certain number of hours a day or a week because we want them well and alert because they are flying precious cargo — human beings — in those planes."

Despite the ongoing difficulties in state budget negotiations, Rauner said his administration would "look forward to working with members of the General Assembly on a bipartisan basis to explore all options" to see what can be done to prevent dangerous drug interactions.

Carmen Catizone, executive director of the National Association of Boards of Pharmacy, previously told the Tribune he would like to see all states require pharmacists to provide counseling about first-time medications and changes of doses. Catizone also said authorities should examine whether to set minimum staffing levels for pharmacies to address workload issues. Pharmacies sometimes have to fill hundreds of prescriptions a day.

The president and CEO of the Illinois Retail Merchants Association, Rob Karr, said the Tribune reporting "highlights a systemwide issue from prescriber to pharmacy."

"No one party carries a larger responsibility," said Karr, whose group represents retail, independent and grocery pharmacy chains throughout Illinois. "A knee-jerk reaction focused solely on pharmacy will miss the mark."

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TRIBUNE WATCHDOG DANGEROUS DOSES

## Big data finds harmful drug combinations

Odd side effects lead scientists down right trail

BY SAM ROE Chicago Tribune

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By Mark Z. Barabak and Lisa Mascaro



OK. Fine. Let's talk about Bill Clinton

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By Rick Pearson





Tuesday, October 11, 2016

#### TRIBUNE WATCHDOG DANGEROUS DOSES

# Big data finds harmful drug combinations

Odd side effects lead scientists down right trail

### **By Sam Roe**

A new method of mining data shows great promise in identifying dangerous drug interactions that had been overlooked by more traditional approaches, according to a new study in a top cardiovascular journal.

The study by scientists at Columbia University Medical Center was the result of a unique collaboration with the Chicago Tribune, which set out to do what had never been done before: search the vast universe of prescription medications to discover which combinations might trigger a potentially fatal heart arrhythmia.

By examining big data in entirely new ways, the team uncovered several drug combinations associated with increased risk. One pair included the popular antibiotic ceftriaxone and the heartburn medication lansoprazole, a former blockbuster drug best known by the brand name Prevacid. The Tribune reported on the results in February.

On Monday, the Journal of the American College of Cardiology published a paper by the scientists involved in the project, along with an editorial that calls the research "an important new contribution" in the effort to identify drug interactions.

"The results and their interpretation," wrote Dr. Dan Roden, a leading expert on cardiac arrhythmia at Vanderbilt University who was not involved in the research, "provide important lessons for investigators interested in using 'big data' approaches to study (adverse drug reactions), other drug effects and indeed, many other aspects of the human condition."

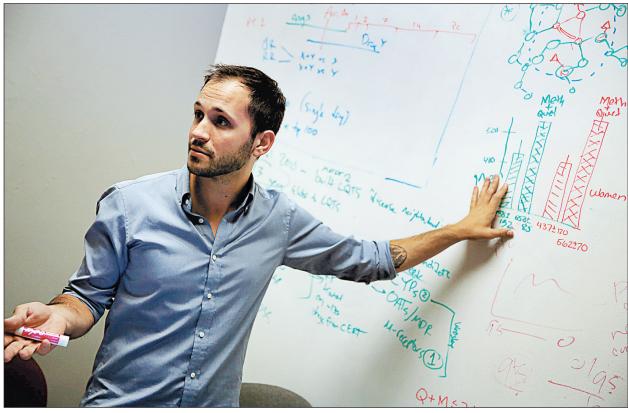
No one knows how many people die each year from drug interactions, but the risks are escalating. One in 5 Americans take three or more drugs. One in 10 people take five or more — twice the percentage as in 1994.

The study stated that an interaction between ceftriaxone and lansoprazole "has the potential for significant morbidity and mortality." But the scientists said more research was needed, a conclusion shared by Roden. The results, he wrote, are probably not sufficient at this point to advise doctors to avoid the drug combination.

In an interview, Roden said the study demonstrates that "big data sets offer us the opportunity to find things that we wouldn't be able to find otherwise."

"The message for the community is: Stay tuned. There are going to be a lot more ways of analyzing these big data sets," he said.

Some drug interactions are well-documented, but many remain hidden and may come to light only after a large number of patients have been harmed.



E. JASON WAMBSGANS/CHICAGO TRIBUNE

"It is no longer sufficient to take a wait-and-hope approach," said Nicholas Tatonetti.

"It is no longer sufficient to take a wait-and-hope approach," Nicholas Tatonetti, a Columbia data scientist and one of the authors of the paper, said in an interview. "Our study demonstrates that we may be able to take a more active strategy for drug combination safety."

Dr. Raymond Woosley, an author of the study and former dean of the University of Arizona medical school, lauded the research collaboration between the Tribune and the scientists.

"This is a great example of where investigative reporting and good science come together to save lives," he said. "I have no question in my mind that there will be lives saved."

The authors said they created an innovative pipeline for discovering drug interactions by combining novel data-mining techniques and traditional laboratory experiments.

The team used sophisticated algorithms to analyze a massive government database of drug complaints for signs of the heart condition. Then they used 380,000 electronic patient files at Columbia's medical center to confirm which drug combinations were indeed associated with an increased risk.

To further check findings, Columbia cellular researchers tested the drug pair ceftriaxone and lansoprazole on individual cells.

They found the combination blocked an electrical channel crucial to the heart, providing a biological explanation for why these drugs might be interacting.

Dr. Valentin Fuster, editor-in-chief of the Journal of the American College of Cardiology and physician-in-chief of Mount Sinai Hospital in New York, said in an interview that such methods could be used to identify other potential drug interactions, especially given that electronic health records are becoming more standardized.

"My view is that we are going to be discovering more and more types of interactions of drugs," he said.

Tatonetti agreed. "There is currently a lot of doubt about if big data is worth the hype," he said. "I hope that our study ameliorates some of this doubt and demonstrates that careful analysis coupled with extensive corroboration can lead to new discoveries."

The research began in 2013, when the Tribune was investigating drug combinations linked to sudden cardiac death. The newspaper approached Tatonetti because he had pioneered a powerful data-mining technique that intentionally looked for evidence where none was visible.

Tatonetti's technique can be compared to the way astronomers detect black holes. Astronomers can't see black holes, but they can find them by focusing on the effects around them, such as the gravitational pull on neighboring stars.

Similarly, scientists analyzing health data can't always detect drug interactions because in some cases too few patients file complaints. But by analyzing an array of secondary side effects, Tatonetti could infer which drug combinations might be causing serious problems.

The Tribune proposed to Tatonetti that his model be used to find drug pairs causing an abnormality of the heart's electrical activity known as QT prolongation. The newspaper then enlisted the help of Woosley, a top expert on the condition.

Using Tatonetti's "black hole" data-mining method, the scientists combed the Food and Drug Administration database of patient complaints, identifying hundreds of suspect drug pairs.

These results were checked against electrocardiogram measurements from actual Columbia patients, and the list of potentially risky drug pairs was narrowed to eight.

Four pairs were considered the best candidates for cellular testing. The drugs included several widely prescribed medications, none of them linked to the cardiac condition on its own.

The team zeroed in on the combination of the antibiotic ceftriaxone and the heartburn medication lansoprazole. The patient records showed the pair was associated with sizable increases in the QT interval, the time between when the heart starts squeezing to when it finishes relaxing and prepares to beat again.

"If this effect size was observed for a single drug," the scientists wrote in the journal article, "it would be well above the threshold for regulatory concern during the approval stage."

Plus, lansoprazole is a proton pump inhibitor, a popular group of medications used to reduce stomach acid. Lansoprazole, commonly sold as Prevacid, once generated annual sales of more than \$3 billion; it is now also available over the counter.

An interaction with a proton pump inhibitor, the authors wrote, could have "a profound impact on patient safety."

When the team tested lansoprazole and the antibiotic on individual cells, they found the drug combination blocked an electrical pathway called the hERG channel, which helps coordinate the heartbeat.

Roden, who wrote the editorial accompanying the study, said a valuable next step would be research on human subjects, measuring the effects of the drugs individually and in combination.

Tatonetti said he hoped to do just that. Columbia scientists have applied for a government grant to investigate up to 100 drug interactions and evaluate some in human trials.

Swiss drugmaker Roche, which discovered ceftriaxone, also known by the brand name Rocephin, said Monday: "We are reviewing the study findings and will assess next steps. Roche will work closely with relevant stakeholders to communicate any potential resulting actions or updates regarding Rocephin."

Japanese drugmaker Takeda, which helped develop lansoprazole, did not immediately respond to a request for comment. The firm previously said no evidence had emerged since the drug hit the market to indicate it would adversely affect the heart.

Woosley, who maintains www.CredibleMeds.org, a website that lists drugs linked to QT prolongation and drug interactions, said lansoprazole is being added to a list of medications that can create conditions increasing the risk of an abnormal heart rhythm.

The study's authors raised the issue of whether additional proton pump inhibitors, or PPIs, might be interacting with other medications.

"There have been a large number of deaths reported to the FDA for patients taking this class of drugs, although this association is not statistically significant," they wrote. "Our discovery of a drug interaction with a PPI may explain these observations, although this requires follow-up study."



#### THE BACKFIELD OF BLOOMINGDALE







TRIBUNE WATCHOOG UPDATE DANGEROUS DOSES

# Rauner rolls out drug safety plan Tribune investigation found patients often get no warning about drug interactions BY KAY LONG AND SAM ROE. Classify The process of the first time of when subgright of the first time of when subgright of the first time of when subgrights and the subgright of the first time of when subgrights affect to warn existence is unwelling a major plan be offered counseling, a mandate often subgrights to be offered counseling, a mandate often subgrights affect to warn existence is unwelling a major plan be offered counseling, a mandate often subgrights affect in the state often subgrights affect in the state of pharmacies throughout the state. This war in the state of the subgright of the subgrights affect in the state of pharmacies throughout the state. This war in the state of the subgrights affect in the subgrights affect in the state of the subgrights affect in the





Trump goes to work

## Chicago Tribune

Tuesday, January 24, 2017

# Rauner rolls out drug safety plan

Tribune investigation found patients often get no warning about drug interactions

#### By Ray Long and Sam Roe

Responding to a Tribune investigation that found drugstores frequently failed to warn customers about potentially dangerous drug interactions, Gov. Bruce Rauner is unveiling a major plan designed to improve public safety at pharmacies throughout the state.

The administration's proposal would require pharmacists to counsel patients about risky drug combinations and other significant issues when buying a medication for the first time or when a prescription changes. Illinois law now requires only that patients be offered counseling, a mandate often addressed at the cash register with a brief inquiry, such as: "Any questions for the pharmacist today?"

The governor also plans to beef up state oversight, including directing inspectors to put more emphasis on adverse drug reactions and launching a "mystery shopper" program to test how well pharmacists comply with the law.

"The Tribune investigation revealed deficiencies in the state's current pharmacy system that put patients at risk," Rauner said in a statement. "Our team conducted an immediate review to find out what pro-active steps state government could take to address those gaps."

More broadly, Rauner said he wants to seek input from pharmacists and other health care providers on ways to protect patients at a time when many people use multiple prescription drugs obtained through various doctors and pharmacies.

The package of initiatives, expected to be announced Tuesday, represents "commonsense changes that we can quickly implement to ensure that pharmacists are able to carry out their important work while protecting the people of Illinois from adverse drug reactions," he said.

The Republican governor took action as the leading Illinois House Democrat on health matters is preparing for legislative hearings beginning next month on other contentious issues the Tribune raised, including whether to regulate the hours worked by pharmacists who sometimes handle hundreds of prescriptions a day.

The Tribune's investigation, published in December, found that 52 percent of 255 chain and independent pharmacies tested sold potentially dangerous drug pairs to reporters without a warning.

Among the seven pharmacy chains tested, CVS had the highest failure rate at 63 percent. Walgreens had the lowest, at 30 percent. Independent pharmacies had the highest failure rate overall, at 72 percent.

CVS, Walgreens and Wal-Mart each promised to take significant steps to improve patient safety nationwide. Combined, the actions affect 22,000 drugstores and involve additional training for 123,000 pharmacists and technicians. Wal-Mart had a 43 percent failure rate in the Tribune's tests.

CVS "is committed to assisting our pharmacists in providing the highest standard of care to their patients, and we look forward to reviewing Governor Rauner's proposed changes" to state rules, a spokesman said Monday.

A Walgreens spokesman said: "Our goal is to provide the highest level of care to patients, and we are supportive of the governor's effort to further promote a culture of safety in community pharmacies."

Rauner's plans to use existing inspectors and new mystery shoppers to improve safety at Illinois pharmacies can be achieved through executive orders. But changing the counseling requirement would need the approval of a bipartisan House-Senate panel, as would his proposal to post signs in pharmacies with a consumer hotline along with information about a patient's right to counseling.

The changes could be approved by summer if the proposal can avoid the Capitol's ongoing political gridlock.

Under the proposed counseling requirement, the pharmacist must have a conversation with any patient who gets a new medication or whose doctor has made significant changes to an existing prescription, such as dosage or frequency.

The goal would be to educate the patient on how to take the medicine and how to avoid risks, such as drug interactions.

Currently, customers often reflexively decline the required "offer to counsel," not knowing to ask questions about dangerous drug combinations or other potential problems. Required counseling places the responsibility on the pharmacist to address such issues, said Greg Bassi, the governor's policy adviser for health and human services.

The administration said it surveyed other states and determined more than 40 have tougher counseling standards than Illinois.

One major proponent of required counseling is Carmen Catizone, executive director of the National Association of Boards of Pharmacy, who commended Rauner for taking "quick and definitive action" that would address "critical areas identified by the Tribune study and story."

Garth Reynolds, executive director of the Illinois Pharmacists Association, said the proposed new counseling requirement would be "reflecting what pharmacists should be doing."

Reynolds also welcomed the governor's proposal to establish a task force to determine best practices in situations when patients use multiple doctors and pharmacies. Though pharmacists' practices affect patient safety, the doctors who write the prescriptions also should be part of any effort to improve care, Reynolds said.

Rep. Mary Flowers, the Chicago Democrat who chairs the Health Care Availability and Accessibility Committee, said she is seeking the governor's input at the legislative hearings she will hold and praised him "for making an effort."

"But I think it doesn't go quite far enough," Flowers said.

Pharmacists should be limited to shifts of "eight hours, no more than nine at the most," because overworked pharmacists are more likely to make mistakes, she said.

Reynolds said he does not favor a law that sets such limits. "You can't cookiecutter that into every pharmacy practice setting," he said.

Flowers also said she wants pharmacists to deal less with daily distractions, such as pitching flu shots to patients, and focus more on safety checks for drug interactions.

Higher standards are needed for the computer programs pharmacists use to

check for interactions, Flowers said. Experts told the Tribune that programs often issue so many alerts, including for rare and minor interactions, that pharmacists can get "alert fatigue" and skip over serious warnings that should be communicated to patients.

Rauner spokesman Lance Trover said the governor is open to ideas from law-makers that could be implemented without creating a Byzantine oversight process.

In Washington, U.S. Sen. Dick Durbin, D-Ill., has called on the federal Centers for Disease Control and Prevention to determine how software can be better used to alert pharmacists to the risks of drug interactions and how common it is for pharmacists nationwide to dispense dangerous drug pairs without warning patients.

Durbin asked the agency to establish concrete steps to ensure consumer safety and to issue guidelines to state boards of pharmacy and private industry groups. He also asked the agency to examine how company metrics that track prescriptions, workload and customer wait times might affect patient safety and pharmacy error.

Story about the Tribune-Columbia collaboration published on the website of Columbia University's Department of Biomedical Informatics.



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## **BIG DATA & SCIENCE JOURNALISM** Multidisciplinary Collaboration **Drives Healthcare Insights**

DBMI professor Nicholas Tatonetti teamed up with Pulitzerprize-winning Chicago Tribune reporter Sam Roe to investigate how big data can help identify deadly drug combinations.

Read the full story

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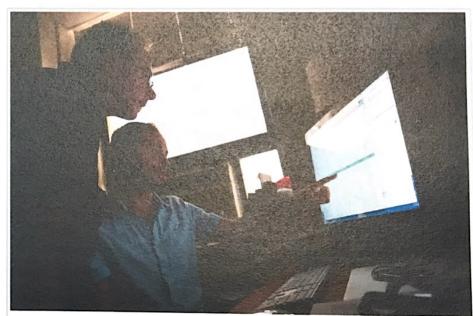
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## How a DBMI Scientist and a Chicago Journalist Teamed Up to Discover Dangerous Drug Interactions

In February, Sam Roe and Karisa King published a <u>front-page Chicago Tribune story</u> investigating how big data could be used to discover deadly drug combinations. The article was a result of years of research and a unique collaboration between Roe, a Pulitzer-prize-winning reporter, and <u>DBMI professor Nicholas Tatonetti</u>.

The editorial process for the piece was unusual. Roe had been interested in dangerous drug interactions for years, but lacked the background and data resources to investigate the topic fully. He had tried searching the newspaper's databases, but came up empty. After attending a talk in Chicago on big data by Stanford professor Russ Altman, Roe met with Altman, who told him that he should go out to Columbia and talk with DMBI's Nick Tatonetti. Roe took the tip and booked his ticket to New York.

Having long believed a story on drug interactions was beyond his reach, Roe decided to pursue it after meeting with Tatonetti. "What really attracted me to Nick's work is that he's been a pioneer,"



Nicholas Tatonetti, PhD, Assistant Professor of Biomedical Informatics at Columbia University in New York with Chicago Tribune reporter Sam Roe, Thursday, Aug. 21, 2014. (E. Jason Wambsgans/Chicago Tribune)

w-a-dbmi-scientist-and-a-chicago-journalist-teamed-up-to-discover-data-driven-health-solutions/

How a DBMI Scientist and a Chicago Journalist Teamed Up to Discover Dangerous Drug Interactions | Columbia University says Roe.

Tatonetti had been developing a method called latent signal detection, which infers the presence of hidden events by examining the effects of something after it happens. "It's similar to how astronomers look for black holes," says Roe. It also has all sorts of possibilities for finding drug combinations.

Meanwhile, Roe was interested in a particular type of drugs that impacted the QT interval – the time between heartbeats. Together with Raymond Woosley, an expert on such drugs, Tatonetti and Roe formed a team that worked together for more than two years.

As chronicled in the Tribune article, their unlikely collaboration ultimately identified four drug combinations that can potentially lead to a fatal arrhythmia. The team used Tatonetti's methods to analyze a massive government database of drug complaints for signs of the heart condition. Then they combed through 380,000 electronic hospital patient files to confirm which drug pairs were indeed associated with an increased risk.

Tatonetti says the algorithms that drove these discoveries are based on the same logic that doctors use to diagnose patients. "When you are feeling ill and you say you have fever or pain or aching joints, the physician listening is building a mental model of what is going on in your body," he explains. "That physician can't see your disease but he can use little pieces of evidence in combination to come up with a diagnosis." In short, the algorithm that led to Roe and Tatonetti's breakthrough works by learning what an adverse event looks like based on effects it observes indirectly.

It's not typical for a newspaper and a university to team up so closely, but Tatonetti believes citizen science is collaborative in its nature.

"Nowadays there is so much data and so many techniques and so much expertise to bring into just one project that it's foolish to try to do that yourself," he says. "The days of lone scientists are over, and we need collaborations to move our research forward." Collaboration, he adds, creates "a whole pipeline of discovery."

Scientists and journalists dig for truth in different ways, which may have led to this project's success. Journalists are trained to ask good questions, while scientists, says Tatonetti, "are trained to evaluate whether something is true or not." "We can pursue questions with high impact in a systematic and thorough way and then present the evidence."

Roe believes that journalists are uniquely trained at connecting with people to find answers. "At the end of the research, we can call the people who are accountable for these drugs and ask the difficult questions," he says. For Roe, working with Tatonetti and Columbia University was a uniquely productive experience. "We have worked with scientists before, partnering with different scientific labs to do testing for us when we were looking at lead in toys and mercury in fish," he says. "But this is different because we weren't paying scientists for their time – the folks at Columbia were involved because they also wanted to find something." He adds that a mutual passion shared with Tatonetti made this project one of his most exciting. "I remember one time we were walking out of his office, and Nick said: 'Yeah, let's change the world.' That's someone I want to work with."

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(I-r) Robert Kass, Tribune reporter Sam Roe, Kevin Sampson and Nicholas Tatonetti wait for results in a test of combinations of two drugs, Ceftriaxone and Lansoprazole, in individual cells to see if an electrical channel crucial to the heart would be blocked, at the Cellular Research Lab at Columbia University Medical Center in New York, Wednesday Feb. 25, 2015. (E. Jason Wambsgans/Chicago Tribune) Together, the team is still working to uncover more hard-to-find drug interactions and continuing the experimental exploration of the interactions they found initially. There has already been one scientific paper published on the work, and another is due for release in the near future. "There's a lot of talk out there, but here's a really solid example of how big data can improve the average person's life," says Roe.

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## How The Chicago Tribune used 'rock-solid science' to shake up pharmacies

**THE DAY BEFORE** President Donald Trump's chief strategist advised the media to shut up (https://www.nytimes.com/2017/01/26/business/media/stephen-bannon-trump-news-media.html?\_r=0), Chicago's leading daily newspaper reminded its audience exactly why good journalism must keep talking.

The Chicago Tribune detailed Illinois Governor Bruce Rauner's proposal for broad regulatory changes (http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-illinois-pharmacies-rauner-met-20170124-story.html) to how pharmacies alert their customers to dangerous drug combinations—the most recent result of the Tribune's "Dangerous Doses" series. The Tribune's top investigations editor said the project, which culminated in December with a sweeping indictment (http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html) of the pharmaceutical industry, was one of the largest and most extensive undertaken by the paper in the past two decades. Rauner credited the Tribune with revealing "deficiencies in the state's current pharmacy system that put patients at risk."

At a time when many scientists and journalists believe the reception to their work to be unfairly politicized, the *Tribune*'s investigation is an unequivocal success. "Dangerous Doses"—a finalist for the annual Goldsmith Prize for Investigative Reporting (http://news.harvard.edu/gazette/story/newsplus/shorenstein-center-announces-finalists-for-2017-goldsmith-prize/)—hinged on a unique collaboration (http://www.cjr.org/first\_person/could\_collaborating\_with\_scientists\_be\_the\_next\_step\_for\_investigative\_reporting.phj

between journalists and scientists that enabled the *Tribune* essentially to conduct its own scientific investigation. The impact of that investigation is a credit to the *Tribune*'s reporting as well as to the science that supported it.

The three-part investigative project focuses on hidden interactions between prescription medicines that could have life-threatening consequences if taken together. The first of the "Dangerous Doses" series (http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-signal-detection-met-20160209-story.html), published a year ago, identified four potentially unsafe drug combinations; one pairing, according to the report, "blocked an electrical channel crucial to the heart." The second story (http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-skin-reaction-met-20160209-story.html) focused on a woman whose drug combination of Lamictal and Depakote left her legally blind and fighting for her life. Neither the doctor who dispensed her medications nor the pharmacist who filled her two prescriptions warned her of the potential risk.

For the final story (http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-pharmacy-met-20161214-story.html) in the series, a Chicago physician wrote prescriptions for drugs with dangerous interactions and gave them to the *Tribune*. Led by reporters Sam Roe, Ray Long, and Karisa King (who has since left the paper for a position as investigations editor (http://www.reviewjournal.com/news/las-vegas/award-winning-journalist-karisa-king-lead-review-journal-investigative-team) at the *Las Vegas Review-Journal*), the *Tribune* dispersed those prescriptions among 15 staff reporters. At each of the pharmacies that reporters visited—in Chicago, downstate Illinois, and neighboring Indiana, Wisconsin, and Michigan—reporters presented prescriptions and noted whether pharmacists warned them of potential drug interactions. Although they did not identify themselves as journalists, the reporters used their real names and answered questions truthfully. The filled prescriptions were collected and stored in a secure location.

In all, the *Tribune* tested 255 pharmacies; of that number, 52 percent failed to provide reporters with adequate warnings.

"We set out to do this as scientifically as possible. In order for this to work, to impact the country, it had to be extremely scientific and solid in every way," Roe says. "We felt that, if we hadn't done this, there was good reason to believe that people would be harmed unnecessarily. That pushed us forward. It was a public service."

The impact of the pharmacy investigation was quick. CVS, Walgreens, and Wal-Mart, whose pharmacies were tested as part of the project, "vowed to take significant steps to improve patient safety" at their stores nationwide, according to the *Tribune*. "Combined, the actions affect 22,000 drugstores and involve additional training for 123,000 pharmacists and technicians."

In the days following publication, the National Association of Boards of Pharmacy, the nation's top association for pharmacy regulators, called on states

(http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-reforms-20161219-story.html) to enact laws requiring pharmacists to counsel those patients who pick up medications that could be dangerous if taken together. (State laws vary as to whether pharmacists are required to offer counseling or simply ask patients if they have questions, the *Tribune* reported.) In Illinois, Rauner, a probusiness Republican, ordered state agencies

(http://www.chicagotribune.com/news/watchdog/druginteractions/ct-drug-interactions-illinois-met-20161219-story.html) to figure out how to hold pharmacies accountable. Lawmakers have begun drafting legislation that would set minimum requirements for staffing at pharmacies.

"There's no way Walgreens or Wal-Mart [were] going to make substantial changes to the way they do business unless this piece was...not just rock-solid journalism, but rock-solid science," Roe told me during an interview at Columbia College Chicago, where Roe and I are co-teaching a graduate course this spring on legislative and investigative reporting. "This is why it took so long."

Often, when a news organization reports on a scientific finding, it will seek out qualified scientists in the relevant field to explain the finding's significance. The *Tribune* distinguished itself by performing its own independent testing and analysis, says Deborah Blum, director of the Knight Science Journalism Program at MIT. She notes that *Consumer Reports* accomplished something similar in 2012 (http://www.consumerreports.org/cro/magazine/2012/01/arsenic-in-your-juice/index.htm), when it analyzed arsenic in apple and grape juice and found that children were being exposed to unhealthy levels of the poison.

When journalists produce their own science, "my feeling about it is that it's really unusual and it's really a powerful tool," Blum says. "In the right circumstances, I'd love to see us do it more often."

George Papajohn, the *Tribune's* assistant managing editor of investigations, says that, in the past, the *Tribune* typically outsourced its scientific work—for instance, sending toys to a lab (http://www.chicagotribune.com/news/nationworld/chi-leadmain-story-story.html) to be tested for lead or fish samples to be tested for mercury (http://www.chicagotribune.com/news/nationworld/chi-mercury-3-story-story.html). "Then you'd await the results," he says.

For "Dangerous Doses," the *Tribune* worked with data scientists, pharmacologists and cellular researchers and "used novel data-mining techniques to identify four drug combinations associated with a heart condition that can lead to a potentially fatal arrhythmia," Roe explained in a first-person account for CJR last year

(http://www.cjr.org/first\_person/could\_collaborating\_with\_scientists\_be\_the\_next\_step\_for\_investigative\_reporting.ph] "In the process, the team created an innovative scientific model with the potential to flag hundreds of additional drug interactions, offering a new way to protect patients and save lives."

Papajohn says that approach distinguishes "Dangerous Doses" from previous investigations. The *Tribune* journalists, he says, were "actually helping to think about how the scientists should approach the work and in some cases looking over their shoulder. It was much more of a collaboration."

Jeff Lyon, a 34-year veteran reporter at the *Chicago Tribune* who won a Pulitzer Prize in 1987 for a medical series on gene therapy (http://archives.chicagotribune.com/1986/10/16/page/1/article/scientists-find-muscular-dystrophy-gene/index.html), says the *Tribune* has a long history of consumer-based science reporting. That work is particularly important now, when so much of the public is questioning science and the media, he says.

"Our job is to try to educate people and, between the smaller budgets and the increasing resistance by a large segment of the public to understand the realities of science, it's making it very hard," he says. The more that news organizations report on global warming and species becoming extinct, "the more people

turn a deaf ear because they think we are lying or don't know what we are talking about." That frustration is likely shared by journalists and scientists, says Lyon.

Such resistance makes journalism—and science journalism, in particular—more urgent than ever, says Lyon.

"I think we have to pile on," he says. "We have to keep going and get the message out there and work with scientists."

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