Health An Indian Drugmaker, Investigated by ProPublica Last Year, Has Recalled Two Dozen Medications Sold to U.S. Patients

<p>   </p><p style="text-align:justify">Glenmark Pharmaceuticals has recalled two dozen generic medicines sold to American patients because the Indian factory that made them failed to comply with U.S. manufacturing standards and the Food and Drug Administration determined that the faulty drugs could harm people, federal records show.</p> <p style="text-align:justify" data-pp-blocktype="copy" data-pp-id="3.0">In February, the FDA found problems with cleaning and testing at the plant in Madhya Pradesh, India, which was the subject of a ProPublica investigation last year. The current recalls, listed in an FDA enforcement report last week, cover a wide range of commonly prescribed medicines, including ones that treat epilepsy, diabetes, multiple sclerosis, heart disease and high blood pressure, among other ailments. ??A full list of the recalled medications is available here.</p> <p style="text-align:justify" data-pp-blocktype="copy" data-pp-id="4.0">The agency determined that the drugs could cause temporary or reversible harm and that the chance of more serious problems was remote. However, the FDA didn’t say what symptoms the flawed drugs could cause. ProPublica asked the FDA and Glenmark for more specifics, but neither responded.</p> <p style="text-align:justify" data-pp-blocktype="copy" data-pp-id="6.0">Records show that Glenmark first alerted wholesalers about the recalls in a March 13 letter. That letter suggests that Glenmark pulled the drugs because of potential cross-contamination. Thomas Callaghan, Glenmark’s executive director of regulatory affairs for North America, wrote that 148 batches of the recalled medicines were made “in a shared facility” with two cholesterol-lowering drugs, ezetimibe and a combination of that drug and simvastatin.</p> <p style="text-align:justify" data-pp-blocktype="copy" data-pp-id="8.0">That’s a concern because the chemical structure of ezetimibe contains what’s known as a beta-lactam ring. FDA safety experts pay attention to this because many beta-lactam drugs, particularly penicillin, can cause life-threatening allergies and hypersensitivity reactions. It’s the most commonly reported drug allergy<span style="font-family: "Helvetica";" helvetica";"=""> in the U.S. Because of that danger, the FDA

requires manufacturers to follow <span style="font-family: "Helvetica";" helvetica";"="">special precautions to prevent cross-contamination<span style="font-family: "Helvetica";" helvetica";"=""> with drugs that contain a beta-lactam ring, even if they aren't antibiotics. <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-size: 11pt; font-family: "Helvetica";" helvetica";"="">The chemical structure of ezetimibe, Callaghan wrote to Glenmark's wholesalers, shows it is unlikely to cause such hypersensitivity reactions. Nevertheless, Glenmark was recalling the drugs "based on risk assessment and out of an abundance of caution," Callaghan wrote. He added, "This recall is being made with knowledge of the Food and Drug Administration." <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-size: 11pt; font-family: "Helvetica";" helvetica";"="">According to Callaghan's letter, the potential problem dates back years. The executive wrote that Glenmark began shipping the drugs on Oct. 4, 2022. <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-size: 11pt; font-family: "Helvetica";" helvetica";"="">In December, ProPublica revealed that the Glenmark factory was responsible for an outsized share of U.S. recalls for pills that didn't dissolve properly and could harm people. At the time, the FDA hadn't inspected the plant since before the COVID-19 pandemic, even though one of those recalls had been linked to deaths of American patients. <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-family: "Helvetica";" helvetica";"="">About two months after that investigation was published, <span style="font-family: "Helvetica";" helvetica";"="">FDA officials returned to the factory<span style="font-family: "Helvetica";" helvetica";"=""> — the agency's first inspection in five years. Inspectors discovered that Glenmark hadn't properly cleaned equipment to prevent contamination of medicines with residues from other drugs. The federal investigators also noted that Glenmark routinely released some drugs to the U.S. market using test methods that hadn't been adequately validated, according to the inspection report. <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-size: 11pt; font-family: "Helvetica";" helvetica";"="">What's more, when some Glenmark tests found problems with a drug, the company at times declared those results invalid and "retested with new samples to obtain passing results," the inspection report said. "The batches were ultimately released to the US market." <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-family: "Helvetica";" helvetica";"="">In <span style="font-family: "Helvetica";" helvetica";"="">their detailed report<span style="font-family: "Helvetica";" helvetica";"="">, the inspectors listed drugs shipped to U.S. customers who had been affected by the potential contamination and testing problems, but FDA censors redacted page after page, making it impossible to know which medicines may not be safe. An FDA attorney said the information was being withheld because it contained trade secrets or commercial information that was considered privileged or confidential. <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-size: 11pt; font-family: "Helvetica";" helvetica";"="">ProPublica first asked Glenmark about that inspection on March 7 after obtaining the FDA report through the Freedom of Information Act. Glenmark alerted wholesalers about the recalls less than a week later, but the company and the FDA didn't tell ProPublica. <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-size: 11pt; font-family: "Helvetica";" helvetica";"="">Instead, a Glenmark spokesperson sent a statement saying the company was "committed to working diligently with the FDA to ensure compliance with manufacturing operations and quality systems." And the FDA said it could discuss potential compliance matters only with the company

involved. <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-family: "Helvetica";" helvetica";"="">The FDA first mentioned the recalls publicly in its April 8 <span style="font-family: "Helvetica";" helvetica";"="">enforcement report<span style="font-family: "Helvetica";" helvetica";"="">, which is like an electronic filing cabinet for recalls. The recalls do not appear on the FDA’s <span style="font-family: "Helvetica";" helvetica";"="">recalls website<span style="font-family: "Helvetica";" helvetica";"="">, which compiles press releases written by pharmaceutical companies. <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-size: 11pt; font-family: "Helvetica";" helvetica";"="">ProPublica asked the FDA and Glenmark why they didn’t alert the public last month that these medicines had been recalled, but neither responded. <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-family: "Helvetica";" helvetica";"="">Glenmark is embroiled in a federal lawsuit that alleges recalled potassium chloride capsules made at its Madhya Pradesh factory caused the death of a 91-year-old Maine woman in June. The FDA had determined last year that more than 50 million of those recalled Glenmark extended-release capsules <span style="font-family: "Helvetica";" helvetica";"="">had the potential to kill<span style="font-family: "Helvetica";" helvetica";"=""> U.S. patients because they didn’t dissolve correctly and could lead to a perilous spike in potassium. In court filings, Glenmark has denied responsibility for the woman’s death. <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-size: 11pt; font-family: "Helvetica";" helvetica";"="">Since that potassium chloride recall, Glenmark has told federal regulators it has received reports of eight deaths in the U.S. of people who took the recalled capsules, FDA records show. Companies are required to file such reports so the agency can monitor drug safety. The FDA shares few details, though, so ProPublica was unable to independently verify what happened in each case. In general, the FDA says these adverse event reports reflect the opinions of the people who reported the harm and don’t prove that the drug caused it. <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-size: 11pt; font-family: "Helvetica";" helvetica";"=""> <span style="font-family: "Helvetica";" helvetica";"=""> <span lang="EN-US" style="font-size: 11pt; font-family: "Helvetica";" helvetica";"="">Photo Credit <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-family: "Helvetica";" helvetica";"="">Photo by <a href="https://unsplash.com/@haberdoedas?utm_content=creditCopyText&utm_medium=referral&utm_so
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helvetica";"=""> <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-family: "Helvetica";" helvetica";"="">Republished from <span style="font-family: "Helvetica";" helvetica";"="">Propublica <span style="font-family: "Helvetica";" helvetica";"=""> <span style="font-family: "Helvetica";" helvetica";"=""> <style><span style="font-family: "Helvetica";">@font-face {font-family:Helvetica; panose-1:0 0 0 0 0 0 0 0 0 0; mso-font-charset:0; mso-generic-font-family:auto; mso-font-pitch:variable; mso-font-signature:-536870145 1342208091 0 0 415 0;}@font-face {font-family:"Cambria Math"; panose-1:2 4 5 3 5 4 6 3 2 4; mso-font-charset:0; mso-generic-font-family:roman; mso-font-pitch:variable; mso-font-signature:-536870145 1107305727 0 0 415 0;}@font-face {font-family:Calibri; panose-1:2 15 5 2 2 2 4 3 2 4; mso-font-charset:0; mso-generic-font-family:swiss; mso-font-pitch:variable; mso-font-signature:-536859905 -1073697537 9 0 511 0;}p.MsoNormal, li.MsoNormal, div.MsoNormal {mso-style-unhide:no; mso-style-qformat:yes; mso-style-parent:""; margin:0cm; mso-pagination:widow-orphan; font-size:12.0pt; font-family:"Calibri",sans-serif; mso-ascii-font-family:Calibri; mso-ascii-theme-font:minor-latin; mso-fareast-font-family:Calibri; mso-fareast-theme-font:minor-latin; mso-hansi-font-family:Calibri; mso-hansi-theme-font:minor-latin; mso-bidi-font-family:"Times New Roman"; mso-bidi-theme-font:minor-bidi; mso-font-kerning:1.0pt; mso-ligatures:standardcontextual; mso-fareast-language:EN-US;}a:link, span.MsoHyperlink {mso-style-priority:99; color:blue; text-decoration:underline; text-underline:single;}a:visited, span.MsoHyperlinkFollowed {mso-style-noshow:yes; mso-style-priority:99; color:#954F72; mso-themecolor:followedhyperlink; text-decoration:underline; text-underline:single;}p {mso-style-noshow:yes; mso-style-priority:99; mso-margin-top-alt:auto; margin-right:0cm; mso-margin-bottom-alt:auto; margin-left:0cm; mso-pagination:widow-orphan; font-size:12.0pt; font-family:"Times New Roman",serif; mso-fareast-font-family:"Times New Roman";}.MsoChpDefault {mso-style-type:export-only; mso-default-props:yes; font-family:"Calibri",sans-serif; mso-ascii-font-family:Calibri; mso-ascii-theme-font:minor-latin; mso-fareast-font-family:Calibri; mso-fareast-theme-font:minor-latin; mso-hansi-font-family:Calibri; mso-hansi-theme-font:minor-latin; mso-bidi-font-family:"Times New Roman"; mso-bidi-theme-font:minor-bidi; mso-fareast-language:EN-US;}div.WordSection1 {page:WordSection1;}</style>
