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January 28, 2015

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Tom Frieden, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
WO 2200
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Secretary Burwell and Drs. Frieden and Hamburg:

Public Citizen, a consumer advocacy group with more than 350,000 members and supporters nationwide, is writing to express concern with inadequate steps taken by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) to notify the public of the risks associated with a recent disease outbreak related to the distribution of simulated intravenous (IV) saline products to more than 50 health care facilities nationwide. These products were subsequently used in over 40 patients.

We ask that you investigate why the CDC and FDA did not organize a more aggressive public outreach campaign to control this outbreak, and that you take corrective steps to ensure prompt, coordinated action in the future.

In addition, we ask that the CDC and FDA issue a joint public announcement to manufacturers of products designed to simulate medical products informing them regarding the design and placement of adequate warning labels to prevent these products from being mistakenly administered to patients. We ask that the announcement also include instructions for distributors and health care professionals regarding best practices to avoid similar confusion between real medical products and simulated training products in the future.

On December 30, 2014, the FDA issued an alert to health care professionals warning them not to use in humans simulated IV products produced by San Diego-based Wallcur. The agency did so after learning that some of the manufacturer's simulated plastic bags, labeled as containing 0.9% sodium chloride IV solution, had been distributed to health care facilities and used in patients.¹ Real sodium chloride IV solutions are used daily in nearly all health care facilities in the U.S. and have been in short supply over the past year.

Wallcur makes a variety of simulated IV products that are intended only for use in training and educating nurses, pharmacists, paramedics, and other health care professionals.² These products are not intended for the treatment of patients, as they are neither sterile nor assessed for purity and quality, and their use in patients would pose an immediate, life-threatening hazard.

On January 7, 2015, Wallcur announced a voluntary recall of its simulated 0.9% sodium chloride IV solution products.³ However, presumably concerned about an ongoing threat to patient safety, the FDA on January 14 issued an updated announcement noting that these Wallcur products had been shipped to about 50 medical clinics, surgical centers, and urgent care facilities in numerous states.^{4,5} The agency further reported that more than 40 patients in seven states (Florida, Georgia, Idaho, Louisiana, North Carolina, New York, and Colorado) had received infusions of the Wallcur products, resulting in many adverse events in at least 17 patients, including fever, chills, tremor, muscle aches, and headache.^{6,7} Some patients were hospitalized, and one died, though the cause of death is still being investigated.⁸

This situation signals unacceptable lapses in procedures for protecting patient safety and public health at multiple levels:

First, although Wallcur's home page prominently indicates in red, bolded text that its products "ARE FOR TRAINING PURPOSES ONLY AND NOT INTENDED FOR HUMAN OR ANIMAL USE,"⁹ such an explicit warning does not appear to be stamped on the bags of

¹ Food and Drug Administration. FDA's investigation into patients being injected with simulated IV fluids continues. Updated January 14, 2015. <http://www.fda.gov/Drugs/DrugSafety/ucm428431.htm>. Accessed January 20, 2015.

² Wallcur Practi-Products for Clinical Simulation. Homepage. <http://www.wallcur.com/>. Accessed January 20, 2015.

³ Food and Drug Administration. Recall — Firm press release: Wallcur Practi-0.9% sodium chloride-IV bags 50 mL, 250 mL, 500 mL, and 1000 mL Wallcur Practi-0.9% sodium chloride-IV bag with distilled water 100 mL. Updated January 9, 2015. <http://www.fda.gov/Safety/Recalls/ucm429724.htm>. Accessed January 20, 2015.

⁴ Food and Drug Administration. FDA's investigation into patients being injected with simulated IV fluids continues. Updated January 14, 2015. <http://www.fda.gov/Drugs/DrugSafety/ucm428431.htm>. Accessed January 20, 2015.

⁵ Tavernise S. F.D.A. begins inquiry after death and illnesses from saline bags meant for training. January 15, 2015. *The New York Times*. <http://www.nytimes.com/2015/01/16/science/earth/fda-begins-inquiry-after-death-and-illnesses-from-saline-bags-meant-for-training.html?ref=health&r=2>. Accessed January 20, 2015.

⁶ Food and Drug Administration. FDA's investigation into patients being injected with simulated IV fluids continues. Updated January 14, 2015. <http://www.fda.gov/Drugs/DrugSafety/ucm428431.htm>. Accessed January 20, 2015.

⁷ Tavernise S. F.D.A. begins inquiry after death and illnesses from saline bags meant for training. January 15, 2015. *The New York Times*. <http://www.nytimes.com/2015/01/16/science/earth/fda-begins-inquiry-after-death-and-illnesses-from-saline-bags-meant-for-training.html?ref=health&r=2>. Accessed January 20, 2015.

⁸ Food and Drug Administration. FDA's investigation into patients being injected with simulated IV fluids continues. Updated January 14, 2015. <http://www.fda.gov/Drugs/DrugSafety/ucm428431.htm>. Accessed January 20, 2015.

⁹ Wallcur Practi-Products for Clinical Simulation. Homepage. <http://www.wallcur.com/>. Accessed January 20, 2015.

solution recently distributed to health care facilities across the U.S.¹⁰ The absence of such warnings on the simulated IV sodium chloride solution products created the potential for dangerous misuse in patients.¹¹ (The labels did have, in very small print, “Practi-Products for Clinical Simulation,” but this likely went unnoticed or was not understood by health care providers who administered the fluids.) All simulation IV products made by Wallcur — or any other company — should carry an explicit warning label prominently displayed in red, large-print text on the product packaging. This warning should appear both on the simulated bag of IV fluid (or simulated drug vial) and on any boxes or larger packaging units, to prevent mix-ups at every level of the product distribution chain.

Second, the FDA and CDC failed to conduct an appropriately aggressive public outreach campaign to prevent additional harm to patients. The FDA’s initial alert to health care professionals on December 30 was not sufficient to address the scope of the threat to public health: Many health care providers routinely miss FDA safety alerts regardless of the time of year, and the release of the Wallcur alert during the holiday season probably further decreased the likelihood that the intended target audience saw it. The outbreak was not listed at all on the CDC’s website,¹² nor was it announced through the CDC’s Health Alert Network.¹³ The CDC could have dramatically increased the reach of the warning to health care professionals had it chosen to use either of these resources in response to the outbreak. This level of response was unacceptable. Since these circumstances represented a public health emergency, both the FDA and the CDC should have acted more swiftly and more aggressively to alert health care providers and facilities across the country to be on the lookout for the harmful products.

Third, distributors that purchased these simulated products from Wallcur never should have introduced them into the supply chain for clinical products intended for patient care.

Finally, the health care providers who injected these products failed to use due diligence in assessing whether the simulated products were appropriate for use in patients. While the products appear to have lacked a clear warning and were made to look realistic upon a cursory glance, the product labeling omitted many details typically found on IV fluids, the most important of which being a statement that the product is sterile and nonpyrogenic (free of substances produced by bacteria that can cause fever and inflammatory reactions).¹⁴ The lack of detail should have been a tipoff that something was amiss.

¹⁰ Food and Drug Administration. Wallcur Practi-0.9% sodium chloride-IV Bags 50 mL, 250 mL, 500, mL, and 1000 mL Wallcur Practi-0.9% sodium chloride-IV bag with distilled water 100 mL: Photo.

<http://www.fda.gov/Safety/Recalls/ucm429718.htm>. Accessed January 20, 2015.

¹¹ Wallcur Practi-Products for Clinical Simulation. Practi-1000 ml IV bag Lactatd Ringrs.

http://www.wallcur.com/Products/Practi-1000-mL-IV-bag-Lactatd-Ringrs_278LR.aspx. Accessed January 20, 2015.

¹² Centers for Disease Control. CDC Current Outbreak List. Page last reviewed September 12, 2014.

<http://www.cdc.gov/outbreaks/index.html>. Accessed January 20, 2015.

¹³ Centers for Disease Control. Health Alert Network (HAN). Page last reviewed January 9, 2015.

<http://emergency.cdc.gov/HAN/>. Accessed January 20, 2015.

¹⁴ See the product labels for B. Braun Medical’s product label for 2.5% dextrose and 0.45% sodium chloride injection USP and similar products at <http://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=8e6569ce-9714-497f-a94b-c6975c1d76f6&type=display>. Accessed January 20, 2015.

We recognize that simulated medical products are not regulated by the FDA and that the agency therefore lacks regulatory authority to require labeling changes by the manufacturers of these products. However, the manufacturer in this case, Wallcur, has stated that it generally follows any advice offered by the FDA regarding product labeling.¹⁵ Other manufacturers of training products would likely respond in a similar manner to labeling advice by the FDA or another federal agency, particularly if delivered promptly following investigation of the current outbreak. While we hope the FDA has been communicating privately with Wallcur and its distributors regarding potential corrective actions, we believe that both the CDC and the FDA have a responsibility to take additional public steps to stop similar life-threatening mistakes from occurring in the future.

We therefore ask that you:

1. Investigate why the CDC and FDA did not organize a more aggressive public outreach campaign to control this outbreak.
2. Take corrective steps to ensure that the CDC and FDA are ready to pursue prompt, coordinated action should a similar outbreak occur in the future.
3. Coordinate a joint public announcement between the CDC and the FDA advising manufacturers of products designed to simulate medical products regarding the proper placement of warning labels to prevent these products from being mistakenly administered to patients. These products should carry an explicit warning label prominently displayed in red, large-print text on the product packaging. This warning should appear both on the bag of fluid (or simulated drug vial) and on any boxes or larger packaging units, to prevent mix-ups at every level of the product distribution chain.
4. Issue a similar announcement for distributors and health care professionals instructing them on best practices to avoid confusion between medical products and simulated training products in the future.

Thank you for your attention to this important public safety matter.

Sincerely,

Sarah Sorscher, J.D., M.P.H.
Attorney
Public Citizen's Health Research Group

Michael Carome, M.D.
Director
Public Citizen's Health Research Group

¹⁵ Szabo, L. 40 patients mistakenly given unsterile intravenous fluid. *USA Today*. January 15, 2015. <http://www.usatoday.com/story/news/nation/2015/01/14/unsterile-fluid-recall/21782015/>. Accessed January 20, 2015.