July 12, 2017

Submitted to U.S. Regulations.gov website, docket number **FDA-2017-P-0867**

We are writing, as internationally recognized researchers in intensive care and related disciplines, in support of the petition submitted by Public Citizen, Dr. Charles Natanson, and Dr. Ian Roberts to the Food and Drug Administration (FDA)[1] requesting that the FDA require the removal of hydroxyethyl starch (HES) intravenous (IV) solutions from the market in the U.S. because the solutions cause kidney failure, bleeding, and increased risk of death, and there are numerous intravenous fluids available in the U.S. that are safer and just as effective as HES solutions.

The petition offers a point-by-point rebuttal, supported by an exhaustive review of the scientific literature, of the various arguments offered by the producers of HES solutions and others for keeping the products on the market. The petition also explains that HES solutions offer no unique benefit over the other types of intravenous solutions on the market and that there is therefore no compelling reason to continue to expose patients to the unique risks of HES products.

In 2014, in response to the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee's (PRAC's) October 2013 decision to reverse its recommendation to remove the marketing authorization for HES solutions in Europe, an open letter was sent to the EMA's executive director expressing concern about the PRAC's decision and the risk of harm to which patients treated with HES products would be exposed.[2] Since that open letter, even more evidence (also detailed in Public Citizen's petition) has emerged that confirms the dangerous side effects of HES solutions and the absence of any unique benefit of HES solutions compared with other intravenous fluids.

We call on the FDA to review Public Citizen's petition as soon as possible and to accept the petition's request to require the removal of HES IV solutions from the market in the U.S., which would save many patients from harm and death.

Sincerely,

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[1] Public Citizen. Petition to the FDA to ban hydroxyethyl starch solutions. February 8, 2017. http://www.citizen.org/hrg2358. Accessed July 10, 2017.

[2] Bellomo R, Bion J, Finfer S, et al. Open letter to the Executive Director of the European Medicines Agency concerning the licensing of hydroxyethyl starch solutions for fluid resuscitation. *Br J Anaesth*. 2014;112(3):595-600.

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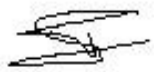

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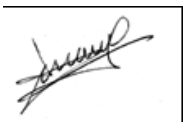

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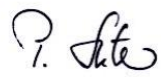

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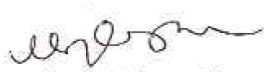

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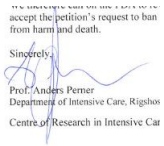

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