Regarding: A Proposed Rule by the Food and Drug Administration on 05/01/2015.

Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record.

To whom it may concern:

We are writing this comment to address concerns we have with regard to the proposed FDA "rule to address data gaps for certain active ingredients in health care antiseptics".

We would like to strongly recommend the inclusion of Chlorhexidine in this initiative. Chlorhexidine is undergoing a rapidly expanding role in the prevention of hospital acquired infections. Many researchers are advocating the use of chlorhexidine every day on every patient in the ICU.

However, we feel both the safety and efficacy of chlorhexidine has not been substantiated. There are significant concerns regarding the developing of antibiotic resistance and the long term effects of expanded chlorhexidine usage on the patient's and facility's microbiome.(1-3)

Several researchers have found evidence of developing resistance to chlorhexidine. Suwantarat N, et al.(4) reported that patients who were bathed daily with chlorhexidine were more likely to develop CLABSIs with reduced susceptibility to chlorhexidine and Lee AS, et al found that chlorhexidine resistance independently predicted failure in MRSA decolonization.(5) It has also been asserted that usage of chlorhexidine may have been one of the driving initiators for the emergence of the extremely-drug-resistant epidemic strain of Klebsiella pneumonia.(6)

In addition, there are also significant concerns regarding industry influence and research integrity of Chlorhexidine.(1-3,7) For example, such issues were behind a 40 million dollar U.S. Dept. of Justice Settlement with CareFusion.(7) Other authors have found significant problems related to overstating the findings and the change of metrics after study initiation.(1-3) There have been at least four articles which have compared chlorhexidine plus alcohol to another antiseptic but attributed the increase in efficacy to chlorhexidine alone.(3)

This proposal's FDA press release references the advisory committee meeting on Sept. 3rd, 2014 (in Silver Springs) and states that this initiative is designed to address concerns brought up at the meeting: http://www.fda.gov/AdvisoryCommittees/Calendar/ucm407136.htm

It should be noted that our concerns regarding the greatly expanded role and use of Chlorhexidine were also presented at a Sept. 5th, 2014 FDA advisory meeting in Silver Springs.(8) The decision to only address concerns on antiseptics, which were expressed on Sept. 3rd, 2014, and not address the comments expressed on Sept. 5th, 2014, seems arbitrary. Concerns at both meetings should be addressed.

The proposed FDA initiative will only evaluate antiseptics that were marketed before 1972, which excludes Chlorhexidine simply because it was first marketed after that year. The selection of this date also seems too restrictive, for it is the newer antiseptics which are being used for expanded indications

that have not been as time tested. These are the antiseptics which are in the most need of additional safety and efficacy data.

We therefore recommend that Chlorhexidine be included in the FDA's proposed regulation calling for more complete safety and effectiveness data on antiseptics.

Thank you for this consideration,

Kevin T. Kavanagh, MD, MS

Health Watch USA
Lexington, KY 40509
healthwatchusa@gmail.com

Lisa McGiffert
Consumers Union Safe Patient Project project.org
Austin, TX 78752
www.safepatientproject.org

Jean Rexford
CT Center for Patient Safety
Fairfield, CT 06824
www.http://ctcps.org

Kathy Day, RN
McCleary MRSA Prevention
Bangor, Maine

John T. James, PhD.
Patient Safety America
Houston, TX

Patty J Skolnik
Founder & Director
Citizens for Patient Safety
Denver, CO 80230

Julia Hallisy, DDS
The Empowered Patient Coalition
San Francisco, CA 94132

Rex Johnson and Yanling Yu, PhD
Washington Advocates for Patient Safety
Seattle, WA 98155

Kerry O'Connell
Patient Advocate
Denver, CO 80238

Lenore Alexander
Executive Director, LeahLegacy
Oak Park CA 91377

Al Levine
Retired Office of Inspector General Senior Program Analyst
Washington, DC

Helen Haskell, MA
Mothers Against Medical Error
Columbia, SC 29205

Suzan Shinazy, RN
Patient Advocate, California

Joleen Chambers
FAILED Implant Device Alliance
Dallas, TX 75201

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