Containment Technologies Group, Inc.

February 24, 2016

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FEB 29 2016
IOWA BOARD OF PHARMACY

Iowa Board of Pharmacy
400 SW 8th St, Suite E
Des Moines, IA 50309-4688

Attn: Andrew Funk, PharmD, Executive Director

RE: False and misleading training

Dear Mr. Funk,

Containment Technologies Group, Inc. ("CTG") is a manufacturer of the MIC family of isolators, which include the MIC Single, MIC Dual, MIC TPNs, and MIC Single Chemo, MIC 797P, MIC Nuclear, and MIC-EDU Systems. The MIC was designed by engineers with hazardous containment and aseptic expertise. The MIC product line is currently implemented in nearly every state, over a dozen countries overseas and the United States Air Force, Army and Navy.

It has come to our attention that a company named Critical Point has been selling training programs to state boards of pharmacy and their respective inspectors on various topics that relate to the use of isolators by pharmacies, including compliance with USP <797>. CTG has learned that the training materials provided by Critical Point contains false and misleading statements about the requirements of USP <797> in general and the application of USP <797> to CTG's MIC isolators in particular.

CTG has taken affirmative actions to correct the erroneous information being sold by Critical Point to various state board of pharmacies and their respective inspectors. Specifically, CTG has repeatedly informed Susan deMars, Chief Legal Counsel for USP, of several examples of Critical Point having provided misinformation about USP <797> in its training materials. For example, CTG provided USP a copy of Critical Point's training slide stating that "CAI/CACI's with static airlocks are required to be placed into an ISO 7 cleanroom." even though USP <797> 2014 contains no such requirement.

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In addition, CTG has learned that Critical Point's affiliated consultants have provided misinformation about the MIC isolator's ability to achieve an ISO 5 environment. CTG, has hundreds of certifications by independent certifiers, which verify that CTG's MIC isolator is fully capable of achieving and does achieve ISO 5 during dynamic testing.

Finally, Critical Point's own executives have been involved in the dissemination of false and misleading information about the technology of CTG's MIC isolator. Specifically, Critical Point has erroneously stated that the MIC isolator does not have unidirectional airflow as required by USP <797>.

CTG previously sent validation materials to your board in accordance with USP <797> requirements, including a video clearly demonstrating unidirectional requirement of the MIC.

CTG is greatly concerned that the purported training and consulting services disseminated by Critical Point related to USP <797> and perhaps USP <800>, misstates the content of USP <797> and USP <800> chapters. The erroneous information being disseminated by Critical Point as a part of their training programs is causing irreparable harm to state board of pharmacies, their respective staff and inspectors, and the pharmacies who rely on CTG's MIC to safely and efficiently provide sterile product delivery to its customers and patients.

Please contact me immediately if you need another copy of the CTG validation materials, or if you have any questions regarding this issue.
Thank you for your attention to this important mater.

Sincerely

Hank Rahe

Hank Rahe
Director Technology CTG
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nabp

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: March 21, 2016

RE: CriticalPoint Isolators Discussion

You probably received communications involving CriticalPoint, LLC and Clinical IQ regarding isolators and the applicable USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations.

NABP has worked closely with CriticalPoint and Clinical IQ for some time. Throughout that time and continuing, CriticalPoint and Clinical IQ have provided invaluable expertise to NABP, the state boards of pharmacy, and other stakeholders regarding pharmaceutical compounding. The documents, presentations, and guidance prepared by CriticalPoint and Clinical IQ have been, and are, accurate and of the highest integrity.

NABP recommends that any state board of pharmacy with questions about the current matter contact CriticalPoint (Peter Cantor or Eric Kastango) or Clinical IQ (Eric Kastango) directly for clarification and validation of the information provided by CriticalPoint and Clinical IQ. NABP continues to partner with CriticalPoint and Clinical IQ on a number of critical projects that assist the state boards of pharmacy in developing appropriate regulations for pharmaceutical compounding. In every instance, the information, guidance, and determinations of CriticalPoint and Clinical IQ have been precise and supported by verifiable data and sources. NABP continues to rely upon CriticalPoint and Clinical IQ as the experts for the development of model regulations and standards for pharmaceutical compounding.

cc: NABP Executive Committee