Citizen Petition

Date: 10/19/2014
The undersigned submits this petition under the Food and Drug Administration Department of Health and Human Services Part 880 Subchapter H,—Medical Devices: Subpart G(b) Classification of High Level Disinfectants [Code of Federal Regulations, Title 21, Volume 8 (21CFR880.6885, Revised as of April 1, 2014)] and the associated content/format outlined within the Premarket Notification Submissions for Liquid Chemical Sterilants/High Level Disinfectants [510k] of the Federal Food, Drug, and Cosmetic Act regulated by guidelines established through the collaboration of the U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Infection Control Devices Branch, Division of Dental, Infection Control and General Hospital Devices, and Office of Device Evaluation to request the Commissioner of Food and Drugs to amend the current content and format of high level disinfectant characterization for use with semi critical items employed in the healthcare setting.

A. Action Requested
(1) Requests Commissioner amend the requirements for high level disinfectant characterization outlined in the Food and Drug Administration Department of Health and Human Services Part 880 Subchapter H,—Medical Devices: Subpart G(b) Classification of High Level Disinfectants [Code of Federal Regulations, Title 21, Volume 8 ] and associated Premarket Notification Submissions for Liquid Chemical Sterilants/High Level Disinfectants [510k] to include in the potency testing requirements the inclusion of organisms specifically representative of the type of worst case organic load to which the device is exposed during actual use. For example, those chemical high level disinfectants indicated for use with semi critical items such as endoscopes and endocavity ultrasound transducers should include potency tests against the organisms to which exposure is known or for which there is a high risk of transmission should the high level disinfectant fail to demonstrate efficacy against them. Endocavity ultrasound transducers used in performing transvaginal ultrasounds should include all sexually transmitted disease organisms, including but not limited to HPV.
(2) Requests the Commissioner revoke approval of chemical products that contain ortho-phthalaldehyde and glutaraldehyde for the high level disinfection of flexible endoscopes and endocavity ultrasound transducers following the recent publication of scientific research finding these chemicals ineffective at reducing HPV 16 (linked to cervical and oropharyngeal cancers).
(3) Requests Commissioner expand enforcement of high level disinfectant application in free standing facilities that are not under the jurisdictional enforcement of CMS and Joint Commission in the interest of patient safety and disease prevention.

B. Statement of Grounds
Summary of Issues:
Glutaraldehyde and Ortho-phthalaldehyde are ineffective against HPV 16 [1]
FDA defines HLD characterization as a process that kills all forms of microbial life except for large numbers of bacterial spores. HPV falls under the definition of microbial life, yet it is not included in the efficacy testing procedures for HLD characterization.

Current guidelines published by governing agencies recommend glutaraldehyde and ortho-phthalaldehyde for HLD on semi-critical items. There is no enforcement of HLD compliance in outpatient facilities which results in variance in equipment cleaning; inadequate processing puts patients at risk for a number of diseases of which they are not informed.

Semi-critical items include endocavity probes such as transvaginal and transrectal as well as orally introduced scopes used in endoscopic procedures; the risk of HPV transmission is high and prevention should be a priority when determining which chemicals are suitable in achieving HLD. HLD chemicals recommended for these types of probes should be effective at HPV reduction to prevent the facilitation of a hearty virus that has been linked to cervical and oropharyngeal cancers and serves as an impetus for many anti-cancer and disease prevention and patient safety initiatives.

Research published earlier this year demonstrated several of the most commonly used HLD products in healthcare are not effective at HPV 16 reduction, specifically products containing glutaraldehyde and ortho-phthalaldehyde, yet these products continue to be characterized as high level disinfectants by the FDA. These chemicals are also included in the HLD recommendations by the CDC, ACR, APIC, AORN, AIUM, OSHA, Joint Commission, CMS etc. As a result, most practices are utilizing glutaraldehyde and ortho-phthalaldehyde to disinfect probes in between patients. Considering the prevalence of HPV in the United States, providers performing endocavity ultrasounds and scope procedures who employ HLD according to current guidelines are essentially exposing all patients to potential disease transmission. Given this is a known issue, failure to disclose this known exposure presents a legal concern related to informed consent. In light of quality improvement measures related to nosocomial infections, it is noteworthy that the clinical presentation of HPV is not as readily apparent as other hospital acquired infections targeted by disease prevention organizations; this also increases provider liability for patient exposure to known risks without disclosure.

FDA characterization of high level disinfection products inadequately addresses organisms to which patients are currently exposed during endocavity ultrasounds and flexible endoscopes. Equally critical is the inclusion of ineffective chemicals in the current guidelines established by the CDC (2008) that cite glutaraldehyde and ortho-phthalaldehyde as approved methods of high level disinfection. These guidelines are also referenced in all regulatory agencies’ standards (ACR, AIUM, SDMS, Joint Commission, CMS etc). A study published this year researched the prevalence of HPV in the healthcare setting and its resistance to the most commonly used HLD in healthcare [1]. The chemicals currently being recommended by the CDC to high level disinfect (glutaraldehyde and ortho phthalaldehyde) were determined to be ineffective against HPV 16. [1] Research also establishes an alarming failure of endocavity probe covers [5] which is mitigated only by post-procedural HLD processing of the equipment, however: if the HLD process employed uses the chemicals currently recommended by the CDC (glutaraldehyde and ortho phthalaldehyde, patients are still being put at risk—without being informed of the potential biological hazards of likely exposure to HPV. Providers are currently, albeit unwittingly, transmitting the HPV virus to patients if they are using these chemical disinfectants.
HLD is required for semi critical devices and enforcement of proper procedure is assured by the Joint Commission/CMS inspections performed in hospitals that require the accreditation for reimbursement. There is no such enforcement currently being conducted at the growing number of outpatient facilities that are independent of hospitals. These include physician practices/OB/GYN offices, Urology groups (performing transrectal ultrasounds), fertility clinics, as well as any specialty groups that perform injections/biopsies under image guidance such as orthopedic, endocrinology, and breast clinics. While these physician groups are licensed by the state in which they reside, the inspections inadequately address the significance of appropriate HLD methods required to preserve patient safety. This lack of oversight places every patient receiving a transvaginal, transrectal or ultrasound guided invasive procedure at risk for contracting a number of infectious diseases that have been established through research.

Summary of Actions Needed:

- FDA revision of the characterization of HLD to specifically include those organisms to which the patient is most likely to be exposed based on its use; i.e. sexually transmitted diseases such as HPV 16 should be demonstrated as organisms against which the chemical is effective at reduction.
- Governing agencies such as the CDC should be informed of the changes immediately and revise the guidelines by removing the ineffective chemicals from being labeled and sold as HLD
- Until HLD guideline revision takes place, facilities using Glutaraldehyde and Orthophthalaldehyde are required by law to inform patients of the risk of contracting HPV and the hazards to which gametes and fetuses are susceptible.
- Outpatient facilities should be prevented from performing endocavity ultrasounds if they do not employ approved HLD methods in the interest of patient safety and disease prevention.
- Standardization and universal enforcement of HLD is necessary to prevent patient harm and the spread of disease.

I urge you to consider the implication in the context of legalities, patient care, accountability, safety, and disease prevention. Current initiatives in health care surround increasing the quality of health care, decreasing patient risk, and preventing the spread of disease transmitted by health care facilities. Our current structure lacks the framework that promotes continued education on HLD, standardization of and compliance with the process, and enforceability independent of the payer mix. These issues warrant alarm and immediate mitigation; I do hope it will not be met with inaction on behalf of the federal bodies responsible for the health of our nation. Supporting research and information enclosed.

C. Environmental Impact
(A) N/A

D. Economic Impact
(A) Economic impact information will be provided upon request of the Commissioner.

E. Certification
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

____________________________________________________________(Signature)
Tia Gonnella (Name of petitioner)
_________________________ ______(Mailing address)
(b) (6)
REFERENCES


