Whereas, At Annual 2023, the AMA House of Delegates adopted the Council on Science and Public Health’s (CSAPH) report *Improving Research Standards, Approval Processes and Post-Market Surveillance Standards for Medical Devices* (AMA Policy H-480.934); and

Whereas, Exponentially increasing adverse infectious events coincident with the increased use of lumened and other medical devices for diagnostic and therapeutic protocols highlights the need to augment existing re-processing steps of such devices to ensure: 1) safety of patients; 2) limiting fiscal expense and medical waste; and 3) aggressive stewardship of our natural resources and ecologic sustainability\(^{(1-12)}\); and

Whereas, Within the said CSAPH report, no specific consideration was given to the outstanding concerns for patient safety protocols (such as optimal re-processing of devices amid growing antibiotic resistance of hospital microbes)\(^{(13-39)}\); and

Whereas, Within the said CSAPH report, no specific consideration was given to the outstanding concerns for environmental stewardship such as reducing uses of fossil fuel-derived, non-biodegradable medical waste (e.g., “forever chemicals” or “endocrine-disrupting chemicals”) perhaps by restricting the increased use of single-use disposable lumened device entities\(^{(40-41)}\); and

Whereas, Due to the increasing presence of antibiotic-resistant microbes such as *Candida aureas*, *Acinetobacter baumannii*, *Psudomonas aeruginosa*, *Staphyccocus aureas*, *Klebsiella pneumonia*, and *B-lactamase-producing Enterobacteriaceae* some hospital diagnostic and surgical suites recently have been temporarily closed down, and relevant patients altered, as a result of inadequate reprocessing of reusable medical devices—a major cause of preventable transmission of infectious disease in hospital settings\(^{(42-46)}\); and

Whereas, Affected hospital venues include dental, endoscopic, urologic, podiatric, optometric, and sleep study, as well as general operative, suites\(^{(42-46)}\); and

Whereas, Preventable risks to patient safety include the presence of “forever chemicals” and “endocrine-disruptive chemicals” that can impact both individual patient safety and environmental sustainability via increased medical waste and subsequent chemical leaching from landfills into groundwater\(^{(40, 41)}\); and
Whereas, Overriding guidelines in the use of management of medical devices should address 1) patient safety given increased presence of antibiotic resistant microbes and 2) protection of our global ecosystem; therefore be it

Resolved, That our American Medical Association develop policy that specifically addresses concerns about the design, use, and maintenance of reusable medical devices in the context of the growth of antibiotic-resistant microbes, as it threatens patient safety (Directive to Take Action); and be it further

Resolved, That our AMA develop policy that specifically addresses single use/disposable medical devices with regards to 1) adverse environmental consequences (material use and medical waste), and 2) the balance of fiscal expense vs. patient safety concerns (Directive to Take Action); and be it further

Resolved, That our AMA advocate for an augmented recommendation on medical devices that addresses patient safety as it intersects with fiscal and environmental considerations to the U.S. Food and Drug Administration’s Center for Devices and Radiological Health and advocate for its incorporation into the Center’s policies regarding approval and continuance of medical devices. (Directive to Take Action).

Fiscal Note: TBD

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References


4. Centre de Recherche, Centre hospitalier de l'Universite de Montreal (crCHUM). (2023) Infectious SARS-CoV-2 Found in Hospital Air. Online. <https://email.pio.newswise.com/c/eJxMzE2KAYeEQQOHTIEvRUvxZuBgl3sN0ldNCrnzQg4_WH7LJ_76PEFL0iwUm7oQP0JjhxJkvFxRCfWXDxis5qgDVVXMh0gKpZFS2NVfXZ5Tus2gVUh3nO3yf4d3Gic617gvkBzI57yv2_A8BcxmrHxRMw_zXegNlHFaL6DCBPAPA8yj73UDuru9wTy0VsaLkUahLmp8mvoOq3lZ9yP8AADD_6iOPy4>


40. Endocrine Society - May 11, 2023 - Endocrine Society Calls for Plastic Treaty to Protect Public <https://email.pio.newswise.com/c/eJxMzEFuwvAQQNHTDEuEZzDYCxaVlu5BPOOa1iSuQSHg6Svuvv_cRCevWEIYXDTeNChJ7WFuxuNIYnczMODv5g9Xf7HFe2MiVVOZyv7_b11r_uydksOYhvfZcRS_PovawtXZUoA_ACBh77_p_ABiT2fKySwWMrywdMPqZcMRoFgXoFvp7QB0R34C3YbBkFdnOBMMXXVPRe36ANZ8lf5oi_wIAAP__ZsE-0g>


42. GAO. (2018) VA Healthcare : Improved Oversight Needed for Reusable Medical Equipment Report to Committee on Veterans Affairs, House of Representatives. GAO #18-474

44. VA Medical Center Warning 526 Patients on Risk From Scopes (2017) 


RELEVANT AMA POLICY

Improving Research Standards, Approval Processes, and Post-Market Surveillance Standards for Medical Devices H-480.934

Our AMA believes that to support innovation while protecting patient safety, approval pathways for medical devices should incorporate the following principles:

a. Evidence-based, measurable performance benchmarks, such as those used in the Safety and Performance Based Pathway, should be used wherever possible for classes of known, well-studied medical devices;

b. For a subset of higher risk devices receiving approval but have not completed clinical trials, time-limited approvals may be appropriate, after which the manufacturer may be required to provide post-market data to support full device approval;

c. Medical devices with known safety concerns should not be usable as predicate devices for the purposes of proving substantial equivalence. In the event safety concerns of predicate devices arise after approval has been granted, additional due diligence should be initiated as appropriate; and

d. Approval for medical devices should include criteria for adequate performance in racialized, minoritized, or otherwise historically excluded groups when feasible.

Citation: CSAPH Rep. 02, A-23

Reprocessing of Single-Use Medical Devices H-480.959

1. Our AMA: (a) supports the Food and Drug Administration (FDA) guidance titled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" that was issued on August 2, 2000; (b) supports the development of device-specific standards for the reuse and reprocessing of single-use medical devices involving all appropriate medical and professional organizations and the medical device industry; (c) encourages increased research by the appropriate organizations and federal agencies into the safety and efficacy of reprocessed single-use medical devices; and (d) supports the proper reporting of all medical device failures to the FDA so that surveillance of adverse events can be improved.

2. Our AMA strongly opposes any rules or regulations regarding the repair or refurbishment of medical tools, equipment, and instruments that are not based on objective scientific data.

Citation: CSA Rep. 3, I-00; Reaffirmed: CSAPH Rep. 1, A-10; Appended: Res. 217, I-17; Reaffirmed: Res. 936, I-22

Stewardship of the Environment H-135.973

The AMA: (1) encourages physicians to be spokespersons for environmental stewardship, including the discussion of these issues when appropriate with patients; (2) encourages the medical community to cooperate in reducing or recycling waste; (3) encourages physicians and the rest of the medical community to dispose of its medical waste in a safe and properly prescribed manner; (4) supports enhancing the role of physicians and other scientists
in environmental education; (5) endorses legislation such as the National Environmental Education Act to increase public understanding of environmental degradation and its prevention; (6) encourages research efforts at ascertaining the physiological and psychological effects of abrupt as well as chronic environmental changes; (7) encourages international exchange of information relating to environmental degradation and the adverse human health effects resulting from environmental degradation; (8) encourages and helps support physicians who participate actively in international planning and development conventions associated with improving the environment; (9) encourages educational programs for worldwide family planning and control of population growth; (10) encourages research and development programs for safer, more effective, and less expensive means of preventing unwanted pregnancy; (11) encourages programs to prevent or reduce the human and environmental health impact from global climate change and environmental degradation.(12) encourages economic development programs for all nations that will be sustainable and yet nondestructive to the environment; (13) encourages physicians and environmental scientists in the United States to continue to incorporate concerns for human health into current environmental research and public policy initiatives; (14) encourages physician educators in medical schools, residency programs, and continuing medical education sessions to devote more attention to environmental health issues; (15) will strengthen its liaison with appropriate environmental health agencies, including the National Institute of Environmental Health Sciences (NIEHS); (16) encourages expanded funding for environmental research by the federal government; and (17) encourages family planning through national and international support.


Environmental Preservation H-135.972

It is the policy of the AMA to support state society environmental activities by:

(1) identifying areas of concern and encouraging productive research designed to provide authoritative data regarding health risks of environmental pollutants;

(2) encouraging continued efforts by the CSAPH to prepare focused environmental studies, where these studies can be decisive in the public consideration of such problems;

(3) maintaining a global perspective on environmental problems;

(4) considering preparation of public service announcements or other materials appropriate for public/patient education; and

(5) encouraging state and component societies that have not already done so to create environmental committees.

Citation: Res. 52, A-90; Reaffirmed: Sunset Report, I-00; Modified: CSAPH Rep. 1, A-10; Reaffirmed: CSAPH Rep. 01, A-20
AMA Advocacy for Environmental Sustainability and Climate H-135.923

Our AMA (1) supports initiatives to promote environmental sustainability and other efforts to halt global climate change; (2) will incorporate principles of environmental sustainability within its business operations; and (3) supports physicians in adopting programs for environmental sustainability in their practices and help physicians to share these concepts with their patients and with their communities.

Citation: Res. 924, I-16; Reaffirmed: I-19