

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES (A-22)

Preliminary Document of Reference Committee E

Kenneth M. Certa, MD, Chair

Pursuant to Policy D-600.956, adopted at the November 2021 Special Meeting, commentary submitted to the online member forums will be used to generate a preliminary document to inform the discussion at the in-person reference committee hearings.

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- 24 Unsupported Clinical Treatments
- 25 18. Resolution 517 - Safeguard the Public from Widespread Unsafe Use of “Mild
- 26 Hyperbaric Oxygen Therapy”
- 27 19. Resolution 518 - Over-the-Counter Access to Oral Contraceptives
- 28 20. Resolution 519 - Advanced Research Projects Agency for Health (ARPA-H)
- 29 21. Resolution 520 - Addressing Informal Milk Sharing
- 30 22. Resolution 521 - Encouraging Brain and Other Tissue Donation for Research and
- 31 Educational Purposes
- 32 23. Resolution 522 - Encouraging Research of Testosterone and Pharmacological
- 33 Therapies for Post-Menopausal Individuals with Decreased Libido
- 34 24. Resolution 523 - Improving Research Standards, Approval Processes, and Post-
- 35 Market Surveillance Standards for Medical Devices
- 36 25. Resolution 524 - Increasing Access to Traumatic Brain Injury Resources in
- 37 Primary Care Settings

1 (1) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT
2 3 – CORRECTING POLICY H-120.958
3

4 1. That Policy H 120.958, “Supporting Safe Medical Products as a Priority Public Health
5 Initiative,” be amended by addition and deletion to read as follows:
6

7 Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt
8 methodology to help prevent “look alike-sound alike” errors in giving new drugs generic
9 names; (2) continue participation in efforts to advance the science of safety in the
10 medication use process, including work with on the National Coordinating Council for
11 Medication Error Reporting and Prevention; (3) support the FDA’s Medwatch program by
12 working to improve physicians’ knowledge and awareness of the program and
13 encouraging proper reporting of adverse events; (4) vigorously work to support the Drug
14 Supply Chain and Security Act (DSCSA, Public Law 113-54), including provisions on
15 product identification and verification, data sharing, detection and response, and
16 encourage efforts to create and expeditiously implement a national coding system for
17 prescription medicine packaging in an effort to improve patient safety; (5) participate in the
18 work of the Healthy People 2030 initiative in the area of safe medical products especially
19 as it relates to existing AMA policy and (56) seek opportunities to work collaboratively with
20 other stakeholders to provide information to individual physicians and state medical
21 societies on the need for public health infrastructure and local consortiums to work on
22 problems related to medical product safety.
23

24 Preliminary testimony on CSAPH Report 3 was limited (less than 2 commenters) and
25 unanimously supportive. The policy changes contained within CSAPH Report 3 have
26 previously been approved by the House of Delegates and the report seeks to rectify a
27 drafting error.
28

29 (2) RESOLUTION 501 – MARKETING GUARDRAILS FOR
30 THE “OVER-MEDICALIZATION” OF CANNABIS USE
31

32
33 RESOLVED, That our American Medical Association send a formal letter to the Food and
34 Drug Administration and Federal Trade Commission requesting more direct oversight of
35 the marketing of cannabis for medical use. (Directive to Take Action)
36

37 Testimony for Resolution 501 was supportive. Several individuals and delegations,
38 particularly from states which have more permissive marijuana laws, noted the difficulty of
39 dealing with the perception of cannabis and medical use. A significant portion of testimony
40 focused on the complicated status of cannabis regulation, including whether the FDA or
41 FTC had the regulatory authority to achieve the goals of the proposed resolution. Other
42 commenters noted that the AMA’s Cannabis Task Force is currently active in this space
43 and may be a useful resource for clarifying some misperceptions of the legal landscape
44 around cannabis.
45

46 (3) RESOLUTION 502 – ENSURING CORRECT DRUG
47 DISPENSING
48

49
50 RESOLVED, That our American Medical Association request that the United States Food
51 and Drug Administration work with the pharmaceutical and pharmacy industries to

1 facilitate the ability of pharmacies to ensure that a color photo of a prescribed medication
2 and its dosage is attached to the sales receipt to ensure that the drug dispensed is that
3 which has been prescribed. (Directive to Take Action)

4
5 Preliminary testimony on Resolution 502 was supportive of the effort to reduce prescription
6 errors, but some questioned the economics of the approach proposed, including concerns
7 that prescription drug prices could be impacted, and if color photos would be a cost-
8 effective measure. Another commenter noted that pharmacies currently distribute generic
9 information sheets and believes that the cost to add a photograph would be minimal. They
10 also added that many insurance companies may require filling of substitutes rather than
11 what the patient discussed with their physician, which would reduce the patient's ability to
12 catch dispensing errors without visual aids.

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15 (4) RESOLUTION 503 – PHARMACY BENEFIT MANAGERS
16 AND DRUG SHORTAGES

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19 RESOLVED, That our American Medical Association conduct a study which will
20 investigate the role pharmacy benefit managers play in drug shortages. (Directive to Take
21 Action)

22
23 Preliminary testimony for Resolution 503 was positive. Several testified to the long-
24 standing interest of the AMA in monitoring both drug shortages and the oversight of
25 pharmacy benefit managers. All who testified were supportive of the AMA studying the
26 issue.

27
28 (5) RESOLUTION 504 – SCIENTIFIC STUDIES WHICH
29 SUPPORT LEGISLATIVE AGENDAS

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31
32 RESOLVED, That our American Medical Association continue and expand its efforts to
33 work with allied groups, health care policy influencers such as think tanks, and entities
34 that can produce high quality scientific evidence, to help generate support for the AMA's
35 key advocacy goals. (Directive to Take Action)

36
37 Online testimony for Resolution 504 was limited and unanimously supportive.

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40 (6) RESOLUTION 505 – CBD OIL USE AND THE
41 MARKETING OF CBD OIL

42
43
44 RESOLVED, That our American Medical Association support banning the advertising of
45 cannabidiol (CBD) as a component of marijuana in places that children frequent (New
46 HOD Policy); and be it further

47
48 RESOLVED, That our AMA support legislation to prohibit companies from selling CBD
49 products if they make any unproven health and therapeutic claims, and to require
50 companies to include a Food and Drug Administration-approved warning on CBD product
51 labels. (New HOD Policy)

1
2 Online testimony on Resolution 505 was supportive. Testimony noted the similarities
3 between the practices observed in advertisements targeting children and other forms of
4 medical misinformation. Another member, however, questioned if the FDA had the
5 regulatory authority to place warning labels for Schedule I drugs.
6

7 (7) RESOLUTION 506 – DRUG MANUFACTURING SAFETY
8
9

10 RESOLVED, That our American Medical Association support efforts to ensure that the
11 U.S. Food and Drug Administration (FDA) resumes safety testing for all drug
12 manufacturing facilities on a frequent and rigorous basis, as done in the past (Directive to
13 Take Action); and be it further

14
15 RESOLVED, That our AMA call for the FDA to reaffirm the safety of the manufacture of
16 drugs and the adequacy of volume in the pipeline. (Directive to Take Action)
17

18 Preliminary online testimony for Resolution 506 was limited and unanimously supportive.
19
20

21 (8) RESOLUTION 507 – FEDERAL INITIATIVE TO TREAT
22 CANNABIS DEPENDENCE
23
24

25 RESOLVED, That our American Medical Association urge the National Institutes of Health
26 to award appropriate incentive grants to universities, pharmaceutical companies and other
27 capable entities to develop treatment options for cannabis dependence; and that the cost
28 of these grants be financed by taxes on those who profit from selling cannabis. (New HOD
29 Policy)
30

31 Online testimony was unanimously supportive. One commenter noted that the language
32 used within the resolution may need to be updated from “cannabis dependence” to
33 “cannabis use disorder”, which is the nomenclature used in the DSM-5.
34
35

36 (9) RESOLUTION 508 – SUPPLEMENTAL RESOURCES
37 FOR INFLIGHT MEDICAL KIT
38
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40 RESOLVED, That our American Medical Association advocate for U.S. passenger airlines
41 to carry standard pulse oximeters, automated blood pressure cuffs and blood glucose
42 monitoring devices in their emergency medical kits. (Directive to Take Action)
43

44 Resolution 508 received universally supportive online testimony, with one commenter
45 noting that inflight medical kits have historically been outdated and often inadequate to
46 provide the requisite emergency care. One commenter added, however, that the proposed
47 resolution may be streamlined by amending existing policy (Improvement in US Airlines
48 Aircraft Emergency Kits H-45.981) rather than creating a new standalone policy.
49
50

1 (10) RESOLUTION 509 – REGULATION AND CONTROL OF
2 SELF-SERVICE LABS
3
4

5 RESOLVED, That our American Medical Association study issues with patient-directed
6 self-service testing, including the accreditation and licensing of laboratories that sell self-
7 ordered tests and physician liability related to non-physician-ordered tests. (Directive to
8 Take Action)

9
10 Preliminary testimony was limited and unanimously positive.
11

12
13 (11) RESOLUTION 510 – EVIDENCE-BASED DEFERRAL
14 PERIODS FOR MSM CORNEAS AND TISSUE DONORS
15
16

17 RESOLVED, That our American Medical Association amend current policy H-50.973,
18 “Blood Donor Deferral Criteria,” by addition and deletion as follows:
19

20 **Blood and Tissue Donor Deferral Criteria**

21 Our AMA: (1) supports the use of rational, scientifically-based ~~blood and~~
22 ~~tissue donation~~ deferral periods for donation of blood, corneas, and other tissues that are
23 fairly and consistently applied to donors according to their individual risk; (2) opposes all
24 policies on deferral of blood and tissue donations that are not based on evidence; (3)
25 supports a blood and tissue donation deferral period for those determined to be at risk for
26 transmission of HIV that is representative of current HIV testing technology; and (4)
27 supports research into individual risk assessment criteria for blood and
28 tissue donation (Modify Current HOD Policy); and be it further
29

30 RESOLVED, That our AMA continue to lobby the United States Food and Drug
31 Administration to use modern medical knowledge to revise its decades-old deferral criteria
32 for MSM donors of corneas and other tissues. (Directive to Take Action)
33

34 Preliminary testimony for this resolution was unanimously supportive. Several
35 commenters noted that the AMA supports evidence-based deferrals for other forms of
36 donation and supported the idea of bringing policy more in line with modern science.
37
38

39 (12) RESOLUTION 511 – OVER THE COUNTER (OTC)
40 HORMONAL BIRTH CONTROL
41
42

43 RESOLVED, That our American Medical Association recommend elimination of the
44 requirement for a physician’s prescription to purchase birth control pills (BCP) and over
45 the counter (OTC) hormonal contraceptives and allow OTC purchase (New HOD Policy);
46 and be it further
47

48 RESOLVED, That our AMA advocate for the revocation of Food and Drug Administration
49 and/or Congressional regulations requiring a prescription for OTC hormonal BCP.
50 (Directive to Take Action)
51

1 Testimony for this resolution was supportive, noting that the current political landscape is
2 becoming increasingly restrictive of reproductive health, and it is likely that access to
3 abortions will be dramatically reduced in the coming years, particularly for rural and low-
4 income populations. Concern was noted that there are potential health risks but low
5 enough to support the resolution.
6

7
8 (13) RESOLUTION 512 – SCHEDULING AND BANNING THE
9 SALE OF TIANEPTINE IN THE UNITED STATES

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11
12 RESOLVED, That our American Medical Association advocate to schedule Tianeptine as
13 Schedule II whilst supporting research into the safety and efficacy of the substance
14 (Directive to Take Action); and be it further

15
16 RESOLVED, That our AMA advocate to ban the sale of Tianeptine directly to the public.
17 (Directive to Take Action)

18
19 Online testimony was limited and unanimously supportive.
20

21
22 (14) RESOLUTION 513 – EDUCATION FOR PATIENTS ON
23 OPIATE REPLACEMENT THERAPY

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25
26 RESOLVED, That our American Medical Association amend Policy D-95.987, “Prevention
27 of Drug-Related Overdose,” by addition to read as follows:
28

29 1. Our AMA: (a) recognizes the great burden that substance use disorders (SUDs) and
30 drug-related overdoses and death places on patients and society alike and reaffirms its
31 support for the compassionate treatment of patients with a SUD and people who use
32 drugs; (b) urges that community-based programs offering naloxone and other opioid
33 overdose and drug safety and prevention services continue to be implemented in order to
34 further develop best practices in this area; (c) encourages the education of health care
35 workers and people who use drugs about the use of naloxone and other harm reduction
36 measures in preventing opioid and other drug-related overdose fatalities; and (d) will
37 continue to monitor the progress of such initiatives and respond as appropriate.
38

39 2. Our AMA will: (a) advocate for the appropriate education of at-risk patients and their
40 caregivers in the signs and symptoms of a drug-related overdose; and (b) encourage the
41 continued study and implementation of appropriate treatments and risk mitigation methods
42 for patients at risk for a drug-related overdose.
43

44 3. Our AMA will support the development and implementation of appropriate education
45 programs for persons receiving treatment for a SUD or in recovery from a SUD and their
46 friends/families that address harm reduction measures.
47

48 4. Our AMA will advocate for and encourage state and county medical societies to
49 advocate for harm reduction policies that provide civil and criminal immunity for the use of
50 “drug paraphernalia” designed for harm reduction from drug use, including but not limited
51 to drug contamination testing and injection drug preparation, use, and disposal supplies.

1
2 5. Our AMA implement an education program for patients on opiate replacement therapy
3 and their family/caregivers to increase understanding of their increased risk of death with
4 concurrent opiate maintenance therapy and the onset of a serious respiratory illness such
5 as SARS-CoV-2. (Modify Current HOD Policy)
6

7 Preliminary testimony for Resolution 513 was mixed. While some commenters testified in
8 support of the resolution as written, others commented in opposition stating that the
9 proposed resolution could give the impression that medication for an opioid use disorder
10 (MOUD) increases the risk of death with a concurrent respiratory illness (such as COVID-
11 19). Compared to an individual with an untreated opioid use disorder, this is untrue, and
12 may instead discourage people from seeking MOUD treatment. In addition, opposition
13 noted that the language in the proposed resolution should be updated to use the preferred
14 terminology of MOUD rather than opioid replacement therapy.
15

16
17 (15) RESOLUTION 514 – OPPOSE PETITION TO THE DEA
18 AND FDA ON GABAPENTIN
19

20
21 RESOLVED, our American Medical Association actively oppose the placement of (a)
22 gabapentin (2-[1-(aminomethyl) cyclohexyl] acetic acid), including its salts, and all
23 products containing gabapentin (including the brand name products Gralise and
24 Neurontin) and (b) gabapentin enacarbil (1-[[[(1RS)-1-[(2- methylpropanoyl)oxy]ethoxy}
25 carbonyl)amino]methyl] cyclohexyl) acetic acid), including its salts, (including the brand
26 name product Horizant) into schedule V of the Controlled Substances Act; and be it further
27

28 RESOLVED, our American Medical Association submit a timely letter to the Commissioner
29 of Food and Drug for the proceedings assigned docket number FDA-2022-P-0149 in
30 opposition to placement of gabapentin and gabapentin enacarbil into the schedule V of
31 the Controlled Substance Act.
32

33 Preliminary testimony was in support of Resolution 514, which opposes the scheduling of
34 gabapentin and its salts. Commenters testified that some states have already classified
35 gabapentin as a Schedule V substance, which limits prescriptions to 30 days or less.
36 Others noted that gabapentin is one of the only non-opioid pain therapies available to
37 clinicians, and that in their experience overdoses involving gabapentin are not from those
38 using gabapentin recreationally, but rather those who are seeking pain relief. Finally,
39 testimony highlighted the number of clinical settings in which gabapentin has been used
40 safely and is a critical tool for physicians in their practice.
41

42
43 (16) RESOLUTION 515 – REDUCING POLYPHARMACY AS A
44 SIGNIFICANT CONTRIBUTOR TO SENIOR MORBIDITY
45

46
47 RESOLVED, That our American Medical Association work with other organizations e.g.,
48 AARP, other medical specialty societies, PhRMA, and pharmacists to educate patients
49 about the significant effects of all medications and most supplements, and to encourage
50 physicians to teach patients to bring all medications and supplements or accurate,

1 updated lists including current dosage to each encounter (Directive to Take Action); and
2 be it further

3
4 RESOLVED, That our AMA along with other appropriate organizations encourage
5 physicians and ancillary staff if available to initiate discussions with patients on improving
6 their medical care through the use of only the minimal number of medications (including
7 prescribed or over-the-counter, including vitamins and supplements) needed to optimize
8 their health (Directive to Take Action); and be it further

9
10 RESOLVED, That our AMA work with other stakeholders and EHR vendors to address
11 the continuing problem of inaccuracies in medication reconciliation and propagation of
12 such inaccuracies in electronic health records, and to include non-prescription medicines
13 in medication compatibility screens. (Directive to Take Action)

14
15 Online testimony was universally in support of the effort to reduce the burden of
16 polypharmacy. Several commenters spoke to the problems faced by the senior population
17 when dealing with multiple prescriptions all with unique dosing regimens, often prescribed
18 by more than one physician. In addition, commenters noted the added complexity from
19 over-the-counter herbs and supplements which are often not considered in the traditional
20 polypharmacy burden. Much of the testimony was particularly supportive of the third
21 resolve clause, calling for improved electronic health record tools to help manage this
22 problem.

23
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25 (17) RESOLUTION 516 – OPPOSE “MILD HYPERBARIC”
26 FACILITIES FROM DELIVERING SUPPORTED CLINICAL
27 TREATMENTS

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29
30 RESOLVED, That our American Medical Association oppose the operation of “mild
31 hyperbaric facilities” unless and until effective treatments can be delivered in safe facilities
32 with appropriately trained staff including physician supervision and prescription and only
33 when the intervention has scientific support or rationale. (New HOD Policy)

34
35 There was limited but supportive testimony on this item.

36
37
38 (18) RESOLUTION 517 – SAFEGUARD THE PUBLIC FROM
39 WIDESPREAD UNSAFE USE OF “MILD HYPERBARIC
40 OXYGEN THERAPY”

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42
43 RESOLVED, That our American Medical Association oppose the operation of unsafe “Mild
44 Hyperbaric Facilities” (New HOD Policy); and be it further

45
46 RESOLVED, That our AMA work with the U.S. Food and Drug Administration and other
47 regulatory bodies to close these facilities until and unless they adopt and adhere to all
48 established safety regulations, adhere to the established principles of the practice of
49 hyperbaric oxygen under the prescription and oversight of a licensed and trained
50 physician, and ensure that staff are appropriately trained and adherent to applicable safety
51 regulations. (Directive to Take Action)

1
2 There was limited but supportive testimony on this item.
3

4
5 (19) RESOLUTION 518 – OVER-THE-COUNTER ACCESS TO
6 ORAL CONTRACEPTIVES
7

8
9 RESOLVED, That our American Medical Association amends policy D-75.995, “Over-the-
10 Counter Access to Oral Contraceptives,” by addition and deletion to read as follows:

11
12 Our AMA:

13
14 1. Encourages ~~manufacturers of oral contraceptives to submit the required application and~~
15 ~~supporting evidence to the US Food and Drug Administration for the Agency to consider~~
16 approving a to swiftly review and approve a switch in status from prescription to over-the-
17 counter for ~~such products~~ oral contraceptives, without age restriction.

18
19 2. Encourages the continued study of issues relevant to over-the-counter access for oral
20 contraceptives.

21
22 3. Will work with expert stakeholders to advocate for the availability of hormonal
23 contraception as an over-the-counter medication. (Modify Current HOD Policy)
24

25 Testimony for this resolution was mostly supportive, noting that the current political
26 landscape is becoming increasingly restrictive of reproductive health, and it is likely that
27 access to abortions will be dramatically reduced in the coming years, particularly for rural
28 and low-income populations.

29
30 One commenter testified that the removal of an age restriction may have unintended
31 consequences. In addition, one commenter noted that for young people, visits to renew
32 birth control prescriptions are often their only interaction with a physician and serve as a
33 useful opportunity for an annual exam. The issue of different forms of oral contraceptives
34 (progestin only vs. combined) and their relative safety profiles was raised.
35

36
37 (20) RESOLUTION 519 – ADVANCED RESEARCH
38 PROJECTS AGENCY FOR HEALTH (ARPA-H)
39

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41 RESOLVED, That our American Medical Association urge Congress and the
42 Administration to ensure that while providing adequate funding for the promising research
43 conducted at Advanced Research Projects Agency for Health (ARPA-H), it also provides
44 robust annual baseline increases in appropriations for other research agencies, centers,
45 and institutes, including, but not limited to, the NIH and NCI. (Directive to Take Action)
46

47 Online testimony for Resolution 519 was supportive. The testimony noted that while
48 ARPA-H funding is important, it will only be successful if it is not at the expense of funding
49 for existing research agencies.
50
51

1 (21) RESOLUTION 520 – ADDRESSING INFORMAL MILK
2 SHARING
3
4

5 RESOLVED, That our AMA discourage the practice of informal milk sharing when said
6 practice does not rise to health and safety standards comparable to those of milk banks,
7 including but not limited to screening of donors and/or milk pasteurization; (New HOD
8 Policy) and be it further
9

10 RESOLVED, That our AMA encourage breast milk donation to regulated human milk
11 banks instead of via informal means; (Directive to Take Action) and be it further
12

13 RESOLVED, That our AMA supports further research into the status of milk donation in
14 the U.S. and how rates of donation for regulated human milk banks may be improved.
15 (New HOD Policy)
16

17 There was robust, mixed online testimony on Resolution 520. Both supportive and
18 opposing testimony noted that this resolution is backdropped by an ongoing infant formula
19 shortage, and members disagreed as to whether the proposed resolution was the
20 appropriate solution. Those testifying in support noted that during the formula shortage,
21 desperate parents may be more susceptible to predatory actors or may be more inclined
22 to minimize risks around questionably sourced milk. Opponents, however, argued that at
23 a time in which parents are struggling to find formula and feed their infants, the AMA
24 should not be limiting their options. Additional comments noted that milk procured from
25 milk banks is often prohibitively expensive and risks deepening health inequity for those
26 that cannot afford it. Disagreement between commenters largely centered around the first
27 two resolve clauses, but there was a larger level of agreement for the third resolve clause,
28 which calls upon the AMA to support research into how milk banking can be improved.
29
30

31 (22) RESOLUTION 521 – ENCOURAGING BRAIN AND
32 OTHER TISSUE DONATION FOR RESEARCH AND
33 EDUCATIONAL PURPOSES
34
35

36 RESOLVED, That our AMA support the production and distribution of educational
37 materials regarding the importance of postmortem tissue donation for the purposes of
38 medical research and education; (Directive to Take Action) and be it further
39

40 RESOLVED, That our AMA encourage the inclusion of additional information and consent
41 options for brain and other tissue donation for research purposes on appropriate donor
42 documents; (Directive to Take Action) and be it further
43

44 RESOLVED, That our AMA encourage all persons to consider consenting to tissue
45 donation including brain tissue for research purposes; (Directive to Take Action) and be it
46 further
47

48 RESOLVED, That our AMA encourage efforts to facilitate recovery of postmortem tissue
49 including brain tissue for research and education purposes. (Directive to Take Action)
50

1 Online testimony for this item was unanimously supportive with minimal additional
2 commentary.

3
4 (23) RESOLUTION 522 – ENCOURAGING RESEARCH OF
5 TESTOSTERONE AND PHARMACOLOGICAL
6 THERAPIES FOR POST-MENOPAUSAL INDIVIDUALS
7 WITH DECREASED LIBIDO
8
9

10 RESOLVED, That our AMA encourage expansion of research on the use of testosterone
11 therapy and other pharmacological interventions in treatment of decreased libido in
12 postmenopausal individuals. (Directive to Take Action)

13
14 There was limited but supportive testimony for Resolution 522.

15
16 (24) RESOLUTION 523 – IMPROVING RESEARCH
17 STANDARDS, APPROVAL PROCESSES, AND POST-
18 MARKET SURVEILLANCE STANDARDS FOR MEDICAL
19 DEVICES
20
21

22 RESOLVED, That our AMA support improvements to the Food and Drug Administration
23 510(k) exception to ensure the safety and efficacy of medical devices to: (a) make more
24 stringent guidelines for which devices can qualify for the 510(k) exceptions; (b) mandate
25 all 510(k) devices demonstrate equivalent or improved safety and effectiveness compared
26 to market devices for the same clinical purpose; (Directive to Take Action) and be it further
27

28 RESOLVED, That our AMA support stronger post-market surveillance requirements of
29 medical devices, including but not limited to (a): conditional approval of devices until
30 sufficient post-market surveillance data determining device safety can be collected,
31 followed by confirmatory trials, and (b) a publicly available summary of medical devices
32 approved under expedited programs along with associated clinical trial data and list of
33 reported adverse events; (Directive to Take Action) and be it further
34

35 RESOLVED, That our AMA amend policy H-100.992 to include medical devices by
36 addition as follows:
37

38 **FDA, H-100.992**
39

40 1. Our AMA reaffirms its support for the principles that:
41

42 (a) an FDA decision to approve a new drug or medical device, to withdraw a drug or
43 medical device's approval, or to change the indications for use of a drug or medical device
44 must be based on sound scientific and medical evidence derived from controlled trials,
45 real-world data (RWD) fit for regulatory purpose, and/or postmarket incident reports as
46 provided by statute;
47

48 (b) this evidence should be evaluated by the FDA, in consultation with its Advisory
49 Committees and expert extramural advisory bodies; and
50

1 (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds
2 for limiting access to or indications for use of a drug or medical device unless the weight
3 of the evidence from clinical trials, RWD fit for regulatory purpose, and post market reports
4 shows that the drug or medical device is unsafe and/or ineffective for its labeled
5 indications. (Modify Current HOD Policy)
6

7 Online testimony for Resolution 523 was supportive. Some members testified that while
8 supporting the underlying principles of reforming 510(k) medical device approval pathways
9 to support patient safety, they felt that the language in the proffered resolution could be
10 improved. Commenters in opposition were concerned with the first resolve clause's use
11 of the phrase "more stringent", as it was unclear what specific regulations the authors were
12 seeking. In addition, they noted that the conditional approval pathways outlined in the
13 second resolve clause could cause payers to not cover medical devices that are safe and
14 medically necessary simply due to the conditional approval classification.
15

16
17 (25) RESOLUTION 524 – INCREASING ACCESS TO
18 TRAUMATIC BRAIN INJURY RESOURCES IN PRIMARY
19 CARE SETTINGS
20

21 RESOLVED, That our AMA recognize disparities in the care for traumatic brain injuries,
22 and acknowledge non-athletic traumatic brain injuries as a significant cause of morbidity
23 and mortality, particularly for ethnic minorities and victims of domestic violence; (New HOD
24 Policy) and be it further
25

26 RESOLVED, That our AMA supports increased access to traumatic brain injury resources
27 in primary care settings which advocate for early intervention, encourage follow-up
28 retention of patients for post-injury rehabilitation, and improved patient quality of life. (New
29 HOD Policy)
30

31 Online testimony was supportive of Resolution 524. Much testimony commented on how
32 difficult managing TBI can be in a clinical setting due to lack of understanding and minimal
33 supportive resources. Commenters testified for a desire to see additional resources for
34 TBI care in rural settings, differentiating between athletic and non-athletic TBI, victims of
35 domestic abuse, concerns of health inequities for minoritized populations, and the role of
36 technological approaches for assessing and managing TBI.