

DISCLAIMER

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES (November 2020 Meeting)

Report of Reference Committee E

Joanna T. Bisgrove, MD, Chair

1 Your reference committee recommends the following consent calendar for acceptance:
2

3 **RECOMMENDED FOR ADOPTION**
4

- 5 1. Council on Science and Public Health Report 3 – Dietary Supplements: Update on
6 Regulation, Industry, and Product Trends
7

8 **RECOMMENDED FOR ADOPTION AS AMENDED**
9

- 10 2. Council on Science and Public Health Report 1 – Drug Shortages: 2020 Update
11

- 12 3. Council on Science and Public Health Report 2 – Neuropathic Pain as a Disease
13 Update
14

- 15 4. Council on Science and Public Health Report 4 – Public Health Impacts of Cannabis
16 Legalization
17

- 18 5. Resolution 508 – Home Infusion of Hazardous Drugs
19

20 **RECOMMENDED FOR NOT ADOPTION**
21

- 22 6. Resolution 509 – Hydroxychloroquine and Combination Therapies – Off-Label Use

Click here to submit an amendment.

RECOMMENDED FOR ADOPTION

- 1
2
3 (1) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 3 –
4 DIETARY SUPPLEMENTS: UPDATE ON REGULATION,
5 INDUSTRY, AND PRODUCT TRENDS
6

RECOMMENDATION A:

7
8
9 **Recommendations in Council on Science and Public Health**
10 **Report 3 be adopted.**

11
12 **HOD ACTION: Council on Science and Public Health Report 3**
13 **adopted.**
14
15

16 The Council on Science and Public Health recommends that the following be adopted and
17 The remainder of the report be filed:

- 18
19 1. That Policy H-150.954, “Dietary Supplements and Herbal Remedies” be amended by
20 addition and deletion to read as follows:

21
22 (1) Our AMA supports efforts to enhance U.S. Food and Drug Administration (FDA)
23 resources, particularly to the Office of Dietary Supplement Programs, to
24 appropriately oversee the growing dietary supplement sector and adequately
25 increase inspections of dietary supplement manufacturing facilities.

26
27 (2) Our AMA supports the FDA having appropriate enforcement tools and policies
28 related to dietary supplements, which may include mandatory recall and related
29 authorities over products that are marketed as dietary supplements but contain
30 drugs or drug analogues, the utilization of risk-based inspections for dietary
31 supplement manufacturing facilities, and the strengthening of adverse event
32 reporting systems.

33
34 (3) Our AMA supports continued research related to the efficacy, safety, and long-
35 term effects of dietary supplement products.

36
37 (4) Our AMA will work with the FDA to educate physicians and the public about FDA's
38 MedWatch program Safety Reporting Portal (SRP) and to strongly encourage
39 physicians and the public to report potential adverse events associated with dietary
40 supplements and herbal remedies to help support FDA's efforts to create a
41 database of adverse event information on these forms of
42 alternative/complementary therapies.

43
44 (5) Our AMA strongly urges physicians to inquire about patients' use of dietary
45 supplements and engage in risk-based conversations with them about dietary
46 supplement product use.

47
48 (6) Our AMA continues to strongly urge Congress to modify and modernize the Dietary
49 Supplement Health and Education Act to require that:

- 1 (a) dietary supplements and herbal remedies including the products already
2 in the marketplace undergo FDA approval for evidence of safety and
3 efficacy;
- 4 (b) dietary supplements meet standards established by the United States
5 Pharmacopeia for identity, strength, quality, purity, packaging, and
6 labeling;
- 7 (c) FDA establish a mandatory product listing regime that includes a unique
8 identifier for each product (such as a QR code), the ability to identify and
9 track all products produced by manufacturers who have received warning
10 letters from the FDA, and FDA authorities to decline to add labels to the
11 database if the label lists a prohibited ingredient or new dietary ingredient
12 for which no evidence of safety exists or for products which have reports
13 of undisclosed ingredients; and
- 14 (d) regulations related to new dietary ingredients (NDI) are clarified to foster
15 the timely submission of NDI notifications and compliance regarding NDIs
16 by manufacturers; and
- 17
- 18 (7) Our AMA supports FDA postmarketing requirements for manufacturers to report
19 adverse events, including drug interactions; and legislation that declares
20 metabolites and precursors of anabolic steroids to be drug substances that may
21 not be used in a dietary supplement.
- 22
- 23 (8) Our AMA will work with the Federal Trade Commission (FTC) to support
24 enforcement efforts based on the FTC Act and current FTC policy on expert
25 endorsements and supports adequate funding and resources for FTC enforcement
26 of violations of the FTC Act.
- 27
- 28 (9) Our AMA strongly urges that criteria for the rigor of scientific evidence needed to
29 support a structure/function claim on a dietary supplement be established by the
30 FDA and minimally include requirements for robust human studies supporting the
31 claim.
- 32
- 33 (10) Our AMA strongly urges dietary supplement manufacturers and distributors to
34 clearly label all products with truthful and not misleading information and for
35 supports that the product labeling of dietary supplements and herbal remedies to:
- 36 ~~(a) that bear structure/function claims contain the following disclaimer as a~~
37 ~~minimum requirement: "This product has not been evaluated by the Food~~
38 ~~and Drug Administration and is not intended to diagnose, mitigate, treat,~~
39 ~~cure, or prevent disease." This product may have significant adverse side~~
40 ~~effects and/or interactions with medications and other dietary~~
41 ~~supplements; therefore it is important that you inform your doctor that you~~
42 ~~are using this product;~~
- 43 (a) not include structure/function claims that are not supported by evidence
44 from robust human studies;
- 45 (b) should not contain prohibited disease claims;
- 46 (c) eliminate "proprietary blends" and list and accurately quantify all
47 ingredients contained in the product;

RECOMMENDED FOR ADOPTION AS AMENDED

- 1
2
3 (2) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 1 –
4 DRUG SHORTAGES: 2020 UPDATE

5
6 **RECOMMENDATION A:**

7
8 **Recommendation in Council on Science and Public Health**
9 **Report 1 be amended by addition and deletion to read as**
10 **follows:**

- 11
12 **5. The Council on Science and Public Health shall**
13 **continue to evaluate the drug shortage issue, including**
14 **the impact of group purchasing organizations on drug**
15 **shortages, and report back at least annually at least**
16 **annually to the House of Delegates ~~when warranted~~ on**
17 **progress made in addressing drug shortages.**

18
19 **RECOMMENDATION B:**

20
21 **The recommendation in Council on Science and Public**
22 **Health Report 1 be adopted as amended and the**
23 **remainder of the report be filed.**

24
25 **HOD ACTION: Council on Science and Public Health Report 1**
26 **adopted as amended and the remainder of the report filed.**

27
28 The Council on Science and Public Health recommends the following be adopted and the
29 remainder of the report be filed:

30
31 That Policy H-100.956, “National Drug Shortages” be amended by addition and deletion to
32 read as follows:

- 33
34 1. Our AMA considers drug shortages to be an urgent public health crisis, and recent
35 shortages have had a dramatic and negative impact on the delivery and safety of
36 appropriate health care to patients.
37
38 2. Our AMA supports recommendations that have been developed by multiple stakeholders
39 to improve manufacturing quality systems, identify efficiencies in regulatory review that
40 can mitigate drug shortages, and explore measures designed to drive greater investment
41 in production capacity for products that are in short supply, and will work in a collaborative
42 fashion with these and other stakeholders to implement these recommendations in an
43 urgent fashion.
44
45 3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human
46 Services (DHHS) to expedite facility inspections and the review of manufacturing changes,
47 drug applications and supplements that would help mitigate or prevent a drug shortage.
48
49 4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress
50 require drug manufacturers to establish a plan for continuity of supply of vital and life-

1 sustaining medications and vaccines to avoid production shortages whenever possible.
2 This plan should include establishing the necessary resiliency and redundancy in
3 manufacturing capability to minimize disruptions of supplies in foreseeable circumstances
4 including the possibility of a disaster affecting a plant.
5

6 5. The Council on Science and Public Health shall continue to evaluate the drug shortage
7 issue, including the impact of group purchasing organizations on drug shortages, and
8 report back at least annually to the House of Delegates when warranted on progress made
9 in addressing drug shortages.

10
11 6. Our AMA urges continued analysis of the development of a comprehensive independent
12 report on the root causes of drug shortages that includes consideration of. ~~Such an~~
13 ~~analysis should consider federal actions, the number of~~ evaluation of manufacturer,s
14 Group Purchasing Organization (GPO), and distributor practices, as well as contracting
15 practices by market participants on competition, access to drugs, and pricing, and . ~~In~~
16 ~~particular, further transparent~~ In particular, a further analysis of economic drivers is
17 warranted. The federal Centers for Medicare & Medicaid Services (CMS) should review
18 and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6%
19 for unintended consequences including serving as a root cause of drug shortages.
20

21 7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs
22 by ensuring that such products are not removed from the market due to compliance issues
23 unless such removal is clearly required for significant and obvious safety reasons.
24

25 8. Our AMA supports the view that wholesalers should routinely institute an allocation system
26 that attempts to fairly distribute drugs in short supply based on remaining inventory and
27 considering the customer's purchase history.
28

29 9. Our AMA will collaborate with medical specialty society partners and other stakeholders
30 in identifying and supporting legislative remedies to allow for more reasonable and
31 sustainable payment rates for prescription drugs.
32

33 10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving
34 pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to
35 determine whether such an activity has the potential to worsen drug shortages.
36

37 11. Our AMA urges the FDA to require manufacturers to provide greater transparency
38 regarding the pharmaceutical product supply chain, including production locations of
39 drugs, and provide more detailed information regarding the causes and anticipated
40 duration of drug shortages.
41

42 12. Our AMA supports the collection and standardization of pharmaceutical supply chain data
43 in order to determine the data indicators to identify potential supply chain issues, such as
44 drug shortages.
45

46 13. Our AMA encourages global implementation of guidelines related to pharmaceutical
47 product supply chains, quality systems, and management of product lifecycles, as well as
48 expansion of global reporting requirements for indicators of drug shortages.

14. Our AMA urges drug manufacturers to accelerate the adoption of advanced manufacturing technologies such as continuous pharmaceutical manufacturing.
15. Our AMA supports the concept of creating a rating system to provide information about the quality management maturity, resiliency and redundancy, and shortage mitigation plans, of pharmaceutical manufacturing facilities to increase visibility and transparency and provide incentive to manufacturers. Additionally, our AMA encourages GPOs and purchasers to contractually require manufacturers to disclose their quality rating, when available, on product labeling.
16. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes.
17. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities.
18. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan.

Your Reference Committee heard nearly unanimous testimony on the AMA's work, including this comprehensive report, related to drug shortages. Several commentors noted concern about changing language related to the frequency at which the Council reports back to the HOD. Therefore, your Reference Committee recommends that Council on Science and Public Health Report 1 be adopted as amended to return to original, yearly reporting, language.

(3) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 2 –
NEUROPATHIC PAIN AS A DISEASE UPDATE

RECOMMENDATION A:

Recommendation 1 in Council on Science and Public Health Report 2 be amended by addition to read as follows:

1. That a new policy, Neuropathic Pain, be adopted:

Our AMA:

- a. Supports the designation of neuropathic pain as a disease state distinct from nociceptive pain, encompassing metabolic, toxic, mechanical, and other injuries to nerve cells, as well as neuroplastic and neuroimmune adaptations to nerve cells in response to chronic pain.
- b. Encourages research related to neuropathic pain, payer coverage of treatment options for neuropathic pain, and improved resources for patients suffering with neuropathic pain.
- c. Encourages physicians to engage in meaningful conversation with their patients about what is known about the pathology of neuropathic pain and

1 **to set appropriate expectations collaboratively with**
2 **their patients.**

- 3 **d. Cautions that a neuropathic pain disease**
4 **designation should only be used when appropriate,**
5 **not overused, and that the cause of the neuropathic**
6 **pain be carefully elucidated and documented.**

7
8 **RECOMMENDATION B:**

9
10 **The recommendations in Council on Science and**
11 **Public Health Report 2 be adopted as amended and the**
12 **remainder of the report be filed.**

13
14 **HOD ACTION: Council on Science and Public Health Report 2**
15 **adopted as amended and the remainder of the report filed.**

16
17
18 The Council on Science and Public Health recommends that the following and the remainder
19 of the report be filed:

- 20
21 1. That a new policy, Neuropathic Pain, be adopted:

22 Our AMA:

- 23 a. Supports the designation of neuropathic pain as a disease state distinct from
24 nociceptive pain, encompassing metabolic, toxic, mechanical, and other injuries to
25 nerve cells, as well as neuroplastic and neuroimmune adaptations to nerve cells
26 in response to chronic pain.
27 b. Encourages research related to neuropathic pain, payer coverage of treatment
28 options for neuropathic pain, and improved resources for patients suffering with
29 neuropathic pain.
30 c. Encourages physicians to engage in meaningful conversation with their patients
31 about what is known about the pathology of neuropathic pain and to set
32 appropriate expectations collaboratively with their patients.
33 d. Cautions that a neuropathic pain disease designation should only be used when
34 appropriate, not overused, and that the cause of the neuropathic pain be carefully
35 elucidated.

- 36
37 2. That part (d) of Policy D-160.922, "Future of Pain Care," which called for the AMA Pain
38 Care Task Force to evaluate the merits of declaring neuropathic pain as a distinct disease
39 state and provide a recommendation to the Council on Science and Public Health, be
40 rescinded.

41
42 Your Reference Committee heard testimony unanimously supportive of the recommendations
43 put forth by the Pain Care Task Force and the Council and thanked them for their excellent
44 analysis and work on the issue. Testimony also requested a minor amendment to the policy
45 to include documentation of neuropathic pain disease by physicians; your Reference
46 Committee found this amendment appropriate. Therefore, your Reference Committee
47 recommends that Council on Science and Public Health Report 2 be adopted as amended.

- 48
49 (4) **COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 4 –**
50 **PUBLIC HEALTH IMPACTS OF CANNABIS LEGALIZATION**
51

1 **RECOMMENDATION A:**

2
3 **Recommendation in Council on Science and Public Health**
4 **Report 4 be amended by addition to read as follows:**

5
6 **That Policy H-95.924, “Cannabis Legalization for**
7 **Recreational Use,” be amended by addition and deletion to**
8 **read as follows:**

9
10 **Cannabis Legalization for Recreational Adult Use**
11 **(commonly referred to as recreational use)**

12 **Our AMA: (1) believes that cannabis is a dangerous drug**
13 **and as such is a serious public health concern; (2) believes**
14 **that the sale of cannabis for recreational adult, defined as**
15 **age 21 and older, use should not be legalized; (3)**
16 **discourages cannabis use, especially by persons**
17 **vulnerable to the drug's effects and in high-risk**
18 **populations such as youth, pregnant women, and women**
19 **who are breastfeeding; (4) believes states that have already**
20 **legalized cannabis (for medical or recreational adult use or**
21 **both) should be required to take steps to regulate the**
22 **product effectively in order to protect public health and**
23 **safety including but not limited to: regulating retail sales,**
24 **marketing, and promotion intended to encourage use;**
25 **limiting the potency of cannabis extracts and concentrates;**
26 **requiring packaging to convey meaningful and easily**
27 **understood units of consumption, and requiring that for**
28 **commercially available edibles, packaging must be child-**
29 **resistant and come with messaging about the hazards**
30 **about unintentional ingestion in children and youth; (5) that**
31 **laws and regulations related to legalized cannabis use**
32 **should consistently be evaluated to determine their**
33 **effectiveness; (5~~6~~) encourages local, state, and federal**
34 **public health agencies to improve surveillance efforts to**
35 **ensure data is available on the short- and long-term health**
36 **effects of cannabis, especially emergency department**
37 **visits and hospitalizations, impaired driving, workplace**
38 **impairment and worker-related injury and safety, and**
39 **prevalence of psychiatric and addictive disorders,**
40 **including cannabis use disorder; (6~~7~~) supports public**
41 **health based strategies, rather than incarceration, in the**
42 **handling of individuals possessing cannabis for personal**
43 **use; (7,~~8~~) encourages research on the impact of**
44 **legalization and decriminalization of cannabis in an effort**
45 **to promote public health and public safety; (8,~~9~~)**
46 **encourages dissemination of information on the public**
47 **health impact of legalization and decriminalization of**
48 **cannabis; (9,~~10~~) will advocate for stronger public health**
49 **messaging on the health effects of cannabis and**
50 **cannabinoid inhalation and ingestion, with an emphasis on**
51 **reducing initiation and frequency of cannabis use among**

1 **adolescents, especially high potency products; use among**
2 **women who are pregnant or contemplating pregnancy; and**
3 **avoiding cannabis-impaired driving; (11) supports social**
4 **equity programs to address the impacts of cannabis**
5 **prohibition and enforcement policies that have**
6 **disproportionately impacted marginalized and minoritized**
7 **communities, and (4012) will coordinate with other health**
8 **organizations to develop resources on the impact of**
9 **cannabis on human health and on methods for counseling**
10 **and educating patients on the use cannabis and**
11 **cannabinoids.**

12
13 **RECOMMENDATION B:**

14
15 **Council on Science and Public Health Report 4 be amended**
16 **by addition of a second Recommendation to read as**
17 **follows:**

18
19 **That our AMA study the expungement, destruction, and**
20 **sealing of criminal records for legal offenses related to**
21 **cannabis use or possession.**

22
23 **RECOMMENDATION C:**

24
25 **The recommendation in Council on Science and Public**
26 **Health Report 4 be adopted as amended and the remainder**
27 **of the report be filed.**

28
29 **HOD ACTION: Council on Science and Public Health Report 4**
30 **adopted as amended and the remainder of the report filed.**

31
32 The Council on Science and Public Health recommends that the following statement be
33 Adopted in lieu of Resolution 408-A-19, Resolution 411-A-19, and the additional proposed
34 resolve from Alternate Resolution 913-I-19 and the remainder of the report be filed:

35
36 That Policy H-95.924, "Cannabis Legalization for Recreational Use," be amended by addition
37 and deletion to read as follows:

38
39 Cannabis Legalization for ~~Recreational~~ Adult Use (commonly referred to as
40 recreational use)

41 Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious
42 public health concern; (2) believes that the sale of cannabis for ~~recreational~~ adult use
43 should not be legalized; (3) discourages cannabis use, especially by persons
44 vulnerable to the drug's effects and in high-risk populations such as youth, pregnant
45 women, and women who are breastfeeding; (4) believes states that have already
46 legalized cannabis (for medical or ~~recreational~~ adult use or both) should be required
47 to take steps to regulate the product effectively in order to protect public health and
48 safety including but not limited to: regulating retail sales, marketing, and promotion
49 intended to encourage use; limiting the potency of cannabis extracts and concentrates;
50 requiring packaging to convey meaningful and easily understood units of consumption,
51 and requiring that for commercially available edibles, packaging must be child-

1 resistant and come with messaging about the hazards about unintentional ingestion in
2 children and youth. (5) that laws and regulations related to legalized cannabis use
3 should consistently be evaluated to determine their effectiveness; (56) encourages
4 local, state, and federal public health agencies to improve surveillance efforts to
5 ensure data is available on the short- and long-term health effects of cannabis,
6 especially emergency department visits and hospitalizations, impaired driving, and
7 prevalence of psychiatric and addictive disorders, including cannabis use disorder;
8 (67) supports public health based strategies, rather than incarceration, in the handling
9 of individuals possessing cannabis for personal use; (7,8) encourages research on the
10 impact of legalization and decriminalization of cannabis in an effort to promote public
11 health and public safety; (8,9) encourages dissemination of information on the public
12 health impact of legalization and decriminalization of cannabis; (9,10) will advocate for
13 stronger public health messaging on the health effects of cannabis and cannabinoid
14 inhalation and ingestion, with an emphasis on reducing initiation and frequency of
15 cannabis use among adolescents, especially high potency products; use among
16 women who are pregnant or contemplating pregnancy; and avoiding cannabis-
17 impaired driving; (11) supports social equity programs to address the impacts of
18 cannabis prohibition and enforcement policies that have disproportionately impacted
19 marginalized and minoritized communities, and (1012) will coordinate with other health
20 organizations to develop resources on the impact of cannabis on human health and
21 on methods for counseling and educating patients on the use cannabis and
22 cannabinoids.

23
24 Your Reference Committee heard substantial and passionate testimony on Council and
25 Science and Public Health Report 4. The majority of the testimony was in favor of the Council's
26 report. There were several amendments proffered, some of which your Reference Committee
27 agreed were beneficial and should be included in AMA policy. These amendments include
28 defining the age of an adult as 21 years of age and older. This definition is consistent with the
29 majority of current state laws legalizing the adult use of cannabis. Your Reference Committee
30 also supported the inclusion of workplace impairment and worker-related injuries and safety
31 among the issues for which local, state, and federal public health agencies should be
32 encouraged to improve surveillance efforts.

33
34 Your Reference Committee also heard testimony in support of an amendment on the
35 expungement of criminal records for cannabis-related offenses. The Council on Legislation
36 testified that this amendment has legal implications and should not be included in this report.
37 The Council on Science and Public Health suggested that this topic requires further study to
38 ensure that the language of any policy related to expungement of records is accurate. Your
39 Reference Committee agrees that this is an important, though complex issue and
40 recommends further study.

41
42 Additional testimony was heard suggesting that AMA policy be amended to address the use
43 of cannabis in public spaces, Your Reference Committee thinks this topic is outside of the
44 scope of this report, and that it could be considered as a possible future resolution. We also
45 note that the US Public Health Service encouraged future reports to more accurately reflect
46 the legal distinctions between the terms "hemp" and "marijuana" where appropriate.

47
48 Limited testimony was heard in support of the AMA changing our current stance on the issue
49 of cannabis legalization for adult use to a neutral position, and not one of opposition. Your
50 Council on Science and Public Health just completed a review on the public health impacts of
51 legalization of adult use in this report, which identified concerning trends, which include an

1 increase in report poison control exposures, cannabis-related hospitalization, increasing traffic
2 crashes and fatalities, and increasing use by pregnant women. Therefore, Your Reference
3 Committee does not support changing our organization’s position on legalization at this time.
4 However, a member of the Board of Trustees noted that the AMA has created a Cannabis
5 Task Force, including representatives from more than 20 state and national medical specialty
6 societies, that will evaluate and disseminate relevant scientific evidence to health care
7 professionals and the public on this issue. Your Reference Committee encourages this issue
8 be re-visited upon the completion of additional evidence reviews.

9
10 Some individuals that testified supported referral of this entire report to the Cannabis Task
11 Force or holding off on this report until the Cannabis Task Force completes its work. However,
12 a member of the Board of Trustees testified that the task force will not be engaging in policy
13 development, though their work may inform it. Therefore, your Reference Committee
14 recommends that Council on Science and Public Health Report 4 be adopted as amended.

15
16 (5) RESOLUTION 508 – HOME INFUSION OF HAZARDOUS
17 DRUGS

18
19 **RECOMMENDATION A:**

20
21 **The first Resolve of Resolution 508 be amended by addition**
22 **and deletion to read as follows:**

23
24 **RESOLVED, That our American Medical Association**
25 **update its existing home infusion policy, H-55.986, “Home**
26 **Chemotherapy and Antibiotic Infusions,” by addition and**
27 **deletion to read as follows:**

28
29 **Our AMA (1) endorses the use of home injections and/or**
30 **infusions of FDA approved drugs and group C drugs**
31 **(including ~~chemotherapy and/or antibiotic therapy~~) for**
32 **appropriate patients under physicians’ recommendation**
33 **and supervision if requested as a result of informed,**
34 **shared decision making between the physician and patient;**
35 **and (2) only considers extension of ~~discourages~~**
36 **home infusions for biologic agents, immune modulating**
37 **therapy, and anti-cancer therapy as allowed under the**
38 **public health unless emergency when circumstances are**
39 **present such that where the benefits of doing so to the**
40 **patient outweigh the potential risks; (3) encourages CMS**
41 **and/or other insurers to provide adequate reimbursement**
42 **for such treatment; and (4) supports educating legislators**
43 **and administrators about the risks and benefits of such**
44 **home infused antibiotics and supportive care treatments in**
45 **terms of cost saving, increased quality of life and**
46 **decreased morbidity, and about the need to provide**
47 **emphasize ensure patient and provider safety when**
48 **considering emergency at home infusions for such**
49 **treatment as access to such treatments biologic, immune**
50 **modulating, and anti-cancer therapy; and (5) advocates for**

1 **by appropriate reimbursement policies when for home**
2 **infusions are utilized.** (Modify Current HOD Policy)
3

4 **RECOMMENDATION B:**

5
6 **Resolution 508 be adopted as amended.**

7
8 **HOD ACTION: Resolution 508 adopted as amended to read as**
9 **follows:**

10
11 **RESOLVED, That our American Medical Association**
12 **update its existing home infusion policy, H-55.986,**
13 **“Home Chemotherapy and Antibiotic Infusions,” by**
14 **addition and deletion to read as follows:**

15 **“Our AMA (1) endorses the use of home injections**
16 **and/or infusions of FDA approved drugs and group C**
17 **drugs (including chemotherapy and/or antibiotic**
18 **therapy) for appropriate patients under physicians’**
19 **recommendation and supervision; and (2) only**
20 **considers extension of the use of home infusions for**
21 **biologic agents, immune modulating therapy, and anti-**
22 **cancer therapy as allowed under the public health**
23 **emergency when circumstances are present such that**
24 **the benefits to the patient outweigh the potential risks;**
25 **(3) encourages CMS and/or other insurers to provide**
26 **adequate reimbursement and liability protections for**
27 **such treatment; and (4) supports educating legislators**
28 **and administrators about the risks and benefits of such**
29 **home infused antibiotics and supportive care**
30 **treatments in terms of cost saving, increased quality of**
31 **life and decreased morbidity, and about the need to**
32 **provide ensure patient and provider safety when**
33 **considering home infusions for such treatment as**
34 **biologic, immune modulating, and anti-cancer therapy;**
35 **and (5) advocates for by appropriate reimbursement**
36 **policies for home infusions. (Modify Current HOD**
37 **Policy); and be it further**

38
39 **RESOLVED, That our AMA oppose any requirement by**
40 **insurers for home administration of drugs, if in the**
41 **treating physician’s clinical judgment it is not**
42 **appropriate, or the precautions necessary to protect**
43 **medical staff, patients and caregivers from adverse**
44 **events associated with drug infusion and disposal are**
45 **not in place; this includes withholding of payment or**
46 **prior authorization requirements for other settings. (New**
47 **HOD Policy)**

48
49 **RESOLVED, That our American Medical Association update its existing home infusion policy,**
50 **H-55.986, “Home Chemotherapy and Antibiotic Infusions,” by addition and deletion to read as**
51 **follows:**

1 “Our AMA (1) endorses the use of home injections and/or infusions of FDA approved
2 drugs and group C drugs (including ~~chemotherapy~~ and/or antibiotic therapy) for
3 appropriate patients under physicians' supervision if requested as a result of informed,
4 shared decision making between the physician and patient; and (2) discourages the
5 use of home infusions for biologic agents, immune modulating therapy, and anti-
6 cancer therapy unless emergency circumstances are present where the benefits of
7 doing so outweigh the potential risks; (3) encourages CMS and/or other insurers to
8 provide adequate reimbursement for such treatment; and (4) supports educating
9 legislators and administrators about the risks and benefits of such ~~home infused~~
10 antibiotics and supportive care treatments in terms of cost saving, increased quality of
11 life and decreased morbidity, and about the need to ~~provide~~ emphasize patient and
12 provider safety when considering emergency at home access to such ~~treatments~~
13 biologic, immune modulating, and anti-cancer therapy; and (5) advocates for by
14 appropriate reimbursement policies when home infusion services are utilized. (Modify
15 Current HOD Policy); and be it further

16
17 RESOLVED, That our AMA oppose extension of the temporary flexibility related to home
18 infusion for Part B drugs, specifically biologics and anti-cancer drugs, that was approved as
19 part of the response to the public health emergency (New HOD Policy); and be it further

20
21 RESOLVED, That our AMA oppose any requirement by insurers for home administration of
22 drugs, if in the treating physician's clinical judgment it is not appropriate, or the precautions
23 necessary to protect medical staff, patients and caregivers from adverse events associated
24 with drug infusion and disposal are not in place; this includes withholding of payment for other
25 settings. (New HOD Policy)

26
27 Your Reference Committee heard supportive testimony for Resolution 508 and its intent to
28 protect the safety of patients and physicians. Amendments to the original resolution were
29 offered to allow for clinician judgment regarding risks and benefits of permitting home infusion
30 in lieu of being completely opposed to these services. Further amended language addresses
31 payers' policy/flexibility to dictate infusion setting and are consistent with the goals of the
32 resolution. Therefore, your Reference Committee recommends that Resolution 508 be
33 adopted as amended.

RECOMMENDED FOR NOT ADOPTION

(6) RESOLUTION 509 – HYDROXYCHLOROQUINE AND COMBINATION THERAPIES – OFF-LABEL USE

RECOMMENDATION A:

Resolution 509 not be adopted.

RECOMMENDATION B:

Policy H-120.988 be reaffirmed.

HOD ACTION: Policy H-120.988 reaffirmed.

RESOLVED, that our American Medical Association rescind its statement calling for physicians to stop prescribing hydroxychloroquine and chloroquine until sufficient evidence becomes available to conclusively illustrate that the harm associated with use outweighs benefit early in the disease course. Implying that such treatment is inappropriate contradicts AMA Policy H-120.988 that addresses off label prescriptions as appropriate in the judgement of the prescribing physician; (New HOD Policy) and be it further

RESOLVED, that our AMA rescind its joint statement with the American Pharmacists Association and American Society of Health System Pharmacists, and update it with a joint statement notifying patients that further studies are ongoing to clarify any potential benefit of hydroxychloroquine and combination therapies for the treatment of COVID-19; (New HOD Policy) and be it further

RESOLVED, that our AMA reassure the patients whose physicians are prescribing hydroxychloroquine and combination therapies for their early-stage COVID-19 diagnosis by issuing an updated statement clarifying our support for a physician’s ability to prescribe an FDA-approved medication for off label use, if it is in her/his best clinical judgement, with specific reference to the use of hydroxychloroquine and combination therapies for the treatment of the earliest stage of COVID-19; (New HOD Policy) and be it further

RESOLVED, that our AMA take the actions necessary to require local pharmacies to fill valid prescriptions that are issued by physicians and consistent with AMA principles articulated in AMA Policy H-120.988, including working with the American Pharmacists Association and American Society of Health System Pharmacists. (New HOD Policy)

Your Reference Committee reviewed passionate and mixed testimony from both the online testimony and in the live hearing on this resolution.

Your AMA Board of Trustees (BOT) provided testimony in opposition of this Resolution and supportive of the AMA statement. The BOT noted that several commentators misconstrued the language in the statement and outlined that it very clearly says, “Novel off-label use of FDA-

1 approved medications is a matter for the physician's or other prescriber's professional
2 judgment" and also emphasized the need for physicians to rely on their professional judgment
3 and medical evidence for any potential COVID-19 treatment option. The statement further
4 notes that any use of these medications should be coordinated with a treating physician with
5 full understanding of the potential risks and benefits. The statement was accurate at the time
6 it was issued and took the best evidence available into account. The BOT, CSAPH, and the
7 majority of those who testified noted that while hydroxychloroquine has demonstrated benefits
8 for multiple chronic autoimmune and rheumatologic diseases, the benefit for treatment of
9 COVID-19, at the time of the statement, had not been established, and that the AMA should
10 base statements and policy on evidence and science. Many commentators, including the BOT
11 and CSAPH noted that since the release of the statement several well-designed studies have
12 failed to find benefit in the use of hydroxychloroquine for treatment of COVID-19 in multiple
13 settings. Several who testified also noted that it would be an embarrassment to the AMA and
14 call the credibility of the AMA into question to rescind a statement that was evidence-based
15 and accurate.

16
17 Those supportive of Resolution 509 noted that the statement was offensive to physicians and
18 could undermine the patient-physician relationship. Your Reference Committee understands,
19 and agrees with the need for physician autonomy, but also agrees with the BOT testimony
20 that the AMA statement does not infringe on physician autonomy and thus should not be
21 rescinded. Your Reference Committee feels that AMA Policy H-120.988, "Patient Access to
22 Treatments Prescribed by Their Physicians," very clearly articulates the AMA's strong support
23 for autonomous clinical decision-making authority of physicians. Therefore, your Reference
24 Committee recommends that Resolution 509 not be adopted and Policy H-120.988 be
25 reaffirmed.

26
27 H-120.988, "Patient Access to Treatments Prescribed by Their Physicians"

- 28 1. Our AMA confirms its strong support for the autonomous clinical decision-making
29 authority of a physician and that a physician may lawfully use an FDA approved
30 drug product or medical device for an off-label indication when such use is based
31 upon sound scientific evidence or sound medical opinion; and affirms the position
32 that, when the prescription of a drug or use of a device represents safe and
33 effective therapy, third party payers, including Medicare, should consider the
34 intervention as clinically appropriate medical care, irrespective of labeling, should
35 fulfill their obligation to their beneficiaries by covering such therapy, and be
36 required to cover appropriate 'off-label' uses of drugs on their formulary.
- 37 2. Our AMA strongly supports the important need for physicians to have access to
38 accurate and unbiased information about off-label uses of drugs and devices, while
39 ensuring that manufacturer-sponsored promotions remain under FDA regulation.
- 40 3. Our AMA supports the dissemination of generally available information about off-
41 label uses by manufacturers to physicians. Such information should be
42 independently derived, peer reviewed, scientifically sound, and truthful and not
43 misleading. The information should be provided in its entirety, not be edited, or
44 altered by the manufacturer, and be clearly distinguished and not appended to
45 manufacturer-sponsored materials. Such information may comprise journal
46 articles, books, book chapters, or clinical practice guidelines. Books or book
47 chapters should not focus on any particular drug. Dissemination of information by
48 manufacturers to physicians about off-label uses should be accompanied by the
49 approved product labeling and disclosures regarding the lack of FDA approval for
50 such uses, and disclosure of the source of any financial support or author financial
51 conflicts.

- 1 4. Physicians have the responsibility to interpret and put into context information
- 2 received from any source, including pharmaceutical manufacturers, before making
- 3 clinical decisions (e.g., prescribing a drug for an off-label use).
- 4 5. Our AMA strongly supports the addition to FDA-approved labeling those uses of
- 5 drugs for which safety and efficacy have been demonstrated.
- 6 Our AMA supports the continued authorization, implementation, and coordination
- 7 of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity
- 8 Act.

1 Madam Speaker, this concludes the report of Reference Committee E. I would like to thank
2 Luis Alvarado, MD, Peter C. Amadio, MD, Karen Dionesotes, MD, Chadd Kraus, DO, Arthur
3 N. Lurvey, MD, Maximilian Pany, and all those who testified before the Committee as well as
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