AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES
(November 2020 Meeting)

Report of Reference Committee E

Joanna T. Bisgrove, MD, Chair

Your reference committee recommends the following consent calendar for acceptance:

RECOMMENDED FOR ADOPTION

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

RECOMMENDED FOR ADOPTION AS AMENDED

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

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

4. Council on Science and Public Health Report 4 – Public Health Impacts of Cannabis Legalization

5. Resolution 508 – Home Infusion of Hazardous Drugs

RECOMMENDED FOR NOT ADOPTION

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

Click here to submit an amendment.

RECOMMENDED FOR ADOPTION

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

RECOMMENDATION A:

Recommendations in Council on Science and Public Health Report 3 be <u>adopted</u>.

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

1. That Policy H-150.954, "Dietary Supplements and Herbal Remedies" be amended by addition and deletion to read as follows:

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

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

(3) <u>Our AMA supports continued research related to the efficacy, safety, and long-term effects of dietary supplement products.</u>

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

(5) <u>Our AMA strongly urges physicians to inquire about patients' use of dietary supplements and engage in risk-based conversations with them about dietary supplement product use.</u>

(6) Our AMA continues to <u>strongly</u> urge Congress to modify <u>and modernize</u> the Dietary Supplement Health and Education Act to require that:

(a) dietary supplements and herbal remedies including the products already in the marketplace undergo FDA approval for evidence of safety and efficacy;

(b) dietary supplements meet standards established by the United States Pharmacopeia for identity, strength, quality, purity, packaging, and labeling;
(c) FDA establish a mandatory product listing regime that includes a unique identifier for each product (such as a QR code), the ability to identify and track all products produced by manufacturers who have received warning letters from the FDA, and FDA authorities to decline to add labels to the database if the label lists a prohibited ingredient or new dietary ingredient for which no evidence of safety exists or for products which have reports of undisclosed ingredients; and
(d) regulations related to new dietary ingredients (NDI) are clarified to foster the timely submission of NDI notifications and compliance regarding NDIs by manufacturers; and

(7) Our AMA supports FDA postmarketing requirements for manufacturers to report adverse events, including drug interactions; and legislation that declares metabolites and precursors of anabolic steroids to be drug substances that may not be used in a dietary supplement.

(8) Our AMA will work with the Federal Trade Commission (FTC) to support enforcement efforts based on the FTC Act and current FTC policy on expert endorsements and supports adequate funding and resources for FTC enforcement of violations of the FTC Act.

(9) Our AMA strongly urges that criteria for the rigor of scientific evidence needed to support a structure/function claim on a dietary supplement be established by the FDA and minimally include requirements for robust human studies supporting the claim.

(10) Our AMA strongly urges dietary supplement manufacturers and distributors to clearly label all products with truthful and not misleading information and for ~~supports that~~ the product labeling ~~of dietary supplements and herbal remedies~~ to:
~~(a) that bear structure/function claims contain the following disclaimer as a minimum requirement: "This product has not been evaluated by the Food and Drug Administration and is not intended to diagnose, mitigate, treat, cure, or prevent disease." This product may have significant adverse side effects and/or interactions with medications and other dietary supplements; therefore it is important that you inform your doctor that you are using this product;~~
(a) not include structure/function claims that are not supported by evidence from robust human studies;
(b) ~~should~~ not contain prohibited disease claims~~.~~;
(c) eliminate "proprietary blends" and list and accurately quantify all ingredients contained in the product;
(d) require advisory statements regarding potential supplement-drug and supplement-laboratory interactions and risks associated with overuse and special populations; and
(e) include accurate and useful disclosure of ingredient measurement.

(11) Our AMA supports and encourages the FDA's regulation and enforcement of labeling violations and FTC's regulation and enforcement of advertisement violations of prohibited disease claims made on dietary supplements and herbal remedies.

(12) Our AMA urges that in order to protect the public, manufacturers be required to investigate and obtain data under conditions of normal use on adverse effects, contraindications, and possible drug interactions, and that such information be included on the label.

(13) Our AMA will continue its efforts to educate patients and physicians about the ~~possible ramifications~~ risks associated with the use of dietary supplements and herbal remedies~~.~~ and supports efforts to increase patient, healthcare practitioner, and retailer awareness of resources to help patients select quality supplements, including educational efforts to build label literacy.

2. That Policy H-120.926, "Expedited Prescription Cannabidiol Drug Rescheduling," be amended by addition and deletion to read as follows:

Regulation of Cannabidiol Products
Our AMA will: (1) encourage state controlled substance authorities, boards of pharmacy, and legislative bodies to take the necessary steps including regulation and legislation to reschedule U.S. Food and Drug Administration (FDA)-approved cannabidiol products, or make any other necessary regulatory or legislative change, as expeditiously as possible so that they will be available to patients immediately after approval by the FDA and rescheduling by the U.S. Drug Enforcement Administration; ~~and~~ (2) advocate that an FDA-approved cannabidiol medication should be governed only by the federal and state regulatory provisions that apply to other prescription-only products, such as dispensing through pharmacies, rather than by these various state laws applicable to unapproved cannabis products~~.~~; and (3) support comprehensive FDA regulation of cannabidiol products and practices necessary to ensure product quality, including identity, purity, and potency.

3. That policy D-150.991, "Herbal Products and Drug Interactions," that notes our AMA's support of FDA efforts to create a publicly accessible database of adverse event and drug interaction information on dietary supplements, be reaffirmed.

Your Reference Committee heard unanimously supportive testimony for this report. Commentors lauded the work of the Council, the completeness of the policy updates, and are appreciative of the work of the AMA on bringing attention to this issue. A few comments posted online proposed amendments to include additional language related to cannabidiol (CBD). The Council testified online that they prefer their original language, and your Reference Committee agrees that the additional language related to CBD is beyond the scope of the current report. Therefore, your Reference Committee recommends that Council on Science and Public Health Report 3 be adopted.

RECOMMENDED FOR ADOPTION AS AMENDED

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

RECOMMENDATION A:

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

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

RECOMMENDATION B:

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

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

That Policy H-100.956, "National Drug Shortages" be amended by addition and deletion to read as follows:

1. Our AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients.

2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.

3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.

4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in

manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.

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

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

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

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

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

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

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

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

13. Our AMA encourages global implementation of guidelines related to pharmaceutical product supply chains, quality systems, and management of product lifecycles, as well as 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 to set appropriate expectations collaboratively with their patients.

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

RECOMMENDATION B:

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

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

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 to set appropriate expectations collaboratively with their patients.
   d. Cautions that a neuropathic pain disease designation should only be used when appropriate, not overused, and that the cause of the neuropathic pain be carefully elucidated.
2. That part (d) of Policy D-160.922, “Future of Pain Care,” which called for the AMA Pain Care Task Force to evaluate the merits of declaring neuropathic pain as a distinct disease state and provide a recommendation to the Council on Science and Public Health, be rescinded.

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

(4) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 4 – PUBLIC HEALTH IMPACTS OF CANNABIS LEGALIZATION

RECOMMENDATION A:

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

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

Cannabis Legalization for ~~Recreational~~ Adult Use (commonly referred to as recreational use)
Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for ~~recreational~~ adult, defined as age 21 and older, use should not be legalized; (3) discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding; (4) believes states that have already legalized cannabis (for medical or ~~recreational~~ adult use or both) should be required to take steps to regulate the product effectively in order to protect public health and safety including but not limited to: regulating retail sales, marketing, and promotion intended to encourage use; limiting the potency of cannabis extracts and concentrates; requiring packaging to convey meaningful and easily understood units of consumption, and requiring that for commercially available edibles, packaging must be child-resistant and come with messaging about the hazards about unintentional ingestion in children and youth; (5) ~~that~~ laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (~~5~~6) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis, especially emergency department visits and hospitalizations, impaired driving, workplace impairment and worker-related injury and safety, and prevalence of psychiatric and addictive disorders, including cannabis use disorder; (~~6~~7) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use; (~~7~~,8) encourages research on the impact of legalization and decriminalization of cannabis in an effort to promote public health and public safety; (~~8~~,9) encourages dissemination of information on the public health impact of legalization and decriminalization of cannabis; (~~9~~,10) will advocate for stronger public health

messaging on the health effects of cannabis and cannabinoid inhalation and ingestion, with an emphasis on reducing initiation and frequency of cannabis use among adolescents, especially high potency products; use among women who are pregnant or contemplating pregnancy; and avoiding cannabis-impaired driving; (11) supports social equity programs to address the impacts of cannabis prohibition and enforcement policies that have disproportionately impacted marginalized and minoritized communities, and (~~10~~12) will coordinate with other health organizations to develop resources on the impact of cannabis on human health and on methods for counseling and educating patients on the use cannabis and cannabinoids.

RECOMMENDATION B:

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

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

RECOMMENDATION C:

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

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

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

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

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

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

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

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

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

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

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

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

(5) RESOLUTION 508 – HOME INFUSION OF HAZARDOUS DRUGS

RECOMMENDATION A:

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

RESOLVED, That our American Medical Association update its existing home infusion policy, H-55.986, "Home Chemotherapy and Antibiotic Infusions," by addition and deletion to read as follows:

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

RECOMMENDATION B:

Resolution 508 be adopted as amended.

RESOLVED, That our American Medical Association update its existing home infusion policy, H-55.986, "Home Chemotherapy and Antibiotic Infusions," by addition and deletion to read as follows:

"Our AMA (1) endorses the use of home injections and/or infusions of FDA approved drugs and group C drugs (including ~~chemotherapy and/or~~ antibiotic therapy) for appropriate patients under physicians' supervision if requested as a result of informed, shared decision making between the physician and patient; ~~and~~ (2) discourages the use of home infusions for biologic agents, immune modulating therapy, and anti-cancer therapy unless emergency circumstances are present where the benefits of

doing so outweigh the potential risks; (3) encourages CMS and/or other insurers to provide adequate reimbursement for such treatment; ~~and~~ (4) supports educating legislators and administrators about the risks and benefits of ~~such~~ home infused antibiotics and supportive care treatments in terms of cost saving, increased quality of life and decreased morbidity, and about the need to ~~provide~~ emphasize patient and provider safety when considering emergency at home access to ~~such treatments~~ biologic, immune modulating, and anti-cancer therapy; and (5) advocates for ~~by~~ appropriate reimbursement policies when home infusion services are utilized. (Modify Current HOD Policy); and be it further

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

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

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

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 n 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 commentors misconstrued the language in the statement and outlined that it very clearly says, "Novel off-label use of FDA-approved medications is a matter for the physician's or other prescriber's professional judgment" and also emphasized the need for physicians to rely on their professional judgment and medical evidence for any potential COVID-19 treatment option. The statement further notes that any use of these medications should be coordinated with a treating physician with full understanding of the potential risks and benefits. The statement was accurate at the time it was issued and took the best evidence available into account. The BOT, CSAPH, and the

majority of those who testified noted that while hydroxychloroquine has demonstrated benefits for multiple chronic autoimmune and rheumatologic diseases, the benefit for treatment of COVID-19, at the time of the statement, had not been established, and that the AMA should base statements and policy on evidence and science. Many commentors, including the BOT and CSAPH noted that since the release of the statement several well-designed studies have failed to find benefit in the use of hydroxychloroquine for treatment of COVID-19 in multiple settings. Several who testified also noted that it would be an embarrassment to the AMA and call the credibility of the AMA into question to rescind a statement that was evidence-based and accurate.

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

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

1. Our AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as clinically appropriate medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate 'off-label' uses of drugs on their formulary.
2. Our AMA strongly supports the important need for physicians to have access to accurate and unbiased information about off-label uses of drugs and devices, while ensuring that manufacturer-sponsored promotions remain under FDA regulation.
3. Our AMA supports the dissemination of generally available information about off-label uses by manufacturers to physicians. Such information should be independently derived, peer reviewed, scientifically sound, and truthful and not misleading. The information should be provided in its entirety, not be edited, or altered by the manufacturer, and be clearly distinguished and not appended to manufacturer-sponsored materials. Such information may comprise journal articles, books, book chapters, or clinical practice guidelines. Books or book chapters should not focus on any particular drug. Dissemination of information by manufacturers to physicians about off-label uses should be accompanied by the approved product labeling and disclosures regarding the lack of FDA approval for such uses, and disclosure of the source of any financial support or author financial conflicts.
4. Physicians have the responsibility to interpret and put into context information received from any source, including pharmaceutical manufacturers, before making clinical decisions (e.g., prescribing a drug for an off-label use).
5. Our AMA strongly supports the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated.

6. Our AMA supports the continued authorization, implementation, and coordination of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.

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

Luis Alvarado, MD
Louisiana Medical Association

Chadd Kraus, DO (Alternate)
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