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


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


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 adopted.

HOD ACTION: Council on Science and Public Health Report 3
adopted.

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) 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.

(2) 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.

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

(4) Our AMA will work with the FDA to educate physicians and the public about FDA’s
MedWatch program Safety Reporting Portal (SRP) 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) 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.

(6) Our AMA continues to strongly urge Congress to modify and modernize 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.

HOD ACTION: Council on Science and Public Health Report 1
adopted as amended and the remainder of the report 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; (56) 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; (67) 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 cannabinoi...
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) 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; (56) 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;
(67) 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) 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
tested 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.

HOD ACTION: Resolution 508 adopted as amended 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; and (2) only considers extension of the use of home infusions for biologic agents, immune modulating therapy, and anti-cancer therapy as allowed under the public health emergency when circumstances are present such that the benefits to the patient outweigh the potential risks; (3) encourages CMS and/or other insurers to provide adequate reimbursement and liability protections 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 ensure patient and provider safety when considering home infusions for such treatment as biologic, immune modulating, and anti-cancer therapy; and (5) advocates for by appropriate reimbursement policies for home infusions. (Modify Current 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 or prior authorization requirements for other settings. (New HOD Policy)

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 emphasis to protect the
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.

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

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