### Reference Committee D

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### REPORT OF THE BOARD OF TRUSTEES

B of T Report 11-A-19

Subject: Policy and Economic Support for Early Child Care

(Resolution 416-A-17)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee D

(Diana Ramos, MD, MPH, Chair)

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### INTRODUCTION

At the 2017 Annual Meeting of the House of Delegates (HOD), Resolution 416-A-17 was referred. Introduced by the New England Delegation and the Minority Affairs Section, Resolution 416-A-17 asked that our American Medical Association (AMA) advocate for: (1) improved social and economic support for paid family leave to care for newborns, infants and young children; and (2) federal tax incentives to support early child care and unpaid child care by extended family members. Board of Trustees Report 27 was submitted to the HOD at the 2018 Annual Meeting.

 Reference Committee D received testimony that supported the general policy intent of the original resolution and also the recommendations in BOT Report 27-A-18. Testimony was also received pointing out that that smaller employers (including small practices) could face potential challenges in running their businesses if they were required to comply with new time off policies that may be more appropriate for larger employers as was pointed out in the original Board Report. There was further testimony and suggestions that the House go back to the original language in Resolution 416-A-17. The HOD referred BOT 27-A-18 back to the Board for additional study.

This report addresses the recommendations of Reference Committee D, and discusses the language in the original resolution, and any new developments in additional research. It also adopts by reference the analysis and recommendations of the original BOT Report 27-A-18 and provides additional recommendations.

The Background, policy discussion, research and legislative activities noted below are from the original BOT Report 27-A-18 and are considered still relevant to the issue today. New information in response to the testimony and referral from Reference Committee D is in italics in the discussion and recommendation porrtion of this Board Report.

BACKGROUND (From: BOT Report 27-A-18)

Increases in paid parental leave were associated with decreases in perinatal, neonatal, post-neonatal, infant, and child mortality in a sample of 18 Organization for Economic Co-operation and Development countries.<sup>1</sup>

Unpaid maternal leave provided through the Family and Medical Leave Act of 1993 (FMLA) in the US was associated with decreases in neonatal, post-neonatal, and infant mortality, but only among

women who were married and had graduated from college, suggesting that women of lower socioeconomic position were unable to benefit from unpaid leave.

Although the FMLA requires larger employers to provide unpaid job-protected time off, there is no current federal law that requires employers to provide paid time off for the birth or care of children. About 38 percent of employers offer paid parental leave for employees who are new parents.<sup>2</sup> Paid parental leave is distinct from other paid-leave programs such as short-term disability, sick days, and government-funded disability or insurance payments.<sup>3</sup> Smaller employers in particular are less likely to provide meaningful paid time off beyond generic vacation or sick time. Further, much of the time off that is provided as it relates to children is oriented toward the period surrounding the birth of a child and typically does not extend to infants and young children as contemplated by Resolution 416-A-17. What success there has been in providing paid parental leave has been primarily at the state and local level and with a small number of high profile employers. For example, IBM offers 20 weeks of paid maternity leave to both salaried and hourly workers who are birth mothers and offers 12 weeks of paid paternity leave for all other parents.<sup>4</sup> A few states have enacted paid medical and family leave laws - California, New Jersey, New York and Rhode Island. Additionally, a number of cities have enacted paid leave policies but most are oriented toward paid sick leave. While upwards of 20 other states have proposed their own paid leave laws, none have yet enacted a law. Regarding tax incentives to support early child care, tax law changes for 2018 raised child care tax credits up to a maximum of \$2000 per child. The amount of the credit is indexed by income level. The credits do not differentiate between medically-related child care and general day care. This provision of the tax code already allows amounts paid to certain extended family members to be considered in the tax credit calculation under certain circumstances. For instance, if a child was sick at home and both parents had to work, a grandmother could provide care and if paid, the expense could be considered in the credit calculation, but the expenses are still subject to the maximums.

### **AMA POLICY**

AMA policy supports voluntary employer policies that provide employees with reasonable job security and continued availability of health plan benefits in the event leave becomes necessary due to documented medical conditions (Policy H-420.979). The AMA recognizes the public health benefits of paid sick leave and other paid time off, although mandatory paid sick leave is not specifically endorsed by the AMA. Council on Medical Service (CMS) Report 3-A-16 provided a comprehensive review of sick leave and paid leave policies. The HOD adopted the recommendations in the report, which established policy supporting employer policies that provide employees with unpaid sick days to care for themselves or a family member (Policy H-440.823).

As it relates specifically to physician practices, AMA Policies for Parental, Family and Medical Necessity Leave (Policy H-405.960) established guidelines that encourage medical group practices to incorporate and/or encourage development of leave policies, including parental, family, and medical leave policies, as part of the physician's standard benefit agreement.

Existing AMA policy also includes Policy H-405.954, "Parental Leave." BOT Report 9-I-17 was written and filed as an informational report, primarily to address possible expansion of the FMLA, but also made reference to paid parental leave. Policy H-405.954 states that the AMA will: "(1) encourage the study of the health implications among patients if the United States were to modify one or more of the following aspects of the Family and Medical Leave Act (FMLA) (a) a reduction in the number of employees from 50 employees; (b) an increase in the number of covered weeks from 12 weeks; (c) creating a new benefit of paid parental leave; and (2) study the effects of FMLA expansion on physicians in varied practice environments."

### RESEARCH AND LEGISLATIVE ACTIVITIES

Currently, federal law does not require employers to provide paid family or parental leave. The FMLA requires employers of a certain size to provide medically-related unpaid time off.

The most recent effort at the federal level to provide a broad paid parental leave approach is currently stalled. The Family and Medical Insurance Leave Act ("FAMILY Act," H.R. 947/S. 337) was introduced in Congress in 2017. The bill would, among other things, provide paid family and medical leave to individuals who meet certain criteria. It would be financed through a tax on every individual and employer, and all self-employment income. Thus far, the bill has been supported by Democratic members of Congress and has seen little action since introduction. The bill as originally drafted would:

- Create a national program to provide all workers, regardless of company size, with up to 12 weeks of partially paid leave; and
- Enable workers to receive up to 66 percent of their monthly wages, up to a capped amount, during their time of leave.

The AMA has not taken a position on this bill. In 2016 the Society for Human Resources Management (SHRM) partnered with the Families and Work Institute to conduct a National Study of Employers (NSE) practices on workplace benefits, and paid parental leave was part of that study. The study seems to be the most recent and relevant broad-based employer analysis of what policies are in place today for parental leave as well as trends for the future.

The NSE's surveys have been conducted five times since 2005, providing both snapshots in time and current trends in employer practices and attitudes. The 2016 study samples 920 employers with more than 50 employees, with a blend of for-profit and non-profit as well as single and multi-cite locations. Note that the findings cited below all relate to employers with more than 50 employees.

The NSE noted that despite announcements of expanded parental leave benefits from Netflix, Amazon, Microsoft, Johnson & Johnson, Ernst & Young and a few others, "The media blitz over the past few years regarding paid parental leave was not representative of the majority of U.S. employers with 50 or more employees in 2016." It also noted that the average maximum number of weeks of parental and caregiving leaves did not change significantly between 2012 and 2016, and in fact the average number of weeks provided had slightly declined when looking back to prerecession 2005. 2016 data showed that employers seemed to be more supportive of easing the transition of a parent back into the workforce upon the birth of child (81% of employers), and more supportive of work from home options (40 percent of employers), but the percentage of employers allowing at least some employees to take time off during the workday for family or personal needs without loss of pay had declined from 87 percent to 81 percent.

Another finding demonstrated that employer support for flexible work arrangements had dropped dramatically from 31 percent in 2005 to 14 percent in 2016. While definitive research was not available to explain this change, it may be that many employers had narrowed benefit offerings during the prolonged period of economic difficulty that began in 2008. While the study tended to focus more on whether employers provided time off, it did note that of those employers providing at least some pay to women during maternity leave, most (78 percent) did so by providing some type of short term disability pay. The survey also indicated that for those employers that do offer pay, 6 percent of employers offered full pay, 39 percent offered partial pay, and 11 percent said it depends on the situation. Forty-two percent of the employers responding offered no pay at all.

However, in contrast to those findings, the same report indicated that 39 percent of employers

allowed employees to take time off (at least 5 days) to care for *mildly ill* children without having to use vacation days or losing pay. The implication of this particular data is that employer policies on paid time off lack consistency.

As articulated in Board of Trustees Report 9-I-17, there is an abundance of literature about the benefits of employee access to medical leave provided under existing law, much of which was summarized in CMS Report 3-A-16.<sup>6</sup> Paid sick leave has been increasing throughout the United States whether by state or local law mandates or decisions by employers. However, paid leave to care for others outside of paid vacation, PTO (generic paid time off), or paid sick leave is still not prevalent in the US.

Given that only a handful of states have enacted paid parental leave programs, research on their effectiveness is limited. However, what little research there is has demonstrated generally neutral to positive feedback from employers. In particular, BOT Report 9-I-17 noted California's experience:

In California, for example, the Paid Family Leave program provides employees with up to six weeks of paid leave to care for a new child or ill family member. The program is funded by employee payroll contributions, so while employers do not face financial burden as a result of the law, they are faced with ensuring the employees' workload is covered and that gaps in staffing are filled. The program in California, however, does not assure job protection during leave, provides wage replacement at only 55 percent, and does not cover care for grandparents, grandchildren, parents-in-law, or siblings. A 10-year review of California's expansion demonstrated that the Paid Family Leave benefit promoted family well-being, improved family economic security, equalized access to leave across occupations and income levels, and bolstered businesses by reducing workforce turnover. It was also noted that overall awareness of the program among those most likely to utilize it was low, implying that utilization rates could be higher if education and outreach were improved upon. Similar outcomes have been reported for other cities and states.<sup>7-9</sup>

An analysis published by IMPAQ International, Inc. and the Institute for Women's Policy Research summarizes a simulation of five paid family and medical leave model programs based on working programs in three states and a federal proposal, all applied to the national workforce. The findings suggest that expansion of FMLA laws, through covering more eligible workers, replacing a larger percentage of usual earnings, and offering more weeks of paid leave would increase costs. If based on any of the five models in the simulation, the cost for benefits would range from \$31 billion to \$43 billion. This report also projects that a national paid family and medical leave policy, depending on the type of expansion, would increase the amount of leave taken by 6 to 11 percent annually. <sup>10</sup>

Some employer groups claim paid leave policies or policies that provide coverage for more employees may burden and negatively impact employer operations.

 When predicting employer reactions to programs, policies and benefits related to caregiving leaves and child and elder care, the NSE research articulated four primary factors: (1) the demographics of their workplace; (2) the demographics of the workforce; (3) financial health of the employer; and (4) human resources issues such as the difficulty or ease of attracting and retaining employees as well as the costs of employee benefits.

The attitude and approach of employers is fundamental to progress on a broad national approach to paid parental leave. It is not atypical for employers to consider all four of these factors when

considering what benefits to offer their employees. As it relates to paid time off, some employers are specific about how that time can be used (vacation, sick time). Other employers are more flexible ("paid time off"), wherein the employer provides a bank of paid time off that employees can use for any purpose. Employers typically review benefits offerings every year, with time off being only one of a myriad of benefits being evaluated.

As noted above, recent changes in the federal tax code increased the child care tax credit up to \$2000 per child. While it may be debatable whether the increase goes far enough, it is a positive step forward toward the intent of Resolution 416 and supporting the child care efforts of people with lower economic status.

While there has been recent publicity about proposals to have some type of child care financial assistance by allowing people to draw down future Social Security benefits, it does not seem at present that such proposals will receive meaningful consideration in Congress.

### **DISCUSSION**

 The Board's review of existing research has demonstrated that despite positive health outcomes for children being cared for by their parents, meaningful progress on national policy mandating paid parental leave is unlikely in the near term. The necessary broad-based support of employers to support such policy is simply not present at this point in time. Additionally, the anti-regulatory views of the current Administration and political climate in Washington DC may not be ripe for federal policy or action on paid family leave.

The first resolve of Resolution 416-A-17 asked the AMA to advocate for improved social and economic support for paid family leave to care for newborns, infants and young children. The Board of Trustees believes that there would be considerable challenges to pursuing a public policy that would require employers to provide paid parental leave. Nevertheless, the Board believes that HOD policy supporting paid parental leave for the care of children is good public policy. Policy H-440.823 does support employer policies that allow employees to accrue paid time off and to use such time to care for themselves or a family member. As noted earlier in this report, approximately 38 percent of employers currently offer paid parental leave for employees who are new parents. Accordingly, the Board of Trustees also supports encouraging employers to offer and/or to expand these types of policies. The Board believes that state medical associations should also be encouraged to work with their state legislatures to establish and promote parental leave policies.

The second resolve of Resolution 416-A-17 asked the AMA to advocate for federal tax incentives to support early child care and unpaid child care by extended family members. As previously noted in this report, recent changes to Federal tax law have raised child care tax credits to a maximum of \$2000 per child, beginning in 2018. The expense of paying extended family members to perform child care can be considered in the calculation of this credit under certain circumstances.

As noted in prior Board reports on paid parental leave proposals, there are several primary sources that influence progress. The first is the general proposition that such policies are, in and of themselves, the right thing to do for the betterment of public health as noted in the original Resolution 416-A-17. The second and third would be governmental action at the state or federal level either requiring or encouraging via incentives compliance with potentially new law or regulations. The fourth is action by employers in making decisions on benefit offerings to their employees.

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1 It should be noted that there is little new additional research available to inform these issues 2 beyond that articulated in Board Report 27-A-18. However, at the federal level several new bills 3 have been introduced new Congress. The FAMILY Act, originally introduced in both the House 4 and Senate in 2017 has been reintroduced, but as of yet has support only from Democrats. HR 5 1185 has been introduced in the House with 178 Democratic co-sponsors. S 463 has been introduced in the Senate with 34 Democratic cosponsors. No hearings have yet been scheduled on 6 7 any of the bills and none of them yet seem to have traction with Republicans.

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Given that testimony at Reference Committee D suggested the possibility of going back to the original language of Resolution 416 A-17, and the fact that there are competing proposals in Congress the Board believes it prudent to support the original resolutions but also restate portions 12 of the Board's recommendations from BOT Report 27-A-18 and continue to study and monitor developments as more specifics be available.

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### RECOMMENDATIONS

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Therefore, the Board of Trustees recommends that the following be adopted in lieu of Resolution 416-A-17 and the remainder of this report be filed.

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1. That our AMA reaffirm Policy H-440.823, which recognizes the public health benefits of paid sick leave and other discretionary paid time off, and supports employer policies that allow employees to accrue paid time off and to use such time to care for themselves or a family member. (Reaffirm HOD Policy)

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2. That our AMA encourage employers to offer and/or expand paid parental leave policies. (New HOD Policy)

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That our AMA encourage state medical associations to work with their state legislatures to establish and promote paid parental leave policies. (New HOD Policy).

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31 4. That our AMA advocate for improved social and economic support for paid family leave to 32 care for newborns, infants and young children (New HOD Policy).

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34 5. That our AMA advocate for federal tax incentives to support early child care and unpaid child 35 care by extended family members (New HOD Policy).

Fiscal Note: Less than \$500.

### **REFERENCES**

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### REPORT OF THE BOARD OF TRUSTEES

B of T Report 16-A-19

Subject: Developing Sustainable Solutions to Discharge of Chronically-Homeless Patients

(Resolution 826-I-18)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee D

(Diana Ramos, MD, MPH, Chair)

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1 At the 2018 Interim Meeting, the House of Delegates referred Resolution 826, Developing

2 Sustainable Solutions to Discharge of Chronically-Homeless Patients, which was introduced by the

3 Resident and Fellow Section. Resolution 826 asked that our AMA "work with relevant

4 stakeholders in developing sustainable plans for the appropriate discharge of chronically-homeless

5 patients from hospitals." The resolution further asked that our AMA reaffirm Policy H-270.962,

6 Unfunded Mandates, and Policy H-130.940, Emergency Department Boarding and Crowding.

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This report (1) explores how homelessness contributes to emergency department (ED) overuse and hospitalization, (2) outlines current regulatory requirements related to homelessness and discharge planning, and (3) describes the need for broader efforts to address the unique healthcare and social needs of homeless patients.

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#### **BACKGROUND**

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Homeless individuals are more likely than the general population to experience behavioral health disorders, acute and chronic conditions, and injuries resulting from assaults and accidents. This increased prevalence, in concert with lack of insurance or access to a usual source of medical care, leads homeless individuals to seek care at EDs at a high rate and increases their rates of hospitalization. Indeed, as many as two-thirds of homeless individuals visit an ED each year, as compared to just one-fifth of the general population, and the hospitalization rate for homeless individuals is as much as four times higher than that for non-homeless individuals.<sup>1-6</sup>

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Not only are homeless patients more likely to visit an ED, but they are also more likely to re-visit an ED. Indeed, an analysis of national ED utilization rates found that homeless patients were more than three times as likely as non-homeless patients to have been evaluated in the same ED within the previous three days, and were more than twice as likely to visit an ED within a week of discharge from the hospital.<sup>7</sup>

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ED utilization is not uniform across the homeless population, with one study representative of the literature on the topic finding that a small proportion of frequent users (7.9%) account for an outsized proportion of total use (54.5%).<sup>5</sup> Anecdotal accounts, which are not uncommon, cite cases of individual homeless patients with more than 100 ED visits in a year and total costs topping

33 \$1 million.<sup>8,9</sup>

### **DISCUSSION**

 Discharge planning and ED overuse

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As suggested by Resolution 826-I-18, hospital and ED discharge planning plays a key role in ending the revolving door of ED visits, hospitalizations, and readmissions, especially among homeless frequent users. Specifically, evidence shows that well-coordinated case management (the development and initiation of which is a key outcome of discharge planning) may reduce ED use and costs, and improve both clinical and social outcomes for homeless patients. Despite these findings, discharge planning for homeless patients remains rare: one analysis found that 64% of ED visits resulted in homeless patients being discharged back to the street, with only 4% having a discharge plan addressing their housing status.

Current approaches to discharge planning also overlook important opportunities to improve the health of homeless patients in areas unrelated to their ED visits. For example, given that the CDC Advisory Committee on Immunization Practices now recognizes "homelessness" as an indication for hepatitis A vaccination, <sup>14</sup> patient encounters in the ED present an excellent opportunity to assess immunization status and need for vaccination, and to administer vaccines or refer patients for vaccination. <sup>15</sup> As an added bonus, this holistic approach ensures that homeless patients are immunized, which helps keep them well and out of the ED.

Hospital requirements for discharge planning

Recognizing the value of discharge planning in preventing hospital readmissions, the Centers for Medicare and Medicaid Services (CMS) Conditions of Participation (CoPs) include comprehensive discharge planning requirements for hospitals participating in the Medicare or Medicaid programs. These requirements include:

(1) Identifying inpatients for whom discharge planning is necessary;\*

(2) Providing a discharge plan evaluation to each identified patient, which "must include an evaluation of the likelihood of a patient's capacity for selfcare or of the possibility of the patient being cared for in the environment from which he or she entered the hospital;"

(3) Developing and "[arranging] for the initial implementation of the patient's discharge plan;"

(4) Transferring or referring the patient, "along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care;" and

(5) Reassessing the discharge planning process "on an on-going basis;" which must include "a review of discharge plans to ensure that they are responsive to discharge needs." <sup>16</sup>

 The CoPs do not require discharge planning for ED visits without hospital admission, which are categorized as outpatient visits. However, in recent revisions to its interpretive guidelines for discharge planning, CMS observes that "many of the same concerns for effective posthospital care coordination arise [for outpatients] as for inpatients" and therefore recommends that "hospitals

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<sup>\*</sup> Note that "in the absence of a finding by the hospital that a patient needs a discharge plan, the patient's physician may request a discharge plan...[and] the hospital must develop a discharge plan for the patient."

might consider utilizing, on a voluntary basis, an abbreviated post-hospital planning process for certain categories of outpatients...and for certain categories of emergency department discharges."<sup>17</sup>

At the state level, in 2018 California adopted regulations requiring more stringent discharge planning requirements and services for homeless patients. Set to take effect July 1, 2019, these new regulations require California hospitals to "include a written homeless patient discharge planning policy and process within the hospital discharge policy." The law further requires hospitals to perform a variety of specific tasks and in a specific manner, including but not limited to:

- logging all discharges of homeless patients;
- providing a meal, clothing, medication, and transportation upon discharge;
- coordinating with social service agencies; and
- discharging homeless patients only during the daytime. 19,20

The California law was met with concern by many in the healthcare community, including the California chapter of the American College of Emergency Physicians and the California Hospital Association. Only While recognizing the importance of and supporting appropriate discharge planning and protocols, critics questioned the feasibility of many aspects of the law—for example, how exactly would a hospital go about maintaining a supply of clothing for homeless patients? They also pointed to severe unintended consequences of the law—for example, that prohibiting overnight discharges would further exacerbate ED overcrowding and constrain hospitals' capacity to provide timely, lifesaving care to those patients who need it most. And, at the broadest level, they questioned why the societal costs of homelessness should be borne by hospitals, especially safety net hospitals that treat a disproportionately large share of homeless patients and are least able to comply with unfunded mandates.

## Moving beyond discharge planning

Effective ED and hospital discharge planning constitutes just one component of what ought to be a more comprehensive approach to addressing the unique healthcare needs of homeless patients—one which, as stated by CMS in its interpretive guidelines for discharge planning, "moves away from a focus primarily on a patient's hospital stay to consideration of transitions among the multiple types of patient care settings that may be involved at various points in the treatment of a given patient."<sup>17</sup>

Central to these more comprehensive efforts is housing security, an area in which, in the absence of comprehensive state and local homelessness strategies, hospitals and health systems have been obligated to take action in recent years. In 2017, for example, the American Hospital Association published a guidebook, *Housing and the Role of Hospitals*, identifying how hospitals can address this particular social determinant of health. This resource outlines strategies and provides case studies on:

- neighborhood revitalization;
- home assessment and repair programs;
- medical care for the homeless;
- medical respite care; and
- transitional or permanent supportive housing.<sup>22</sup>

The last of these strategies has received considerable attention, with hospitals and health systems investing an estimated \$75 to \$100 million in housing for homeless patients.<sup>23</sup> Insurers and local units of government also have contributed to these efforts, typically in partnership with hospitals

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and health systems.<sup>24-26</sup> Initial outcomes data on these endeavors suggest that providing housing for homeless patients can decrease ED use and hospitalizations while yielding net savings on combined expenditures for healthcare and social services.<sup>27</sup> Despite these outcomes, the long-term desirability and feasibility of this approach is uncertain, as questions of appropriate resource allocation (is there a better way to spend these monies?), cost-sharing (is it appropriate to ask hospitals to cover the cost of social services for homeless patients?), and society's overall approach to eliminating homelessness remain unresolved.

AMA policy on discharge planning and care for homeless patients

 AMA policy recognizes the link between housing security and health outcomes, and supports a coordinated, collaborative approach to care for homeless patients that combines clinical and social services. For example, Policy H-160.903, Eradicating Homelessness, "supports improving the health outcomes and decreasing the health care costs of treating the chronically homeless through clinically proven, high quality, and cost-effective approaches which recognize the positive impact of stable and affordable housing coupled with social services."

 Furthermore, Policy H-160.978, The Mentally III Homeless, avers that "public policy initiatives directed to the homeless, including the homeless mentally ill population, should...[promote] care that is sensitive to the overriding needs of this population for food, clothing, and residential facilities."

Finally, the AMA's comprehensive Evidence-Based Principles of Discharge and Discharge Criteria (Policy H-160.942), while not explicitly addressing homelessness, "calls on physicians, specialty societies, insurers, and other involved parties to join in developing, promoting, and using evidence-based discharge criteria that are sensitive to the physiological, psychological, social, and functional needs of patients."

## **CONCLUSION**

Homelessness is an exacerbating factor in ED overuse, excess hospitalization, and preventable readmissions. Hospital discharge planning for homeless patients, with a holistic focus on case management that coordinates clinical and social services, has been shown to alleviate some of these problems. Despite this evidence, focused discharge planning remains rare for homeless ED patients. Our AMA should educate physicians about the importance of discharge planning for homeless patients, and encourage the development of holistic, cost-effective, evidence-based discharge plans for homeless patients who present to the emergency department but are not admitted to the hospital.

While critical, discharge planning alone will not prevent unnecessary ED visits and hospitalizations for homeless individuals. Instead, a more comprehensive approach to addressing the unique healthcare and social needs of homeless patients is required, with efforts reaching beyond the hospital and into the community. Our AMA should encourage collaborative efforts to address homelessness that do not leave hospitals and physicians alone to bear their costs.

### RECOMMENDATIONS

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The Board of Trustees recommends that the following be adopted in lieu of Resolution 826-I-18 and that the remainder of the report be filed:

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1. That our American Medical Association partner with relevant stakeholders to educate physicians about the unique healthcare and social needs of homeless patients and the importance of holistic, cost-effective, evidence-based discharge planning, and physicians' role therein, in addressing these needs. (Directive to Take Action)

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2. That our AMA encourage the development of holistic, cost-effective, evidence-based discharge plans for homeless patients who present to the emergency department but are not admitted to the hospital. (New HOD Policy)

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That our AMA encourage the collaborative efforts of communities, physicians, hospitals, health systems, insurers, social service organizations, government, and other stakeholders to develop comprehensive homelessness policies and plans that address the healthcare and social needs of homeless patients. (New HOD Policy)

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20 That our AMA reaffirm Policy H-160.903, Eradicating Homelessness, which "supports 21 improving the health outcomes and decreasing the health care costs of treating the chronically 22 homeless through clinically proven, high quality, and cost-effective approaches which 23 recognize the positive impact of stable and affordable housing coupled with social services." 24 (Reaffirm HOD Policy)

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5. That our AMA reaffirm Policy H-160.978, The Mentally Ill Homeless, which states that "public policy initiatives directed to the homeless, including the homeless mentally ill population, should...[promote] care that is sensitive to the overriding needs of this population for food, clothing, and residential facilities." (Reaffirm HOD Policy)

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That our AMA reaffirm Policy H-160.942, Evidence-Based Principles of Discharge and Discharge Criteria, which "calls on physicians, specialty societies, insurers, and other involved parties to join in developing, promoting, and using evidence-based discharge criteria that are sensitive to the physiological, psychological, social, and functional needs of patients." (Reaffirm HOD Policy)

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37 7. That our AMA reaffirm Policy H-130.940, Emergency Department Boarding and Crowding, which "supports dissemination of best practices in reducing emergency department boarding 38 39 and crowding." (Reaffirm HOD Policy)

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41 8. That our AMA reaffirm Policy H-270.962, Unfunded Mandates, which "vigorously opposes any unfunded mandates on physicians." (Reaffirm HOD Policy) 42

Fiscal Note: \$5,000

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### AMA POLICIES RECOMMENDED FOR REAFFIRMATION

## H-160.942 Evidence-Based Principles of Discharge and Discharge Criteria

- (1) The AMA defines discharge criteria as organized, evidence-based guidelines that protect patients' interests in the discharge process by following the principle that the needs of patients must be matched to settings with the ability to meet those needs.
- (2) The AMA calls on physicians, specialty societies, insurers, and other involved parties to join in developing, promoting, and using evidence-based discharge criteria that are sensitive to the physiological, psychological, social, and functional needs of patients and that are flexible to meet advances in medical and surgical therapies and adapt to local and regional variations in health care settings and services.
- (3) The AMA encourages incorporation of discharge criteria into practice parameters, clinical guidelines, and critical pathways that involve hospitalization.
- (4) The AMA promotes the local development, adaption and implementation of discharge criteria.
- (5) The AMA promotes training in the use of discharge criteria to assist in planning for patient care at all levels of medical education. Use of discharge criteria will improve understanding of the pathophysiology of disease processes, the continuum of care and therapeutic interventions, the use of health care resources and alternative sites of care, the importance of patient education, safety, outcomes measurements, and collaboration with allied health professionals.
- (6) The AMA encourages research in the following areas: clinical outcomes after care in different health care settings; the utilization of resources in different care settings; the actual costs of care from onset of illness to recovery; and reliable and valid ways of assessing the discharge needs of patients.
- (7) The AMA endorses the following principles in the development of evidence-based discharge criteria and an organized discharge process:
  - (a) As tools for planning patients' transition from one care setting to another and for determining whether patients are ready for the transition, discharge criteria are intended to match patients' care needs to the setting in which their needs can best be met.
  - (b) Discharge criteria consist of, but are not limited to: (i) Objective and subjective assessments of physiologic and symptomatic stability that are matched to the ability of the discharge setting to monitor and provide care. (ii) The patient's care needs that are matched with the patient's, family's, or caregiving staff's independent understanding, willingness, and demonstrated performance prior to discharge of processes and procedures of self care, patient care, or care of dependents. (iii) The patient's functional status and impairments that are matched with the ability of the care givers and setting to adequately supplement the patients' function. (iv) The needs for medical follow-up that are matched with the likelihood that the patient will participate in the follow-up. Follow-up is time-, setting-, and service-dependent. Special considerations must be taken to ensure follow-up in vulnerable populations whose access to health care is limited.
  - (c) The discharge process includes, but is not limited to: (i) Planning: Planning for transition/discharge must be based on a comprehensive assessment of the patient's physiological, psychological, social, and functional needs. The discharge planning process should begin early in the course of treatment for illness or injury (prehospitalization for elective cases) with involvement of patient, family and physician from the beginning. (ii)

Teamwork: Discharge planning can best be done with a team consisting of the patient, the family, the physician with primary responsibility for continuing care of the patient, and other appropriate health care professionals as needed. (iii) Contingency Plans/Access to Medical Care: Contingency plans for unexpected adverse events must be in place before transition to settings with more limited resources. Patients and caregivers must be aware of signs and symptoms to report and have a clearly defined pathway to get information directly to the physician, and to receive instructions from the physician in a timely fashion. (iv) Responsibility/Accountability: Responsibility/accountability for an appropriate transition from one setting to another rests with the attending physician. If that physician will not be following the patient in the new setting, he or she is responsible for contacting the physician who will be accepting the care of the patient before transfer and ensuring that the new physician is fully informed about the patient's illness, course, prognosis, and needs for continuing care. If there is no physician able and willing to care for the patient in the new setting, the patient should not be discharged. Notwithstanding the attending physician's responsibility for continuity of patient care, the health care setting in which the patient is receiving care is also responsible for evaluating the patient's needs and assuring that those needs can be met in the setting to which the patient is to be transferred. (v) Communication: Transfer of all pertinent information about the patient (such as the history and physical, record of course of treatment in hospital, laboratory tests, medication lists, advanced directives, functional, psychological, social, and other assessments), and the discharge summary should be completed before or at the time of transfer of the patient to another setting. Patients should not be accepted by the new setting without a copy of this patient information and complete instructions for continued care.

- (8) The AMA supports the position that the care of the patient treated and discharged from a treating facility is done through mutual consent of the patient and the physician; and
- (9) Policy programs by Congress regarding patient discharge timing for specific types of treatment or procedures be discouraged.

### H-160.978 The Mentally Ill Homeless

- (1) The AMA believes that public policy initiatives directed to the homeless, including the homeless mentally ill population, should include the following components:
  - (a) access to care (e.g., integrated, comprehensive services that permit flexible, individualized treatment; more humane commitment laws that ensure active inpatient treatment; and revisions in government funding laws to ensure eligibility for homeless persons);
  - (b) clinical concerns (e.g., promoting diagnostic and treatment programs that address common health problems of the homeless population and promoting care that is sensitive to the overriding needs of this population for food, clothing, and residential facilities);
  - (c) program development (e.g., advocating emergency shelters for the homeless; supporting a full range of supervised residential placements; developing specific programs for multiproblem patients, women, children, and adolescents; supporting the development of a clearinghouse; and promoting coalition development);
  - (d) educational needs;
  - (e) housing needs; and
  - (f) research needs.
- (2) The AMA encourages medical schools and residency training programs to develop model curricula and to incorporate in teaching programs content on health problems of the homeless population, including experiential community-based learning experiences.

(3) The AMA urges specialty societies to design interdisciplinary continuing medical education training programs that include the special treatment needs of the homeless population.

## H-160.903 Eradicating Homelessness

Our American Medical Association:

- supports improving the health outcomes and decreasing the health care costs of treating the chronically homeless through clinically proven, high quality, and cost effective approaches which recognize the positive impact of stable and affordable housing coupled with social services;
- (2) recognizes that stable, affordable housing as a first priority, without mandated therapy or services compliance, is effective in improving housing stability and quality of life among individuals who are chronically-homeless;
- (3) recognizes adaptive strategies based on regional variations, community characteristics and state and local resources are necessary to address this societal problem on a long-term basis;
- (4) recognizes the need for an effective, evidence-based national plan to eradicate homelessness; and
- (5) encourages the National Health Care for the Homeless Council to study the funding, implementation, and standardized evaluation of Medical Respite Care for homeless persons.

### REPORT OF THE BOARD OF TRUSTEES

B of T Report 28-A-19

Subject: Opposition to Measures that Criminalize Homelessness

(Resolution 410-A-18)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee D

(Diana Ramos, MD, MPH, Chair)

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### INTRODUCTION

Resolution 410-A-18, "Opposition to Measures that Criminalize Homelessness," introduced by the Medical Student Section and referred by the House of Delegates asks that:

Our American Medical Association oppose measures that criminalize necessary means of living among homeless persons, including but not limited to, sitting or sleeping in public spaces; and advocate for legislation that requires non-discrimination against homeless persons, such as homeless bills of rights.

### **CURRENT AMA POLICY**

Existing AMA policy supports improving health outcomes and decreasing the health care costs of treating people who are chronically homeless through clinically proven, high quality, and cost-effective approaches, which recognize the positive impact of stable and affordable housing coupled with social services. The AMA recognizes that stable, affordable housing as a first priority, without mandated therapy or services compliance, is effective in improving housing stability and quality of life among individuals who are chronically-homeless. Furthermore, the AMA recognizes that lack of identification is a barrier to accessing medical care and fundamental services that support health; and supports policy changes that streamline, simplify, and reduce or eliminate the cost of obtaining identification cards for the homeless population. Current policy does not specifically address criminalizing homelessness.

## **BACKGROUND**

Insufficient income and lack of affordable housing are leading causes of homelessness in the United States. The Great Recession contributed to a shortage of affordable housing. It is estimated that we currently have a shortage of 7.2 million rental homes affordable and available to extremely low-income renters (those whose income is at or below the poverty guideline or 30 percent of their area median income). Extremely low-income households face a shortage of affordable housing in every state and major metropolitan area. In addition to the shortage of affordable housing, in many U.S. cities, there are fewer shelter beds than are needed, leaving people experiencing homelessness with no choice, but to live in public places.<sup>2</sup>

In January 2018, almost 553,000 people were homeless on a single night in the United States, with nearly two-thirds found in emergency shelters or transitional housing programs.<sup>3</sup> While the number

- of people experiencing homelessness increased by less than one percent between 2017 and 2018, overall homelessness has declined by more than 84,000 people (13 percent) since 2010. In the United States, sixty percent of people experiencing homelessness in 2018 were men or boys, and 39 percent were women or girls.<sup>5</sup> Less than one percent were transgender or gender nonconforming.<sup>6</sup> Nearly half (49 percent) of all people experiencing homelessness self-identified as white and almost 40 percent identified as black or African American. People identifying as white were underrepresented compared to their share of the U.S. population (72 percent), while African Americans were considerably overrepresented compared to their share of the U.S. population (13 percent).8 One in five people experiencing homelessness was Hispanic or Latino (22 percent), which is slightly higher than their share of the U.S. population (18 percent).
  - Substance use disorders and mental health problems are more prevalent among people who are homeless than in the general population. According to the Office of National Drug Control Policy, approximately 30 percent of people experiencing chronic homelessness have a serious mental illness, and around two-thirds have a primary substance use disorder or other chronic health condition. Lack of stable housing leaves them vulnerable to substance use and/or relapse, exacerbation of mental health problems, and a return to homelessness. 11

19 Laws Criminalizing Homelessness

Criminalizing homelessness refers to laws enacted by municipalities to prohibit life-sustaining activities such as sitting, sleeping, loitering, panhandling, camping, eating, storing belongings, and urinating in public spaces. Laws criminalizing homelessness trap vulnerable populations in the criminal justice system. <sup>12</sup> The continuous threat of citations and possibility of arrest contributes to a pervasive sense of fear and insecurity among the homeless population. For individuals experiencing homelessness, fines typically cannot be paid, leaving individuals to contest citations in court. <sup>13</sup> Without a reliable address or transportation, citations can result in not receiving a notice to appear in court or having no way to get there. Failure to appear in court can result in a warrant for arrest. <sup>14</sup> Arrests and criminal records make housing, employment, and social services more difficult to access thereby perpetuating the cycle of homelessness and health inequity. <sup>15</sup>

Laws criminalizing homelessness have increased in cities across the United States over the past 10 years. <sup>16</sup> Since 2006, citywide bans on loitering, loafing, and vagrancy increased by 88 percent, bans on camping increased by 69 percent, bans on sitting and lying down in certain public places increased by 52 percent, bans on panhandling grew by 43 percent, and bans on sleeping in public increased by 31 percent. <sup>17</sup> These laws are designed to move visibly homeless people out of commercial and tourist districts and are often justified based on the government's responsibility to maintain orderly, aesthetically pleasing public parks and streets as well as the responsibility to protect public health and safety.

## **DISCUSSION**

Laws criminalizing homelessness have been found to violate international and, in some instances, federal law. In 2014, the United Nation's (UN) Committee on the Elimination of Racial Discrimination, called on the United States to abolish laws and policies making homelessness a crime and ensure cooperation among stakeholders to find solutions for people experiencing homelessness in accordance with human rights standards. Furthermore, the UN encouraged the United States to provide incentives to decriminalize homelessness, including financial support to local authorities that implement alternatives to criminalization, and withdrawing funding from local authorities that criminalize homelessness. 19

In 2017, the UN Special Rapporteur on extreme poverty and human rights visited the United States to report to the Human Rights Council on the extent to which the government's policies and programs relating to extreme poverty are consistent with its human rights obligations and to offer recommendations to the government and other stakeholders. The report stated that:

In many cities, homeless persons are effectively criminalized for the situation in which they find themselves. Sleeping rough<sup>1</sup>, sitting in public places, panhandling, public urination and myriad other offences have been devised to attack the 'blight' of homelessness... Ever more demanding and intrusive regulations lead1 to infraction notices for the homeless, which rapidly turn into misdemeanours, leading to warrants, incarceration, unpayable fines and the stigma of a criminal conviction that in turn virtually prevents subsequent employment and access to most housing. <sup>20</sup>

Courts in the United States have come to differing conclusions on laws criminalizing homelessness, particularly anti-camping ordinances, due to differing interpretations of whether the Eighth Amendment's protection against cruel and unusual punishment prohibits only criminalization of status or also the criminalization of involuntary conduct.<sup>21</sup> In 2015, the United States government issued a statement indicating its position on the issue in the case of *Bell et al v. City of Boise*:

If the Court finds that it is impossible for homeless individuals to secure shelter space on some nights because no beds are available, no shelter meets their disability needs, or they have exceeded the maximum stay limitations, then the Court should also find that enforcement of the ordinances under those circumstances criminalizes the status of being homeless and violates the Eighth Amendment to the Constitution.<sup>22</sup>

 In the case in question, the 9<sup>th</sup> Circuit Court of Appeals held that the Cruel and Unusual Punishments Clause of the Eighth Amendment precluded enforcement of a statute prohibiting sleeping outside against homeless individuals with no access to alternative shelter. The court held that as long as there is no option of sleeping indoors, the government cannot criminalize indigent, homeless people for sleeping outdoors, on public property, on the false premise that they had no choice in the matter.<sup>23</sup> The court further explained that "[e]ven where shelter is unavailable, an ordinance prohibiting sitting, lying, or sleeping outside at particular times or in particular locations might well be constitutionally permissible. So, too, might an ordinance barring the obstruction of public rights of way or the erection of certain structures."<sup>24</sup>

## Homeless Bill of Rights

Rhode Island, Illinois, and Connecticut, and Puerto Rico have enacted laws that protect the civil rights of people experiencing homelessness, these laws are referred to as a Homeless Bill of Rights. While the laws vary by jurisdiction, they specify that a person who is homeless has the same rights and privileges as any other state resident. The laws each outline the rights of persons experiencing homelessness (i.e. move freely in public spaces, receive equal treatment by state and municipal authorities, not face discrimination while seeking or maintaining employment, access to emergency medical services, etc.). The impact these laws have had is unclear.

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<sup>&</sup>lt;sup>1</sup> Sleeping rough" – refers to sleeping outside without shelter

### Public Health Nuisance Laws

Actions by government officials aimed at individuals experiencing homelessness are often justified based on public health and safety concerns. While laws criminalizing homelessness are of concern, it should be clear that there are legitimate instances in addressing homeless populations where the government needs to act to protect the health of the public. For example, the environmental conditions associated with homelessness, which can include overcrowding in encampments and shelters, exposure to the elements, and poor hygiene, facilitate the transmission of infectious diseases.

The United States is currently experiencing the worst multi-state outbreak of hepatitis A virus (HAV) in over 20 years, due in part to the lack of access to proper sanitation and hygiene among persons experiencing homelessness. <sup>26</sup> In response to this multi-state HAV outbreak, the CDC's Advisory Committee on Immunization Practices, voted in 2018 to add a new policy recommending that everyone ages 1 and older who is experiencing homelessness routinely be immunized against hepatitis. <sup>27</sup> In some jurisdictions, there have been campaigns to vaccinate and educate people at risk and to provide portable hygiene facilities in areas where people who are homeless congregate. To address public health risks, some jurisdictions have created sanctioned tent encampments where they provide essential public services to help ensure that residents are in a safe environment. It has been cautioned that while these measures may prevent immediate harm, they are not long-term solutions to the problem of homelessness in the United Sates. <sup>28</sup>

## **CONCLUSION**

Insufficient income and lack of affordable housing are leading causes of homelessness in the United States. Laws criminalizing homelessness, or laws prohibiting life-sustaining activities in public spaces when there are no sheltered alternatives, have increased in U.S. cities over the past 10 years. These laws trap vulnerable populations in the criminal justice system and raise both human rights and constitutional concerns. Actions by government officials aimed at individuals experiencing homelessness are often justified based on public health and safety concerns. While there are instances where the government needs to act to protect public health and safety, such as during an infectious disease outbreak, governments should work to mitigate hazards and direct individuals to resources and services outside of the criminal justice system. Criminal sanctions should be a last resort.

 Current AMA policy recognizes that stable, affordable housing as a first priority, without mandated therapy or services compliance, is effective in improving housing stability and quality of life among individuals who are chronically-homeless. In addition, to reaffirming this policy, the AMA should recognize the lack of affordable housing as a leading cause of homelessness and support measures to address this problem through policies that preserve and expand affordable housing across all neighborhoods.

### **RECOMMENDATIONS**

The Board of Trustees recommends that the following statements be adopted in lieu of Resolution 410-A-18 and the remainder of the report be filed.

1. That our American Medical Association: (1) supports laws protecting the civil and human rights of individuals experiencing homelessness and (2) opposes laws and policies that criminalize individuals experiencing homelessness for carrying out life-sustaining activities conducted in public spaces that would otherwise be considered non-criminal activity (i.e.,

### B of T Rep. 28-A-19 -- page 5 of 6

eating, sitting, or sleeping) when there is no alternative private space available. (New HOD Policy)

4 2. That our AMA recognizes that stable, affordable housing is essential to the health of individuals, families, and communities, and supports policies that preserve and expand affordable housing across all neighborhoods. (New HOD Policy)

7

8 That our AMA reaffirm Policy H-160.903, "Eradicating Homelessness" 9 Our American Medical Association: (1) supports improving the health outcomes and 10 decreasing the health care costs of treating the chronically homeless through clinically proven, 11 high quality, and cost effective approaches which recognize the positive impact of stable and 12 affordable housing coupled with social services; (2) recognizes that stable, affordable housing 13 as a first priority, without mandated therapy or services compliance, is effective in improving housing stability and quality of life among individuals who are chronically-homeless; 14 15 (3) recognizes adaptive strategies based on regional variations, community characteristics and state and local resources are necessary to address this societal problem on a long-term basis; 16 17 (4) recognizes the need for an effective, evidence-based national plan to eradicate homelessness; and (5) encourages the National Health Care for the Homeless Council to study 18 19 the funding, implementation, and standardized evaluation of Medical Respite Care for 20 homeless persons. (Reaffirm Current HOD Policy)

Fiscal Note: less than \$500

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- <sup>5</sup> *Id*.
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### REPORT OF THE BOARD OF TRUSTEES

B of T Report 29-A-19

Subject: Improving Safety and Health Code Compliance in School Facilities

(Resolution 413-A-18)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee D

(Diana Ramos, MD, MPH, Chair)

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### INTRODUCTION

Resolution 423-A-18, "Improving Safety and Health Code Compliance in School Facilities," which was introduced by the Medical Student Section, and was referred by the House of Delegates, asked:

 That our American Medical Association (1) support the development and implementation of standardized, comprehensive guidelines for school safety and health code compliance inspections; and (2) That our AMA support policies aiding schools in meeting said guidelines, including support for financial and personnel-based aid for schools based in vulnerable neighborhoods; and (3) That our AMA support creation of a streamlined reporting system for school facility health data potentially through application of current health infrastructure.

Testimony during reference committee noted that there are already extensive guidelines provided for schools by the Centers for Disease Control and Prevention, Environmental Protection Agency, and state departments of health, and that our American Medical Association should review guidelines from these sources. It was further noted that there is no governing body that enforces the compliance of safety standards in schools. This report addresses school environmental health and safety.

### **CURRENT AMA POLICY**

Existing American Medical Association (AMA) policy addresses environmental health and safety, including drinking water and indoor air quality (see Appendix for full text). Relevant to this report is AMA Policy H-135.928, "Safe Drinking Water," that supports creating and implementing standardized protocols and regulations pertaining to water quality testing, and reporting and remediation to ensure the safety of water in schools. AMA Policy H-135.998, "AMA Position on Air Pollution," also supports maximum feasible reduction of all forms of air pollution, including biologically and chemically active pollutants, by all responsible parties, as governmental control programs are implemented primarily by local, regional, or state jurisdictions which possess the resources to bring about equitable and effective control.

### **BACKGROUND**

School Environmental Health and Safety

Children are a vulnerable population with smaller body size and higher metabolism, which may increase susceptibility to environmental contaminants. Children may also be more likely to encounter contaminants, due to proximity to the ground, where they may ingest substances such as toxic dust by placing objects in their mouths, and where levels of airborne pollutants may also be higher. Regardless of route of administration, encounters with toxins such as heavy metals can lead to lifelong negative health and behavioral impacts, including via altered brain development.

Safety implies prevention of unintentional injuries, a leading cause of death and disability among children. Unsafe environments can lead to chronic health conditions, including asthma and allergies. As many as 25 percent of school-age children in the United States have a chronic health condition. Children spend large amounts of time in schools, where better management of their chronic health conditions may be associated with improved academic achievement.<sup>4</sup>

Budget shortfalls for school infrastructure impact school operating resources, negatively affecting routine and preventative maintenance, particularly in lower-income districts. Lack of well-maintained school environments can pose obstacles to student learning and well-being, negatively affect surrounding communities, and contribute to health inequities.<sup>5</sup>

Environmental health and safety laws and guidelines have been designed to protect private and public employees, students, the public, and the environment.<sup>6</sup> A complex jurisdictional arrangement throughout federal, state, county, and municipal levels may create confusion for schools about which regulations apply. The following provides a broad overview of various agencies and entities with interests in school environmental health and safety.

## FEDERAL AGENCIES

The federal government's role in education has traditionally been limited, due to the Tenth Amendment of the U.S. Constitution, which reserves powers not assigned to the federal government for the states of the people. Rather than mandating direct federal oversight of schools, state and local districts have generally retained school regulatory authorities under existing law.

U.S. Environmental Protection Agency (EPA)

The EPA is responsible for protecting the environment and public through legislative mandates. These laws include air pollution, drinking water, pesticides, hazardous waste, and asbestos, among other topics. The Energy Independence and Security Act of 2007 added a requirement for the EPA to develop voluntary guidelines (together with other relevant federal agencies) for K-12 schools, and then assist states in establishing and implementing environmental health programs.<sup>7</sup>

Other recent EPA mandates address drinking water and aging infrastructure, including: the Drinking Water State Revolving Fund of 2013 that provides loans that support lead pipe replacement projects across the United States; the Water Infrastructure Improvements for the Nation Act of 2016 that supports grant programs<sup>8</sup> (e.g., the State Lead Testing in School and Child Care Program Drinking Water Grant<sup>9</sup>): the Water Infrastructure Finance and Innovation Act of 2018 that leverages funding for water infrastructure projects to reduce exposure to lead and other contaminants; and the America's Water Infrastructure Act of 2018 that offers programs and resources to help reduce lead in drinking water.

The EPA assists states and local school districts by providing grant support<sup>10</sup> and capacity building, developing policy and data tools,<sup>11</sup> and offering guidance on compliance and monitoring. The EPA's voluntary guidelines provide examples of best practices from existing state environmental health programs for schools, recommend a six-step plan states can use to build or enhance a sustainable school environmental health program, and provide extensive resources for states to promote healthy learning environments for children and school staff.

 In addition to the voluntary guidelines, in 2018 the EPA announced the Tools for Schools program to support schools in ensuring clean, healthy, and environmentally conscious school communities. The Tools for Schools approach provides strategies and a robust suite of tools to help schools identify, correct, and prevent a wide range of environmental health and safety risks, and to put in place a sustainable system to institutionalize a successful program at the school or school district level. The EPA also offers comprehensive Healthy Schools, Healthy Kids educational resources and tools to help maintain and enhance environmental health programs. These resources include educating students and school staff about prevention and management, as well as hands-on resources such as inspection manuals for staff and pest management professionals.

Centers for Disease Control and Prevention (CDC)

The CDC conducts critical science and provides health information that protects our nation against dangerous health threats, and responds when these arise. The CDC serves a key role in environmental health, as well as health promotion and education activities designed to improve health.

Various CDC centers and agencies address environmental health and safety, including the Agency for Toxic Substances and Disease Registry, which works towards minimizing risks associated with exposure to hazardous substances, and maintains toxicological profiles for substances; the Division of Adolescent and School Health, which collects data to monitor healthy and safe school environments such as School Health Policies and Practices Study<sup>15</sup> and conducts surveys of schools including School Health Profiles<sup>16</sup> covering asthma and other chronic conditions; and the National Center for Environmental Health which conducts research including the Environmental Public Health Tracking Program<sup>17</sup> and collects state surveillance data<sup>18</sup> on children affected by lead.

The National Institute for Occupational Safety and Health (NIOSH) has a Safety Checklist for Schools<sup>19</sup> to help K-12 schools with health compliance, including with EPA regulations and Occupational Safety and Health Administration (OSHA) standards. NIOSH also responds to requests to investigate health and safety problems in the workplace, via the Division of Surveillance, Hazard Evaluations, and Field Studies, including in public schools<sup>20</sup>. It also provides training in occupational safety and health, conducts occupational disease and injury research, and recommends standards to OSHA.

The School Health Index<sup>21</sup> was developed by the CDC as a confidential online self-assessment and planning tool that schools can use to help improve health and safety policies and programs. The CDC also has additional resources for drinking water access<sup>22</sup> through Healthy Schools,<sup>23</sup> which offers the Whole School, Whole Community, Whole Child (WSCC) model as a framework for addressing health in schools.<sup>24</sup> According to the WSCC model:

The physical school environment encompasses the school building and its contents, the land on which the school is located, and the area surrounding it. A healthy school environment will address a school's physical condition during normal operation as well as during renovation

1 (e.g., ventilation, moisture, temperature, noise, and natural and artificial lighting), and protect 2 occupants from physical threats (e.g., crime, violence, traffic, and injuries) and biological and 3 chemical agents in the air, water, or soil as well as those purposefully brought into the school 4 (e.g., pollution, mold, hazardous materials, pesticides, and cleaning agents). 5 A recent report<sup>25</sup> provided a comprehensive analysis of state policies for alignment with the CDC's 6 7 WSCC model, and these findings are available by state and category, <sup>26</sup> including physical 8 environment. 9 10 STATE AGENCIES 11 12 State agencies also play a role in school environmental health and safety, and these vary by 13 jurisdiction. Those that may be relevant include the state departments of education, labor, environmental protection, community affairs, and health.<sup>19</sup> 14 15 16 Departments of Education 17 18 State departments of education issue regulations that deal with private and public schools, as well 19 as regulations related to school construction. Besides regulations for environmental safety and 20 health regulations, a state department of education or school district may also provide policies 21 and/or guidelines related to environmental safety and health programs. 22 23 Departments of Labor 24 25 Although students are not generally covered by federal OSHA, state legislative mandates may "adopt by reference" the OSHA standards. "Adoption by reference" requires compliance in the 26 27 state with federal OSHA requirements. State OSHA programs then assume responsibility for 28 enforcing regulations through the state department of labor, including health and safety. 29 30 Departments of Environmental Protection 31 32 In most states, the state EPA covers the same areas addressed by federal EPA, such as air pollution, 33 drinking water, hazardous waste, pesticides, and noise pollution. When incorporated into state 34 regulations, state EPAs are authorized by the U.S. EPA to enforce almost all EPA regulations. 35 States have typically assumed responsibility for enforcement of EPA mandates, following adoption 36 of their own state regulations, including inspections and enforcing EPA regulations in schools. The 37 U.S. EPA provides voluntary guidelines for states to follow, and encourages a leadership role from 38 state agencies, such as more comprehensive strategies, including by using available resources such 39 as model programs for indoor air quality.<sup>27</sup> 40 41 Departments of Community Affairs 42 43 Agencies such as the Department of Community Affairs may enforce state fire safety and building 44 regulations. In many states, cities and counties are free to adopt their own codes, in the absence of 45 state codes. 46 47 Departments of Health 48 49 State departments of health enforce health regulations directed by legislative mandate. Health

departments may also work with schools and local health departments to provide technical assistance on school environmental health and safety issues and promote best practices.

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### LOCAL GOVERNMENTS

Various codes and standards have been adopted by states, counties, cities/towns and districts to help ensure school safety. One example includes building codes, which may also regulate children's play spaces and equipment. Another example is fire protection codes that address topics such as means of egress from buildings. Many safety codes apply to public schools via entities such as the local building or fire department,<sup>28</sup> and some cover environmental health areas such as radon testing and elimination. At state or city levels, additional public safety statutes may apply.<sup>29</sup>

### KEY AREAS OF SCHOOL ENVIRONMENTAL HEALTH AND SAFETY

## Air Quality

Airborne contaminants including mold<sup>30</sup> and chemicals such as cleaning products and pesticides, can trigger a variety of health issues, including allergies and asthma. Various state indoor air quality statutes cover topics such as HVAC system inspection and inadequate ventilation, while others focus primarily on green cleaning. Nearly every state has a statute that heavily regulates smoking in schools and most prohibit smoking in schools completely. There is no state statute that encompasses all facets of indoor air quality safety in schools.

### Chemical Hazards

<u>Asbestos.</u> Asbestos minerals are a group of silicate compounds that cause chronic lung disease and have been classified as a known human carcinogen.<sup>31</sup> Asbestos statutes generally pertain to any public building and not just schools, and require certification and licensure before any contracting can occur for an asbestos abatement program, and substantial monitoring before and during any programs. Most state statutes provide for state or federal money for abatement programs in public buildings, including schools.

<u>Radon.</u> Radon is a colorless, odorless radioactive gas that seeps into buildings from surroundings, and can become trapped inside. Some states have radon statutes that provide that schools must be checked for radon, but most states delegate authority to various departments in the state.

 <u>Lead.</u> Lead is a neurotoxin for which young children are particularly susceptible. Lead exposure is linked to impaired brain and nervous system development during childhood and associated with adverse effects including behavioral problems and additional health conditions later in life. Nearly every state has a statute that mitigates lead risks, though most are focused on reducing the risks of lead-based paint. Of the states that specifically address children, many only address children up to age six. The EPA offers voluntary guidance<sup>13</sup> for preventing and mitigating some lead hazards in schools, including drinking water.<sup>32</sup>

## Water Quality

Currently, no federal law requires testing for lead in school drinking water. Although public water systems are regulated by the EPA, this regulation does not apply to downstream users such as schools. To date, federal agencies including the EPA, Department of Education and CDC have had a limited role in monitoring school drinking water. Improved federal guidance has been called for by the Government Accountability Office.<sup>33</sup>

In 2017, 41 percent of school districts nationwide had not tested their water for lead, and additional 16 percent reported that they did not know whether the water had been tested.<sup>33</sup> In 2016, New York became the first state to require lead testing in school drinking water and by 2018, 15 states had requirements for lead testing in school drinking water<sup>34</sup> but many jurisdictions do not have programs to test for lead in drinking water.

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Recent findings have highlighted challenges due a lack of standardized practices in data collection, reporting, and decision making. When testing has been performed, elevated levels of lead have often been found, and many schools must decide the levels that trigger retesting, prevent continued use of the source, and eventually spur remediation efforts.

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## **CONCLUSION**

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Children are a vulnerable population and are susceptible to environmental contaminants. Given the amount of time children spend in schools, promoting healthy school environments is of importance. Existing guidelines recommend steps towards sustainable school environmental health programs, and additional tools are available to help schools implement guidelines to promote children's health. While some state and local governments have adopted these guidelines into law, overall adoption and enforcement of such guidelines remains voluntary. Budgets and school operating expenses directly impact school building infrastructure and maintenance. Schools in lower-income districts may be particularly vulnerable to environmental health hazards, which can pose obstacles to student learning and well-being, and contribute to health inequities.

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## **RECOMMENDATIONS**

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The Board of Trustees recommends that the following recommendations be adopted in lieu of Resolution 413-A-18 and that the remainder of this report be filed.

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1. That our AMA adopt the following new policy:

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"Environmental Health and Safety in Schools" Our AMA supports the adoption of standards in schools that limit harmful substances from school facility environments, ensure safe drinking water, and indoor air quality, and promote childhood environmental health and safety in an equitable manner. (New HOD Policy)

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That the following policies be reaffirmed: H-135.928, "Safe Drinking Water," and H-135.998, "AMA Position on Air Pollution." (Reaffirm HOD Policy)

Fiscal Note: Less than \$500.

## APPENDIX - Current AMA Policy

## H-135.928, "Safe Drinking Water"

Our AMA supports updates to the U.S. Environmental Protection Agency's Lead and Copper Rule as well as other state and federal laws to eliminate exposure to lead through drinking water by: (1) Removing, in a timely manner, lead service lines and other leaded plumbing materials that come into contact with drinking water; (2) Requiring public water systems to establish a mechanism for consumers to access information on lead service line locations; (3) Informing consumers about the health-risks of partial lead service line replacement; (4) Requiring the inclusion of schools, licensed daycare, and health care settings among the sites routinely tested by municipal water quality assurance systems; (5) Creating and implementing standardized protocols and regulations pertaining to water quality testing, reporting and remediation to ensure the safety of water in schools and child care centers; (6) Improving public access to testing data on water lead levels by requiring testing results from public water systems to be posted on a publicly available website in a reasonable timeframe thereby allowing consumers to take precautions to protect their health; (7) Establishing more robust and frequent public education efforts and outreach to consumers that have lead service lines, including vulnerable populations; (8) Requiring public water systems to notify public health agencies and health care providers when local water samples test above the action level for lead; (9) Seeking to shorten and streamline the compliance deadline requirements in the Safe Drinking Water Act; and (10) Actively pursuing changes to the federal lead and copper rules consistent with this policy.

### H-135.998, "AMA Position on Air Pollution"

Our AMA urges that: (1) Maximum feasible reduction of all forms of air pollution, including particulates, gases, toxicants, irritants, smog formers, and other biologically and chemically active pollutants, should be sought by all responsible parties. (2) Community control programs should be implemented wherever air pollution produces widespread environmental effects or physiological responses, particularly if these are accompanied by a significant incidence of chronic respiratory diseases in the affected community. (3) Prevention programs should be implemented in areas where the above conditions can be predicted from population and industrial trends. (4) Governmental control programs should be implemented primarily at those local, regional, or state levels which have jurisdiction over the respective sources of air pollution and the population and areas immediately affected, and which possess the resources to bring about equitable and effective control.

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### REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 3-A-19

Subject: Low Nicotine Product Standard

(Resolution 431-A-18)

Presented by: Robyn F. Chatman, MD, MPH, Chair

Referred to: Reference Committee D

(Diana Ramos, MD, MPH, Chair)

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Resolution 431-A-18, introduced by the American Thoracic Society and referred by the House of Delegates asks:

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That our American Medical Association (AMA) direct the Council on Science and Public Health to develop a report on the individual health and public health implications of a low nicotine standard for cigarettes. Such a report should consider and make recommendations on scientific criteria for selection of a nicotine standard that is non-addictive, regulatory strategies to ensure compliance with an established standard, how a low nicotine standard should work with other nicotine products in a well-regulated nicotine market.

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### **METHODS**

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English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from January 2018 to January 2019 using the search terms "nicotine standard," "nicotine content," and "very low nicotine content cigarette."

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## **BACKGROUND**

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At the 2018 Annual Meeting of the House of Delegates, the Council on Science and Public Health (CSAPH) presented a report on "Tobacco Harm Reduction: A Comprehensive Nicotine Policy to Reduce Death and Disease Caused by Smoking." That report outlined the Food and Drug Administration's (FDA) plan to reduce the devastating toll of tobacco use and noted that the plan involves two primary parts: (1) reducing the addictiveness of combustible cigarettes and (2) recognizing and clarifying the role that potentially less harmful tobacco products could play in improving public health. The FDA also has acknowledged the need for medicinal nicotine and other therapeutic products to play a greater role in helping smokers to quit and remain nonsmokers.

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- On July 16, 2018, the AMA along with 39 other medical and public health organizations submitted
- comments to the Food and Drug Administration (FDA) on Docket No. FDA-2017-N-6189,
- 30 Tobacco Product Standard for Nicotine Level of Combusted Cigarettes (See Appendix). These
- 31 comprehensive comments on the FDA's Advance Notice of Proposed Rule Making (ANPRM)
- 32 addressed the following issues:

I. Public Health Impact of Reducing Nicotine in Combustible Tobacco Products

A. Reducing the Nicotine Content of Cigarettes Will Help Smokers Quit

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3 B. Reducing the Nicotine Content of Combustibles Will Prevent Kids from Becoming 4 Addicted Smokers 5 C. Vulnerable Populations Will Benefit from a Nicotine Reduction Policy 6 7 II. A Nicotine Content Standard Should Apply to Other Combustible Tobacco Products 8 A. The Tobacco Industry Manipulates Loopholes in Product Regulation 9 B. Cigars Are a Harmful and Addictive Substitute for Cigarettes C. Hookah (Waterpipe) Tobacco is Harmful and Addictive 10 D. The rule should prohibit other changes in cigarettes that might counteract the effect of the 11 12 reduction in nicotine. 13 14 III. Implementation Considerations 15 A. Maximum Nicotine Level B. An Immediate Nicotine Content Reduction Will Have a Larger Public Health Impact than a 16 17 **Gradual Reduction** 18 C. Reducing the Nicotine Content of Combustibles Will Not Lead to Compensation 19 D. FDA Must Counter Misperceptions about the Harms of Reduced Nicotine Products 20 21 IV. Technical Achievability 22 A. Reducing Nicotine in Cigarettes is Technologically Feasible 23 B. FDA Should Make the Effective Date of the Rule as Early as Possible. C. Manufacturers, Distributors, and Retailers Should Not Be Allowed to Sell Off Existing 24 25 Nonconforming Inventories. D. FDA Should Require a Standard Method of Product Testing to Analyze Nicotine Levels. 26 27 28 V. Possible Countervailing Effects A. The Product Standard Should Prohibit the Sale or Distribution of Liquid Nicotine or Any 29 30 Other Tobacco Product Designed to Supplement the Nicotine Content of Combusted 31 Tobacco Products. 32 B. Illicit Trade 33 34 VI. Other Considerations 35 A. The Potential Consumer Surplus or Utility Loss from the Removal of Nicotine from 36 Combusted Tobacco Products is Minimal in Light of the Availability of Other Sources of Nicotine and the Continued Availability of Tobacco Products. 37 B. FDA Should Consider Externalities, Such as the Reduction in Secondhand Smoke, in 38 39 Evaluating the Consequences of the Rule 40 C. Post-market Surveillance is Critical 41 42 The AMA also submitted individual comments (see Appendix) calling on the FDA to: 43 44 create a non-addictive nicotine level standard for all tobacco products, not just cigarettes. This includes smokeless tobacco, electronic nicotine delivery systems (ENDS), 'heat not burn 45 products,' and any other tobacco products containing nicotine for recreational use. If FDA 46 47 reduces nicotine content in combustible tobacco products without already having a regulatory 48 strategy in place that appropriately addresses ENDS, it will miss a critical opportunity to 49 reduce overall nicotine addiction and use of tobacco products. Comprehensive and specific 50 regulations are necessary to prevent new products that may circumvent the nicotine level 51 requirement.

#### **DISCUSSION**

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Several studies have been released on the issue of low nicotine cigarette product standards since the AMA submitted comments to the FDA regarding a tobacco product standard for nicotine. These studies have largely been consistent with the AMA's comments or have addressed gaps where information was not previously available. One study found that when nondaily smokers switch to very low nicotine content cigarettes, they reduced their cigarette consumption by 51 percent, though they did not necessarily stop smoking.<sup>2</sup> A study looking at whether smoking intensity increased when intermittent smokers switched to very low nicotine content cigarettes found that smoking intensity decreased.<sup>3</sup> Another study examined the effects of immediate vs. gradual reduction in nicotine content to very low levels and as compared with usual nicotine level cigarettes on biomarkers of toxicant exposure. Among smokers, immediate reduction of nicotine in cigarettes (to 0.4 mg of nicotine per gram of tobacco) led to significantly greater decreases in biomarkers of smoke exposure across time compared with gradual reduction (from 15.5 mg to 0.4 mg of nicotine per gram of tobacco cigarettes with 5 monthly dose changes) or a control group (maintenance on 15.5 mg of nicotine per gram of tobacco cigarettes), with no significant differences between gradual reduction and control.<sup>4</sup>

A search on clinicaltrials.gov indicates that there are a number of clinical trials underway that will provide additional information on very low nicotine content cigarettes and nicotine product standards.

#### **CURRENT AMA POLICY**

 Existing AMA policy acknowledges that all tobacco products are harmful to health, and that there is no such thing as a safe cigarette. Policy also recognizes that complete cessation of the use of tobacco and nicotine-related products is the goal and supports the use of FDA-approved tools for smoking cessation. The AMA supports the FDA's regulatory authority over tobacco products and encourages the FDA and other appropriate agencies to conduct or fund research on how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and elimination of additives (e.g., ammonia) that enhance addictiveness.

#### RECOMMENDATION

The Council on Science and Public Health recommends that the following be adopted in lieu of Resolution 431-A-18 and the remainder of the report be filed:

 1. That AMA Policy H-495.988, "FDA Regulation of Tobacco Products" be amended by addition to read as follows:

1. Our AMA: (A) acknowledges that all tobacco products (including but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco) are harmful to health, and that there is no such thing as a safe cigarette; (B) recognizes that currently available evidence from short-term studies points to electronic cigarettes as containing fewer toxicants than combustible cigarettes, but the use of electronic cigarettes is not harmless and increases youth risk of using combustible tobacco cigarettes; (C) encourages long-term studies of vaping (the use of electronic nicotine delivery systems) and recognizes that complete cessation of the use of tobacco and nicotine-related products is the goal; (D) asserts that tobacco is a raw form of the drug nicotine and that tobacco products are delivery devices for an addictive substance; (E) reaffirms its position that the Food and Drug Administration (FDA) does, and should continue to have, authority to regulate tobacco products, including their manufacture, sale,

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distribution, and marketing; (F) strongly supports the substance of the August 1996 FDA regulations intended to reduce use of tobacco by children and adolescents as sound public health policy and opposes any federal legislative proposal that would weaken the proposed FDA regulations; (G) urges Congress to pass legislation to phase in the production of less hazardous and less toxic tobacco, and to authorize the FDA have broad-based powers to regulate tobacco products; (H) encourages the FDA and other appropriate agencies to conduct or fund research on how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and elimination of additives (e.g., ammonia) that enhance addictiveness; and (I) strongly opposes legislation which would undermine the FDA's authority to regulate tobacco products and encourages state medical associations to contact their state delegations to oppose legislation which would undermine the FDA's authority to regulate tobacco products.

2. Our AMA: (A) supports the US Food and Drug Administration (FDA) as it takes an important first step in establishing basic regulations of all tobacco products; (B) strongly opposes any FDA rule that exempts any tobacco or nicotine-containing product, including all cigars, from FDA regulation; and (C) will join with physician and public health organizations in submitting comments on FDA proposed rule to regulate all tobacco products.

3. Our AMA: (A) will continue to monitor the FDA's progress towards establishing a low nicotine product standard for tobacco products and will submit comments on the proposed rule that are in line with the current scientific evidence and (B) recognizes that rigorous and comprehensive post-market surveillance and product testing to monitor for unintended tobacco use patterns will be critical to the success of a nicotine reduction policy. (Modify Current HOD Policy)

2. That American Medical Association Policy H-495.972, "Electronic Cigarettes, Vaping, and Health" be reaffirmed. (Reaffirm HOD Policy)

Fiscal Note: Less than \$500.

#### REFERENCES

- Food and Drug Administration, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes. 83 FR 11818, pgs. 11818-11843. Available at: https://www.federalregister.gov/documents/2018/03/16/2018-05345/tobacco-product-standard-for-nicotine-level-of-combusted-cigarettes. Accessed March 1, 2019
- 2. Shiffman S, Kurland BF, Scholl SM, Mao JM. Nondaily Smokers' Changes in Cigarette Consumption With Very Low-Nicotine-Content Cigarettes: A Randomized Double-blind Clinical Trial. *JAMA Psychiatry*. 2018;75(10):995–1002.
- 3. Shiffman S, Mao JM, Kurland BF, Scholl SM. Do non-daily smokers compensate for reduced cigarette consumption when smoking very-low-nicotine-content cigarettes? *Psychopharmacology* (Berl). 2018; 235(12):3435-3441.
- Hatsukami, D. K., Luo, X., Jensen, J. A., Al'Absi, M., Allen, S. S., Carmella, S. G., Donny, E. C. Effect of immediate vs gradual reduction in nicotine content of cigarettes on biomarkers of smoke exposure a randomized clinical trial. *JAMA Journal of the American Medical Association*. 2018; 320(9): 880-891.



July 16, 2018

Dockets Management Staff [HFA-305] Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: Docket No. FDA-2017-N-6189, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes

The undersigned organizations submit these comments in the above-designated docket regarding the FDA's Advance Notice of Proposed Rulemaking on a Tobacco Product Standard for Nicotine Level of Combusted Cigarettes.

#### Introduction

For decades, researchers have agreed that nicotine is the fundamental addictive agent in tobacco, leading the U.S. Surgeon General to affirmatively conclude in the 1988 report, *The Health Consequences of Smoking: Nicotine Addiction*, that, "nicotine is the drug in tobacco that causes addiction." Now, strong scientific evidence also demonstrates that reducing the nicotine

U.S. Department of Health and Human Services (HHS). *The Health Consequences of Smoking: Nicotine Addiction. A Report of the Surgeon General.* 1988.

content to a very low level can reduce smoking and nicotine addiction.<sup>2</sup> Reducing nicotine levels in combustible tobacco products provides enormous potential to accelerate progress in preventing and reducing smoking and the death and disease it causes. We urge you to move forward with this proposal as quickly as possible.

As FDA noted in the Advance Notice of Proposed Rulemaking (ANPRM at 11822), reducing the nicotine content of cigarettes will: "(1) Give addicted users of cigarettes the choice and ability to quit more easily by reducing the nicotine to a minimally addictive or nonaddictive level and (2) reduce the risk of progression to regular use and nicotine dependence for persons who experiment with the tobacco products covered by the standard." Making cigarettes minimally or non-addictive will prevent most kids from ever becoming regular smokers and will increase the number of smokers who make a quit attempt and successfully quit. The FDA estimates that this proposal would prevent more than 33 million youth and young adults from becoming regular smokers this century, prompt 5 million smokers to quit within one year (rising to 13 million in five years) and save more than 8 million lives by the end of the century. The impact of this policy would be historic. There are few actions FDA could take that would prevent as many young people from smoking and save as many lives.

It is important, however, that FDA consider a nicotine product standard as part of a comprehensive set of regulatory policies to curb the use of combustible tobacco products. Thus, moving toward adoption of such a standard would not obviate the need to implement, as soon as possible, proposals that include prohibiting menthol in cigarettes and characterizing flavors in all tobacco products, as well as graphic health warnings for cigarettes. Moreover, there is, and will continue to be, a need for FDA to exercise its full authority to reduce the use of and pursue public education campaigns directed at informing the public of the health risks of all tobacco products, including those subject to the nicotine reduction proposal. Reducing nicotine in combustible products to minimally or non-addictive levels will not make those products "safe," and the public, particularly young people, need to understand that any use of these products will continue to carry substantial health risks.

#### I. Public Health Impact of Reducing Nicotine in Combustible Tobacco Products

Despite great progress in curbing smoking prevalence in recent years, tobacco use – primarily smoking – remains the leading cause of preventable death and disease in the United States, killing more than 480,000 Americans every year. A Nearly 38 million Americans currently

World Health Organization (WHO) Study Group on Tobacco Product Regulation, *Global Nicotine Reduction Strategy*, 2015, <a href="http://apps.who.int/iris/bitstream/10665/189651/1/9789241509329\_eng.pdf?ua=1">http://apps.who.int/iris/bitstream/10665/189651/1/9789241509329\_eng.pdf?ua=1</a>.

Apelberg, BJ, et al., "Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States," *New England Journal of Medicine*, published online March 15, 2018. See also Tobacco Product Standard for Nicotine Level of Combusted Cigarettes; Advanced Notice of Proposed Rulemaking, 83 Fed. Reg. at 11818 (March 16, 2018).

HHS, The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General, 2014.

smoke and every day about 2,300 kids try their first cigarette and another 350 additional kids become regular smokers.<sup>5</sup> Approximately half of continuing smokers will die prematurely as a result of their addiction, losing at least a decade of life on average compared to nonsmokers.<sup>6</sup>

Reducing the nicotine content in cigarettes to minimally or non-addictive levels will prevent young people who experiment from becoming addicted and save them from a lifetime of addiction, tobacco-caused disease, and premature death. It also will reduce the level of nicotine dependence in adult smokers, making it easier for them to quit. Ultimately, this will dramatically reduce the number of adult smokers. The FDA estimates that reducing nicotine levels in combusted tobacco products would prevent more than 33 million youth and young adults from initiating regular smoking by 2100. In addition, within five years, the FDA estimates it would cause 13 million smokers to quit, including five million within just the first year of implementation. Ultimately, more than 8 million lives would be saved by the end of the century.<sup>7</sup>

#### A. Reducing the Nicotine Content of Cigarettes will Help Smokers Quit

As stated by a Philip Morris researcher in 1972, "No one has ever become a cigarette smoker by smoking cigarettes without nicotine." Nicotine is the primary addictive agent in cigarettes. According to the U.S. Surgeon General, "the addiction caused by the nicotine in tobacco smoke is critical in the transition of smokers from experimentation to sustained smoking and, subsequently, in the maintenance of smoking for the majority of smokers who want to quit." Most adult smokers want to quit (nearly 70 percent) and wish they had never started (about 90 percent), but overcoming an addiction to nicotine is difficult and smokers often need to make multiple quit attempts before succeeding. 11

CDC, "Current Cigarette Smoking Among Adults – United States, 2016," *Morbidity and Mortality Weekly Report (MMWR)* 67(2):53-59, January 19, 2018. <a href="https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6702a1-H.pdf">https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6702a1-H.pdf</a>; Substance Abuse and Mental Health Services Administration (SAMHSA), HHS, *Results from the 2016 National Survey on Drug Use and Health, NSDUH: Detailed Tables*, 2017. <a href="https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.pdf">https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2016/NSDUH-DetTabs-2016.pdf</a>.

HHS, The Health Consequences of Smoking – 50 Years of Progress: A Report of the Surgeon General, 2014.

Apelberg, BJ, et al., "Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States," *New England Journal of Medicine*, published online March 15, 2018. See also Tobacco Product Standard for Nicotine Level of Combusted Cigarettes; Advanced Notice of Proposed Rulemaking, 83 Fed. Reg. at 11818 (March 16, 2018).

Philip Morris, Dunn, W Jr., "Motives And Incentives In Cigarette Smoking"; R107. 1972. <a href="https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/jspf0085">https://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/jspf0085</a>. For additional industry quotes on nicotine, see Campaign for Tobacco-Free Kids fact sheet, "Tobacco Company Quotes: Nicotine as a Drug," <a href="https://www.tobaccofreekids.org/research/factsheets/pdf/0009.pdf">https://www.tobaccofreekids.org/research/factsheets/pdf/0009.pdf</a>.

HHS, How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General, 2010.

HHS, The Health Consequences of Smoking—50 Years of Progress, A Report of the Surgeon General, 2014. See also, HHS, How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General, 2010, <a href="http://www.ncbi.nlm.nih.gov/books/NBK53017/">http://www.ncbi.nlm.nih.gov/books/NBK53017/</a>.

Babb, S, et al., "Quitting Smoking Among Adults—United States, 2000—2015," *MMWR* 65:1457–1464, 2017. Fong, G., et al., "The Near-Universal Experience of Regret Among Smokers in Four Countries: Findings from

Research demonstrates that significantly reducing nicotine levels holds great promise for accelerating progress in reducing smoking. Scientific evidence establishes that it is possible to lower nicotine levels in ways that dramatically reduce dependence. Based on a comprehensive review of the evidence, the World Health Organization Study Group on Tobacco Product Regulation concluded that reducing nicotine content in cigarettes could: 12

- Reduce smoking acquisition and progression to addiction;
- Increase cessation and reduce relapse; and, ultimately,
- Reduce smoking prevalence.

The first large scale clinical trial of very low nicotine content (VLNC) cigarettes in the US, conducted in 2013-2014, randomly assigned over 800 smokers to use their usual brand of cigarettes or cigarettes with varying levels of nicotine for six weeks. Smokers assigned to smoke cigarettes with lower nicotine content smoked fewer cigarettes, reduced their exposure and dependence to nicotine, and reduced cravings, compared to the control group. The same study also found that those smoking cigarettes with the lowest nicotine content (0.4 mg/g) were twice as likely to report trying to quit in the 30 days after the study ended compared to those smoking cigarettes with 15.8 mg/g (34% vs. 17%). Smokers assigned to smoke cigarettes with 2.4 mg/g nicotine or less smoked between 23 and 30 percent fewer cigarettes per day at six-week follow-up compared to smokers assigned to smoke cigarettes with 15.8 mg/g nicotine. <sup>13</sup>

Other smaller studies have shown that use of reduced nicotine cigarettes leads to reductions in smoking, nicotine dependence, and biomarkers of exposure to nicotine and other toxins. <sup>14</sup> Research also shows that reduced nicotine cigarettes increase abstinence among smokers trying to quit. <sup>15</sup> For example, a 2009-2010 randomized controlled trial in New Zealand assigned over 1400 smokers seeking treatment from the Quitline to receive VLNC cigarettes with standard Quitline care (nicotine replacement therapy and behavioral counseling) for six

the International Tobacco Control Policy Evaluation Survey," *Nicotine & Tobacco Research*, Vol. 6, Supplement 3, December 2004.

WHO, Global Nicotine Reduction Strategy, 2015.

Donny, EC, et al., "Randomized trial of reduced-nicotine standards for cigarettes," *New England Journal of Medicine*, 373: 1340-1349, 2015.

See e.g., Donny EC, et al. Smoking in the absence of nicotine: behavioral, subjective and physiological effects over 11 days. *Addiction* 2007; 102: 324-34. Benowitz NL, et al., Nicotine and carcinogen exposure with smoking of progressively reduced nicotine content cigarette. *Cancer Epidemiol Biomarkers Prev* 2007; 16: 2479-85. Benowitz NL, et al., Urine nicotine metabolite concentrations in relation to plasma cotinine during low-level nicotine exposure. *Nicotine & Tobacco Research* 2009; 11: 954-60. Benowitz NL, et al. Smoking behavior and exposure to tobacco toxicants during 6 months of smoking progressively reduced nicotine content cigarettes. *Cancer Epidemiol Biomarkers Prev* 2012; 21: 761-9. Hatsukami DK, et al. Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation. *Addiction* 2010; 105: 343-55.

See e.g., Walker, N, et al., "The combined effect of very low nicotine content cigarettes, used as an adjunct to usual Quitine care (nicotine replacement therapy and behavioural support), on smoking cessation: a randomized controlled trial," *Addiction*, 107(10): 1857-1867, 2012. McRobbie, H, et al., "Complementing the standard multicomponent treatment for smokers with denicotinized cigarettes: a randomized controlled trial," *Nicotine & Tobacco Research*, 18(5): 1134-1141, 2016.

weeks, or Quitline care alone. At 6-month follow-up, smokers who had received VLNC cigarettes were more likely to have quit smoking (33% vs. 28% seven-day point prevalence abstinence; 23% vs. 15% continuous abstinence). <sup>16</sup> This evidence suggests that VLNC cigarettes can help smokers who are making a quit attempt.

### B. Reducing the Nicotine Content of Combustibles Will Prevent Kids from Becoming Addicted Smokers

The FDA noted in the ANPRM (at 11821, 11823-11824) the powerful addictiveness of nicotine, particularly on the adolescent brain. Tobacco use almost always begins during adolescence and adolescents are particularly vulnerable to the addictive effects of nicotine because the brain continues to develop until about age 25. Because adolescence and young adulthood are critical periods of growth and development, exposure to nicotine may have lasting, adverse consequences on brain development. 17 The parts of the brain most responsible for decision making, impulse control, sensation seeking, and susceptibility to peer pressure continue to develop and change through young adulthood. 18 As a result, nicotine exposure during adolescence may result in impaired attention and memory, problems with learning, reduced selfcontrol and anxiety. 19 Nicotine not only harms the adolescent brain, but is critical to the progression to regular smoking behavior, reinforcing a behavior that exposes smokers to the harmful chemicals responsible for tobacco-related death and disease. While ethical considerations limit the possibilities for research of VLNC on adolescents, a secondary analysis of data from the randomized controlled trial described earlier (Donny et al., 2015), found that young adults smoked fewer VLNC cigarettes per day than older adults after two weeks in the trial, suggesting that younger populations may be more sensitive and responsive to a nicotine reduction policy.<sup>20</sup>

#### C. Vulnerable Populations Will Benefit from a Nicotine Reduction Policy

As smoking rates have declined nationally, smoking has become increasingly concentrated among certain vulnerable populations. According to data from the 2012-2014

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Walker, N, et al., "The combined effect of very low nicotine content cigarettes, used as an adjunct to usual Quitine care (nicotine replacement therapy and behavioural support), on smoking cessation: a randomized controlled trial," *Addiction*, 107(10): 1857-1867, 2012.

HHS. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General, 2014; Institute of Medicine, Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products, Washington, DC: The National Academies Press, 2015.

Institute of Medicine, *Public Health Implications of Raising the Minimum Age of Legal Access to Tobacco Products*, Washington, DC: The National Academies Press, 2015.

England, LJ, et al., "Nicotine and the Developing Human: A Neglected Element in the Electronic Cigarette Debate." *American Journal of Preventive Medicine*, 2015; Goriounova NA, Mansvelder HD, "Short-and Long-Term Consequences of Nicotine Exposure During Adolescence for Prefrontal Cortex Neuronal Network Function," *Cold Spring Harbor Perspectives in Medicine*, 2012; Steinberg, Laurence, "Should the Science of Adolescent Brain Development Inform Public Policy?," Issues in Science and Technology, Volume XXVIII, Issue 3, Spring 2012.

Cassidy, RN, et al., "Age moderates smokers' subjective response to very low nicotine content cigarettes: evidence from a randomized controlled trial," *Nicotine & Tobacco Research*, published online April 28, 2018.

National Survey on Drug Use and Health (NSDUH), 33.3% of adults with any mental illness were current (past month) smokers, compared to 20.7% of adults without any mental illness. <sup>21</sup> Further, about three out of ten smokers (29.5%) have a mental illness. <sup>22</sup> Additional national data from the National Health Information Survey (NHIS) of adults ages 18 and over find that 35.8 percent of adults with serious psychological distress are current smokers, compared to 14.7 percent of adults without serious psychological distress. <sup>23</sup>

It is important to ensure that a nicotine reduction policy would not exacerbate existing disparities by causing negative side effects for those with affective disorders. Fortunately, the evidence to date indicates that these populations do in fact benefit from VLNC cigarettes. A secondary analysis of data from the randomized controlled trial described earlier (Donny et al., 2015) found that smokers with elevated depressive symptoms at baseline who were assigned to smoke VLNC cigarettes did in fact show lower smoking rates and nicotine dependence, without worsening depressive symptoms. <sup>24</sup> Preliminary *ad libitum* smoking session studies have also found that VLNC cigarettes do not affect psychiatric symptoms in schizophrenic patients and result in a reduction in cigarette craving, total puff volume, and nicotine withdrawal symptoms. <sup>25</sup> VLNC cigarettes also have reduced addiction potential in other vulnerable populations, including smokers with opioid dependence and socioeconomically disadvantaged women, without substantial impact on withdrawal, craving, or compensatory smoking. <sup>26</sup>

## II. A Nicotine Content Standard Should Apply to Other Combustible Tobacco Products (ANPRM Section A, Scope, Question 1)

To realize the potential public health benefits of a nicotine product standard, FDA must extend that standard beyond cigarettes, to other combustible tobacco products, particularly those that serve as or might serve as substitutes for cigarettes, such as roll-your-own tobacco (RYO)

behavioral, or emotional disorder, excluding developmental and substance use disorders, in the past 12 months" and defines current smoking as "smoking all or part of a cigarette within the 30 days preceding the interview."

Lipari, R.N. and Van Horn, S.L. "Smoking and mental illngess among adults in the United States." *The CBHSQ Report:* March 30, 2017. Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, Rockville, MD, https://www.samhsa.gov/data/sites/default/files/report 2738/ShortReport-2738.html.

CDC, "Vital Signs: Current Cigarette Smoking Among Adults Aged ≥18 Years with Mental Illness— United States, 2009-2011," MMWR, 62(5): 81-87, 2013. NSDUH defines any mental illness as "having a mental, behavioral or emotional disorder, excluding developmental and substance use disorders in the past 12 months" a

<sup>&</sup>lt;sup>23</sup> CDC, "Current Cigarette Smoking Among Adults – United States, 2016," *MMWR* 67(2):53-59, January 19, 2018. Serious psychological distress defined by the Kessler psychological distress scale. Across all age groups, current cigarette smoking increased significantly for each of the four categories of psychological distress (no, low, moderate, high).

Tidey, JW, et al., "Effects of 6-week use of reduced-nicotine content cigarettes in smokers with and without elevated depressive symptoms," *Nicotine & Tobacco Research*, 19(1): 59-67, 2017.

Tidey, JW, et al., "Smoking topography characteristics of very low nicotine contenet cigarettes, with and without nicotine replacement, in smokers with schizophrenia and controls," *Nicotine & Tobacco Research*, 18(9): 1807-1812, 2016. Tidey, JW, et al., "Separate and combined effects of very low nicotine cigarettes and nicotine replacement in smokers with schizophrenia and controls," *Nicotine & Tobacco Research*, 15(1): 121-129, 2013.

Higgins, ST, et al., "Addiction potential of cigarettes with reduced nicotine in populations with psychiatric disorders and other vulnerabilities to tobacco addiction," *JAMA Psychiatry*, 74(1): 1056-1064, 2017

and smaller cigars. As FDA noted in the ANPRM (at 11825), other combusted tobacco products have similar negative health effects to cigarettes and cigarette smokers may switch to these products if the nicotine reduction standard is only applied to cigarettes. Extending the proposed nicotine reduction policy to other combustible tobacco products will limit the possibility that cigarette smokers will switch to other dangerous combustible products. Furthermore, extending the nicotine standard to these products, which are often flavored and popular among youth, will prevent youth experimenters from becoming addicted to these and other tobacco products. It will also prevent tobacco manufacturers from circumventing a nicotine content standard in cigarettes by marketing and developing non-cigarette substitutes like the small flavored cigars the industry introduced after flavored cigarettes were removed from the market.

#### A. The Tobacco Industry Manipulates Loopholes in Product Regulation

History shows that the tobacco industry is adept in manipulating loopholes in tobacco control regulations. Tobacco companies have skillfully modified their products to circumvent regulation and minimize the effectiveness of policies designed to reduce tobacco use. For example, in the 1960s and 1970s, "little cigars" that look like cigarettes were developed to avoid the ban on broadcast advertising of cigarettes and higher cigarette taxes. <sup>27</sup>

More recently, manufacturers have modified their products to be classified as cigars rather than cigarettes to evade the TCA's prohibition of characterizing flavors in cigarettes and the use of misleading cigarette descriptors such as "light" and "low." The 2012 Surgeon General's report, *Preventing Tobacco Use Among Youth and Young Adults*, noted that flavored cigarettes such as Sweet Dreams re-emerged as Sweet Dreams flavored cigars after the federal restriction on flavored cigarettes went into effect. In October 2009, U.S. Representatives Henry Waxman and Bart Stupak sent letters to two flavored cigarette companies, Cheyenne International and Kretek International, that began making little cigars shortly after the federal flavored cigarette ban went into effect. Rep. Waxman discovered that Kretek International

Delnevo, CD & Hrywna, M, "A Whole 'Nother Smoke' or a Cigarette in Disguise: How RJ Reynolds Reframed the Image of Little Cigars," *American Journal of Public Health* 97(8):1368-75, August 2007.

Delnevo, CD, et al., "Close, but no cigar: certain cigars are pseudo-cigarettes designed to evade regulation," *Tobacco Control* 26(3):349-354, May 2017. Delnevo, CD & Hrywna, M, "Clove cigar sales following the US flavoured cigarette ban," *Tobacco Control* 24(e4):e246-50, December 2015.

See generally, Campaign for Tobacco-Free Kids, *Not Your Grandfather's Cigar: A New Generation of Cheap and Sweet Cigars Threatens a New Generation of Kids*, March 13, 2013, at 14-15 (*Not Your Grandfather's Cigar*),

http://www.tobaccofreekids.org/content/what\_we\_do/industry\_watch/cigar\_report/2013CigarReport\_Full.pdf.

HHS, Preventing Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012, http://www.cdc.gov/Features/YouthTobaccoUse/.

House Committee on Energy & Commerce, "Energy and Commerce Committee Requests Information on Sales and Marketing of Flavored Tobacco Products," October 2, 2009, accessed April 18, 2012 at <a href="http://democrats.energycommerce.house.gov/index.php?q=news/energy-and-commerce-committee-requests-information-on-sales-and-marketing-of-flavored-tobacco-p">http://democrats.energycommerce.house.gov/index.php?q=news/energy-and-commerce-committee-requests-information-on-sales-and-marketing-of-flavored-tobacco-p</a>.

intentionally changed its cigarettes to cigars to exploit a loophole in the TCA. <sup>32</sup> In December 2016, the FDA issued warning letters to four tobacco manufacturers – Swisher International, Inc., Cheyenne International LLC, Prime Time International Co. and Southern Cross Tobacco Company Inc. – for marketing and selling fruit-flavored cigarettes labeled as cigars, in violation of the Tobacco Control Act. <sup>33</sup>

Tobacco companies have also added weight to filters to allow for reclassification of their cigarettes or "little cigars" as "large cigars" subject to lower federal excise taxes. <sup>34</sup> Moreover, tobacco companies intentionally designed and marketed little cigars as similar products to cigarettes to appeal to cigarette smokers. <sup>35</sup>

FDA recognized reclassification as a potential problem in its Final Regulatory Impact Analysis of the final deeming rule when it stated, "Deeming all tobacco products, except accessories of a newly deemed tobacco product, to be subject to chapter IX of the FD&C Act would be the necessary first step to rectify an institutional failure in which tobacco products that are close substitutes are not regulated by FDA in a like manner. ...Historically, when products have been taxed or regulated differently, substitutions have occurred."<sup>36</sup>

There is little doubt that tobacco companies will promote cigars and potentially other combustible tobacco products as alternatives to cigarettes if the nicotine policy does not address other forms of combustible tobacco. Failure to extend the prohibition to other combusted tobacco products would greatly limit the chances for the regulation to accomplish its goal.

Representative Henry A. Waxman, "Rep. Waxman Urges FDA to Ban Clove-Flavored Cigars," Letter to FDA Commissioner Margaret Hamburg, March 28, 2011, accessed April 18, 2012 at <a href="http://democrats.energycommerce.house.gov/index.php?q=news/rep-waxman-urges-fda-to-ban-clove-flavored-cigars">http://democrats.energycommerce.house.gov/index.php?q=news/rep-waxman-urges-fda-to-ban-clove-flavored-cigars</a>.

FDA, Center for Tobacco Products, "FDA takes action against four tobacco manufacturers for illegal sales of flavored cigarettes labeled as little cigars or cigars," December 9, 2016, <a href="http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532563.htm">http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm532563.htm</a>.

Delnevo, CD, et al., "Close, but no cigar: certain cigars are pseudo-cigarettes designed to evade regulation," *Tobacco Control* 26(3):349-354, May 2017. Campaign for Tobacco-Free Kids, *Not Your Grandfather's Cigar: A New Generation of Cheap and Sweet Cigars Threatens a New Generation of Kids*, March 13, 2013, at 14-15 (*Not Your Grandfather's Cigar*),

http://www.tobaccofreekids.org/content/what\_we\_do/industry\_watch/cigar\_report/2013CigarReport\_Full.pdf at 15.

Delnevo, CD, et al., "Close, but no cigar: certain cigars are pseudo-cigarettes designed to evade regulation," *Tobacco Control* 26(3):349-354, May 2017.

FDA, Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations Restricting the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Product Packages and Advertisements, Final Regulatory Impact Analysis; Final Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, May 2016, at 60-61.

https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf.

### B. Cigars Are a Harmful and Addictive Substitute for Cigarettes

There is no rational basis for reducing nicotine levels in cigarettes, while leaving cigars highly addictive. Cigars pose an increased risk of disease and addiction. Cigar smoke contains many of the same harmful constituents as cigarette smoke and may have higher levels of several harmful compounds. Cigar smoking causes cancer of the oral cavity, larynx, esophagus and lung and some cigar smokers are at increased risk for heart disease, chronic obstructive pulmonary disease (COPD) and an aortic aneurysm.<sup>37</sup>

Furthermore, cigars contain nicotine and can deliver nicotine at levels high enough to produce dependence among cigar smokers.<sup>38</sup> Nicotine content is not always associated with the size of the cigar. A study found that some cigarillos had higher levels of free nicotine per mass compared to large cigars, leading the authors to state, "consumers smoking the same brand of cigar may unintentionally be exposed to varying doses of nicotine and potentially other smoke constituents."<sup>39</sup>

Nicotine levels in cigars vary by product and the type of tobacco used. One full-size cigar may contain as much tobacco as a whole pack of cigarettes and thus contains much more nicotine than one cigarette. Cigarettes contain an average of about 10-15 mg of nicotine; 40 many popular brands of larger cigars contain between 100 and 200 mg. 41

The amount of nicotine delivered to the cigar smoker depends on various factors, such as how the cigar is smoked, the number of puffs taken, and the degree of inhalation. <sup>42</sup> The high pH of cigar smoke means that the nicotine is in its free, unprotonated form, making it easily

National Cancer Institute (NCI), *Cigars: Health Effects and Trends. Smoking and Tobacco Control Monograph No. 9*, 1998, <a href="http://cancercontrol.cancer.gov/Brp/tcrb/monographs/9/m9\_complete.pdf">http://cancercontrol.cancer.gov/Brp/tcrb/monographs/9/m9\_complete.pdf</a>.

Henningfield, JE, et al., "Nicotine concentration, smoke pH and whole tobacco aqueous pH of some cigar brands and types popular in the United States," *Nicotine & Tobacco Research* 1(2):163-168, 1999, at 166. NCI Monograph 9, at 186, 191. Baker, F, et al., "Health Risks Associated With Cigar Smoking," *Journal of the American Medical Association* 284(6):735-740, 2000, at 737. Fabian, LA, et al., "*Ad lib* Smoking of Black & Mild Cigarillos and Cigarettes," *Nicotine & Tobacco Research* 14(3):368-371, March 2012, at 370. Goel, R, et al., "A Survey of Nicotine Yields in Small Cigar Smoke: Influence of Cigar Design and Smoking Regimens," *Nicotine & Tobacco Research*, published online September 15, 2017. Pickworth, WB, et al., "Dual Use of Cigarettes, Little Cigars, Cigarillos, and Large Cigars: Smoking Topography and Toxicant Exposure," *Tobacco Regulatory Science* 3(Suppl 1):S72-S83, April 2017, at S79. Claus, ED, "Use Behaviors, Dependence, and Nicotine Exposure Associated with Ad Libitum Cigar Smoking," *Tobacco Regulatory Science* 4(1):548-561, 2018, at 558.

Koszowski, B, et al., "Nicotine Content and Physical Properties of Large Cigars and Cigarillos in the United States," *Nicotine & Tobacco Research* 20(3):393-398, 2018, at 395, 397.

American Cancer Society, "Is Any Type of Smoking Safe?" March 6, 2018, <a href="https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/is-any-type-of-smoking-safe.html">https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/is-any-type-of-smoking-safe.html</a>.

Benowitz, N and Henningfield, J., "Reducig the nicotine content to make cigarettes less addictive," Tobacco Control, 22:i14-i17, 2013.

American Cancer Society, "Is Any Type of Smoking Safe?" March 6, 2018, https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/is-any-type-of-smoking-safe.html.

Henningfield, JE, et al., "Nicotine concentration, smoke pH and whole tobacco aqueous pH of some cigar brands and types popular in the United States," *Nicotine & Tobacco Research* 1(2):163-168, 1999, at 165. NCI Monograph 9, at 186.

absorbed through the oral mucosa, even if the users do not fully inhale the smoke.<sup>43</sup> A leading review of the science of cigar smoking concluded that, "[c]igars are capable of providing high levels of nicotine at a sufficiently rapid rate to produce clear physiological and psychological effects that lead to dependence, even if the smoke is not inhaled."<sup>44</sup>

Authors of a recent study looking at a variety of cigar products noted, "it is clear that all cigar products delivered significant and addictive quantities of nicotine and CO – findings that support the rationale for their regulation."

Exempting cigars from a reduced nicotine standard is likely to lead current cigarette smokers to switch to cigars or use both cigarettes and cigars to satisfy their need for nicotine. It is not uncommon for cigarette smokers to replace cigarettes with cigars. According to 2013-2014 data from the Population Assessment of Tobacco and Health (PATH) study, nearly 30 percent of premium cigars smokers were former cigarette smokers, as were 10 to 15 percent of non-premium cigar users (non-premium large cigars, cigarillos, filtered cigars). The 2012-2013 National Adult Tobacco Survey (NATS) found similar results - 23 percent of premium cigar smokers, 15.3 percent of cigarillo/mass market cigar smokers, and 12.3 percent of little filtered cigar smokers were former cigarette smokers.

Secondary cigar smokers, those who smoked cigarettes before smoking cigars, often inhale and smoke more than cigar smokers who have never used cigarettes (primary cigar smokers). <sup>49</sup> Because of their tendency to inhale the smoke, secondary cigar smokers can take in

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NCI Monograph 9, at ii, 4, 11, 97, 183, 191.

Baker, F., et al., "Health Risks Associated With Cigar Smoking," *Journal of the American Medical Association*, 284(6): 735-740, 2000, at 737.

Pickworth, WB, et al., "Dual Use of Cigarettes, Little Cigars, Cigarillos, and Large Cigars: Smoking Topography and Toxicant Exposure," *Tobacco Regulatory Science* 3(Suppl 1):S72-S83, April 2017, at S79.

Corey, CG, et al., "U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-14," *Nicotine & Tobacco Research*, published online September 15, 2017. Cohn, A, et al., "The Other Combustible Products: Prevalence and Correlates of Little Cigar/Cigarillo Use Among Cigarette Smokers," *Nicotine & Tobacco Research* 17(12):1473-1481, 2015.

Corey, CG, et al., "U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-14," *Nicotine & Tobacco Research*, published online September 15, 2017.

Corey, CG, et al., "Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults — United States, 2012-2013," *MMWR* 63(30):650-654, August 1, 2014, at 652, 653. The study authors defined premium cigar smokers as "those reporting their usual cigar did not have a filter or tip and the name of their usual brand was a brand name of a hand-rolled cigar or a cigar described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder, or wrapper."

Claus, ED, "Use Behaviors, Dependence, and Nicotine Exposure Associated with Ad Libitum Cigar Smoking," *Tobacco Regulatory Science* 4(1):548-561, 2018. Rosenberry, ZR, Pickworth, WB, & Koszowski, B, "Large Cigars: Smoking Topography and Toxicant Exposure," *Nicotine & Tobacco Research* 20(2):183-191, 2018, at 189.

more nicotine compared to primary cigar smokers.<sup>50</sup> They also show higher scores of nicotine dependence than primary cigar smokers.<sup>51</sup>

PATH data from 2013-2014 show that a fair number of cigar smokers also smoke cigarettes (dual use): nearly 30 percent (29.9%) of premium cigar users and more than half of users of other cigar products (non-premium large cigars, cigarillos, filtered cigars) were also current cigarette smokers. <sup>52</sup> The 2012-2013 NATS reported similar results, with 35.1 percent of premium cigar smokers, 58.3 percent of cigarillo/mass market cigar smokers, and 75.2 percent of little filtered cigar smokers dual using with cigarettes. <sup>53</sup> Cigarette use in the past 30 days can predict current cigar use. <sup>54</sup>

Like secondary cigar smokers, dual users tend to inhale cigar smoke, compared to cigar smokers who never smoked cigarettes. <sup>55</sup> Dual users smoke cigars in such a way as to obtain a satisfactory level of nicotine, <sup>56</sup> but they also show greater levels of dependence than exclusive cigar users. <sup>57</sup> Adolescents who ever used cigars products (cigars, cigarillos, or little cigars) or used them in the past 30 days reported more frequent cigarette smoking in the past month, more daily smoking in the past month, and, notably, higher levels of nicotine dependence compared to adolescents who did not use cigar products. <sup>58</sup>

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NCI Monograph 9, at 94.

Claus, ED, "Use Behaviors, Dependence, and Nicotine Exposure Associated with Ad Libitum Cigar Smoking," *Tobacco Regulatory Science* 4(1):548-561, 2018.

Corey, CG, et al., "U.S. adult cigar smoking patterns, purchasing behaviors, and reasons for use according to cigar type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-14," *Nicotine & Tobacco Research*, published online September 15, 2017.

Corey, CG, et al., "Little Filtered Cigar, Cigarillo, and Premium Cigar Smoking Among Adults — United States, 2012-2013," *MMWR* 63(30):650-654, August 1, 2014, at 652, 653. The study authors defined premium cigar smokers as "those reporting their usual cigar did not have a filter or tip and the name of their usual brand was a brand name of a hand-rolled cigar or a cigar described by the manufacturer or merchant as containing high-grade tobaccos in the filler, binder, or wrapper."

Cullen, J, et al., "Seven-Year Patterns in US Cigar Use Epidemiology Among Young Adults Aged 18–25 Years: A Focus on Race/Ethnicity and Brand," *American Journal of Public Health* 101(10):1955-62, October 2011, at 1958-1959.

Baker, F, et al., "Health Risks Associated With Cigar Smoking," *Journal of the American Medical Association* 284(6):735-740, 2000, at 737. NCI Monograph 9, at 185.

Pickworth, WB, et al., "Dual Use of Cigarettes, Little Cigars, Cigarillos, and Large Cigars: Smoking Topography and Toxicant Exposure," *Tobacco Regulatory Science* 3(Suppl 1):S72-S83, April 2017, at 7. Rosenberry, ZR, Pickworth, WB, & Koszowski, B, "Large Cigars: Smoking Topography and Toxicant Exposure," *Nicotine & Tobacco Research* 20(2):183-191, 2018, at 189.

Rostron, BL, Schroeder, MJ, & Ambrose, BK, "Dependence symptoms and cessation intentions among US adult daily cigarette, cigar, and e-cigarette users, 2012-2013," *BMC Public Health* 16:814, 2016.

Schuster, RM, Hertel, AW, & Mermelstein, R, "Cigar, Cigarillo, and Little Cigar Use Among Current Cigarette-Smoking Adolescents," *Nicotine & Tobacco Research* 15(5):925-931, May 2013, at 927-928.

### C. Hookah (Waterpipe) Tobacco is Harmful and Addictive (<u>ANPRM Section A</u>, <u>Question 4</u>)

In a typical waterpipe session, smokers are subjected to up to more than twice the nicotine exposure as the smoker of a single cigarette. <sup>59</sup> Research shows that waterpipe tobacco use is associated with nicotine dependence, including experiences of withdrawal and difficulty quitting, at least among some users. <sup>60</sup> Given its addiction potential, waterpipe tobacco should not be excluded from a nicotine product standard.

Studies have shown that hookah smoke contains many of the toxins and carcinogens found in cigarettes. Some of these harmful components are in gaseous form and others are particulates. At least 82 toxicants and carcinogens have been identified in waterpipe tobacco smoke, including tobacco-specific nitrosamines (TSNAs), polycyclic aromatic hydrocarbons (PAHs), and heavy metals. In addition, the aerosol contains the toxins and carcinogens from the burning of the charcoal, including carbon monoxide. A recently published meta-analysis that analyzed 17 studies of waterpipe tobacco smoking found that a single waterpipe tobacco smoking session was associated with carbon monoxide exposure equivalent to more than half a pack of cigarettes and exposure to tar equivalent to more than two full packs of cigarettes. None of these harmful components are eliminated by the passage of the smoke through the water and many of these harmful substances are delivered to the user's lungs.

According to the CDC, using a waterpipe to smoke tobacco poses serious health risks to smokers and others exposed to the smoke from the waterpipe tobacco. <sup>64</sup> Waterpipe tobacco use is linked to many of the same adverse health effects as cigarette smoking, such as lung, bladder and oral cancers and heart disease. <sup>65</sup> Other documented long-term effects include impaired

Letters, 205(3): 279-284, 2011. Jacob, P., et al. "Nicotine, Carbon Monoxide and Carcinogen Exposure After a Single Use of a Water Pipe," Cancer Epidemiology, Biomarkers, & Prevention, 20: 2345-2353, 2011.

Primack B, et al. 2016. HHS, *Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General*, 2012. Eissenberg, T and Shihadeh, A., 2009. Maziak, W, et al., "CO exposure, puff topography, and subjective effects in waterpipe tobacco smokers," *Nicotine & Tobacco Research*, 11(7): 806-811, 2006.

Aboaziza, E and Eissenberg, T., "Waterpipe tobacco smoking: what is the evidence that it supports nicotine/tobacco dependence?" *Tobacco Control*, published online December 9, 2014.

HHS, Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012.
Ward, KD, et al., "The waterpipe: an emerging epidemic in need of action," Tobacco Control, 24(S1): i1i2, 2015. Sepetdijian, E, et al., "Measurement of 16 Polycyclic Aromatic Hydrocarbons in Narghile Waterpipe
Tobacco Smoke," Food and Chemical Toxicology, 46: 1582-1590, 2008. Schubert, J., et al., "Mainstream Smoke of the Waterpipe: Does this Environmental Matrix Reveal as Significant Source of Toxic Compounds?" Toxicology

Primack B, et al. Systematic review and meta-analysis of inhaled toxicants from waterpipe and cigarette smoking. *Public Health Reports* Jan. 2016. See also, HHS, Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012. Eissenberg, T and Shihadeh, A. "Waterpipe tobacco and cigarette smoking: direct comparison of toxicant exposure," *American Journal of Preventive Medicine*, 37(6): 518-523, 2009. Maziak, W, et al., "CO exposure, puff topography, and subjective effects in waterpipe tobacco smokers," *Nicotine & Tobacco Research*, 11(7): 806-811.

Centers for Disease Control and Prevention. "Hookahs." Available at <a href="http://www.cdc.gov/tobacco/data\_statistics/fact\_sheets/tobacco\_industry/hookahs/">http://www.cdc.gov/tobacco/data\_statistics/fact\_sheets/tobacco\_industry/hookahs/</a>. Accessed March 4, 2016.

HHS, Prevention Tobacco Use Among Youth and Young Adults, A Report of the Surgeon General, 2012. Knishkowy B, Amitai, Y. "Waterpipe (narghile) smoking: an emerging health risk behavior," Pediatrics 2005.

pulmonary function, chronic obstructive pulmonary disease, esophageal cancer and gastric cancer. 66 As a result of exposure to the dangerous chemicals in waterpipe tobacco smoke, research shows that even short-term waterpipe tobacco use is associated with acute health effects, including increased heart rate, blood pressure, reduced pulmonary function and carbon monoxide intoxication.<sup>67</sup> In a 2015 report, the World Health Organization Study group on tobacco product regulation surveyed the research to date and corroborated these findings.<sup>68</sup>

#### The rule should prohibit other changes in cigarettes that might counteract D. the effect of the reduction in nicotine. (ANPRM Section B, Question 3)

FDA notes that in addition to nicotine, other substances contained in cigarettes might also have the potential to produce dependence and be addictive and asks whether a proposed rule should establish maximum levels for such substances. It is important for FDA to establish a rule that prohibits any change in products subject to the rule that has the effect of diluting or offsetting the effect produced by the reduction in nicotine. Section 910 of the Tobacco Control Act prohibits tobacco product manufacturers from modifying tobacco products in the absence of a marketing order from FDA. Any product standard establishing a maximum level of nicotine in tobacco products should explicitly prohibit manufacturers from making other changes in a tobacco product with the effect of diluting or offsetting the reduction in dependence produced by reducing the nicotine content of such product.

#### III. **Implementation Considerations**

#### Maximum Nicotine Level (ANPRM Section B, Question 1) A.

When establishing a nicotine reduction level, FDA should seek a level that reduces the population harm caused by smoking. FDA should seek a level that prevents new users from developing dependence and stops the transition from experimental to regular use. The level should also reduce dependence among current users and make it easier for them to stop smoking. Because of variations in sensitivity to nicotine and the risk of dependence across individuals, to minimize the risk of dependence on a population-wide basis, FDA should set the maximum allowable nicotine at a level that produces the greatest reduction in dependence. To date, the research indicates that a nicotine content of 0.4 mg/g or less reduces dependence, taking into account the potential for individual differences in sensitivity to nicotine, and is technically feasible. 69 It is critical that there be no compromise in setting the nicotine level because a higher

El-Zaatari, ZM, et al., "Health effects associated with waterpipe smoking," Tobacco Control, 24(S1): i31i43, 2015.

Id.

World Health Organization, Study Group on Tobacco Product Regulation ("TobReg"), 2015.

Donny, EC, et al., "Randomized trial of reduced-nicotine standards for cigarettes," New England Journal of Medicine, 373: 1340-1349, 2015

nicotine level will not produce the benefits set forth by FDA and is not supported by the scientific evidence that underpins the FDA proposal.

### B. An Immediate Nicotine Content Reduction Will Have a Larger Public Health Impact than a Gradual Reduction (ANPRM Section C)

Research shows that an immediate nicotine content reduction will have a greater public health benefit than a gradual reduction in nicotine content. A 20-week randomized controlled trial of 1200 adult smokers assigned smokers to normal nicotine content cigarettes, reduced nicotine content cigarettes (0.4 mg/g), or cigarettes with the nicotine content gradually reduced over the course of the study (from 15.8 mg/g to 0.4 mg/g). The smokers in the immediate nicotine reduction condition showed greater reduction in cigarettes per day, greater decreases in measures of dependence, higher rates and duration of abstinence, and greater reductions in biomarkers of smoke exposure.<sup>70</sup>

As the FDA noted in the ANPRM (at 11829), a stepped-down approach will likely facilitate more compensatory behavior by smokers. While VLNC cigarettes do not contain enough nicotine for compensation to be feasible, smokers may be able to compensate with intermediate-level nicotine cigarettes, smoking these products more intensely and exposing themselves to more toxicants.

Additionally, a stepped-down approach prolongs the implementation process and is more burdensome on farmers and manufacturers who will have to adjust to multiple nicotine content standards. Finally, this prolonged process increases the opportunities for consumers to stockpile cigarettes.

Given the stronger evidence for cessation for an immediate reduction approach and the greater implementation challenges of a stepped-down approach, it is clear that an immediate reduction in nicotine content is preferable.

### C. Reducing the Nicotine Content of Combustibles Will Not Lead to Compensation (ANPRM Section F, Question 4)

One potential concern about reducing the nicotine level in cigarettes is that smokers may smoke more cigarettes or inhale smoke more deeply in order to obtain the nicotine fix they are accustomed to ("compensatory smoking"), which would have the unintended consequence of exposing them to even more harmful constituents. However, research to date shows that smokers in fact do not compensate in this manner when nicotine content is reduced to very low levels.<sup>71</sup>

See e.g., Donny, EC, et al., "Randomized trial of reduced-nicotine standards for cigarettes," *New England Journal of Medicine*, 373: 1340-1349, 2015. Hatsukami, DK, et al., "Compensatory smoking from gradual and

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Hatsukami, D. Opening Session: Presidential Symposium Reducing Nicotine Content in Cigarettes: A Discussion of the Evidence and Policy Implications Panel Discussion. Society for Research on Nicotine and Tobacco Annual Meeting, 2018.

One study that examined the number of cigarettes smoked per day (CPD), carbon monoxide exposure and cotinine levels among smokers while they smoked reduced nicotine content cigarettes, found significant decreases in CPD and cotinine levels and a decrease (non-significant) in carbon monoxide exposure compared to when they smoked their usual brand, which suggests minimal, if any, compensatory smoking. Similarly, a randomized clinical trial that compared outcomes from reduced nicotine cigarettes to standard nicotine cigarettes found that smokers of reduced nicotine cigarettes inhaled less smoke per cigarette, smoked fewer cigarettes and did not have a significant increase in the level of expired carbon monoxide, indicating that smokers did not compensate for the reduction in nicotine by increasing their smoking behavior. Substantially reducing nicotine in the tobacco makes it almost impossible for smokers to compensate for the lower nicotine level by smoking more cigarettes, taking more puffs on the cigarette, or inhaling more deeply.

### D. FDA Must Counter Misperceptions about the Harms of Reduced Nicotine Products (ANPRM Section, B Question 4)

Reducing the nicotine content of tobacco products will not render them harmless; in fact, products with lower nicotine levels will remain harmful and deadly. While nicotine is the primary addictive agent in cigarettes and is not benign, the overwhelming health consequences of smoking come from the more than 7,000 chemicals and 69 cancer-causing agents produced from combusted cigarettes.<sup>74</sup>

Some studies of adult smokers have shown that they perceive lower nicotine cigarettes to be less harmful than average cigarettes, incorrectly linking nicotine content with risk for smoking-related disease. For example, a 2015-2016 nationally representative survey found that nearly half (47.1%) of smokers thought that smoking VLNC cigarettes would be less likely to cause cancer than smoking regular cigarettes. <sup>75</sup> 2015 data from the FDA's nationally representative Health Information National Trends Survey (HINTS) found that three-quarters of people either did not know the relationship between nicotine and cancer (24%) or incorrectly believe that nicotine causes cancer (49%). It also found that 30 percent of respondents thought

immediate reduction in cigarette nicotine content," *Cancer Epidemiology, Biomarkers & Prevention*, 24: 472-476, 2015. Benowitz, NL, et al., "Smoking behavior and exposure to tobacco toxicants during 6 months of smoking progressively reduced nicotine content cigarettes," *Cancer Epidemiology, Biomarkers & Prevention*, 21: 761-769, 2012. Hatsukami, DK, et al., "Nicotine reduction revisited: science and future directions," *Tobacco Control*, 19: e1-10, 2010. Hatsukami, DK, et al., "Reduced nicotine content cigarettes: effects on toxicant exposure, dependence and cessation," *Addiction*, 105: 343-355, 2010.

Hatsukami, DK, et al., "Compensatory smoking from gradual and immediate reduction in cigarette nicotine content," *Cancer Epidemiology, Biomarkers & Prevention*, 24: 472-476, 2015.

Donny, EC, et al., "Randomized trial of reduced-nicotine standards for cigarettes," *New England Journal of Medicine*, 373: 1340-1349, 2015.

HHS, *The Health Consequences of Smoking—50 Years of Progress*, *A Report of the Surgeon General*, 2014, http://www.surgeongeneral.gov/library/reports/50-years-of-progress/.

Byron, JM, et al., "Public misperception that very low nicotine cigarettes are less carcinogenic," *Tobacco Control*, published online January 23, 2018.

that VLNC were less harmful than regular cigarettes. <sup>76</sup> In research trials, smokers assigned to use VLNC cigarettes also perceive them to be less harmful. <sup>77</sup>

It is critical for the FDA to carefully regulate the marketing of these products, and precede a nicotine reduction policy with public education campaigns to ensure adequate communication about the health risks of these products so as to not encourage non-smokers to experiment. Smokers should be encouraged to quit completely and be educated about the most effective ways to quit successfully.

While much of the public misunderstanding of the health effects of nicotine is to attribute undue heath risk to nicotine, FDA also needs to be careful not to go too far in the other direction. While the most prominent concern about nicotine is its addictive impact, and approved nicotine replacement therapy (NRT) products have demonstrated that at low levels in carefully calibrated doses, nicotine is not the cause of serious disease, nicotine is not benign and the health impact of its long term use at higher levels is not well understood.

#### IV. Technical Achievability

# A. Reducing Nicotine in Cigarettes is Technologically Feasible ( $\underbrace{ANPRM\ Section}$ $\underline{E}$ )

Research demonstrates that reducing nicotine content in cigarettes to minimally or non-addictive levels is technologically feasible. Further, as noted in the ANPRM (at 11830-11832), there is a wide range of techniques available to reduce nicotine content. As FDA notes, more than 96 percent of nicotine can be successfully extracted while achieving a product that was "subjectively rated as average in smoking characteristics." Moreover, the FDA's discussion in the ANPRM identifies several chemical extraction techniques that have been used successfully to reduce the nicotine level in cigarette tobacco (ANPRM, at 11831.)

Tobacco farmers and cigarette manufacturers can reduce the nicotine content of cigarette tobacco by using existing lower-nicotine tobacco plant varieties, creating new plant varieties through genetic manipulation, using tobacco leaves from certain parts of the plant that contain

Denlinger-Apte, RL, et al., "Low nicotine content descriptors reduce perceived health risks and positive cigarette ratings in participants using very low nicotine content cigarettes," *Nicotine & Tobacco Research*, published online January 18, 2017. Pacek, LR, et al., "Perceived nicotine content of reduced nicotine content cigarettes is a correlate of perceived health risks," *Tobacco Control*, published online July 22, 2017. 2017.

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<sup>&</sup>lt;sup>76</sup> O'Brien, EK, et al., "U.S. adults' addiction and harm beliefs about nicotine and low nicotine cigarettes," *Preventive Medicine*, 96: 94-100, 2017.

<sup>83</sup> Fed. Reg. at 11826, citing Grubbs et al, "Process for Removal of Basic Materials," Patent No. 5,018,540, May 28, 1991.

lower nicotine content, or using extraction technology to remove nicotine from tobacco during the manufacturing process.<sup>79</sup>

In fact, tobacco companies have already demonstrated their proficiency in reducing the nicotine level of cigarettes. <sup>80</sup> In the 1980s-1990s, Philip Morris produced three brands of low-nicotine cigarettes: Merit De-Nic, Benson & Hedges De-Nic and Next. Vector Tobacco introduced Quest, a low-nicotine cigarette, in 2003. The tobacco manufacturer, 22<sup>nd</sup> Century, currently produces Spectrum, a very low nicotine U.S.-grown tobacco cigarette, which is currently used in government-funded clinical research studies. Reducing nicotine content in cigarettes to minimally or non-addictive levels is also consistent with several tobacco companies' purported missions of shifting away from combustible tobacco products by "transforming tobacco" (R.J. Reynolds)<sup>81</sup> and investing in a "smoke-free future" (Philip Morris). <sup>82</sup>

The tobacco industry's own documents also show that the industry has a long history of manipulating nicotine levels in cigarettes to make them *more* addictive. Internal company documents from as far back as the 1950s expose the tobacco industry's extensive research on the importance of nicotine and how best to deliver nicotine to smokers and optimize its effects. <sup>83</sup> The documents demonstrate that they have known for decades that the key to their business is creating and sustaining dependence on nicotine, and they have purposely designed their products to do this effectively and efficiently. As U.S. District Judge Gladys Kessler concluded in her landmark 2006 civil racketeering judgment against the major cigarette manufacturers, U.S. v. Philip Morris, Inc.,

"... [C]igarette company defendants researched, developed, and implemented many different methods and processes to control the delivery and absorption of the optimum amount of nicotine which would create and sustain smokers' addiction. These methods and processes included, but were not limited to: altering the physical and chemical make-up of tobacco leaf blends and filler; maintaining or increasing the nicotine to tar ratio by changing filter design, ventilation and air dilution processes, and the porosity and composition of filter paper; altering smoke pH by adding ammonia to speed nicotine absorption by the central nervous system; and using other additives to increase the potency of nicotine."<sup>84</sup>

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Tengs, T.O., et al., "The AMA proposal to mandate nicotine reduction in cigarettes: a simulation of the population health impacts," *Preventive Medicine*, 40: 170-180, 2005.

Cigarettes with reduced nicotine are often referred to as reduced-nicotine cigarettes, very low nicotine content (VLNC) cigarettes, and de-nicotinized cigarettes.

RJ Reynolds, "Our vision: We will achieve market leadership by transforming the tobacco industry," accessed August 8, 2017, http://www.rjrt.com/transforming-tobacco/our-mission-and-vision/.

Philip Morris, "Our Manifesto: Designing a Smoke-Free Future," Accessed August 8, 2017, https://www.pmi.com/who-we-are/designing-a-smoke-free-future.

Wayne, GF & Carpenter, CM, "Tobacco Industry Manipulation of Nicotine Dosing," *Handbook of Experimental Psychology* (192):457-85, 2009.

U.S. v. Philip Morris, USA, Inc., 449 F. Supp. 2d at 383-84 (D.D.C. 2006).

Finally, producing reduced-nicotine tobacco for other combusted tobacco products should be no more difficult than producing it for cigarettes.

### B. FDA Should Make the Effective Date of the Rule as Early as Possible. (ANPRM Section E, Question 5)

The enormous public health benefits that would result from this rule should not be postponed any longer than absolutely necessary. Postponing the effective date of the rule only means that many hundreds of thousands of smokers and prospective smokers will unnecessarily have their lives shortened by an addiction that this rule could have prevented.

As indicated above, tobacco product manufacturers are already capable of extracting nicotine from tobacco and producing VLNC cigarettes. Growing low-nicotine tobacco is only one of several methods of complying with the standard. Thus, a tobacco product standard calling for a nicotine level to be set at non-addictive levels does not necessarily require "substantial changes to the methods of farming domestically grown tobacco;" thus, the statute does not require FDA to postpone the effective date of such a standard until two years after promulgation of the rule. Moreover, industry participants will have been on notice for a significant period of time that such a requirement would be imposed and prudent companies would have been making plans to comply with such a standard. Therefore, in no event should the implementation period be more than the one-year period contemplated for all product standards under Section 907 of the Tobacco Control Act.

Tobacco product manufacturers will no doubt make self-serving claims about how difficult, expensive, and time-consuming it would be to implement such a standard. FDA should view such claims skeptically given the clear economic interest the industry has in resisting or postponing measures designed to shrink the market for a highly profitable product. The public health benefits that will be gained from implementing the rule, however, make it imperative to make the rule effective as soon as possible. These benefits far outweigh the compliance costs the industry will experience.

It is also important for the rule to be applied simultaneously to all manufacturers. The continued availability of combusted products containing conventional levels of nicotine would undermine the effectiveness of the regulatory strategy and would create an opportunity for exempted manufacturers to earn windfall profits by continuing to supply high-nicotine level cigarettes. Manufacturers should not be enabled to undercut the effectiveness of important public health initiatives merely because they are small.

### C. Manufacturers, Distributors, and Retailers Should Not Be Allowed to Sell Off Existing Nonconforming Inventories. (ANPRM Section E, Question 6)

Products currently on the market are both deadly and highly addictive. The public health imperatives that provide the foundations for replacing these products with VLNC cigarettes are inconsistent with permitting the continued sale of non-conforming inventories beyond the effective date of the rule. The presence of non-conforming product on the market after the effective date of the rule will only dilute the effectiveness of the rule and provide a wholly unjustified windfall to companies that have stockpiled an inventory in anticipation of its promulgation. Moreover, there is no unfairness to industry participants in prohibiting the sale of such inventories after the effective date of the rule. As noted above, all industry participants will have had a substantial period of prior notice of the promulgation of such a rule and will have had many opportunities to make arrangements to deal with the consequences.

In addition, permitting industry participants to sell off existing non-conforming inventories would create a massive incentive for companies to accumulate large inventories in the anticipation that they would be able to extract windfall profits from the sale of such products after the rule becomes effective.

Moreover, it is unlikely that any industry participants will be left with substantial inventories of nonconforming products. Current smokers are likely to buy up any available inventories of such products prior to the effective date of the rule. Thus, permitting industry participants at any level to sell off existing nonconforming inventories is not only contrary to the policies that underlie adoption of the rule, but is also wholly unnecessary to address any legitimate interest that a seller of tobacco products might have.

## D. FDA Should Require a Standard Method of Product Testing to Analyze Nicotine Levels. (ANPRM, Section D, Question 6)

FDA asks whether, if it issues a product standard, it should require a standard method of product testing to analyze the nicotine levels in products subject to the standard. Adoption of a standard method of product testing would be helpful to ensure that all products are subject to the same standard and that the standard is actually being adhered to. FDA correctly observes that, "it is critical that the results from the test method used demonstrate a high level of specificity, accuracy, and precision in measuring a range of nicotine levels across a wide variety of tobacco blends and methods." In addition, FDA should require manufacturers to sample their products in a consistent manner to ensure that products do not contain excess levels of nicotine and to test each manufactured batch to ensure compliance.

<sup>85 83</sup> Fed. Reg. at 11820.

### V. Possible Countervailing Effects

A. The Product Standard Should Prohibit the Sale or Distribution of Liquid Nicotine or Any Other Tobacco Product Designed to Supplement the Nicotine Content of Combusted Tobacco Products. (<u>ANPRM Section F</u>, <u>Question 2</u>)

FDA should assess the extent to which it would be feasible for smokers to supplement the nicotine content of combusted tobacco products through the use of liquid nicotine or another tobacco product. If such supplementation is feasible in a substantial number of cases, FDA should include in the rule a prohibition on the sale or distribution of liquid nicotine or any other tobacco product designed to supplement the nicotine content of combusted tobacco products.

#### B. Illicit Trade (ANPRM Section F, Questions 3, 6, 7, 9)

These comments incorporate by reference the Comments filed by the undersigned organizations in Docket No. FDA-2018-N-0529, "Draft Concept Paper: Illicit Trade in Tobacco Products After Implementation of a Food and Drug Administration Product Standard," 83 Fed. Reg. 11754 (March 16, 2018).

#### VI. Other Considerations

A. The Potential Consumer Surplus or Utility Loss from the Removal of Nicotine from Combusted Tobacco Products is Minimal in Light of the Availability of Other Sources of Nicotine and the Continued Availability of Tobacco Products. (ANPRM, Section G, Question 2)

The measurement of consumer surplus or utility loss in the context of the regulation of an addictive product, such as cigarettes, has been the subject of considerable debate. In 2014, a group of distinguished health economists presented to the U.S. Department of Health and Human Services and subsequently published a proposed formulation for the measurement of such consumer surplus or utility loss in this context. <sup>86</sup> After citing the fact that the large majority of smokers started smoking before the legal purchase age, regret the fact that they had started smoking and become addicted, and wished they could quit, the paper concluded:

"Indeed, the data strongly suggest that many smokers do not find smoking pleasurable, and that they derive little consumer surplus from smoking. Instead, most are struggling with or avoiding the withdrawal they would experience if they were able to stop smoking

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Chaloupka FJ, et al., "An Evaluation of the FDA's Analysis of the Costs and Benefits of the Graphid Warning Label Regulation," *Tobacco Control*, 24:112-119, 2015.

and break an addiction they regret having ever started, facing psychological costs from being addicted and lacking the self-control to quit."87

Accordingly, the paper recommended that, "nearly all of the lost pleasure from tobacco use, as represented by conventionally measured consumer surplus, should not be included as a cost in FDA analysis of the economic impact of its tobacco regulations." To the extent that measurement of consumer surplus or utility loss is required in the evaluation of regulations involving tobacco products, the undersigned organizations urge FDA to adopt the methods described in that paper.

In this case, there are further reasons why consumer surplus or utility loss, to the extent the concepts are relevant at all, would be minimal. If it is true that smokers smoke in order to obtain nicotine (an underlying premise of a nicotine products standard), to the extent that nicotine will remain available to them in other forms, either through appropriately regulated ecigarettes, NRT products, or otherwise, means that the "pleasure" of receiving nicotine is not being denied to them. To the extent that these product satisfy the need for nicotine, there is no "lost pleasure." Moreover, to the extent that smokers can satisfy the need for nicotine at a far lower cost to their health indicates that individual smokers will realize a large net economic gain.

Moreover, cigarettes and other combusted tobacco products will remain available for sale. To the extent that smokers derive pleasure from smoking apart from satisfying their need for nicotine, they will continue to be able to purchase cigarettes and other combusted products. Having access to both nicotine and combusted tobacco products, it is questionable whether smokers will experience any loss of consumer surplus, even assuming that such surplus is generated by smoking.

# B. FDA Should Consider Externalities, Such as the Reduction in Secondhand Smoke, in Evaluating the Consequences of the Rule (<u>ANPRM Section G</u>, <u>Question 6</u>)

If, as expected, a product standard reducing the level of nicotine in cigarettes and other combusted products substantially reduces the number of cigarettes and other combusted tobacco products smoked, there will be a corresponding reduction in environmental tobacco smoke and in the death and disease resulting from non-smokers' exposure to such smoke. FDA estimates that from 2005 to 2009, an estimated 7,330 lung cancer and 33,950 heart disease deaths were attributable to secondhand smoke and that secondhand tobacco smoke causes premature death and disease in children and adults who do not smoke. <sup>89</sup> It is apparent that a reduction in environmental tobacco smoke would reduce the burden of death and disease for non-smokers and provide a substantial public health benefit. Any analysis of the effects of such a rule should

Id.

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*Id.* 

<sup>89 83</sup> Fed. Reg. at 11825.

consider the benefits to non-smokers that would result through a reduction in death and disease attributable to environmental tobacco smoke.

#### C. Post-market Surveillance is Critical

Critical to the success of a nicotine reduction policy is a rigorous and comprehensive post-market surveillance and product-testing program to monitor for any unintended tobacco use patterns and to identify any changes in product design that may limit the effectiveness of reduced nicotine content.

#### Respectfully submitted,

Action on Smoking and Health
American Academy of Family Physicians
American Academy of Oral and
Maxillofacial Pathology

Maxillofacial Pathology
American Association for Dental Research
American Association for Respiratory Care
American Cancer Society Cancer Action
Network

American College of Cardiology American College of Physicians

American College of Preventive Medicine

American Heart Association American Lung Association American Medical Association

American Medical Student Association

American Psychological Association

American Public Health Association

American School Health Association

American Society of Addiction Medicine

American Society of Clinical Oncology Americans for Nonsmokers' Rights

Association of State and Territorial Health

Officials

Big Cities Health Coalition

Campaign for Tobacco-Free Kids

Community Anti-Drug Coalitions of

America

**Counter Tools** 

Eta Sigma Gamma - National Health

**Education Honorary** 

Mesothelioma Applied Research Foundation

National Association of County and City

Health Officials

National Hispanic Medical Association

National Network of Public Health Institutes

**Oncology Nursing Society** 

Oral Health America

**Prevention Institute** 

Public Health Law Center | Tobacco Control

Legal Consortium

**Public Health Solutions** 

Society for Cardiovascular Angiography and

Interventions

Society for Public Health Education

Students Against Destructive Decisions

The Society for State Leaders of Health and

**Physical Education** 

Trust for America's Health

Truth Initiative



July 16, 2018

Scott Gottlieb, MD Commissioner U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Re: Docket No. FDA-2017-N-6189; APRM; Tobacco Product Standard for Nicotine Level of Certain Tobacco Products

#### Dear Commissioner Gottlieb:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Food and Drug Administration's (FDA) advance notice of proposed rulemaking (APRM) titled, "Tobacco Product Standard for Nicotine Level of Combusted Cigarettes," as referenced above.

Tobacco use is the leading preventable cause of death in the United States. The AMA applauds the FDA's decision to gather information regarding the development and implementation of a regulation that would reduce nicotine levels in cigarettes to non-addictive levels. This step toward reducing the addictive power of cigarettes is in line with AMA policy, which has for years encouraged the FDA and other appropriate agencies to study how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and other additives that enhance addictiveness.

The AMA has joined other medical and public health organizations in submitting comments in this docket (see letter submitted by the Campaign for Tobacco-Free Kids, American Cancer Society Cancer Action Network, American Heart Association, and American Lung Association). These comments outline the public health impact of reducing nicotine in combustible tobacco products, application of the nicotine standard to other combustible tobacco products, implementation considerations, technical achievability, possible countervailing effects, as well as other considerations. In addition to those comments, the AMA believes the scope of the APRM should be expanded to cover all tobacco products.

The AMA calls on the FDA to create a non-addictive nicotine level standard for all tobacco products, not just cigarettes. This includes smokeless tobacco, electronic nicotine delivery systems (ENDS), "heat not burn products," and any other tobacco products containing nicotine for recreational use. Cigarettes are not the only addictive form of tobacco, and applying this standard across all tobacco products is essential to combating the leading cause of preventable death. If FDA reduces nicotine content in combustible tobacco products without already having a regulatory strategy in place that appropriately addresses ENDS, it will miss a critical opportunity to reduce overall nicotine addiction and use of tobacco products. Comprehensive and specific regulations are necessary to prevent new products that may circumvent the nicotine level requirement.

The AMA acknowledges that all tobacco products (including, but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco) are harmful to health. Furthermore, the use of ENDS is not harmless and increases youth risk of using combustible tobacco cigarettes. We recognize that the use of products containing nicotine in any form among youth, including ENDS, is unsafe and can cause addiction.

In summary, we greatly appreciate the FDA's effort to develop a product standard for a maximum nicotine level for cigarettes, and urge the FDA to extend this rulemaking to all tobacco products, including noncombustible products like ENDS. We thank you for your consideration of these comments, and look forward to a final rule that prioritizes the health of the public. If we may provide further assistance, please contact Margaret Garikes, Vice President, Federal Affairs at 202-789-7409 or <a href="margaret.garikes@ama-assn.org">margaret.garikes@ama-assn.org</a>.

Sincerely,

James L. Madara, MD

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#### REPORT 4 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-19)

Vector-borne Diseases (Resolution 430-A-18, first and second Resolves) (Reference Committee D)

#### **EXECUTIVE SUMMARY**

<u>Background</u>. This report responds to Resolution 430-A-18, "Vector-borne Diseases" introduced by the American Academy of Dermatology along with 24 state and national medical specialty societies, and referred by the House of Delegates. This resolution asked the AMA to study the emerging epidemic of vector-borne diseases.

Methods. English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from January 2014 to January 2019 using the search terms "vector-borne disease," "tick-borne disease," "mosquito-borne disease," "Lyme disease," "post treatment Lyme disease," "chronic Lyme disease," "West Nile virus," and "Zika virus." Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by federal, state, and local agencies and applicable national public health, entomology, and mosquito control organizations also were reviewed for relevant information.

Results. In the United States, nearly 650,000 cases of vector-borne diseases (VBD) were reported from 2004–2016. Reported cases of tick-borne disease (TBD) doubled in the 13-year analysis period. TBDs account for more than 75 percent of VBDs reports throughout the continental United States and Lyme disease accounts for the majority (82 percent) of cumulative reported TBD. West Nile Virus was the most commonly transmitted mosquito-borne disease (MBD) in the continental United States from 2004-2016. Epidemics of dengue, chikungunya, and Zika viruses were mostly confined to the U.S. territories. This report focuses broadly on the prevention of VBDs, followed by specific discussions on the diagnosis and treatment of the most prevalent TBDs and MBDs – Lyme disease and West Nile Virus (WNV), respectively.

Conclusion. VBDs are a growing health threat in the United States and one that climate change is expected to exacerbate. The most common VBDs in the United States are Lyme disease, Rocky Mountain spotted fever, WNV, dengue, and Zika virus disease. From a public health perspective, to effectively reduce transmission and respond to VBD outbreaks, improvements in surveillance, reporting, and adequate vector control will be necessary, but as a nation we currently have limited capacity to respond to vector-borne diseases. With approximately 80 percent of our nation's vector control organizations lacking critical prevention and control capacities, sustained investment in improving these capabilities is needed as are investments in our public health infrastructure and workforce.

For health professionals to adequately care for patients infected with VBDs, clinical research is needed to improve their diagnosis and treatment. Educating health professionals and the public about existing and emerging VBDs will be critical to addressing both prevention and treatment efforts. Lyme disease should be an area of focus in these efforts since it is the most common VBD in the United States. Furthermore, with there being only one nationally notifiable VBD with an FDA approved vaccine available, vaccine development for VBDs should be prioritized. To accomplish these goals, additional and sustained funding for VBDs will be necessary.

#### REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 4-A-19

Subject: Vector-borne Diseases

(Resolution 430-A-18, first and second Resolves)

Presented by: Robyn F. Chatman, MD, MPH, Chair

Referred to: Reference Committee D

(Diana Ramos, MD, MPH, Chair)

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The first and second resolves of Resolution 430-A-18, introduced by the American Academy of Dermatology along with 24 state and national medical specialty societies, and referred by the House of Delegates asks:

That our American Medical Association (AMA) study the emerging epidemic of vector-borne diseases including an analysis of currently available testing and treatment standards and their effectiveness, and issue a white paper on vector-borne diseases (VBD) for the purpose of increasing awareness of the epidemic of vector-borne diseases.

#### **METHODS**

English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from January 2014 to January 2019 using the search terms "vector-borne disease," "tick-borne disease," "mosquito-borne disease," "Lyme disease," "post treatment Lyme disease," "chronic Lyme disease," "West Nile virus," and "Zika virus." Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by federal, state, and local agencies and applicable national public health, entomology, and mosquito control organizations also were reviewed for relevant information.

#### **CURRENT AMA POLICY**

Existing AMA policy on VBD urges the AMA to support educating the medical community on the potential adverse public health effects, including VBDs, of global climate change. Policy also calls on the AMA to advocate for local, state and national research, education, reporting, and tracking on VBDs. Our policy on zoonotic diseases asks the AMA to collaborate with the American Veterinary Medical Association and other stakeholders to take the lead in establishing a robust, coordinated, and effective global surveillance system of zoonotic diseases in humans and syndromic outbreaks in animals. In terms of policy on specific VBDs, existing policy addresses Zika virus by calling for funding and the development of strategies to limit the spread and impact of the virus as well as approaches to minimize the transmission to potentially pregnant women.

#### BACKGROUND

- Vectors are blood-feeding insects and ticks capable of transmitting pathogens between hosts. Wide varieties of pathogens have evolved to exploit vector transmission, including some viruses,
- bacteria, rickettsia, protozoa, and helminths. Mosquitos, ticks, and fleas are the most common

vectors in the United States. Diseases from mosquito and tick bites occur in every U.S. state and territory.<sup>2</sup> The growing incidence of Lyme disease and recent outbreaks of Zika virus and chikungunya points to the need for comprehensive VBD programs and for increased awareness of these diseases by clinicians and patients. Climate change creates additional concern about the spread of VBDs as changing temperatures may expand the geographic range of disease-carrying insects.

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#### **EPIDEMIOLOGY**

VBDs are a major cause of death and illness worldwide. Every year, VBDs such as malaria, dengue, and yellow fever, account for more than 700,000 deaths globally.<sup>3</sup> The burden of these diseases is highest in tropical and subtropical areas and they disproportionately affect poor populations.<sup>3</sup> In the United States, 16 VBDs are reportable to state and territorial health departments and the National Notifiable Disease Surveillance System. The most common VBDs in the United States are Lyme disease, Rocky Mountain spotted fever, West Nile virus (WNV), dengue, and Zika virus disease.<sup>2</sup> Malaria and yellow fever are no longer transmitted in the United States, but are monitored because they have potential to re-emerge. As a group, VBDs in the United States are notable for their wide distribution and resistance to control.<sup>1</sup> Yellow fever is the only nationally notifiable VBD for which there is an FDA-approved vaccine available.<sup>2</sup>

In the United States, nearly 650,000 cases of VBD were reported from 2004–2016. Reported cases of tick-borne disease (TBD) doubled in the 13-year analysis period. TBDs account for more than 75 percent of VBDs reports throughout the continental United States and Lyme disease accounts for the majority (82 percent) of cumulative reported TBD. In addition to Lyme disease, other common illnesses caused by ticks are Rocky Mountain spotted fever, babesiosis, ehrlichiosis, anaplasmosis, tularemia, Colorado tick fever, tick-borne relapsing fever, and Powassan disease. While TBDs are prevalent throughout the country, they are predominately found along the northeastern coast, in the upper Midwest, and along the Pacific coast.

 WNV was the most commonly transmitted mosquito-borne disease (MBD) in the continental United States from 2004-2016, with the largest outbreak occurring in 2012. Epidemics of dengue, chikungunya, and Zika viruses were mostly confined to the U.S. territories. Travelers infected in the territories and Latin America accounted for more than 90 percent of the dengue, chikungunya, and Zika virus cases identified in the continental United States. Limited local transmission of dengue occurred in Florida, Hawaii, and Texas, and of chikungunya and Zika viruses in Texas and Florida. Malaria was diagnosed in approximately 1,500 travelers yearly, but no local transmission was documented from 2004–2016.

Given the broad range of VBDs, CSAPH decided to focus the scope of this report broadly on the prevention of VBDs, followed by specific discussions on the most prevalent TBDs and MBDs – Lyme disease and WNV, respectively.

#### PREVENTION OF VBDs

Vector Control Programs

Vector control programs vary by jurisdiction. These responsibilities may fall to the local health department, mosquito control district, or a variety of other local agencies (public works, streets and sanitation, parks and recreation, or other environmental health services). The result is differing capabilities across the country. The Centers for Disease Control and Prevention (CDC) has outlined core competencies for vector control programs. The competencies include: (1) routine mosquito

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surveillance through standardized trapping and species identification; (2) treatment decisions using surveillance data; (3) larviciding, adulticiding, or both; (4) routine vector control activities (i.e., chemical, biological, source reduction, or environmental management); and (5) pesticide resistance testing. There are five supplemental competencies, these include (1) licensed pesticide application; (2) vector control other than chemical control (i.e., biological, source reduction, or water management); (3) community outreach and education campaigns regarding mosquito-borne diseases, how they spread, and how to prevent infection; (4) regular communication with local health departments regarding surveillance and epidemiology; and (5) outreach (i.e., communication and/or cooperation).

A survey of vector control organizations in the United States (n=1,083) found that based on the CDC competencies, 34 percent of mosquito control districts perform all core competencies versus 6 percent and 7 percent of local health departments and other organizations, respectively.<sup>4</sup> Of the competencies that vector control programs ranked as "needs improvement," nearly all of them (98 percent) lacked the capability or capacity to perform pesticide resistance testing.<sup>4</sup> More than half also lack the ability to perform routine surveillance and species identification.<sup>4</sup>

Another approach to vector control that is being considered to prevent VBDs is the use of novel technologies. One example is the use of genetically engineered mosquitos to prevent the spread of Zika virus. Specifically, the male *Aedes aegypti* mosquitos are genetically engineered to express a gene that encodes a conditional or repressible lethality trait and a red fluorescent marker protein to aid in the identification of these mosquitoes. <sup>26</sup> If a female *Aedes* mosquito mates with a sterile male then it will have no offspring, reducing the next generation's population. <sup>26</sup> Repeated release of insects can reduce the insect population to very low levels. The Environmental Protection Agency (EPA) has been considering a pilot to determine the efficacy of these genetically engineered mosquitos in the Florida Keys.

#### Personal Protection from Vectors

For mosquitos, personal protection from vectors involves using an EPA-registered insect repellent with one of the following active ingredients: DEET, Picaridin, IR3535, oil of lemon eucalyptus or para-methane-diol, or 2-undecanone.<sup>5</sup> Individuals should also treat items such as boots, pants, socks, and tents with permethrin or purchase permethrin-treated clothing and gear.<sup>5</sup> Homes should also be mosquito-proofed by using screens on windows and doors and repairing holes in screens to keep mosquitos outside.<sup>5</sup> It is also recommended to use air conditioning when available and to eliminate standing water outside your home to keep mosquitos from laying eggs.<sup>5</sup> It is important to remember that vector-borne diseases affect the poor disproportionately. Overall, changes in living conditions in the United States have resulted in decreased local transmission of MBD such as yellow fever, malaria, and dengue.<sup>22</sup>

For ticks, the use of EPA-registered insect repellents and permethrin treating clothing and gear is also recommended. Individuals are encouraged to avoid contact with ticks by avoiding wooded and brushy areas with high grass and leaf litter, and walk in the center of trails. Once indoors, individuals should check their clothing and body for ticks after being outdoors. Showering within two hours of coming indoors has been shown to reduce the risk of Lyme disease as it may help wash off unattached ticks. If a tick is attached to the skin the key is to remove it as soon as possible by using fine-tipped tweezers to grasp the tick as close to the skin's surface as possible and pull upward. Testing of ticks for evidence of infection is not recommended.

#### DISCUSSION

Once an individual has been bit by an infected vector and/or suspects they may have been exposed to a VBDs, health care professionals may be consulted for diagnosis and treatment. The CDC has developed a reference manual for health care providers on tick-borne diseases in the United States that provides an overview of ticks and the infections they transmit. The manual also provides information on incubation periods, signs and symptoms, diagnosis, and treatment. A similar manual for MBDs and other VBDs does not currently exist.

#### Lyme Disease

Lyme disease, the leading VBD in the United States, is caused by *Borrelia burgdorferi*, which is transmitted by the bite of the tick species *Ixodes scapularis* and *Ixodes pacificus*. In 2017, a total of 42,743 confirmed and probable cases of Lyme disease were reported to CDC, nearly 9 percent more than the previous year. The geographic distribution of Lyme disease appears to be expanding. The number of counties with an incidence of  $\geq$ 10 confirmed cases per 100,000 persons increased from 324 in 2008 to 454 in 2017.

Signs and Symptoms. The majority (70 to 80 percent) of patients with Lyme disease develop the characteristic skin lesion, erythema migrans (EM). The rash begins at the site of the tick bite and expands. It sometimes has a target or "bull's-eye" appearance. Other early signs include flu like symptoms – fever, chills, headache, fatigue, muscle and joint aches, and swollen lymph nodes. Longer-term symptoms include severe headaches and neck stiffness, additional EM rashes, arthritis, facial palsy, Lyme carditis, nerve pain, and inflammation of the brain and spinal cord. Recurrent large-joint arthritis signals late disseminated disease (more than six months post bite). Late neurologic Lyme disease signaled by peripheral neuropathy, encephalopathy, or encephalomyelitis is uncommon in the United States.

<u>Diagnosis</u>. There are 3 stages of *B. burgdorferi* infection: early localized, early disseminated, and late disseminated. Patients with an EM lesion and epidemiologic risk can receive a Lyme diagnosis without laboratory testing. However, for all other patients, laboratory testing is necessary to confirm the diagnosis. 10

 Serological assays that detect antibodies against *B.burgdorferi* are the only lab test cleared by FDA and recommended by CDC for diagnosis of Lyme disease. A two-step process is used to diagnose Lyme disease (See Figure 1.) The first required test is the Enzyme Immunoassay (EIA) or Immunofluorescence Assay (IFA). If this test yields negative results, the provider should consider an alternative diagnosis; or in cases where the patient has had symptoms for less than or equal to 30 days, the provider may treat the patient and follow up with a convalescent serum. If the first test yields positive or equivocal results, two options are available: (1) If the patient has had symptoms for less than or equal to 30 days, an IgM Western Blot is performed; and (2) if the patient has had symptoms for more than 30 days, the IgG Western Blot is performed. The IgM should not be used if the patient has been sick for more than 30 days. The sensitivity of 2-tiered testing is low (30–40 percent) during early infection while the antibody response is developing. For disseminated Lyme disease, sensitivity is 70–100 percent. Specificity is high (>95 percent) during all stages of disease. <sup>10</sup>

Since serological tests measure a person's past or present immune response to infection, they can be negative during first several days to weeks of infection. This results in patients not being diagnosed with appropriate diseases or receiving proper treatment. Serologic tests also cannot distinguish active infection, past infection, or reinfection. In cases of reinfection, it may be helpful

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to conduct acute-phase and convalescent-phase serologic analysis to detect an increase in EIA titer or an increase in the number of antibody bands that might indicate active infection. <sup>10</sup> When determining whether to test for Lyme disease, clinicians must consider a patient's pretest probability as false-positive results can occur when tests are performed for patients with low pretest probability.<sup>10</sup>

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There have been recent proposals to change the recommended 2-tier algorithm for serologic testing for Lyme disease from the current standard to one in which a second-tier EIA would be used instead of a Western blot. 10,11 This approach would make the tests easier to perform, results would be available sooner, costs would be reduced, and it would eliminate the subjective element inherent in interpretation of Western blots. 11 Further research is needed. 10,11

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Treatment. Patients treated during the early stages of Lyme disease typically recover rapidly and have good outcomes. Treatment guidelines developed by the Infectious Diseases Society of America recommend that early localized disease be treated with oral antibiotics.<sup>23</sup> Doxycycline 100 mg orally twice daily for 10-21 days, or cefuroxime axetil 500 mg orally twice daily or amoxicillin 500 mg orally 3 times daily for 14–21 days, has been shown to be effective in resolving early Lyme disease and in preventing progression.<sup>23</sup> People with certain neurological or cardiac forms of illness may require intravenous treatment with antibiotics such as ceftriaxone or penicillin.<sup>23</sup>

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While most patients diagnosed with early acute Lyme disease who are treated with appropriate courses of antimicrobial therapy become symptom free, 10-20 percent of patients continue to experience symptoms that can persist for six months or longer. Post-treatment Lyme Disease (PTLD) or "chronic Lyme disease" commonly refers to the continuation of such symptoms as fatigue, myalgia, arthralgia, memory loss, and headache after antibiotic therapy for Lyme disease. Whether chronic disease is a legitimate clinical entity has become highly controversial. 12-15,23,30 The mechanism behind this persistence in some patients is unknown, but has been suggested to be due to preexisting damage from the inflammatory response to infection, from persistent low-level infection, or to an autoimmune response. 13 Trials examining the effect of repeated antibiotic treatment in PTLS have shown no significant sustained benefit. 13,23 The Infectious Diseases Society of America is currently in the process of updating their guidelines on Lyme disease, with a project publication date of Winter 2020.

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Costs. A comprehensive understanding of the full economic and societal costs of Lyme disease remains unknown. The total direct medical costs attributable to Lyme disease and PTLD are estimated to be somewhere between \$712 million - \$1.3 billion each year in the United States.<sup>28</sup>

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Vaccine, LYMErix<sup>TM</sup>, a noninfectious recombinant vaccine for Lyme disease, was available in the United States from 1998-2002.<sup>21</sup> The Food and Drug Administration approved vaccine, which reduced new infections in vaccinated adults by nearly 80 percent, was voluntarily withdrawn from the market because of media coverage, fears of vaccine side-effects, and declining sales.<sup>27</sup>

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West Nile Virus

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WNV is the leading cause of mosquito-borne disease in the continental United States. In 2018, 49 states and the District of Columbia reported WNV infections in people, birds, or mosquitoes. 2,544 cases of WNV in people were reported to CDC last year. 25 Of these, 1,594 (63 percent) were classified as neuroinvasive disease and 950 (37 percent) were classified as non-neuroinvasive

disease.<sup>25</sup> In 2018, 137 deaths were reported.<sup>25</sup> 49

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Signs and Symptoms. Most people infected with WNV do not develop any symptoms. 16 1 2 Approximately 1 in 5 people will develop a fever as well as headache, body aches, joint pains, 3 vomiting, diarrhea, or rash. <sup>16</sup> About 1 in 150 people who are infected develop a severe illness affecting the central nervous system such as encephalitis or meningitis. 16 Symptoms of severe 4 5 illness include high fever, headache, neck stiffness, stupor, disorientation, coma, tremors, 6 convulsions, muscle weakness, vision loss, numbness and paralysis. 16

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Diagnosis. Diagnosis of WNV is generally accomplished through laboratory testing of serum or cerebrospinal fluid (CSF) to detect WNV-specific IgM antibodies, which are usually detectable three to eight days after onset of illness and persist for 30 to 90 days. 16 Positive results obtained with these assays should be confirmed by neutralizing antibody testing of acute- and convalescentphase serum specimens at a state public health laboratory or CDC. WNV IgG antibodies generally are detected shortly after IgM antibodies and persist for many years. Therefore, the presence of IgG antibodies alone is only evidence of previous infection.<sup>16</sup>

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Viral cultures and tests to detect viral RNA (i.e., reverse transcriptase-polymerase chain reaction can be performed on serum, CSF, and tissue specimens that are collected early in the course of illness and, if results are positive, can confirm an infection. Immunohistochemistry can detect WNV antigen in formalin-fixed tissue. 16 Negative results of these tests do not rule out WNV infection.<sup>16</sup>

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Treatment. There is no specific treatment for WNV disease. Patients with severe meningeal symptoms may require pain control for headaches and antiemetic therapy and rehydration for associated nausea and vomiting. 16 Patients with encephalitis require close monitoring for the development of elevated intracranial pressure and seizures. <sup>16</sup> Patients with encephalitis or poliomyelitis should be monitored for inability to protect their airway. 16 Acute neuromuscular respiratory failure may develop rapidly and prolonged ventilatory support may be required.<sup>16</sup>

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Costs. Data suggests the total cumulative costs of reported WNV hospitalized case-patients during 1999–2012 were \$778 million, which is an average of approximately \$56 million per year.<sup>29</sup>

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Vaccines. There are no WNV vaccines licensed for use in humans.

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#### **EMERGING AND RE-EMERGING VBDs**

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Since 2004, the United States has seen an increasing number of new or re-emerging vector-borne pathogens. <sup>1,20</sup> This includes previously unknown tick-borne RNA viruses, a tick-borne relapsing fever agent, and two tick-borne spotted fever species as well as the introduction of mosquito viruses, chikungunya and Zika, introduced in Puerto Rico in 2014 and 2015, respectively.<sup>1</sup>

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Zika virus disease

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- 43 Zika virus is a Flavivirus, which is transmitted to humans primarily through the bite of an infected Aedes species mosquito (Ae. aegypti and Ae. albopictus). <sup>17</sup> In 2015 and 2016, outbreaks of 44 45 Zika virus occurred in the Americas, resulting in travel-associated cases in the United States, widespread transmission in the U.S. territories, and limited local transmission in Florida and 46 Texas. 18 Zika virus infection during pregnancy has been demonstrated to cause birth defects such 47 as microcephaly and other severe brain defects. 18 From January 15 through December 27, 2016, a 48 total of 1,297 pregnancies with possible Zika virus infection were reported to the U.S. Zika
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- 50 Pregnancy Registry.<sup>24</sup> Birth defects were reported for 51 (5 percent) of the 972 completed

pregnancies with laboratory evidence of possible recent Zika virus infection.<sup>24</sup> Zika is the only arbovirus known to be transmitted sexually.

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Longhorned Tick (Haemaphysalis longicornis)

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Haemaphysalis longicornis is indigenous to eastern Asia and is an important vector of human and animal disease agents, including Rickettsia, Borrelia, Ehrlichia, Anaplasma, Theileria, and several important viral agents such as Heartland and Powassan viruses. 19 Haemaphysalis longicornis was discovered on a sheep in New Jersey in August 2017. From August 2017 through September 2018, vector and animal surveillance efforts resulted in 53 reports of *Haemaphysalis longicornis* in the United States, including 38 from animal species (23 from domestic animals, 13 from wildlife, and two from humans), and 15 from environmental sampling of grass or other vegetation. <sup>19</sup> Most of these reports have come from the eastern portion of United States. 19 No cases of illness in humans or other species have been reported to date.<sup>19</sup>

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#### **CONCLUSION**

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VBDs are a growing health threat in the United States and one that climate change is expected to exacerbate. The most common VBDs in the United States are Lyme disease, Rocky Mountain spotted fever, WNV, dengue, and Zika virus disease. From a public health perspective, to effectively reduce transmission and respond to VBD outbreaks, improvements in surveillance, reporting, and adequate vector control will be necessary, but as a nation we currently have limited capacity to respond to vector-borne diseases. With approximately 80 percent of our nation's vector control organizations lacking critical prevention and control capacities, sustained investment in improving these capabilities is needed as are investments in our public health infrastructure and workforce.

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For health professionals to adequately care for patients infected with VBDs, clinical research is needed to improve their diagnosis and treatment. Educating health professionals and the public about existing and emerging VBDs will be critical to addressing both prevention and treatment efforts. Lyme disease should be an area of focus in these efforts since it is the most common VBD in the United States. Furthermore, with there being only one nationally notifiable VBD with an FDA approved vaccine available, vaccine development for VBDs should be prioritized. To accomplish these goals, additional and sustained funding for VBDs will be necessary.

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#### RECOMMENDATIONS

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The Council recommends that the following statements be adopted in lieu of Resolution 403-A-18, and the remainder of the report be filed.

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1. That Policy H-440.820, "Vector-Borne Diseases," be amended by addition and deletion to read as follows:

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H-440.820 Vector-Borne Diseases

45 Due to the increasing threat and limited capacity to respond to vector-borne diseases, Our our AMA supports and will advocate for local, state and national research, education, reporting and 46 tracking on vector-borne diseases.

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(1) Improved surveillance for vector-borne diseases to better understand the geographic distribution of infectious vectors and where people are at risk;

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1		(2) The development and funding of comprehensive and coordinated vector-borne disease
2		prevention and control programs at the state and local level;
3		(3) <u>Investments that strengthen our nation's public health infrastructure and the public health</u>
4		workforce;
5		(4) Education and training for health care professionals and the public about the risk of vector-
6		borne diseases and prevention efforts as well as the dissemination of available information;
7		(5) Research to develop new vaccines, diagnostics, and treatments for existing and emerging
8		vector-borne diseases, including Lyme disease;
9		(6) Research to identify novel methods for controlling vectors and vector-borne diseases; and
10		(7) <u>Increased and sustained funding to address the growing burden of vector-borne diseases in</u>
11		the United States. (Modify Current HOD Policy)
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13	2.	That Policy H-135.938, "Global Climate Change and Human Health" and Policy, D-440.940,
14		"Global Tracking System of Zoonotic Diseases," be reaffirmed. (Reaffirm HOD Policy)

Less than \$500.

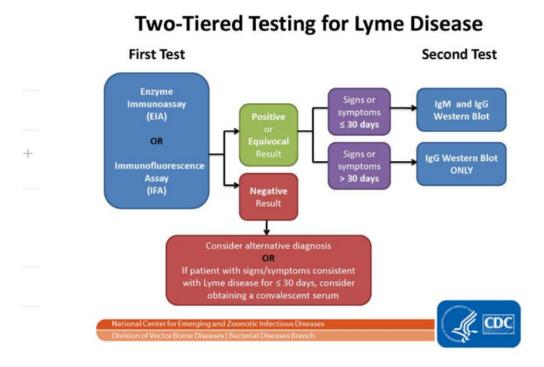
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Figure 1



Resolution: 401

(A-19)

Introduced by: Oregon

Subject: Support Pregnancy Intention Screenings to Improve the Discussion of

Pregnancy Intention, Promote Preventive Reproductive Health Care and Improve Community Health Outcomes by Helping Women Prepare for

Healthy Pregnancies and Prevent Unintended Pregnancies

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, Almost half (51%) of all pregnancies in the United States are unintended, which has significant physical and socio-economic consequences for women and their families, with a real cost in lives and public health; and

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Whereas, Rates of unintended pregnancies disproportionally impact women of color, women in poverty, and women with less education; and

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Whereas, Women with unintended pregnancies are unlikely to have taken folic acid before conceiving and are less likely to receive early prenatal care, thus increasing the risk of babies born with health challenges; and

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Whereas, Women need comprehensive information, services and referrals in order to have optimal health, healthy pregnancies, and the best possible birth outcomes; and

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Whereas, Providers want to use pregnancy intention screening as a routine and proactive intervention to address pregnancy intention with patients and have requested a consistent and efficient way to document care in their electronic health records; therefore be it

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RESOLVED, That our American Medical Association support the use of pregnancy intention screening, such as One Key Question<sup>®</sup>, PATH, or the Centers for Disease Control and

21 Prevention (CDC) reproductive life planning, as part of routine well care and recommend it be

built in electronic health records so that providers can document intention screening and

services provided based on a woman's response. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 03/04/19

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Committee on Health Care for Underserved Women, "Committee Opinion: Reproductive Life Planning to Reduce Unintended Pregnancy," *The American College of Obstetricians and Gynecologists* Number 654 (February 2016): 1. <a href="https://www.acog.org/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co654.pdf?dmc=1&ts=20160131T1016396951">https://www.acog.org/media/Committee-Opinions/Committee-on-Health-Care-for-Underserved-Women/co654.pdf?dmc=1&ts=20160131T1016396951</a>

Resolution: 402

(A-19)

Introduced by: Young Physicians Section

Subject: Bullying in the Practice of Medicine

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, Bullying and disrespectful behavior within the practice of medicine in the U.S. and overseas has been well demonstrated in prior studies, 2,4,6,7,9,12,16 and that perpetrators of bullying within medicine can be other physician colleagues, superior ranking colleagues in training, ancillary staff, and patients<sup>7,9,2</sup>; and

Whereas, "Bullying or aggressive behavior has been defined by criteria such as: intention to cause harm or distress, imbalance of power between the bully (perpetrator, aggressor) and the victim (target), and repeatability over time," and the British Medical Association defines bullying as "persistent behaviour against an individual that is intimidating, degrading, offensive or malicious and undermines the confidence and self-esteem of the recipient and

Whereas, Disrespectful behavior "encompasses a broad array of conduct, from aggressive outbursts to subtle patterns of disruptive behavior so embedded in our culture that they seem normal," and disrespectful behavior can also be considered "any behavior that influences the willingness of staff or patients to speak up or interact with an individual because he or she expects the encounter will be unpleasant or uncomfortable"; and

Whereas, A survey published in 2008 found in the United States "A total of 77% of the respondents reported that they had witnessed disruptive behavior in physicians at their hospitals" 13; and

Whereas, A 2013 survey from Institute for Safe Medication Practices exposed "healthcare's continued tolerance of and indifference to disrespectful behavior. Despite more than a decade of emphasis on safety, little improvement has been made"<sup>8</sup>; and

Whereas, One U.S. longitudinal survey of medical students published in 2006 demonstrated that "most medical students in the U.S. reported having been harassed or belittled during their training,"<sup>7</sup>; and

Whereas, Fnais et al in a 2014 meta-analysis found that "59.4% of medical trainees had experienced at least one form of harassment or discrimination during their training, with verbal harassment being the most commonly cited form of harassment"; and

Whereas, "Workplace bullying is associated with stress, depression, and intention to leave" and increased "absenteeism, career damage, poorer job performance, and lower productivity resulting in poorer quality of healthcare services and patient care"; and

Whereas, "Victims of bullying suffer from anxiety, loss of self-control, depression, lower self-confidence, occupational job stress, job dissatisfaction, dissatisfaction with life, burnout

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syndrome, musculoskeletal complaints, increased risk of cardiovascular disease, suicide attempts, and drug abuse"<sup>2</sup> and disrespectful behaviors "have been linked to adverse events, medical errors, compromises in patient safety, and even patient mortality"<sup>2,8</sup>; and

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Whereas, The Joint Commission in 2008 issued an alert "warning that offensive and hostile behavior among healthcare professionals not only makes for an unpleasant working environment but can also pose a considerable threat to patient safety" and

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Whereas, Creswall et al describe how British medical schools are integrating curricula to teach students how to differentiate undermining and destructive bullying behavior from constructive and supportive firm supervision, and how take action against bullying<sup>3</sup> and positive teaching methods have been recommended within medical education,<sup>12,16</sup> and formal procedures to safely, accurately, and freely report bullying are needed in order to protect bullying victims and address the issue<sup>2,9</sup>; therefore be it

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- 16 RESOLVED, That our American Medical Association help establish a clear definition of
- 17 professional bullying, establish prevalence and impact of professional bullying, and establish
- 18 guidelines for prevention of professional bullying with a report back at the 2020 Annual Meeting.
- 19 (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000.

Received: 04/04/19

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#### **RELEVANT AMA POLICY**

#### **Teacher-Learner Relationship In Medical Education H-295.955**

The AMA recommends that each medical education institution have a widely disseminated policy that: (1) sets forth the expected standards of behavior of the teacher and the learner; (2) delineates procedures for dealing with breaches of that standard, including: (a) avenues for complaints, (b) procedures for investigation, (c) protection and confidentiality, (d) sanctions; and (3) outlines a mechanism for prevention and education. The AMA urges all medical education programs to regard the following Code of Behavior as a guide in developing standards of behavior for both teachers and learners in their own institutions, with appropriate provisions for grievance procedures, investigative methods, and maintenance of confidentiality.

## **CODE OF BEHAVIOR**

The teacher-learner relationship should be based on mutual trust, respect, and responsibility. This relationship should be carried out in a professional manner, in a learning environment that places strong focus on education, high quality patient care, and ethical conduct.

A number of factors place demand on medical school faculty to devote a greater proportion of their time to revenue-generating activity. Greater severity of illness among inpatients also places heavy demands on residents and fellows. In the face of sometimes conflicting demands on their time, educators must work to preserve the priority of education and place appropriate emphasis on the critical role of teacher. In the teacher-learner relationship, each party has certain legitimate expectations of the other. For example, the learner can expect that the teacher will provide instruction, guidance, inspiration, and leadership in learning. The teacher expects the learner to make an appropriate professional investment of energy and intellect to acquire the knowledge and skills necessary to become an effective physician. Both parties can expect the other to prepare appropriately for the educational interaction and to discharge their responsibilities in the educational relationship with unfailing honesty.

Certain behaviors are inherently destructive to the teacher-learner relationship. Behaviors such as violence, sexual harassment, inappropriate discrimination based on personal characteristics must never be tolerated. Other behavior can also be inappropriate if the effect interferes with professional development. Behavior patterns such as making habitual demeaning or derogatory remarks, belittling comments or destructive criticism fall into this category. On the behavioral level, abuse may be operationally defined as behavior by medical school faculty, residents, or students which is consensually disapproved by society and by the academic community as either exploitive or punishing. Examples of inappropriate behavior are: physical punishment or physical threats; sexual harassment; discrimination based on race, religion, ethnicity, sex, age, sexual orientation, gender identity, and physical disabilities; repeated episodes of psychological punishment of a student by a particular superior (e.g., public humiliation, threats and intimidation, removal of privileges); grading used to punish a student rather than to evaluate objective performance; assigning tasks for punishment rather than educational purposes; requiring the performance of personal services; taking credit for another individual's work; intentional neglect or intentional lack of communication.

On the institutional level, abuse may be defined as policies, regulations, or procedures that are socially disapproved as a violation of individuals' rights. Examples of institutional abuse are: policies, regulations, or procedures that are discriminatory based on race, religion, ethnicity, sex, age, sexual orientation, gender identity, and physical disabilities; and requiring individuals to perform unpleasant tasks that are entirely irrelevant to their education as physicians.

While criticism is part of the learning process, in order to be effective and constructive, it should be handled in a way to promote learning. Negative feedback is generally more useful when delivered in a private setting that fosters discussion and behavior modification. Feedback should focus on behavior rather than personal characteristics and should avoid pejorative labeling.

Because people's opinions will differ on whether specific behavior is acceptable, teaching programs should encourage discussion and exchange among teacher and learner to promote effective educational strategies. People in the teaching role (including faculty, residents, and students) need guidance to carry out their educational responsibilities effectively.

Medical schools are urged to develop innovative ways of preparing students for their roles as educators of other students as well as patients.

Citation: (BOT Rep. ZZ, I-90; Reaffirmed by CME Rep. 9, A-98; Reaffirmed: CME Rep. 2, I-99; Modified: BOT Rep. 11, A-07; Reaffirmed: CME Rep. 9, A-13

Resolution: 402 (A-19)

Page 4 of 4

## Violence and Abuse Prevention in the Health Care Workplace H-515.966

Our AMA encourages all health care facilities to: adopt policies to reduce and prevent all forms of workplace violence and abuse; develop a reporting tool that is easy for workers to find and complete; develop policies to assess and manage reported occurrences of workplace violence and abuse; make training courses on workplace violence prevention available to employees and consultants; and include physicians in safety and health committees.

Citation: Res. 424, I-98; Reaffirmation I-99; Reaffirmed: CSAPH Rep. 1, A-09; Modified: BOT Rep. 2, I-12; Reaffirmed in lieu of Res. 423, A-13; Modified: CSAPH Rep. 07, A-16

# **Reduction of Online Bullying H-515.959**

Our AMA urges social networking platforms to adopt Terms of Service that define and prohibit electronic aggression, which may include any type of harassment or bullying, including but not limited to that occurring through e-mail, chat room, instant messaging, website (including blogs) or text messaging. Citation: Res. 401, A-12

Resolution: 403

(A-19)

Introduced by: Young Physicians Section

Subject: White House Initiative on Asian Americans and Pacific Islanders

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, The Asian American and Pacific Islander (AAPI) community is the fastest-growing racial group in the country, growing from 46% from 2000-2010, and projected to double to over 47 million by 2060<sup>1</sup>; and

Whereas, There are approximately 18.9 million AAPIs and Native Hawaiians residing in the U.S., representing over 30 countries and ethnic groups that speak over 100 different languages and dialects<sup>1</sup>; and

Whereas, Some AAPI subgroups have staggering educational needs and health disparities that are often overlooked or masked by aggregated data; and

Whereas, According to the 2010 U.S. Census Bureau, 34% of Laotians, 38.5% of Cambodians, and 39.6% of Hmong adults do not have a high school diploma; and

Whereas, The 2006-2008 American Community Survey showed that 65.8% of Cambodian, 66.5% of Laotian, 63.2% of Hmong, and 51.1% of Vietnamese Americans have not attended college<sup>2</sup> and only 18.2% of Native Hawaiians have a bachelor's degree<sup>3</sup>; and

Whereas, There are differences in health outcomes among AAPIs when compared to other U.S. racial and ethnic groups, including:

- (1) Vietnamese women experience the highest incidence rate of invasive cervical cancer; however, cancer screening rates are dramatically lower among Vietnamese American women compared to women in other ethnic and racial subgroups, with one study reporting that 1 in 3 Vietnamese-American women had never had a Papanicolaou (Pap) smear.<sup>4</sup>
- (2) Native Hawaiians/Pacific Islanders are 2.4 times more likely to be diagnosed with diabetes, compared to non-Hispanic whites.<sup>5</sup>
- (3) Native Hawaiians/Pacific Islanders were 3 times more likely to be obese than the overall Asian American population in 2015.<sup>6</sup>
- (4) South Asians in the U.S. have higher hospitalization and mortality rates from atherosclerotic cardiovascular disease compared with other racial/ethnic minority groups, including a 2-fold higher prevalence of Type 2 Diabetes and a higher mortality from ischemic heart disease compared with non-Hispanic whites<sup>8</sup>; and

Whereas, President Bill Clinton signed Executive Order 13125 to establish the first White House Initiative on Asian Americans and Pacific Islanders "in order to improve the quality of life of Asian Americans and Pacific islanders through increased participation in federal programs where they may be underserved (e.g., health, human services, education, housing, labor, transportation and economic and community development)"<sup>13</sup>; and

Resolution: 403 (A-19)

Page 2 of 3

Whereas, President George W. Bush signed Executive Order 13216 to renew the Initiative and changed the title to "Increasing Opportunity and Improving Quality of Life of Asian Americans and Pacific Islanders," and moved the Initiative from the U.S. Department of Health and Human Services to the U.S. Department of Commerce to focus on economic development<sup>1</sup>; and

Whereas, President Barack Obama signed Executive Order 13515, re-establishing the Initiative and moving the Initiative from the Department of Commerce to the Department of Education<sup>1, 14</sup>; and

Whereas, President Donald Trump issued Executive Order 13811 to re-establish the President's Advisory Commission on AAPIs<sup>15</sup>; and

Whereas, According to the "Healthcare and Housing" section of the website on the White House Initiative on Asian Americans and Pacific Islanders<sup>16</sup>:

- (1) 21.4% of Pacific Islanders have low or very low food security, compared to 8.9% of the general population; and
- (2) One in 12 AAPIs are living with chronic hepatitis B, making up 50% of Americans with chronic hepatitis B; and
- (3) The tuberculosis rate for Native Hawaiians and Pacific Islanders is 18.2 per 100,000, compared with 0.6 per 100,000 in non-Hispanic Whites; and

Whereas, Previous iterations of the White House Initiative Asian Americans and Pacific Islanders have worked extensively on data disaggregation and published best practices on providing disaggregated AAPI data from federal surveys, including the needs to:

- (1) Conduct outreach activities with AAPI community organizations, advocates, and respected leaders;
- (2) Oversample the AAPI population to ensure adequate representation; and
- (3) Develop language assistance programs to account for limited English proficiency; and

Whereas, Our AMA has policy that "urges existing federal agencies, commissions and Asian American and Pacific Islander health organizations to study how to improve the collection, analysis and dissemination of public health data on Asian Americans and Pacific Islanders" but does not have any specific policy regarding disaggregation of AAPI data by subgroups; and

Whereas, President Obama stated in his executive order on the AAPI Initiative: "Some Asian American and Pacific Islanders, particularly new Americans and refugees, still face language barriers...And then there are the disparities that we don't even know about because our data collection methods still aren't up to par. Too often, Asian American and Pacific Islanders are all lumped into one category, so we don't have accurate numbers reflecting the challenges of each individual community. Smaller communities in particular can get lost, their needs and concerns buried in a spreadsheet<sup>17</sup>; therefore be it

RESOLVED, That our American Medical Association advocate for restoration of webpages on the Asian American and Pacific Islander (AAPI) initiative (similar to those from prior administrations) that specifically address disaggregation of health outcomes related to AAPI data (Directive to Take Action); and be it further

RESOLVED, That our AMA support the disaggregation of data regarding AAPIs in order to reveal the AAPI ethnic subgroup disparities that exist in health outcomes (Directive to Take Action); and be it further

Resolution: 403 (A-19)

Page 3 of 3

- 1 RESOLVED, That our AMA support the disaggregation of data regarding AAPIs in order to
- 2 reveal the AAPI ethnic subgroup disparities that exist in representation in medicine, including
- 3 but not limited to leadership positions in academic medicine (Directive to Take Action); and be it

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- 6 RESOLVED, That our AMA report back at the 2020 Annual Meeting on the issue of
- 7 disaggregation of data regarding AAPIs (and other ethnic subgroups) with regards to the ethnic
- 8 subgroup disparities that exist in health outcomes and representation in medicine, including
- 9 leadership positions in academic medicine. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 04/04/19

#### References:

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- "Southeast Asian American Achievement Gaps through Many Factors." Available at <a href="http://aapidata.com/blog/se-aa-achievement-gaps/">http://aapidata.com/blog/se-aa-achievement-gaps/</a>.
- 3. "Data and statistics on Native Hawaiian and Pacific Islanders." Available at https://sites.ed.gov/aapi/data-and-statistics/.
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- "Diabetes and Native Hawaiians/Pacific Islanders." Available at https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=78.
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- 7. Jin H, Pinheiro P, Xu J, Amei A. "Cancer incidence among Asian American populations in the United States, 2009-2011."
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- "Health Insurance Coverage and Access to Care Among Asian Americans and Pacific Islanders." Available at https://kaiserfamilyfoundation.files.wordpress.com/2013/01/health-insurance-coverage-and-access-to-care-among-asian-americans-and-pacific-islanders.pdf.
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- 11. "Health Problems of Korean Americans: Access to Health Care." Available at https://geriatrics.stanford.edu/ethnomed/korean/patterns/access.html.
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- 13. Executive Order 13125, "Increasing Participation of Asian Americans and Pacific Islanders in Federal Programs." Available at <a href="https://www.gpo.gov/fdsys/pkg/FR-1999-06-10/pdf/99-14901.pdf">https://www.gpo.gov/fdsys/pkg/FR-1999-06-10/pdf/99-14901.pdf</a>.
- 14. Executive Order 13515, "Increasing Participation of Asian Americans and Pacific Islanders in Federal Programs." Available at <a href="https://www.gpo.gov/fdsys/pkg/FR-2009-10-19/pdf/E9-25268.pdf">https://www.gpo.gov/fdsys/pkg/FR-2009-10-19/pdf/E9-25268.pdf</a>.
- 16. White House Initiative on Asian Americans and Pacific Islanders. Available at https://sites.ed.gov/aapi/healthcare-and-housing/.
- 17. Remarks by President Obama. Available at <a href="https://obamawhitehouse.archives.gov/the-press-office/remarks-president-aapi-initiative-executive-order-signing-and-diwali-event">https://obamawhitehouse.archives.gov/the-press-office/remarks-president-aapi-initiative-executive-order-signing-and-diwali-event</a>.

## **RELEVANT AMA POLICY**

# Health Initiatives on Asian-Americans and Pacific Islanders H-350.966

Our AMA urges existing federal agencies, commissions and Asian American and Pacific Islander health organizations to study how to improve the collection, analysis and dissemination of public health data on Asian Americans and Pacific Islanders.

Citation: (Res. 404, A-00; Reaffirmed: CSAPH Rep. 1, A-10

Resolution: 404

(A-19)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire,

Rhode Island, Vermont, American Academy of Dermatology, Society for Investigative Dermatology, American Society of

Dermatopathology

Subject: Shade Structures in Public and Private Planning and Zoning Matters

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, Malignant melanoma is now the fifth most common cancer in the United States, and its incidence has increased 33-fold since 1935, with sun exposure being the principle cause: 1,2,3,4 and

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Whereas, The Surgeon General's "Call to Action to Prevent Skin Cancer" of 2014<sup>5</sup> concisely outlined the magnitude of the public health problem which skin cancer represents in this country, and recommended multiple strategies to decrease the risk of this preventable cancer, including special attention to the provision of shade structures in the planning of public and private spaces; and

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Whereas, Shade structures are often treated as accessory buildings in planning and zoning matters, and this can result in the denial of reasonable shade protection in public and private spaces; therefore be it

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RESOLVED, That our American Medical Association support sun shade structures (such as awnings, gazebos and other structures providing shade) in the planning of public and private spaces, as well as in zoning matters and variances in recognition of the critical importance of sun protection as a public health measure. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 04/12/19

#### References

- 1. CA Cancer J Clin 2010; 60: 277-300
- 2. 2.CA Cancer J Clin 2008; 58: 71-96
- 3. Skin Cancer Foundation Journal Vol 29; 65-67
- 4. CA Cancer J Clin 1998; 48: 232
- 5. The Surgeon Generals Call to Action to Prevent Skin Cancer 2014

Resolution: 405

(A-19)

Introduced by: California

Subject: Gun Violence Prevention: Safety Features

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, The ongoing tragedy of gun violence in the United States has been labeled a public health crisis by the AMA and others, with huge attendant financial costs to hospitals, health systems, insurers, and many others; and

Whereas, In 2016, more than 38,000 deaths were caused by firearms; and

Whereas, The economic burden of firearm death and injury is substantial, reaching approximately \$229 billion in aggregate costs and representing about 1.4 percent of U.S. gross domestic product for costs associated with health care, criminal justice, loss of income, pain, suffering and loss of quality of life; and

Whereas, Some companies are working on gun safety technologies, such as magazine discharge mechanisms, and indicators that show a gun is loaded, to reduce the danger of firearms for gun owners and their families; there is also federal legislation to require all gunmakers in five years to retrofit guns with personalization technology that would only allow the owners to shoot the guns; and

Whereas, It has been well established that the gun industry and gun advocacy groups, such as the National Rifle Association, have successfully fought virtually any proposed safety features, regulatory proposals, or epidemiological research that could lessen gun-related accidents and violence; and

 Whereas, The federal government holds manufacturers to strict safety standards regarding almost every consumer product built within U.S. borders, such as toys, cars and medications – which allows consumers to reasonably assume that the products we buy and use every day are safe. But with guns, there are no federal regulations regarding the safety standards of firearms produced within the U.S. – an oversight in consumer protection that often proves deadly; and

Whereas, From 2005-2010, 3,800 people were killed and more than 95,000 injured (42,000 under the age of 25) from unintended shootings that could have been prevented through better gun safety standards and safety testing for mechanical defects; and

Whereas, Public health organizations have produced many evidence-based materials and recommendations to lessen gun-related harms, but many experts believe that, as with the tobacco industry in the past, the gun industry escapes true responsibility and liability for the harms and costs caused by their products; therefore be it

Resolution: 405 (A-19)

Page 2 of 3

- 1 RESOLVED, That our American Medical Association advocate for gun safety features, including
- 2 but not limited to mechanical or smart technology, to reduce accidental discharge of a firearm or
- 3 misappropriation of the weapon by a non-registered user; and support legislation and regulation
- 4 to standardize the use of these gun safety features on weapons sold for non-military and non-
- 5 peace officer use within the U.S.; with the aim of establishing manufacturer liability for the
- 6 absence of safety features on newly manufactured guns. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000.

Received: 04/29/19

#### **RELEVANT AMA POLICY**

#### Gun Violence as a Public Health Crisis D-145.995

Our AMA: (1) will immediately make a public statement that gun violence represents a public health crisis which requires a comprehensive public health response and solution; and (2) will actively lobby Congress to lift the gun violence research ban.

Citation: Res. 1011, A-16; Reaffirmation: A-18; Reaffirmation: I-18

# Firearm Safety and Research, Reduction in Firearm Violence, and Enhancing Access to Mental Health Care H-145.975

- 1. Our AMA supports: a) federal and state research on firearm-related injuries and deaths; b) increased funding for and the use of state and national firearms injury databases, including the expansion of the National Violent Death Reporting System to all 50 states and U.S. territories, to inform state and federal health policy; c) encouraging physicians to access evidence-based data regarding firearm safety to educate and counsel patients about firearm safety; d) the rights of physicians to have free and open communication with their patients regarding firearm safety and the use of gun locks in their homes; e) encouraging local projects to facilitate the low-cost distribution of gun locks in homes; f) encouraging physicians to become involved in local firearm safety classes as a means of promoting injury prevention and the public health; and g) encouraging CME providers to consider, as appropriate, inclusion of presentations about the prevention of gun violence in national, state, and local continuing medical education programs.
- 2. Our AMA supports initiatives to enhance access to mental and cognitive health care, with greater focus on the diagnosis and management of mental illness and concurrent substance use disorders, and work with state and specialty medical societies and other interested stakeholders to identify and develop standardized approaches to mental health assessment for potential violent behavior.
- 3. Our AMA (a) recognizes the role of firearms in suicides, (b) encourages the development of curricula and training for physicians with a focus on suicide risk assessment and prevention as well as lethal means safety counseling, and (c) encourages physicians, as a part of their suicide prevention strategy, to discuss lethal means safety and work with families to reduce access to lethal means of suicide. Citation: Sub. Res. 221, A-13; Appended: Res. 416, A-14; Reaffirmed: Res. 426, A-16; Reaffirmed: BOT Rep. 28, A-18; Reaffirmation: A-18; Modified: CSAPH Rep. 04, A-18; Reaffirmation: I-18

# Firearms as a Public Health Problem in the United States - Injuries and Death H-145.997

Our AMA recognizes that uncontrolled ownership and use of firearms, especially handguns, is a serious threat to the public's health inasmuch as the weapons are one of the main causes of intentional and unintentional injuries and deaths. Therefore, the AMA: (1) encourages and endorses the development and presentation of safety education programs that will engender more responsible use and storage of firearms;

- (2) urges that government agencies, the CDC in particular, enlarge their efforts in the study of firearm-related injuries and in the development of ways and means of reducing such injuries and deaths;
- (3) urges Congress to enact needed legislation to regulate more effectively the importation and interstate traffic of all handguns;
- (4) urges the Congress to support recent legislative efforts to ban the manufacture and importation of nonmetallic, not readily detectable weapons, which also resemble toy guns; (5) encourages the improvement or modification of firearms so as to make them as safe as humanly possible;

Resolution: 405 (A-19)

Page 3 of 3

(6) encourages nongovernmental organizations to develop and test new, less hazardous designs for firearms;

(7) urges that a significant portion of any funds recovered from firearms manufacturers and dealers through legal proceedings be used for gun safety education and gun-violence prevention; and (8) strongly urges US legislators to fund further research into the epidemiology of risks related to gun violence on a national level.

Citation: CSA Rep. A, I-87; Reaffirmed: BOT Rep. I-93-50; Appended: Res. 403, I-99; Reaffirmation A-07; Reaffirmation A-13; Appended: Res. 921, I-13; Reaffirmed: CSAPH Rep. 04, A-18; Reaffirmation: A-18; Reaffirmation: , I-18

Resolution: 406

(A-19)

Introduced by: California

Subject: Reduction in Consumption of Processed Meats

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, Processed meats include (but are not limited to) bacon, sausages, hot dogs, salami, corned beef, beef jerky, ham, canned meat, ground beef processed with ammonia and other cured meat; and

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Whereas, The International Agency for Research on Cancer (IARC) part of the World Health Organization (WHO) has classified processed meats as a Group 1 carcinogen after reviewing over 800 research studies; and

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Whereas, Processed meats are associated with diabetes, hypertension, chronic obstructive pulmonary disease (COPD) and coronary artery disease 2; therefore be it

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RESOLVED, That our American Medical Association support reduction of processed meat consumption, especially for patients diagnosed or at risk for coronary artery disease, type 2 diabetes and colorectal cancer (New HOD Policy); and be it further

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RESOLVED, That our AMA support initiatives to reduce processed meats consumed in public schools, hospitals, food markets and restaurants while promoting healthy alternatives such as a whole foods and plant-based nutrition (New HOD Policy); and be it further

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RESOLVED, That our AMA support public awareness of the risks of processed meat consumption, including research that better defines the health risks imposed by different methods of meat processing (New HOD Policy); and be it further

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RESOLVED, That our AMA support educational programs for health care professionals on the risks of processed meat consumption and the benefits of healthy alternatives. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Resolution: 407 (A-19)

Introduced by:	California
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Subject: Evaluating Autonomous Vehicles as a Means to Reduce Motor Vehicle

Accidents

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, Motor vehicle accidents are responsible for significant morbidity and mortality in the U.S. In 2015, there were 3,176 deaths in California alone; and

Whereas, Over 90% of all motor vehicle accidents are primarily attributable to driver error, and over 40% of fatal accidents involve substance use, fatigue, or a distracted driver; and

Whereas, Existing partially automated systems, such as autonomous emergency braking, demonstrably reduce the incidence of collision-related injury; and

Whereas, Fully autonomous vehicles have the potential to prevent a significant proportion of motor vehicle accidents by substantially reducing driver error, which could in turn reduce injury, death, healthcare resource utilization, and healthcare spending; and

Whereas, The U.S. National Highway Traffic Safety Administration has voiced optimism for the potential of autonomous vehicles to play a significant role in improving transportation safety, and has published a guidance for the automobile industry accordingly; and

Whereas, Age-related loss in the ability to operate motor vehicles increases individuals' risk for depression; therefore be it

RESOLVED, That our American Medical Association monitor the development of autonomous vehicles, with particular focus on the technology's impact on motor vehicle related injury and death (Directive to Take Action); and be it further

RESOLVED, That our AMA promote driver, pedestrian, and general street and traffic safety as key priorities in the development of autonomous vehicles. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Resolution: 408

(A-19)

Introduced by: Illino	ois
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Subject: Banning Edible Cannabis Products

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, In general, children have more severe symptoms from cannabis toxicity (with leukocytosis and elevated lactic acid levels); and

Whereas, The pharmacology of edible cannabis makes this a poorly viable medicinal agent due to its low oral bioavailability (under 25%) and slow peak absorption (almost 3 hours); and

Whereas, Toddlers are increasingly accessing edible cannabis products with subsequent severe neurotoxicity and cardiotoxicity; and

Whereas, No antidote exists for cannabis toxicity, and activated charcoal is apparently not effective; and

Whereas, Unintentional cannabis ingestion by adults can lead to unintended medical and forensic consequences (such as a positive drug test leading to job termination); and

Whereas, There is no US Food and Drug Administration oversight on medicinal edible cannabis products; and

Whereas, Colorado studies along with National Poison Data System encounters due to unintentional pediatric cannabis exposures have increased substantially in legalized cannabis states; and

Whereas, Some states and localities have restricted or outlawed the sale of flavored tobacco products because of the concern that they increase pediatric initiation, i.e., first use of the product; and

Whereas, There is much more risk of initiation with candy marijuana than with flavored tobacco products; and

Whereas, Consumers often do not understand toxic hazards of edible cannabis and may consume a greater than intended amount; therefore be it

RESOLVED, That our American Medical Association adopt policy supporting a total ban on recreational edible cannabis products (New HOD Policy); and be it further

Resolution: 408 (A-19)

Page 2 of 2

1 RESOLVED, That our AMA support or cause to be introduced legislation to ban all recreational

2 edible cannabis products. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 04/25/19

#### References:

- 1. Richards JR, Smith NE, Moulin AK. Unintentional Cannabis Ingestion in Children: A Systemic Review. Journal of Pediatrics. 2017; 190: 142-152
- 2. Benjamin DM, Fossler MJ. Edible Cannabis Products: It is Time for FDA Oversight. J Clin Pharmacology. 2016; 56(9): 1045-1047
- 3. Kim HS, Monte AA. Colorado Cannabis Legalization and its Effect on Emergency Care. Ann Emerg Med. 2016; 68(1): 71-75
- 4. Caulley L, Caplan B, Ross E. Medical marijuana for chronic pain. N Engl J Med. 2018; 379: 1575-1577
- 5. Greydanus DE, Kaplan G, Baxter Sr LE, et al. Cannabis: the never-ending, nefarious mepenthe of the 21st century: what should the clinician know? Disease-a-Month. 2015; 61(4): 118-175
- 6. MacCoun RJ, Mello MM. Half-baked: The Retail Promotion of Marijuana Edibles. N Engl J Med. 2015; 372(11): 989-991
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- 8. Vo TK, Hoing H, Ho RY, et al. Cannabis Intoxication Case Series: The Dangers of Edibles Containing Tetrahydrocanabinol. Ann Emerg Med. 2018; 71(3): 306-313
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- 10. Pelissier F. Claudet I, Pelisser-Alicot A-L, et al. Parental Cannabis Abuse and Accidental Intoxications in Children: Prevention by Detecting Neglectful Situations and At-Risk Families. Ped Emerg Care. 2014;30(12): 862-866

Resolution: 409

(A-19)

Introduced by: New York

Subject: Addressing the Vaping Crisis

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, Vaping / E-cigarettes may be useful in helping smokers stop smoking; and

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Whereas, Vaping has no other healthful purposes and these devices will, on rare occasion,

4 explode; and

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Whereas, Vaping is highly addictive, and is marketed to children, and often leads to smoking;

therefore be it

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RESOLVED, That our American Medical Association advocate to the Food and Drug

Administration that vaping devices should be available only by prescription for smokers who are

11 trying to quit smoking. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000.

Resolution: 410

(A-19)

Introduced by: New York

Subject: Reducing Health Disparities Through Education

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, The favorable direct impact of education on health outcomes has been well documented for years, with improved outcomes at each additional level obtained from high school graduation to post graduate degrees; and

Whereas, The high school graduation rate in the lower socioeconomic group is <30% compared to an overall U.S. graduation rate of >80%; and

Whereas, The cost of a college degree is constantly rising with the average cost of a 4-year degree in the U.S. is presently on average \$28,000 to \$34,000. The former for public college, the latter for private colleges; and

Whereas, There are many environmental factors that impact health outcomes (e.g. a safe out door space to exercise, the concentration of fast food restaurants, the availability of fresh, affordable fruits and vegetables) in poor neighborhoods etc., in spite of the environmental circumstances educational attainment helps to mitigate the negative impact of these circumstances; and

Whereas, Personal behaviors informed by education leads to a decrease in unhealthy behaviors (e.g. smoking); and

Whereas, Educational attainment leads to improved rates of secondary prevention (e.g. age appropriate screenings); therefore be it

RESOLVED, That our American Medical Association work with the Health and Human Services Department (HHS) and Department of Education (DOE) to raise awareness about the health benefits of education (Directive to Take Action); and be it further

RESOLVED, That our AMA work with HHS and DOE to establish a meaningful health curriculum (including nutrition) for grades kindergarten through 12 which is required for high school graduation (Directive to Take Action); and be it further

RESOLVED, That our AMA work nationally toward the same goals and strategies to reduce health disparities. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Resolution: 411 (A-19)

Introduced by: New York

Subject: AMA to Analyze Benefits / Harms of Legalization of Marijuana

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, Rates of marijuana use among the US population has increased in the past decade; and

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Whereas, Marijuana is a complex botanical with many different compounds with potential pharmacological activity; and

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Whereas, There is some high quality evidence for efficacy of some marijuana compounds for treatment of disease or alleviation of symptoms; and

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Whereas, There are structural impediments to high quality research due to marijuana being classified as a Schedule I substance by the Food and Drug Administration; and

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Whereas, There is accumulating evidence about harms associated with marijuana use in regards to accidents, impaired driving, psychosis, depression, and suicide; and

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Whereas, There is little long term data on the efficacy and potential harms associated with medical or non-medical use; and

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Whereas, Practicing clinicians could provide better recommendations for medicinal use with high quality research; and

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Whereas, There is emerging data from the states which have legalized marijuana use; and

232425

Whereas, Review and analysis of the emerging data would be helpful to state medical societies as they provide advice to their governmental representatives and regulators as they formulate policies toward marijuana; therefore be it

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RESOLVED, That our American Medical Association review pertinent data from those states that have legalized marijuana. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Resolution: 412

(A-19)

Introduced by: New York

Subject: Regulating Liquid Nicotine and E-Cigarettes

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, Warnings have been placed on liquid nicotine as "poisonous if swallowed, inhaled or if it comes in contact with skin"; and

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Whereas, Warnings to "keep out of children's reach" as liquid nicotine can be addictive, may increase heart rate, blood pressure, cause dizziness, nausea, and aggravate respiratory conditions; and

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Whereas, Warnings that "ingestion of liquid nicotine may be fatal"; and

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Whereas, Many states have prohibited the sale of tobacco products, liquid nicotine, e-cigarettes and smoking paraphernalia to persons under 21 years of age; and

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14 15 Whereas, According to the NIH- National Institute on Drug Abuse: teens are more likely to use e-cigarettes than cigarettes (eighth grade 3.6% vs 9.5%) and teen e-cigarette users are more likely to start smoking (8.1% vs 30.7%) and 66% of teens claim "just flavoring" is in their e-cigarettes; and

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Whereas, According to the NIH- National Institute on Drug Abuse: "more than 1 in 10 eighth graders say they vaped nicotine in the last year and surveys show vaping among high school seniors increased from 11% in 2017 to 20.9% in 2018; therefore be it

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RESOLVED, That our American Medical Association seek legislation or regulations that limit higher concentration nicotine salts (greater than 10mg) in nicotine vaping pods and restrict bulk sale of vaping products and associated paraphernalia. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Resolution: 413

(A-19)

Introduced by: New York

Subject: End the Epidemic of HIV Nationally

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, In 2014, Governor Andrew Cuomo announced a New York State (NYS) initiative to End the HIV Epidemic by 2020 (EtE 2020) with the goal of fewer than 750 new HIV infections statewide by 2020; and

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Whereas, EtE 2020 is built on New York State's public health leadership since the emergence of AIDS in 1988; and

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Whereas, EtE 2020 has a 3-point plan that:

- 1) Identifies persons with HIV who remain undiagnosed and link them to health care;
- 2) Links and retains persons diagnosed with HIV in health care to maximize virus suppression so they remain healthy and prevent further transmission; and
- 3) facilitates access to Pre-Exposure Prophylaxis (PrEP) for high-risk persons to keep them HIV negative; and

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Whereas, The NYS initiative is at the forefront of similar efforts nationwide and globally as evidenced by a detailed 2015 Blueprint to End the AIDS Epidemic (health.ny.gov/ete) that includes recommendations that address health care and the social determinants of health; and

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Whereas, NYS 2017 surveillance data shows a decrease in incidence of new HIV infections statewide; and

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Whereas, New York's End the Epidemic is an example of state's efforts that can be replicated on the national level; and

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Whereas, The are similar state efforts underway to curtail the epidemic; and

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Whereas, Federal funds are critical to this effort; therefore be it

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RESOLVED, That our American Medical Association advocate that the federal budget include provisions to End the HIV epidemic and that such a plan be structured after New York State's EtE 2020 or other similar state programs. (Directive to Take Action)

Fiscal Note: Minimal - less than \$1,000.

Resolution: 414

(A-19)

Introduced by: Oklahoma

Subject: Patient Medical Marijuana Use in Hospitals

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, By 2018, 33 states, the District of Columbia, Guam, and Puerto Rico, have passed legislation to legalize medical marijuana, including Oklahoma; and

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Whereas, There are many legal implications due to the passage of state medical marijuana laws and the associated regulations passed by State Departments of Health; and

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Whereas, Many community facilities continue to ban marijuana on their campuses pursuant to the Federal Drug-Free Schools and Communities Act, the Drug-Free Workplace Act, and the Federal Controlled Substance Act; and

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Whereas, Hospital medical staffs are struggling when patients with medical marijuana licenses report non-FDA approved marijuana products as home medication and bring these products into their facilities; and

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Whereas, American Medical Association Council on Science and Public Health Report 5, I-17, "Clinical Implications and Policy Considerations of Cannabis Use," does not address patient non-FDA approved medical marijuana use in hospitals; therefore be it

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RESOLVED, That our American Medical Association offer guidance to medical staffs regarding patient use of non-US Food and Drug Administration approved medical marijuana and cannabinoids on hospital property, including product use, storage in patient rooms, nursing areas and/or pharmacy, with report back to the House of Delegates at the 2019 Interim Meeting.

23 (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Resolution: 415

(A-19)

Introduced by: Oklahoma

Subject: Distracted Driver Legislation

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, National Highway Traffic Safety Administration, primarily uses distracted driving to mean "the inattention that occurs when drivers divert their attention away from the driving task to focus on another activity"; and

Whereas, Oklahoma has laws that restrict cell phone use while driving in an effort to reduce distracted driving accidents. Oklahoma is like most states in that many drivers either don't know the applicable distracted driving laws or choose to ignore them; and

Whereas, Nearly one-third of all U.S. drivers 18 to 64 years old read or send text or email messages while driving<sup>2</sup>; and

Whereas, Reading or sending text or email messages while driving and other distracted driving behaviors leads to more than 420,000 injuries and more than 3,100 deaths every year in the United States<sup>3</sup>; and

Whereas, Simply knowing the risks of distracted driving has not yet translated into reducing the behavior<sup>4</sup>; and

Whereas, In 2015, Oklahoma became the 46th state to ban texting while driving. The Oklahoma law, Trooper Nicholas Dees and Trooper Keith Burch Act of 2015, prohibits texting and some other forms of electronic communication--such as taking photos or video and posting to social media--while operating a motor vehicle; and

Whereas, Some states' laws prohibit drivers from talking on hand-held devices all together; some laws apply only to vehicles in motion whereas others also apply to drivers stopped in a travel lane. Laws focused specifically on electronic communication, or "texting," also vary in prohibited conduct. Some statutes prohibit particular behaviors, such as composing, viewing, or transmitting electronic communications, but do not outlaw other actions such as entering a phone number or entering GPS data; and

Whereas, All states put a legal responsibility on drivers to operate in a safe manner, distracted driving laws vary across the United States in what they prohibit and how they can be enforced; and

Whereas, Federal law bans cell phone use while operating commercial motor vehicles or transporting hazardous materials. Specifically, in 2010 and 2011, Federal law banned commercial truck drivers, bus drivers, and drivers transporting hazardous materials from using hand-held cell phones and messaging on electronic devices<sup>5</sup>; and

Resolution: 415 (A-19)

Page 2 of 2

Whereas, Current AMA Policy, H-15.952, "The Dangers of Distraction While Operating Hand-Held Devices," merely states "Our AMA will endorse legislation that would ban the use of handheld devices while driving"; therefore be it

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RESOLVED, That our American Medical Association actively lobby for federal legislation to decrease distracted driving injuries and fatalities by banning the use of electronic communication such as texting, taking photos or video and posting on social media while operating a motor vehicle; (Directive to Take Action) and be it further

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- 10 RESOLVED, That our AMA actively lobby for federal legislation to require automobile
- 11 manufacturers to integrate hands-free technology into new automobiles. (Directive to Take
- 12 Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 04/15/19

#### **RELEVANT AMA POLICY**

#### The Dangers of Distraction While Operating Hand-Held Devices H-15.952

- 1. Our American Medical Association encourages physicians to educate their patients regarding the public health risks of text messaging while operating motor vehicles or machinery and will advocate for state legislation prohibiting the use of hand held communication devices to text message while operating motor vehicles or machinery.
- 2. Our AMA will endorse legislation that would ban the use of hand-held devices while driving.
- 3. Our AMA: (A) recognizes distracted walking as a preventable hazard and encourages awareness of the hazard by physicians and the public; and (B) encourages research into the severity of distracted walking as a public health hazard as well as ways in which to prevent it.
- 4. Our AMA supports public education efforts regarding the dangers of distracted driving, particularly activities that take drivers' eyes off the road, and that the use of earbuds or headphones while driving is dangerous and illegal in some states.
- 5. Our AMA: (A) supports education on the use of earbuds or headphones in both ears during outdoor activities requiring auditory attention, including but not limited to biking, jogging, rollerblading, skateboarding and walking; and (B) supports the use of warning labels on the packaging of hand-held devices utilized with earbuds or headphones, indicating the dangers of using earbuds or headphones in both ears during outdoor activities requiring auditory attention, including but not limited to biking, jogging, rollerblading, skateboarding and walking.

Citation: (Res. 217, I-08; Appended: Res. 905, I-09; Appended: BOT Rep. 10, A-13; Appended: Res. 416, A-13; Modified in lieu of Res. 414, A-15

#### References

<sup>1</sup> National Highway Traffic Safety Administration. (2010, April). Overview of the National Highway Traffic Safety Administration's driver distraction program (Report No. DOT HS 811 299). Washington, DC: Author. Available at www.nhtsa.gov/staticfiles/nti/distracted\_driving/pdf/811299.pdf

<sup>&</sup>lt;sup>2</sup> Centers for Disease Control and Prevention. Mobile Device Use While Driving – United States and Seven European Countries, 2011. Morbidity and Mortality Weekly Report, March 15, 2013/62(10); 177-182.

<sup>&</sup>lt;sup>3</sup> National Center for Statistics and Analysis. (2016, April). Distracted driving 2014 (Traffic Safety Facts Research Note. Report No. DOT HS 812 260). Washington, DC: National Highway Traffic Safety Administration. Available at https://crashstats.nhtsa.dot.gov/Api/Public/ViewPublication/812260

<sup>&</sup>lt;sup>4</sup> Atchley, P., Hadlock, C., & Lane, S. (2012). Stuck in the 70s: The role of social norms in distracted driving, Accident Analysis & Prevention, 40, 279-284.

<sup>5 49</sup> CFR § 392.80 and § 392.82. https://www.fmcsa.dot.gov/regulations

Resolution: 416

(A-19)

Introduced by: Oklahoma

Subject: Non-Medical Exemptions from Immunizations

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, Non-medical exemptions from immunizations endanger the health of unvaccinated individuals, medically exempt patients, and the health of those in his or her group and the community at large; and

Whereas, Vaccinations are critical to protect the health and welfare of Oklahomans; and

Whereas, The Oklahoma State Medical Association supports all efforts to increase vaccination of Oklahoma children; and

Whereas, Oklahoma State Medical Association endorses requiring day care centers and homes to use the recommendations of the Advisory Committee on Immunization Practices as the rules and regulations governing the specific number of vaccine doses required and frequency of their administration to attend day care; and

Whereas, AMA public health policy encourages state medical associations to seek removal of non-medical exemption in statutes requiring mandatory immunizations, including for childcare and school attendance and encourages physicians to grant vaccine exemption requests only when medical contraindications are present (AMA Policy H-440.970); and

Whereas, All states require immunizations for children to attend school. Forty-seven states, all but California, Mississippi, and West Virginia, allow parents to opt out of immunizations if they have religious beliefs against immunizations; and

Whereas, Oklahoma is one of 18 states that allow parents to opt out of vaccines if they have a personal, moral or philosophical belief against immunizations; and

Whereas, In 2016 American Academy of Pediatrics took a stance that personal and religious exemptions should end; and

Whereas, According to the World Health Organization, there has been a 30% increase in measles worldwide in 2017; and

Whereas, The World Health Organization issued a report in January 2019 that said "vaccine hesitancy" has become a global health threat; and

Whereas, In 2019 a measles outbreak has prompted a public health emergency in Washington State: therefore be it

Resolution: 416 (A-19)

Page 2 of 2

1 RESOLVED, That our American Medical Association actively advocate for federal legislation

2 that incentivizes states to eliminate non-medical exemptions to mandated pediatric

3 immunizations. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 04/15/19

#### **RELEVANT AMA POLICY**

# Nonmedical Exemptions from Immunizations H-440.970

Our American Medical Association believes that nonmedical (religious, philosophic, or personal belief) exemptions from immunizations endanger the health of the unvaccinated individual and the health of those in his or her group and the community at large. Therefore, our AMA (1) supports the immunization recommendations of the Advisory Committee on Immunization Practices (ACIP) for all individuals without medical contraindications; (2) supports legislation eliminating nonmedical exemptions from immunization; (3) encourages state medical associations to seek removal of nonmedical exemptions in statutes requiring mandatory immunizations, including for childcare and school attendance; (4) encourages physicians to grant vaccine exemption requests only when medical contraindications are present; (5) encourages state and local medical associations to work with public health officials to develop contingency plans for controlling outbreaks in medically-exempt populations and to intensify efforts to achieve high immunization rates in communities where nonmedical exemptions are common; and (6) recommends that states have in place: (a) an established mechanism, which includes the involvement of qualified public health physicians, of determining which vaccines will be mandatory for admission to school and other identified public venues (based upon the recommendations of the ACIP); and (b) policies that permit immunization exemptions for medical reasons only.

Citation: (CSA Rep. B, A-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmed: Res. 10, A-15; Modified: CSAPH Rep. 1, I-15

Resolution: 417

(A-19)

Introduced by: Pennsylvania

Subject: Improved Health in the United States Prison System through Hygiene and

Health Educational Programming for Inmates and Prison Staff

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, Overcrowding, poor hygiene, and poor-quality food predispose inmates to many preventable diseases; and

Whereas, Lapses in food safety by prison staff have made United States prisoners six times more likely to contract a foodborne illness, such as Clostridium perfringens or Salmonella, than the general population according to a study from the Centers for Disease Control and Prevention (CDC);<sup>2</sup> and

Whereas, Preventing inmates from transmitting illnesses by contact with prison staff, health care providers, and visitors from the community through increased health awareness can contribute to improved community health; and

Whereas, A research study showed that increased hand hygiene was associated with a 24% reduction in the risk of MRSA acquisition. This risk decreased significantly (by 48%) with hand hygiene compliance levels above 80%. Two additional clinical studies supported this data, showing lower incidence rates of MRSA, resistant E. coli and carbapenem resistant P. aeruginosa when achieving compliance levels higher than 70%;<sup>3</sup> and

Whereas, Existing AMA-MSS policy recognizes the importance of oral health as a part of overall patient care and supports an increase in access to oral health services (440.058MSS); and

Whereas, Poor oral health may contribute to the development of endocarditis, cardiovascular disease, and premature birth or low birth weight, and it is typically affected by existing conditions such as diabetes, HIV/AIDS, osteoporosis, and Alzheimer's disease. Risk for poor oral hygiene is high in prison inmates as 1.5% of all inmates in state and federal prisons have HIV or AIDS (21,987 persons), which is 4 times the prevalence rate of HIV in the general populace;<sup>4,5</sup> and

Whereas, Existing AMA policy focuses on increasing health literacy among populace to remove barriers to effective medical diagnosis and treatment through the development of literacy appropriate, culturally diverse, health-related patient education materials (H-160.931); and

Whereas, Adults with limited literacy skills are less likely to manage their chronic diseases and more likely to be hospitalized than people with stronger literacy skills. Only 12 percent of adults have proficient health literacy, according to the National Assessment of Adult Literacy. In other words, nearly 9 out of 10 adults may lack the skills needed to manage their health and prevent disease; 1 therefore be it

Resolution: 417 (A-19)

Page 2 of 3

- 1 RESOLVED, That our American Medical Association collaborate with state medical societies to
- 2 emphasize the importance of hygiene and health literacy information sessions for both inmates
- 3 and staff in state and local prison systems. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Received: 04/26/19

#### References:

<sup>1</sup> America's Health Literacy. Office of Disease Prevention and Health Promotion. 2007. https://health.gov/communication/literacy/issuebrief/.

#### **RELEVANT AMA AND AMA-MSS POLICY:**

#### Health Literacy H-160.931

Our AMA:

- (1) recognizes that limited patient literacy is a barrier to effective medical diagnosis and treatment;
- (2) encourages the development of literacy appropriate, culturally diverse health-related patient education materials for distribution in the outpatient and inpatient setting;
- (3) will work with members of the Federation and other relevant medical and nonmedical organizations to make the health care community aware that approximately one fourth of the adult population has limited literacy and difficulty understanding both oral and written health care information;
- (4) encourages the development of undergraduate, graduate, and continuing medical education programs that train physicians to communicate with patients who have limited literacy skills;
- (5) encourages all third party payers to compensate physicians for formal patient education programs directed at individuals with limited literacy skills;
- (6) encourages the US Department of Education to include questions regarding health status, health behaviors, and difficulties communicating with health care professionals in all future National Assessment of Adult Literacy studies;
- (7) encourages the allocation of federal and private funds for research on health literacy;
- (8) recommends all healthcare institutions adopt a health literacy policy with the primary goal of enhancing provider communication and educational approaches to the patient visit;
- (9) recommends all healthcare and pharmaceutical institutions adopt the USP prescription standards and provide prescription instructions in the patient's preferred language when available and appropriate; and (10) encourages the development of low-cost community- and health system resources, support state legislation and consider annual initiatives focused on improving health literacy.

Citation: (CSA Rep. 1, A-98; Appended: Res. 415, I-99; Modified and Reaffirmed: CSAPH Rep. 1, A-09; Appended: Res. 718, A-13

## Health Information and Education H-170.986

- (1) Individuals should seek out and act upon information that promotes appropriate use of the health care system and that promotes a healthy lifestyle for themselves, their families and others for whom they are responsible. Individuals should seek informed opinions from health care professionals regarding health information delivered by the mass media self-help and mutual aid groups are important components of health promotion/disease and injury prevention, and their development and maintenance should be promoted.
- (2) Employers should provide and employees should participate in programs on health awareness, safety and the use of health care benefit packages.
- (3) Employers should provide a safe workplace and should contribute to a safe community environment. Further, they should promptly inform employees and the community when they know that hazardous

<sup>&</sup>lt;sup>2</sup> Fassler, J. Prison food is making U.S. inmates disproportionately sick. The Atlantic. 2017 Dec. https://www.theatlantic.com/health/archive/2017/12/prison-food-sickness-america/549179/.

<sup>&</sup>lt;sup>3</sup> Girou E, et al. Association between hand hygiene compliance and methicillin-resistant Staphylococcus aureus prevalence in a French rehabilitation hospital. Infect Control Hosp Epidemiol. 2006 Oct;27(10):1128-1130.

<sup>&</sup>lt;sup>4</sup> Maruschak, L. et al. HIV in Prisons, 2007-2008. Department of Justice: Bureau of Justice Statistics Bulletin. 2010.

<sup>&</sup>lt;sup>5</sup> Oral health: a window to overall health. Mayo Clinic. 2016 Apr. https://www.mayoclinic.org/healthy-lifestyle/adult-health/indepth/dental/art-2004747.

<sup>&</sup>lt;sup>6</sup> Rennie, D. et al. Evaluation of Food Hygiene Education. British Food Journal. 1994;96(11):20-25. doi: 10.1108/00070709410074650.

Resolution: 417 (A-19)

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substances are being used or produced at the worksite.

- (4) Government, business and industry should cooperatively develop effective worksite programs for health promotion and disease and injury prevention, with special emphasis on substance abuse.
- (5) Federal and state governments should provide funds and allocate resources for health promotion and disease and injury prevention activities.
- (6) Public and private agencies should increase their efforts to identify and curtail false and misleading information on health and health care.
- (7) Health care professionals and providers should provide information on disease processes, healthy lifestyles and the use of the health care delivery system to their patients and to the local community.
- (8) Information on health and health care should be presented in an accurate and objective manner.
- (9) Educational programs for health professionals at all levels should incorporate an appropriate emphasis on health promotion/disease and injury prevention and patient education in their curricula.
- (10) Third party payers should provide options in benefit plans that enable employers and individuals to select plans that encourage healthy lifestyles and are most appropriate for their particular needs. They should also continue to develop and disseminate information on the appropriate utilization of health care services for the plans they market.
- (11) State and local educational agencies should incorporate comprehensive health education programs into their curricula, with minimum standards for sex education, sexual responsibility, and substance abuse education. Teachers should be qualified and competent to instruct in health education programs.
- (12) Private organizations should continue to support health promotion/disease and injury prevention activities by coordinating these activities, adequately funding them, and increasing public awareness of such services.
- (13) Basic information is needed about those channels of communication used by the public to gather health information. Studies should be conducted on how well research news is disseminated by the media to the public. Evaluation should be undertaken to determine the effectiveness of health information and education efforts. When available, the results of evaluation studies should guide the selection of health education programs.

Citation: (BOT Rep. NN, A-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmation A-07; Reaffirmation A-15

20.002MSS AIDS Education: AMA-MSS: (1) encourages public school instruction, appropriate for a student's age and grade, on the nature of HIV and the prevention of its transmission starting at the earliest age at which health and hygiene are taught; (2) asks the AMA to encourage the training of appropriate school personnel to assure a basic knowledge of the nature of HIV, the prevention of its transmission, the availability of appropriate resources for counseling and referral, and other information that may be appropriate considering the ages and grade levels of pupils. (MSS Sub Res 4, A-87) (Reaffirmed: MSS Rep D, I-97) (Reaffirmed: MSS Rep B, I-02) (Reaffirmed: MSS Rep C, I-07) (Reaffirmed: MSS GC Report C, I-12)

440.058MSS Importance of Oral Health in Medical Practice: AMA-MSS (1) recognizes the importance of managing oral health as a part of overall patient care; (2) supports efforts to educate physicians on oral condition screening and management, as well as the consequences of poor oral hygiene on mental and physical health; (3) supports closer collaboration of physicians with dental providers to provide comprehensive medical care; and (4) support efforts to increase access to oral health services. (MSS Res 22, I-16)

Resolution: 418

(A-19)

Introduced by: Washington

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Subject: Eliminating the Death Toll from Combustible Cigarettes

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, The United States has made great progress in decreasing cigarette smoking since the first Surgeon General's report in 1964; and

Whereas, Combustible cigarettes continue to kill between 450,000 and 500,000 people each year in the United States; and

Whereas, The death toll from all other forms of nicotine is very small and not statistically measurable: and

Whereas, There are many other nicotine-delivering products available to U.S. consumers; and

Whereas, The level of measurable toxins in non-combustible nicotine products is much lower than in combustible products; and

Whereas, Safety concerns (real or imagined) have inhibited smokers' understanding of the benefits of product switching; and

Whereas, Wise regulation and medically accurate labeling can address safety concerns about non-combustible nicotine products; therefore be it

RESOLVED, That our American Medical Association study and report on the conditions under which our country could successfully eliminate the manufacture, distribution, and sale of 23 combustible cigarettes and other combustible tobacco products at the earliest feasible date. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Resolution: 418 (A-19)

Page 2 of 2

#### **RELEVANT AMA POLICY**

# Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes H-495.986

H-495.986 Tobacco Product Sales and Distribution Our AMA

- (1) recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21;
- (2) encourages the passage of laws, ordinances and regulations that would set the minimum age for purchasing tobacco products, including electronic nicotine delivery systems (ENDS) and e-cigarettes, at 21 years, and urges strict enforcement of laws prohibiting the sale of tobacco products to minors;
- (3) supports the development of model legislation regarding enforcement of laws restricting children's access to tobacco, including but not limited to attention to the following issues: (a) provision for licensure to sell tobacco and for the revocation thereof; (b) appropriate civil or criminal penalties (e.g., fines, prison terms, license revocation) to deter violation of laws restricting children's access to and possession of tobacco; (c) requirements for merchants to post notices warning minors against attempting to purchase tobacco and to obtain proof of age for would-be purchasers; (d) measures to facilitate enforcement; (e) banning out-of-package cigarette sales ("loosies"); and (f) requiring tobacco purchasers and vendors to be of legal smoking age;
- (4) requests that states adequately fund the enforcement of the laws related to tobacco sales to minors;
- (5) opposes the use of vending machines to distribute tobacco products and supports ordinances and legislation to ban the use of vending machines for distribution of tobacco products:
- (6) seeks a ban on the production, distribution, and sale of candy products that depict or resemble tobacco products;
- (7) opposes the distribution of free tobacco products by any means and supports the enactment of legislation prohibiting the disbursement of samples of tobacco and tobacco products by mail;
- (8) (a) publicly commends (and so urges local medical societies) pharmacies and pharmacy owners who have chosen not to sell tobacco products, and asks its members to encourage patients to seek out and patronize pharmacies that do not sell tobacco products; (b) encourages other pharmacists and pharmacy owners individually and through their professional associations to remove such products from their stores; (c) urges the American Pharmacists Association, the National Association of Retail Druggists, and other pharmaceutical associations to adopt a position calling for their members to remove tobacco products from their stores; and (d) encourages state medical associations to develop lists of pharmacies that have voluntarily banned the sale of tobacco for distribution to their members; and
- (9) opposes the sale of tobacco at any facility where health services are provided; and (10) supports that the sale of tobacco products be restricted to tobacco specialty stores. Citation: CSA Rep. 3, A-04; Appended: Res. 413, A-04; Reaffirmation A-07; Amended: Res. 817, I-07; Reaffirmation A-08; Reaffirmation I-08; Reaffirmation A-09; Reaffirmation I-13; Reaffirmation A-14; Reaffirmation I-14; Reaffirmation A-15; Modified in lieu of Res. 421, A-15; Modified in lieu of Res. 424, A-15; Reaffirmation I-16; Appended: Res. 926, I-18

Resolution: 419

(A-19)

Introduced by: Washington

Subject: Universal Access for Essential Public Health Services

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, We have not gained a general consensus on what are the essential public health services that everyone in our country are entitled to receive; and

Whereas, Public health governance structures and funding sources greatly vary by region, state, and jurisdiction across the country; and

Whereas, Compartmentalized, competitive, unpredictable, and inflexible funding leaves many health departments without financing for all essential public health services and necessary capabilities; and

Whereas, Hospitals play an important role in local public health systems and possess enormous capacity to provide essential public health services in a cost-effective manner; and

Whereas, We have no means to accurately capture capabilities and spending on essential public health services in every jurisdiction in order to determine if there is a current lack of universal access; and

Whereas, We have no means of collecting outcome data in order the monitor the access to and cost effectiveness of our public health interventions; therefore be it

RESOLVED, That our American Medical Association study the options and/or make recommendations regarding the establishment of:

- 1. A list of all essential public health services that should be provided in every jurisdiction in the United States.
- A federal data system that can capture the amount of federal, state, and local public health capabilities and spending that occurs in every jurisdiction to assure that their populations have universal access to all essential public health services.
- 3. A federal data system that can capture actionable evidence-based outcomes data from public health activities in every jurisdiction (Directive to Take Action); and be it further

RESOLVED, That our AMA prepare and publicize annual reports on current efforts and progress to achieve universal access to all essential public health services. (Directive to Take Action)

Fiscal Note: Modest - between \$1,000 - \$5,000.

Resolution: 419 (A-19)

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- 2. The Public Health System & the 10 Essential Public Health Services. Centers for Disease Control and Prevention. Access at: <a href="https://www.cdc.gov/stitpublichealth/publichealth/services/essentialhealth/services.html">https://www.cdc.gov/stitpublichealth/publichealth/services/essentialhealth/services.html</a>
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- 6. Profile of State and Territorial Public Health. Association of State and Territorial Health officers. 2018. Access at: http://www.astho.org/Profile/
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- 8. Hospital Contributions to the Delivery of Public Health Activities in US Metropolitan Areas: National and Longitudinal Trends. Am J Public Health. 2015;105:1646–1652.
- 9. The Role of Hospitals in Improving Non-Medical Determinants of Community Population Health. Division of Health Policy and Economics, Department of Healthcare Policy and Research, Weill Cornell Medical College. April 2016. Access at: https://nyshealthfoundation.org/resource/hospitals-improving-non-medical-determinants-of-community-population-health/
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- 11. Hartman M, Martin AB, et al. National Health Care Spending In 2016: Spending And Enrollment Growth Slow After Initial Coverage Expansions. Health Affairs 2018. 37 (1): 150–160.

#### **RELEVANT AMA POLICY**

#### Federal Block Grants and Public Health H-440.912

- (1) Our AMA should collaborate with national public health organizations to explore ways in which public health and clinical medicine can become better integrated; such efforts may include the development of a common core of knowledge for public health and medical professionals, as well as educational vehicles to disseminate this information.
- (2) Our AMA urges Congress and responsible federal agencies to: (a) establish set-asides or stable funding to states and localities for essential public health programs and services, (b) provide for flexibility in funding but ensure that states and localities are held accountable for the appropriate use of the funds; and (c) involve national medical and public health organizations in deliberations on proposed changes in funding of public health programs.
- (3) Our AMA will work with and through state and county medical societies to: (a) improve understanding of public health, including the distinction between publicly funded medical care and public health; (b) determine the roles and responsibilities of private physicians in public health, particularly in the delivery of personal medical care to underserved populations; (c) advocate for essential public health programs and services; (d) monitor legislative proposals that affect the nation's public health system; (e) monitor the growing influence of managed care organizations and other third party payers and assess the roles and responsibilities of these organizations for providing preventive services in communities; and (f) effectively communicate with practicing physicians and the general public about important public health issues.
- (4) Our AMA urges state and county medical societies to: (a) establish more collegial relationships with public health agencies and increase interactions between private practice and public health physicians to develop mutual support of public health and clinical medicine; and (b) monitor and, to the extent possible, participate in state deliberations to ensure that block grant funds are used appropriately for health-related programs.
- (5) Our AMA urges physicians and medical societies to establish community partnerships comprised of concerned citizens, community groups, managed care organizations, hospitals, and public health agencies to: (a) assess the health status of their communities and determine the scope and quality of population- and personal-based health services in their respective regions; and (b) develop performance objectives that reflect the public health needs of their states and communities.
- 6. Our AMA: (a) supports the continuation of the Preventive Health and Health Services Block

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Grant, or the securing of adequate alternative funding, in order to assure preservation of many critical public health programs for chronic disease prevention and health promotion in California and nationwide, and to maintain training of the public health physician workforce; and (b) will communicate support of the continuation of the Preventive Health and Health Services Block Grant, or the securing of adequate alternative funding, to the US Congress.

Citation: (CSA Rep. 3, A-96; Reaffirmation A-01; Reaffirmed: CSAPH Rep. 1, A-11; Reaffirmed

# Support for Public Health D-440.997

1. Our AMA House of Delegates request the Board of Trustees to include in their long range plans, goals, and strategic objectives to support the future of public health in order "to fulfill society's interest in assuring the conditions in which people can be healthy." This shall be accomplished by AMA representation of the needs of its members? patients in public health-related areas, the promotion of the necessary funding and promulgation of appropriate legislation which will bring this to pass.

in lieu of Res. 424, A-11; Appended: Res. 935, I-11; Reaffirmation A-15

- 2. Our AMA: (A) will work with Congress and the Administration to prevent further cuts in the funds dedicated under the Patient Protection and Affordable Care Act to preserve state and local public health functions and activities to prevent disease; (B) recognizes a crisis of inadequate public health funding, most intense at the local and state health jurisdiction levels, and encourage all medical societies to work toward restoration of adequate local and state public health functions and resources; and (C) in concert with state and local medical societies, will continue to support the work of the Centers for Disease Control and Prevention, and the efforts of state and local health departments working to improve community health status, lower the risk of disease and protect the nation against epidemics and other catastrophes.
- 3. Our AMA recognizes the importance of timely research and open discourse in combatting public health crises and opposes efforts to restrict funding or suppress the findings of biomedical and public health research for political purposes.

Res. 409, A-99 Modified CLRPD Rep. 1, A-03 Reaffirmed: CSAPH Rep. 1, A-13 Appended: Res. 206, A-13 Reaffirmation A-15 Appended: Res. 902, I-16

Resolution: 420

(A-19)

Introduced by: Resident and Fellow Section

Subject: Coordinating Correctional and Community Healthcare

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, The United States has the highest rate of incarceration in the world<sup>1</sup> with an estimated 6,899,000 individuals held under the supervision of the correctional system at year end 2013<sup>2</sup>; and

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Whereas, The incarcerated population has higher rates of many chronic diseases, including tuberculosis, HIV, hepatitis, asthma, mental health disorders, and substance abuse than the general public<sup>3</sup>; and

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Whereas, The increased aging of the prison population will only increase the rates of chronic medical conditions<sup>4</sup>; and

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14 15 Whereas, The health benefits gained through incarceration, such as food, housing, medication, and access to healthcare are lost upon release, as shown by the increased rate of all-cause mortality in the two weeks following release, as well as the increased rate of hospitalization among recently released inmates compared to the general public and the increased utilization of the emergency department and acute care settings<sup>5-6</sup>; and

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Whereas, Health benefits have been demonstrated from the linkage of care from correctional institutions to community health clinics and resources, with poorer chronic health outcomes seen in those not linked to care on reentry compared to those linked tocare, as well as decreased utilization of emergency department in those linked to community health care upon release<sup>7-8</sup>; therefore be it

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<sup>&</sup>lt;sup>1</sup> Cloud DH, Parsons J, Delany-Brumsey A. Addressing mass incarceration: a clarion call for public health. *Am J Public Health*. 2014;104(3):389-391.

<sup>&</sup>lt;sup>2</sup> Glaze LE, Kaeble D. Correctional populations in the United States, 2013. Bureau of Justice Statistics; 2014. Available at <a href="http://www.bjs.gov/index.cfm?ty=pbdetail&iid=5177(www.bjs.gov">http://www.bjs.gov/index.cfm?ty=pbdetail&iid=5177(www.bjs.gov)</a>. Accessed April 1, 2016.

<sup>&</sup>lt;sup>3</sup> Marks JS and Turner N. The critical link between health care and jails. *Health Affairs*. 2014: 33(3): 443-447.

<sup>&</sup>lt;sup>4</sup> Williams BA, Goodwin JS, Baillargeon J, Ahalt C, Walter LC. Addressing the aging crisis in U.S. criminal justice health care. *J Am Geriatr Soc.* 2012;60(6):1150-1156.

<sup>&</sup>lt;sup>5</sup> Binswanger IA, Stern MF, Deyo RA, et al. Release from prison--a high risk of death for former inmates. *N Engl J Med*. 2007;356(2):157-165.

<sup>&</sup>lt;sup>6</sup> Frank JW, Linder JA, Becker WC, Fiellin DA, Wang, E. Increased hospital and emergency department utilization by individuals with recent criminal justice involvement: results of a national survey. *JGIM*. 29(9): 12256-33.

<sup>&</sup>lt;sup>7</sup> Montague BT, Rosen DL, Sammartino C, et al. Systematic Assessment of Linkage to Care for Persons with HIV Released from Corrections Facilities Using Existing Datasets. *AIDS Patient Care STDS*. 2016;30(2):84-91.

<sup>&</sup>lt;sup>8</sup> Montague BT, Rosen DL, Sammartino C, Costa M, Gutman R, Solomon L, Rich J. Systemic assessment of linkage to care of persons with HIV released from corrections facilities using existing databases. *AIDS Patient Care and STDs.* 2016: 30(2): 84-91.

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23 RESOLVED, That our American Medical Association support linkage of those incarcerated to 24 community clinics upon release in order to accelerate access to primary care and improve 25 health outcomes among this vulnerable patient population, as well as adequate funding (New 26 HOD Policy); and be it further

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RESOLVED, That our AMA support the collaboration of correctional health workers and community health care providers for those transitioning from a correctional institution to the community. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 05/01/19

#### **RELEVANT AMA POLICY**

#### Standards of Care for Inmates of Correctional Facilities H-430.997

Our AMA believes that correctional and detention facilities should provide medical, psychiatric, and substance misuse care that meets prevailing community standards, including appropriate referrals for ongoing care upon release from the correctional facility in order to prevent recidivism.

Citation: (Res. 60, A-84; Reaffirmed by CLRPD Rep. 3 - I-94; Amended: Res. 416, I-99; Reaffirmed:

CEJA Rep. 8, A-09; Reaffirmation I-09; Modified in lieu of Res. 502, A-12; Reaffirmation: I-12

#### Health Care While Incarcerated H-430.986

- 1. Our AMA advocates for adequate payment to health care providers, including primary care and mental health, and addiction treatment professionals, to encourage improved access to comprehensive physical and behavioral health care services to juveniles and adults throughout the incarceration process from intake to re-entry into the community.
- 2. Our AMA supports partnerships and information sharing between correctional systems, community health systems and state insurance programs to provide access to a continuum of health care services for juveniles and adults in the correctional system.
- 3. Our AMA encourages state Medicaid agencies to accept and process Medicaid applications from juveniles and adults who are incarcerated.
- 4. That our AMA encourage state Medicaid agencies to work with their local departments of corrections, prisons, and jails to assist incarcerated juveniles and adults who may not have been enrolled in Medicaid at the time of their incarceration to apply and receive an eligibility determination for Medicaid.
- 5. Our AMA encourages states to suspend rather than terminate Medicaid eligibility of juveniles and adults upon intake into the criminal justice system and throughout the incarceration process, and to reinstate coverage when the individual transitions back into the community.
- 6. Our AMA urges the Centers for Medicare & Medicaid Services (CMS) and state Medicaid agencies to provide Medicaid coverage for health care, care coordination activities and linkages to care delivered to patients up to 30 days before the anticipated release from correctional facilities in order to help establish coverage effective upon release, assist with transition to care in the community, and help reduce recidivism.
- 7. Our AMA advocates for necessary programs and staff training to address the distinctive health care needs of incarcerated women and adolescent females, including gynecological care and obstetrics care for pregnant and postpartum women.

Citation: CMS Rep. 02, I-16

Resolution: 421

(A-19)

Introduced by: Resident and Fellow Section

Subject: Contraception for Incarcerated Women

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, The United States accounts for over 30% of the world's population of incarcerated women<sup>1</sup> and currently houses more than 200,000 female prisoners<sup>2</sup>; and

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Whereas, The population of females in jail or prison worldwide has risen 53% since the year 2003; and

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> Whereas, The majority of incarcerated women in the United States are between the ages of 18 and 44, and therefore are within reproductive age 4; and

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Whereas, Up to 84% of incarcerated women have had a prior unintended pregnancy<sup>5</sup>, 77-84% of incarcerated women plan to be sexually active within six months of release<sup>6</sup> and 72% of incarcerated women were not using a regular form of contraception prior to incarceration; and

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Whereas. The majority of women incarcerated have multiple barriers to accessing healthcare upon release from jail, and incarceration provides a unique opportunity to provide healthcare to a resource poor population; and

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Whereas. Our AMA has policy which advocates for necessary programs and staff training to address the distinctive health care needs of incarcerated women and adolescent females and encourages improved access to comprehensive physical and behavioral health care services to adults and juveniles while incarcerated; and

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Whereas, Our AMA has policy that advocates for necessary programs and staff training to address the distinctive health care needs of incarcerated women and adolescent females, including gynecological care and obstetrics care for pregnant and postpartum; therefore be it

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RESOLVED, That our American Medical Association support incarcerated persons' access to evidence-based contraception counseling, access to all contraceptive methods and autonomy over contraceptive decision-making prior to release. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 05/01/19

#### References:

- 1 Kajstura, Alexis. (2018), "States of Women's Incarceration: The Global Context 2018" Prison Policy Initiative. URL https://www.prisonpolicy.org/global/women/2018.html, accessed August 31, 2018.
- 2 Walmsley, R (2017). World Female Imprisonment List, Fourth Edition. Institute for Criminal Policy Research.
- 3 Kajstura, Alexis (2017), "Women's Mass Incarceration: The Whole Pie 2017". Prison Policy Initiative. URL https://www.prisonpolicy.org/reports/pie2017women.html Accessed August 31, 2018.
- 4 Carson, AE (2018), "Prisoners in 2016" (No. NCJ 251149), Department of Justice, Bureau of Justice Statistics, Washington DC.

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5 Clarke, JG; Hebert, MR; Rosengard, C; et al. "Reproductive healthcare and family planning needs among incarcerated women", Am Journal Public Health, Vol 96, p. 834-839.

6 Larocelle, F; Castro, C; Goldenson, J; Tulsky, JP; et al. (2012), "Contraceptive use and barriers to access among newly arrested women", J Correct Health Care, Vol 18, p. 111-119.

7 Oswalt, K; Hale, GJ; Cropsey, KL; et al. (2010), "The contraceptive needs for STD protection among women in jail", Health Educ. Behav. Off. Publ. Soc. Health Educ., Vol 37, p. 568-579.

#### **RELEVANT AMA POLICY**

#### Health Care While Incarcerated H-430.986

- 1. Our AMA advocates for adequate payment to health care providers, including primary care and mental health, and addiction treatment professionals, to encourage improved access to comprehensive physical and behavioral health care services to juveniles and adults throughout the incarceration process from intake to re-entry into the community.
- 2. Our AMA supports partnerships and information sharing between correctional systems, community health systems and state insurance programs to provide access to a continuum of health care services for juveniles and adults in the correctional system.
- 3. Our AMA encourages state Medicaid agencies to accept and process Medicaid applications from juveniles and adults who are incarcerated.
- 4. That our AMA encourage state Medicaid agencies to work with their local departments of corrections, prisons, and jails to assist incarcerated juveniles and adults who may not have been enrolled in Medicaid at the time of their incarceration to apply and receive an eligibility determination for Medicaid.
- 5. Our AMA encourages states to suspend rather than terminate Medicaid eligibility of juveniles and adults upon intake into the criminal justice system and throughout the incarceration process, and to reinstate coverage when the individual transitions back into the community.
- 6. Our AMA urges the Centers for Medicare & Medicaid Services (CMS) and state Medicaid agencies to provide Medicaid coverage for health care, care coordination activities and linkages to care delivered to patients up to 30 days before the anticipated release from correctional facilities in order to help establish coverage effective upon release, assist with transition to care in the community, and help reduce recidivism
- 7. Our AMA advocates for necessary programs and staff training to address the distinctive health care needs of incarcerated women and adolescent females, including gynecological care and obstetrics care for pregnant and postpartum women.

Citation: CMS Rep. 02, I-16

# Standards of Care for Inmates of Correctional Facilities H-430.997

Our AMA believes that correctional and detention facilities should provide medical, psychiatric, and substance misuse care that meets prevailing community standards, including appropriate referrals for ongoing care upon release from the correctional facility in order to prevent recidivism.

Citation: (Res. 60, A-84; Reaffirmed by CLRPD Rep. 3 - I-94; Amended: Res. 416, I-99; Reaffirmed:

CEJA Rep. 8, A-09; Reaffirmation I-09; Modified in lieu of Res. 502, A-12; Reaffirmation: I-12

#### Reducing Unintended Pregnancy H-75.987

Our AMA: (1) urges health care professionals to provide care for women of reproductive age, to assist them in planning for pregnancy and support age-appropriate education in esteem building, decision-making and family life in an effort to introduce the concept of planning for childbearing in the educational process; (2) supports reducing unintended pregnancies as a national goal; and (3) supports the training of all primary care physicians and relevant allied health professionals in the area of preconception counseling, including the recognition of long-acting reversible contraceptives as efficacious and economical forms of contraception.

Citation: Res. 512, A-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmation A-15; Appended: Res. 502, A-15; Reaffirmation I-16

Resolution: 422

(A-19)

Introduced by: Resident and Fellow Section

Subject: Promoting Nutrition Education Among Healthcare Providers

Referred to: Reference Committee D

(Diana Ramos, MD, Chair)

Whereas, The prevalence of obesity in the United States is on the continuous rise unchecked, with more than one-third of the population being obese; and

Whereas, The growing burden of obesity is enormous, with about \$68 billion direct medical costs and 280,000 deaths each year <sup>1</sup>; and

Whereas, Millions of people in the US file for disability each year<sup>2</sup>; and

Whereas, Clinicians tend to focus more on the complications of obesity such as hypertension, Type II Diabetes and coronary artery disease. However, the importance of primary prevention in early identification and intervention of obesity is seldom discussed by physicians; and

Whereas, The common misconception that nutrition counseling is not their role, but rather the function of dieticians, is still prevalent among healthcare providers; and

Whereas, Some of the important barriers to counseling include lack of nutrition knowledge and skills in nutrition counseling among the medical practitioners.<sup>3</sup> Physicians often do not feel comfortable, confident, or adequately prepared in discussing their patients' diet<sup>3</sup>; and

Whereas, Targeting the dietary habits of our patients and preventing obesity offers a tremendous opportunity to optimize the overall quality of patient care, improve clinical outcomes, and reduce overall healthcare costs; and

Whereas, Nutrition knowledge appears confined largely to books and exams. In fact, according to one study, doctors engage in nutrition counseling with patients only 11% of the time3; and

Whereas, In teaching hospitals, where residents work closely with patients, it is crucial that residents develop a comprehensive knowledge of nutrition science and apply that knowledge to clinical practice; therefore be it

RESOLVED, That American Medical Association Policy H-150.995, "Basic Courses in Nutrition," be reaffirmed (Reaffirm HOD Policy); and be it further

RESOLVED, That AMA Policy H-150.953, "Obesity as a Major Public Health Problem," be reaffirmed. (Reaffirm HOD Policy)

Fiscal Note: Minimal - less than \$1,000.

Received: 05/01/19

Resolution: 422 (A-19)

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#### References:

- 1. Tremmel M, Gerdtham U-G, Nilsson PM, Saha S. Economic burden of obesity: A systemic literature review. Int J Environ Res Public Health.2017; 14(4):435.
- 2. Lazarus K, Weinsier RL, Boker JR. Nutrition knowledge and practices of physicians in a family-practice residency program: the effect of an education program provided by a physician nutrition specialist. Am J Clin Nutr.1993; 58:319-25.
- 3. Vetter ML, Herring SJ, Sood M, Shah NR, Kalet AL. What do resident physicians know about nutrition? An evaluation of attitudes, self-perceived proficiency and knowledge. J Am Coll Nutr.2008; 27(2):287-298.

#### **RELEVANT AMA POLICY**

#### **Basic Courses in Nutrition H-150.995**

Our AMA encourages effective education in nutrition at the undergraduate, graduate, and postgraduate levels.

Citation: (Sub. Res. 116, A-78; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CME Rep. 2, A-11

# Obesity as a Major Public Health Problem H-150.953

Our AMA will: (1) urge physicians as well as managed care organizations and other third party payers to recognize obesity as a complex disorder involving appetite regulation and energy metabolism that is associated with a variety of comorbid conditions;

- (2) work with appropriate federal agencies, medical specialty societies, and public health organizations to educate physicians about the prevention and management of overweight and obesity in children and adults, including education in basic principles and practices of physical activity and nutrition counseling; such training should be included in undergraduate and graduate medical education and through accredited continuing medical education programs;
- (3) urge federal support of research to determine: (a) the causes and mechanisms of overweight and obesity, including biological, social, and epidemiological influences on weight gain, weight loss, and weight maintenance; (b) the long-term safety and efficacy of voluntary weight maintenance and weight loss practices and therapies, including surgery; (c) effective interventions to prevent obesity in children and adults; and (d) the effectiveness of weight loss counseling by physicians;
- (4) encourage national efforts to educate the public about the health risks of being overweight and obese and provide information about how to achieve and maintain a preferred healthy weight;
- (5) urge physicians to assess their patients for overweight and obesity during routine medical examinations and discuss with at-risk patients the health consequences of further weight gain; if treatment is indicated, physicians should encourage and facilitate weight maintenance or reduction efforts in their patients or refer them to a physician with special interest and expertise in the clinical management of obesity;
- (6) urge all physicians and patients to maintain a desired weight and prevent inappropriate weight gain:
- (7) encourage physicians to become knowledgeable of community resources and referral services that can assist with the management of overweight and obese patients; and
- (8) urge the appropriate federal agencies to work with organized medicine and the health insurance industry to develop coding and payment mechanisms for the evaluation and management of obesity. Citation: (CSA Rep. 6, A-99; Reaffirmation A-09; Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmation A-10; Reaffirmation I-10; Reaffirmation A-12; Reaffirmed in lieu of Res. 434, A-12; Reaffirmation A-13; Reaffirmed: CSAPH Rep. 3, A-13