Partnership for Prevention®
Shaping Policies • Improving Health

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A PREVENTION POLICY AGENDA FOR THE 110TH CONGRESS

Partnership for Prevention aims to transform the U.S. health system from one that spends most of its resources treating diseases and injuries to one that focuses "upstream" on prevention. The end result of this goal? Longer, healthier lives, a more productive nation, and lower healthcare costs.

Prevention, however, will not happen on a large-scale without fundamental policy change. Congress must play a critical role by tackling the biggest influencers of poor health nationwide: tobacco use, unhealthy diets and physical inactivity, alcohol misuse, and going without clinical preventive services, such as immunizations, screenings, and counseling.

Partnership has identified high-impact policies in each of these critical areas for which strong evidence exists that the policy will significantly reduce disease or injury and that can be enacted with a very small (or no) budget impact. Enacting the four high-impact policies listed below will save thousands of lives each year and improve the health of millions of Americans.

1. **Authorize FDA regulation of tobacco.**

Tobacco products are currently unregulated; FDA regulation will increase the safety of tobacco products and will reduce tobacco use—the leading preventable cause of death—among minors.

2. **Restore FTC authority to regulate food and beverage marketing aimed at children.**

Parental guidance can be undermined by the marketing of unhealthy foods and beverages aimed at young children. The Federal Trade Commission should be authorized, although not required, to regulate how food is marketed and what kinds of foods are marketed to children.

3. **Increase the cost of alcoholic beverages.**

Increasing the cost of alcohol has been proven to reduce the level and frequency of underage drinking and the serious negative health consequences that result from it. Alcohol excise taxes have not kept pace with inflation, effectively reducing the real cost of alcoholic beverages.

4. **Emphasize prevention in Medicare and Medicaid:**

- Give the Centers for Medicare & Medicaid Services (CMS) authority to add and remove coverage for preventive services in Medicare;
- Extend the eligibility period and remove the deductible from the Welcome to Medicare Visit, which gives new Medicare beneficiaries an important opportunity to receive needed preventive health services; and
- Create an incentive for states to cover tobacco use screening and treatment in their Medicaid programs.

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AUTHORIZE FDA REGULATION OF TOBACCO

Policy: Give the United States Food and Drug Administration (FDA) authority to regulate tobacco products and tobacco advertising.

Intended Outcome: The purpose of this policy is to decrease tobacco use and tobacco-attributable mortality and morbidity by reducing the harmful effects of tobacco products, preventing the sale of tobacco products to minors, and ensuring that consumers are fully informed of the contents of tobacco products.

Burden Addressed: Tobacco use is the leading preventable cause of death in the United States. It accounts for approximately 440,000 deaths per year from diseases including lung cancer, coronary heart diseases, and stroke. CDC estimates that if current smoking patterns continue 5 million people who are currently younger than 18 will die from a tobacco-related illness.[1]

Background: The number of youth, ages 12-17, using any tobacco product has decreased from 15.5% in 2003 to 13.1% in 2005 with females slightly more likely to report having used a tobacco product in the past month than males.[2] Despite this recent decline, 23% of high school students consider themselves cigarette smokers[3] and every day, approximately 3,900 youth ages 12-17 initiate cigarette smoking in the United States.[4]

FDA regulation of tobacco products has three main aims:

1. Regulation of the ingredients of tobacco and of additives found in tobacco products;
2. Restriction of youth access to tobacco products; and
3. Regulation of the marketing and labeling of tobacco products.

The FDA regulates the sale of drugs and medical devices, prohibits the sale of unsafe products, and has the authority to recall items that are found to be unsafe after initial approval.[5] Under the statutory definitions of drugs and medical devices, products regulated by the FDA must either be used in the diagnosis or treatment of a disease, or intended by a manufacturer to affect the structure or function of the body. In accordance with the statutes governing FDA review of drugs and medical devices, the FDA has determined that nicotine is a drug, that tobacco products are designed to introduce measured doses of nicotine into the body, and that they are therefore drug delivery devices. However, the FDA does not have jurisdiction over tobacco products. Therefore currently, tobacco products are subject to minimal oversight by the federal government, and their producers are not required to disclose to consumers the ingredients in tobacco products.[6]

Evidence/Effectiveness: While tobacco products cannot be made to be completely safe, steps can be taken to ensure that they are no more dangerous than those sold in other countries. Tobacco products sold in the United States have been found to be more poisonous than necessary: amounts of nitrosamines, which are carcinogens, are significantly higher in American brands of cigarettes than in comparable brands sold in Germany and Japan.[7]

In 2000, the U.S. Surgeon General issued a report, “Reducing Tobacco Use: A Report of the Surgeon General.” The report reviews and offers numerous strategies for reducing tobacco use. Though the

report does not specifically mention FDA, one of its main findings is that there is a need for more regulation of the sale and promotion of tobacco products, particularly to youth and young adults, to reduce the usage (and to prevent the initiation of usage) of tobacco products. It also finds that product labels should be stronger and more informative. Both recommendations have proven effective in reducing tobacco use.[8]

Legislative Context: In 1994, the FDA began to assert its jurisdiction over tobacco products and on April 25, 1997, Judge William Osteen of the U.S. District Court for the Middle District in Greensboro, NC, ruled that FDA has the authority to regulate tobacco products as drug delivery devices. Unfortunately, in August 1998, the U.S. Court of Appeals for the Fourth Circuit in Richmond, VA reversed Osteen's decision. In March 2000, the U.S. Supreme Court upheld the Court of Appeals' decision. The two higher courts found that neither current federal law nor precedence gives FDA such authority.[9]

Based on these rulings, federal law is necessary for FDA to regulate tobacco products. There have been two attempts to amend the FDA governing statute with the Family Smoking Prevention and Tobacco Control Act both in the 108th (S.2974 and S.2461/H.R.4433) and 109th Congresses (S.666/H.R.1376). The Act would authorize FDA to: restrict tobacco advertising and promotions, especially in children; develop standards that require changes in tobacco product composition and design, such as the reduction or elimination of toxic chemicals; and require manufacturers to obtain agency approval in order to make reduced-risk and reduced-exposure claims for their products. S.666/H.R.1376 are currently in subcommittee. It is worth noting that S.2974 was passed in the Senate without amendment by Unanimous Consent.

RESTORE FTC AUTHORITY TO REGULATE FOOD AND BEVERAGE MARKETNG AIMED AT CHILDREN

Policy: Enact legislation restoring the Federal Trade Commission's (FTC) authority to regulate marketing of unhealthful foods to children.

Intended Outcome: The purpose of this policy is to reduce children's exposure to marketing of unhealthful foods, especially television advertising, thus reducing their demand for and consumption of those foods. This policy would give the federal government a means to accomplish this goal. Restoring FTC authority would give the FTC the means to accomplish this if the food industry does not take substantive voluntary action to limit the marketing of unhealthy foods to children.

Burden Addressed: Over the past 30 years, the prevalence of obesity has more than doubled for children aged 2-5 years and adolescents aged 12-19 years, and tripled for children aged 6-11 years.[1] Over-consumption of fat- and calorie-laden foods and beverages is known to contribute to obesity, particularly when combined with a sedentary lifestyle.[10]

Background: Research has shown that taste preferences, eating habits, and knowledge of brands and products form early in life. The majority of products introduced and marketed to children and youth are unhealthful (i.e., high in sugars, sodium, total calories, and fat, and low in nutrients). Food and beverage television advertising to children is problematic because unlike adults, children have difficulty distinguishing between commercial and programmatic content on television and understanding the selling intent of marketing messages. Due to these cognitive inabilities, it can be argued that advertising to children can be deceptive and misleading.[11]

The FTC has primary responsibility for ensuring advertising is not deceptive or unfair. In the late 1970s, FTC proposed banning television advertising of sugary foods aimed at young children because children are too young to understand the health risks of excessive sugar consumption. After three years of public comment, FTC staff recommended terminating the rulemaking proceeding because a workable solution could not be found. Congress strongly criticized the proposal and allowed FTC's funding to lapse, then passed a law in 1980 prohibiting FTC from using unfairness as a basis for adopting any rule to regulate advertising to children.[12] The Children's Advertising Review Unit (CARU), a self-regulatory program established in 1974 and funded by the children's advertising industry, reviews children's advertisements for deception or unfairness.[13] However, CARU does not limit the volume of advertisements aimed at children and their current guidelines do not address the nutritional content of advertised foods or beverages.

Stronger regulation of children's advertising of unhealthful foods is being revisited due to increasing rates of childhood obesity. Many health organizations support restoring FTC's authority to rule on television advertising to children, arguing that the food and beverage industries have not done enough voluntarily to curb the abundance of unhealthful food advertisements to which children are exposed. Congress recently asked FTC to study the food and beverage industries' marketing activities to children, indicating a growing receptivity to this issue.

The Institute of Medicine (IOM) released a report in December 2005 recommending greater self-regulatory efforts to emphasize healthier food and beverages in children's television advertisements.[2]

The IOM further recommends that Congress enact legislation mandating children's advertising on broadcast and cable television emphasizes healthier foods and beverages if voluntary efforts fail.

Other countries have restricted television advertising of unhealthful foods to children. Sweden and Norway banned all food advertising to children on local television stations.[2] In November 2006, the UK broadcasting regulator, Ofcom, enacted a similar ban on all foods high in fat, salt and sugar that extends to cable and satellite children's stations.[3]

Evidence/Effectiveness: A robust body of evidence demonstrates that food and beverage advertisements negatively impact children's nutrition and contribute to obesity. Recently, a systematic review of 123 studies conducted by the Committee on Food Marketing and the Diets of Children and Youth concluded that: 1) there is strong evidence that television advertising influences the food and beverage preferences of children aged 2-11 years; 2) there is strong evidence that television advertising influences short-term consumption among children aged 2-11 years; and 3) there is strong evidence that exposure to television advertising is associated with adiposity in children and youth aged 2-18 years.[2]

INCREASE THE COST OF ALCOHOLIC BEVERAGES

Policy: Increase the cost of alcoholic beverages by increasing the federal excise tax on alcohol.

Intended Outcome: The purpose of this policy is to reduce the incidence of alcohol-attributable illness and death, especially among youth.

Burden Addressed: Alcohol abuse is the third leading cause of preventable death in the United States and has numerous harmful effects such as cirrhosis of the liver, alcohol psychosis, and breast cancer. In 2001, excessive alcohol consumption was responsible for 75,766 deaths and 2,279,322 years of potential life lost.[14] In 2003, 30% of fatal traffic crashes were alcohol related;[15] 28% of these accidents involved intoxicated drivers ages 16-24. [16]

Background: In fiscal year 2004, taxes on alcoholic beverages generated $8.47 billion at the federal level.[17]

Because there has never been an adjustment for inflation, the real rate of tax, and, as a consequence, the real price of alcoholic beverages has been decreasing since 1951, despite periodic nominal tax increases. [18] Over the past five decades, the real price of beer has fallen by 25% relative to the Consumer Price Index and liquor has decreased by almost 50%.[19]

Evidence/Effectiveness: The most recent increase in the federal excise tax on alcohol took place in 1991. Following the increase, overall per capita alcohol consumption dropped by 6.1%, and has shown a small general decreasing trend since 1991, most likely due to a number of factors.

There is a substantial body of research on the responsiveness of consumption to changes in price – the price elasticity of demand – of alcoholic beverages. The general consensus is that, overall, alcoholic beverages obey the law of demand: higher prices lead to decreased levels of consumption.[20]

Low alcohol prices directly affect underage drinkers. The National Bureau of Economic Research estimates that if alcohol tax increases had kept up with the inflation rate, the number of youth who drink beer would be 24% less that it is today.

Ponicki and Gruenewald (2006) published a study that investigated the relationship between alcohol taxation and liver cirrhosis mortality. The researchers found that cirrhosis rates are indirectly correlated with tax rates on distilled spirits.[21]

Legislative Context: Federal taxes on alcoholic beverages, last increased in the Omnibus Reconciliation Act of 1990 (PL 101-508), are per unit, i.e., they are expressed as a sum of money per quantity of beverage, rather than as a percentage of the price. Since January 1, 1991, the taxes have been $18.00 per 31-gallon barrel of beer, or about 33 cents per six-pack; $1.07 per gallon of table wine, or about 21 cents a bottle; and $13.50 per proof gallon of distilled spirits, or about $2.14 per 750-mL bottle. The 1991 tax increases represented a 100% increase in the tax on beer, a 519% increase in the tax on table wine, and an 8% increase in the tax on spirits.[22]

In May 2005, 59 economists, 3 of whom are winners of the Nobel Prize for Economics, sent a petition to Congress calling for higher taxes on alcoholic beverages stating that an alcohol tax increase is overdue and well justified. The economists said that Congress "would be well advised to increase a tax that would both help close the federal deficit and discourage the continued epidemic of alcohol abuse."[23]

INCREASE UTILIZATION OF PREVENTIVE SERVICES IN MEDICARE AND MEDICAID

Policies:
1) Give the Centers for Medicare & Medicaid Services (CMS) authority to add and remove coverage for preventive services in Medicare.
2) Extend the eligibility period and remove the deductible from the Welcome to Medicare Visit.
3) Create an incentive for states to cover tobacco use screening and treatment in their Medicaid programs.

Intended Outcome: The purpose of this policy is to improve the health of Medicare and Medicaid beneficiaries by increasing their use of clinical preventive services that have been proven effective.

Background/Problem:
***1) Give CMS authority to add and remove coverage for preventive services in Medicare*:**
The statute governing Medicare has consistently been interpreted as limiting coverage to diagnosis and treatment services. Thus, an act of Congress is required to expand or reduce Medicare coverage for clinical preventive services, and no mechanism currently exists for revisiting covered preventive services when new evidence emerges about appropriate screening technologies, periodicities, target populations, etc. Because the legislative process moves slowly, coverage has frequently not been aligned with the latest evidence. Also, because special interests often influence legislation about preventive service benefits, coverage is not always aligned with evidence-based recommendations.

As result of the Medicare Modernization Act of 2003 and other recent changes, most preventive services currently recommended by the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices are currently covered under Medicare (albeit often with different co-pay and deductible requirements) after years of discrepancy between what is recommended and what is covered. However, problems remain and will continue to arise as more preventive services are proven to be effective. For example, the Advisory Committee on Immunization Practices recently approved the herpes zoster vaccine to prevent the painful disease shingles in older adults. However, because CMS does not have authority to cover preventive services under Part B, it cannot reimburse physicians for the cost of administering this vaccine to their patients. In other instances, Medicare coverage for preventive services is too generous, promoting inappropriate demand and overuse of services, which increases costs to Medicare with no corresponding health benefit. For example, Congress mandated that Medicare cover colonoscopy every 24 months for the detection of colorectal cancer. The American Cancer Society and the U.S. Preventive Services Task Force are in agreement that colonoscopy is only necessary every 10 years. Medicare also covers annual prostate cancer screening for all male beneficiaries, which is not recommended by the U.S. Preventive Services Task Force. The American Cancer Society recommends limiting screening to men over 50 with at least a 10-year life expectancy.

2) Extend the eligibility period and remove the deductible from the Welcome to Medicare Visit: The Welcome to Medicare Visit (WMV), which was established by the Medicare Modernization Act of 2003, aims to encourage new Medicare enrollees to visit their primary care provider to obtain a preventive care plan. The value of the WMV is that it establishes a source of primary care for beneficiaries who lack access, and it provides a dedicated opportunity to emphasize the importance of prevention as patients enter the Medicare program. Beneficiaries can be reminded about the benefits of

exercise, healthy diet, smoking cessation, and injury prevention, even after years of inattention. Clinicians can underscore the importance of recommended screening tests and immunizations and can either provide these services during the WMV or arrange referrals or future appointments.

When it enacted the WMV, Congress chose not to waive the deductible for the visit. For new beneficiaries who have not met their deductible, the out-of-pocket costs ($124 for 2006) will likely dampen their interest in the WMV, especially among low-income individuals.

In addition, the WMV must be used within the first 6 months of enrollment in Medicare. One barrier this presents is that beneficiaries may have difficulty making an appointment with a clinician within six months of enrolling in Medicare. Also, because the visit is limited to a small group of beneficiaries, it applies to only a few patients in any given physician practice. This makes it impractical for most primary care practices to organize themselves to promote and deliver the visit.

3) Create incentives for states to cover tobacco use screening and treatment in their Medicaid programs:

The Early Periodic Screening, Diagnosis, and Treatment (EPSDT) program mandates coverage for an array of preventive and diagnostic services for all children and adolescents enrolled in Medicaid. In contrast, however, coverage for preventive services for adults enrolled in Medicaid varies by state.

The most important coverage gap for adults enrolled in Medicaid is coverage for tobacco use screening and treatment.[24] The National Commission on Prevention Priorities, chaired by former U.S. Surgeon General Dr. David Satcher, ranked 25 recommended preventive services, such as mammography, colorectal cancer screening, and flu shots, and found that the three preventive services offering the greatest health benefit and cost savings are 1) tobacco use screening and treatment; 2) childhood immunizations; and 3) advising high-risk adults about daily aspirin use. Increasing delivery of tobacco use screening and treatment above current levels would yield 1.3 million years of healthy life. The National Commission also found that providing tobacco use screening and treatment services to all tobacco users would save $500 in medical care costs per person treated (taking into account that many of those treated will not quit). This translates into billions of dollars of health care savings for the nation.[25]

As of December 31, 2005, 38 state Medicaid programs reported covering at least one form of tobacco-dependence treatment for all Medicaid beneficiaries. Only 14 states, however, offered some form of tobacco-cessation counseling for *all* Medicaid beneficiaries; 12 additional states covered counseling only for pregnant women. Only one state, Oregon, covers all treatments recommend by the U.S. Public Health Service guidelines.[26]

In March 2005, at the urging of Partnership for Prevention, CMS issued a rare national coverage decision requiring all Medicare carriers in the U.S. to pay for tobacco use screening and treatment for all beneficiaries with tobacco-related conditions or who are taking medications that could be affected by tobacco use.[27] Thus, the government pays for tobacco use treatment for adults age 65 and older, but does so inconsistently for younger adults on Medicaid, who have more years to benefit from treatment.

Evidence/Effectiveness: Lack of reimbursement is a major barrier to improving utilization of preventive services. Rigorous studies have demonstrated, for example, that removing financial barriers

increases vaccination rates and breast cancer screening.[28, 29] Reducing out-of-pocket costs has also been shown to increase use of tobacco cessation therapies.[30]

Legislative Context:

Medicare: A string of bills, enacted by Congress between 1980 and 2003, expanded Medicare coverage to include many screening and immunization services, including the WMV that was passed in December 2003 and took effect on January 1, 2005.[31] Thus, most preventive services for older Americans recommended by the USPSTF and ACIP are currently covered under Medicare, with the notable exceptions of hearing and vision screening. Some recommended counseling services are also not specifically covered (such as counseling patients to consider daily aspirin use and counseling women at high-risk about chemoprevention of breast cancer), although minimal counseling should be reimbursable as part of an evaluation and management (E&M) visit. The Deficit Reduction Act of 2005, signed by President Bush in February 2006, removed the deductible for colorectal cancer screening effective in 2007, but the 25% co-pay remains.

Medicaid: States have used the broad flexibility inherent in Medicaid to create many eligibility, coverage, and financing policies that meet the diverse needs of their populations and the states' own financial circumstances. Thus, population groups covered by Medicaid vary considerably by state. Senator Harkin is considering introducing a bill that would amend title XIX of the Social Security Act to encourage states to provide pregnant women enrolled in the Medicaid program with access to comprehensive tobacco cessation services. This bill would offer states the incentive of an enhanced federal medical assistance percentage (FMAP) match for covering a comprehensive tobacco cessation program for pregnant women enrolled in Medicaid. While pregnant women are certainly a key eligibility group in every state's Medicaid program, Partnership believes it is important to encourage state Medicaid programs to cover comprehensive tobacco cessation for *all* adults enrolled in Medicaid (including pregnant women).

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