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August 13, 2010

Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C., 20201

Dear Secretary Sebelius:

The American Thoracic Society (ATS) is a multi-disciplinary society of over 15,000 members committed to the prevention and treatment of respiratory diseases, sleep disorders and critical illnesses through research, education, patient care and advocacy. We thank the Secretary for the opportunity to comment on the Department's Strategic Plan 2010 – 2015. The ATS congratulates the Administration on enactment of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) and stands ready to assist the department in implementation of its measures to increase access to health insurance for Americans, including preventive care, control healthcare costs, reorient the healthcare system to reward the delivery of quality care, and promote chronic disease management, prevention and wellness. We have comments on the following elements of the strategic plan:

Goal 1: Transform Health Care

Objective A: Make coverage more secure for those who have insurance, and extend affordable coverage to the uninsured

The ATS believes health care is a right for all Americans.¹ We support the Department's objective to make coverage more secure for Americans who have insurance through the implementation of private market reforms, including prohibitions on insurance rescissions when people become ill and denials of coverage based on preexisting conditions, and the expansion of insurance coverage through high-risk pools, state insurance exchanges, subsidies for the purchase of insurance, and Medicaid expansions. The ATS is pleased that a measure to make Medicaid pediatric reimbursement equitable with Medicare reimbursement was enacted as part of the Affordable Care Act, and urges the Secretary to fully implement this provision and ensure that all pediatric providers, including pediatric pulmonologists and sleep specialists, are included. This important measure will remove an access barrier for children with respiratory diseases.



*The ATS is a proud participant
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The ATS notes that expanding health insurance coverage, while a laudable goal, does not mean access to physicians has increased. The increased number of insured patients will put additional demands on the existing health care workforce. The physician workforce is already under pressure from severe shortages in some fields (see workforce comments) and economic pressure from payors. The inability of Congress and the Administration to permanently resolve the Medicare SGR formula crisis has eroded many physicians trust in federally sponsored insurance programs. An important process step in expanding insurance coverage will be restoring trust between federal programs and the physician community. Reaching a successfully permanent resolutions of the SGR would go a long way in re-establishing that trust.

Objective B: Improve health care quality and patient safety

Strategy: Increase the availability of patient-centered outcomes research to give patients and practitioners evidence on the most effective medical options

The ATS shares the Department's goal to improve health care quality and patient safety, including the strategy to increase patient-centered outcomes research. The ATS recognizes the need for research to study and establish the clinical benefits of medical treatments to enable the best patient care. Recent data suggests that patient reported outcomes (PROs), such as measures of quality of life, predict survival. It will be important to include such measures in future patient-centered outcomes research.

The following are some of the ATS's additional recommended areas for patient-centered outcomes studies:

- Home-based care of COPD
- Pulmonary rehabilitation therapy for the treatment of interstitial lung disease
- Development of best practices for telemedicine and e-intensive care units
- Support for the development and implementation of evidence-based guidelines for prevention and treatment of sepsis and of acute lung injury, both increasingly common causes of morbidity and mortality in the U.S.
- Mechanisms to track patient outcomes and evidence-based quality of care in pediatric sleep disorders, including creation of a national registry.

We look forward to working with the Secretary on the development of additional research priorities within respiratory, critical care and sleep medicine to ensure adequate representation of these conditions that reflect their public health burden.

Strategy: Implement payment reforms that reward quality care

The ATS supports efforts to link reimbursement to the quality of health care. As the ATS declares in our statement on the issue, *ATS statement on Pay for Performance in Pulmonary, Critical Care and Sleep Medicine*, pay-for performance initiatives are an opportunity to align payor and provider incentives and improve the structure, process, and outcome of health care for patients, if implemented appropriately. Ongoing research will be necessary to measure the effectiveness of programs on patient care quality and the organizational, structural, and cultural factors that may influence program success. The ATS has the following specific recommendations on the implementation of pay for performance programs:

- 1) The Department should work with societies to develop valid, reliable quality measures for quality programs and conduct ongoing evaluation of program effectiveness to ensure the success of pay for performance initiatives and avoid unintended negative consequences.
- 2) In order to avoid adversely impacting quality of care, the Department should ensure that programs reward multiple measurable domains of quality (structure, process, and outcome), and reward both relative quality improvement as well as absolute performance.

- 3) Concerning hospital-acquired infections and adverse events, there are some complications, such as ventilator-associated infection, that can be reduced but not eliminated. Programs that expect elimination of such events may provide incentives for providers to avoid caring for high-risk, vulnerable patients. The Department should work with societies to identify evidence-based exceptions to specific quality measures and rational thresholds in incentive programs, particularly those involving penalties rather than rewards.
- 4) To prevent the unintended consequences of widening health disparities or adversely impacting vulnerable groups, the Department's pay for performance programs should stratify performance measures by high-risk groups, specifically targeting underserved and at-risk populations, and provide financial rewards for clinicians that provide care to high-risk patients. Programs should also account for variation in practice size and resources, to avoid unfairly punishing small and rural practices. Outcome-based quality measures should be used only in cases in which valid risk-adjustment ensures that providers are not punished for caring for high-risk patients.
- 5) The ATS urges the Department to support research on the effect of pay-for-performance on health outcomes and access to health care, including vulnerable populations, as well as the education of the next generation of providers. In particular, the Department should support research through its comparative clinical effectiveness programs to study pay for performance as a mechanism for translating new evidence into clinical practice and reducing health care disparities.

Strategy: Reduce healthcare-associated infections, adverse drug events, and other complications of health care delivery through quality and safety promotion efforts

The ATS shares a common goal with the Secretary to reduce the incidence of hospital-acquired infections (HAI). We are currently involved in an ongoing dialogue with the Department in developing research questions and defining key HAIs, including ventilator-acquired pneumonia. While some HAIs are preventable, there are some acute and complex syndromes within pulmonary and critical care, such as ventilator-associated pneumonia, that can be reduced but not eliminated entirely. The ATS recommends that the Department develop 1) alternative systems to encourage providers to adopt processes to reduce HAIs; and 2) systems to measure whether process steps are being taken. Further, we believe that research will play a key role in how to detect and prevent HAIs and we urge the Secretary to continue efforts to solicit research proposals on the effectiveness and implementation of HAI prevention strategies.

Objective C: Emphasize primary and preventive care linked with community prevention services

The ATS supports the strategies outlined under objective C to emphasize preventive care by expanding access to preventive services through community-based prevention programs and the elimination of financial and cultural barriers to preventive services through public and private health plans. In order to ensure comprehensive chronic disease management, it is essential that primary care providers can quickly and easily refer patients to specialty care.

Smoking kills an estimated 440,000 Americans annually.¹ The ATS encourages the Department to ensure open access to preventive healthcare services, including tobacco cessation services, since this will reduce the incidence and severity of chronic diseases associated with smoking, such as COPD, lung cancer and asthma.

In addition, the burden of asthma among adults and children continues to grow in the U.S. The ATS encourages the Department to support community-based prevention and education programs on strategies to prevent asthma attacks, such as the correct use of inhalers, that will reduce hospital admissions for this disease.

Objective D: Reduce the growth of health care costs while promoting high-value, effective care

The ATS supports the Department's objective to reduce the growth of health care costs while promoting high-value, effective care. The current public and private health care systems do not appropriately reward providers who emphasize primary, secondary, and tertiary care to prevent illness and disability and manage the care of patients with chronic diseases. The ATS encourages the Department to support the development of new models of care that ensure full access to specialty care and to establish reimbursement formulas that reward prevention and disease management.

The ATS remains concerned that malpractice insurance continue to drive up insurance costs. Additionally, regulatory compliance and associated administrative costs also increase care expenditures without providing value in the health care sector. The ATS urges the Department to develop administrative efficiencies for physicians, hospitals and public and private plan administrators.

One area within chronic respiratory disease management care that holds significant potential for reducing system costs is home-care management, with the provision of appropriate devices, for technology-dependant adults and children with respiratory diseases such as cystic fibrosis. We encourage the Department to support the development of models for community-based at-home care.

Finally, the implementation of the Affordable Care Act presents an opportunity to improve end-of-life care. ATS members know that when patients and families have early and effective communication about end-of-life care options, the result is higher quality care that minimizes ineffective treatments and reduces health system costs, as well as increased patient and family satisfaction with end-of-life care. We encourage the Department to work with the ATS and other critical care societies to develop incentives for clinicians, hospitals and other components of the healthcare system to coordinate advance directives and improve communication about end-of-life care across institutions and settings, so that the wishes of patients can be followed.

Objective E: Ensure access to quality, culturally competent care for vulnerable populations

Consistent with its principle of support for guaranteed access to medically necessary preventive, acute, chronic, rehabilitative and palliative care for all Americans, the ATS fully supports the Department's objective and strategies to ensure access to quality, culturally competent care for all vulnerable populations, including children. The ATS supports federal initiatives to achieve this goal and works within the society to support the elimination of disparities in health and remove barriers to health care including, but not limited to, racial, ethnic, geographic or educational barriers, cultural and language barriers, barriers for the physically and mentally impaired, sexual orientation and gender identity, and the ability to pay.

Objective F: Promote the adoption and meaningful use of health information technology

The ATS supports the adoption of health information technology (IT) to modernize the health care system. Information technology applications for health care, such as electronic health records and decision support systems, are needed to improve patient care, patient safety, and care coordination, and reduce administrative burdens. However, substantial investments in time and money will be necessary to acquire the necessary hardware and software, train physicians and staff on their use, transfer data from older records, and sustain these systems once implemented, including the education of the next generation of providers. In order to ensure widespread adoption of health IT systems, the Department must assist physicians, other clinicians, hospitals and other components of the healthcare system with resources to implement the next generation of health information systems. The Department must also establish national standards and regulations that facilitate needed information sharing amongst these systems while also guarding patient confidentiality. Finally, ongoing evaluation of health IT systems will be necessary to ensure that the systems help reduce medical errors.

Goal 2: Advance Scientific Knowledge and Innovation

Objective A: Accelerate the process of scientific discovery to improve patient care

The ATS supports the Department's goal to advance scientific knowledge and innovation and its accompanying objectives and strategies. The National Institutes of Health (NIH) is the global leader in research into the causes, diagnosis, treatment and prevention of diseases affecting millions around the world. The American Reinvestment and Recovery Act (ARRA) is generating remarkable scientific innovation that will pave the way for new medical advances that will improve public health. However, these funds are expiring in 2010. In order for the NIH to generate the scientific discoveries that lead to treatments and cures for diseases affecting millions of Americans, stable, sufficient and sustainable funding for biomedical and health services research must be guaranteed. The ATS urges the Secretary to ensure that sustainable funding for federal research programs through the National Institutes of Health, National Science Foundation and Centers for Disease Control and Prevention (CDC) is an element of health care reform.

Lung disease is the fourth leading cause of death in the U.S., responsible for one of every seven deaths.ⁱⁱ The death rate due to chronic obstructive pulmonary disease (COPD) has doubled within the last 30 years and is still increasing, while the rates for the other three top causes of death (heart disease, cancer and stroke) have decreased by over 50 percent. The number of people with asthma in the U.S. has surged over 150 percent since 1980 and the root causes of the disease are still not fully known. Sleep apnea has been shown to increase health care expenditures in adults and children by more than 215 percent.ⁱⁱⁱ In 2009, the estimated economic cost of lung disease in the U.S. was \$185.7 billion, including \$117 billion in direct health expenditures and \$68.6 billion in indirect morbidity and mortality costs.^{iv}

Despite the rising burden of lung disease, research in this area is underfunded. In FY2009, lung disease research represented just 20.8 percent of the National Heart Lung and Blood Institute's (NHLBI) budget.^v Although COPD is the fourth leading cause of death in the U.S., research funding for the disease is a small fraction of the money invested for the other three leading causes of death, heart disease, cancer and stroke. In recognition of the rising global burden of lung disease and the need for increased awareness and action to promote lung health, the ATS, in conjunction with the Federation of International Respiratory Societies, has declared 2010 to be the Year of the Lung. Throughout 2010, the ATS will be sponsoring a series of congressional briefings and other events to raise lung disease awareness. The ATS urges the Secretary to increase the prioritization of lung disease research to provide an appropriate investment into the nation's fourth leading cause of death.

The burden associated with the provision of care to critically ill patients is enormous, and is anticipated to increase significantly as the population ages. Investigation into diagnosis, treatment and outcomes in critically ill patients should be a high priority, and the ATS urges the Department to expand support for coordinated investigation related to critical illness in order to meet the growing national imperative.

Research studies show that sleep-disordered breathing and sleep-related illnesses affect an estimated 50-70 million Americans. The public health impact of sleep illnesses and sleep disordered breathing is still being determined, but is known to include increased mortality, traffic accidents, lost work and school productivity, cardiovascular disease, obesity, mental health disorders, and other comorbidities. Despite the increased need for study in this area, research on sleep and sleep-related disorders has been underfunded. The ATS urges the Department to support expanded research into sleep disorders.

Goal 3: Advance the Health, Safety, and Well-Being of Our People

Objective D: Promote prevention and wellness

The ATS strongly supports goal three and its objectives. As a society representing healthcare specialists who diagnose, treat and work to prevent tobacco-related diseases and illnesses, the ATS is pleased by the Department's strategy to implement comprehensive efforts to prevent and reduce tobacco use. Cigarette smoking is the leading preventable cause of death in the U.S., responsible for one in five deaths.^{vi} The expansion of tobacco cessation services, including medications and counseling, will reduce the incidence of tobacco-related chronic diseases including lung cancer and COPD. The ATS agrees with the Department's focus on obesity prevention, which is heavily linked with sleep disorders and other respiratory problems.

A strong public health system is essential to protecting Americans from infectious respiratory illnesses such as influenza and tuberculosis, preventing chronic disease and promoting healthy lifestyles. The ATS was a strong supporter of the Prevention and Public Health Investment Fund in healthcare reform legislation. We are hopeful that this initiative will provide a sustainable reinvestment into programs that improve public health. The ATS recommends that eligible grant activities include public health research programs on the respiratory health effects of climate change and design of appropriate public health prevention initiatives, and public education campaigns on these effects and how they can be minimized and prevented.

Objective E: Reduce the occurrence of infectious diseases

Consistent with our roots in tuberculosis (TB) control, the ATS commends the Secretary on inclusion of the objective to reduce infectious diseases in the U.S. The rise in HIV infection levels and the neglect of TB control programs have caused a global resurgence. Tuberculosis is the second leading infectious disease killer globally, claiming 1.8 million lives each year. It is estimated that 9-14 million Americans have latent tuberculosis.

Although prevalence of active TB continues to decline in the U.S., challenges to its elimination persist. These challenges include: (1) racial and ethnic minorities suffer from TB more than majority populations; (2) foreign-born persons are adversely impacted; (3) sporadic outbreaks/clusters occur, outstripping local capacity; (4) continued emergence of drug resistance and increasing complexity of cases; and (5) there are critical needs for new diagnostics, treatment and prevention tools. Drug-resistant TB poses a particular challenge to domestic TB control due to the high costs of treatment and intensive health care resources required.

The ATS looks forward to working with the Secretary to fully implement two important initiatives to put the U.S. back on the path to TB elimination. The Comprehensive TB Elimination Act (CTEA), enacted in 2008, provides CDC and NIH with the authority to strengthen domestic TB control, including targeted support to federal, state, and local health authorities to detect, treat, and prevent drug-resistant TB and TB in foreign-born populations and U.S. minorities. The law also authorizes an urgently needed reinvestment into new TB diagnostic, prevention and treatment tools. Additionally, the Federal TB Task Force *Plan to Combat XDR-TB*, published in 2009 by the CDC and NIAID, provides a public health plan for U.S. government agencies to control and prevent drug resistant TB in the U.S. and provide leadership on global control efforts. Additionally, a plan to accelerate progress toward TB elimination, *A Call for Action on the Tuberculosis Elimination Plan for the United States*, has been published recently by Stop TB USA.

The ATS appreciates the role that the Department plays in global tuberculosis control through the CDC's global health programs and the NIH's research into new TB tools, and is pleased to see global TB control identified in the Department's strategic plan. Because of the inter-relationship between HIV/AIDS and TB, this strategy is an effective counterpart to the Department's strategy to prevent the spread of HIV infection. The ATS urges the Secretary to support the CDC's position as a key partner in global TB control as envisioned under the historic Lantos-Hyde Global HIV/AIDS, TB and Malaria Act of 2008.

Immunizations against infectious illnesses such as influenza are essential elements of our public health system. The ATS agrees that immunizations are an important component of preventive care that should be accessible to all Americans. We encourage the Department to continue supporting public education on the benefits of immunizations, particularly for the protection of vulnerable populations such as young children and the elderly.

Objective F: Protect Americans' health and safety during emergencies, and foster resilience in response to emergencies

Americans with chronic respiratory issues are at high risk during a disaster or public health emergency, particularly individuals requiring home ventilatory support, oxygen therapy, and frequent nebulization of medication. This special needs population can be at risk from simple power failures to interruptions of delivery of medication and oxygen, all common occurrences during emergencies. Public health and medical officials must work within local communities and across larger regions to develop an integrated response to meet the needs of these patients. The ATS urges the Department to work closely with public health and medical providers, including the ATS, to identify individuals with respiratory conditions in communities, develop templates for family emergency plans along with local and state public health plans, and coordinate outreach to support the needs of these patients. The ATS also urges the Department to support research to establish the effectiveness of public health emergency response strategies, including the provision of rapid grants to local academic centers with expertise in critical care response.

Goal 5: Strengthen the Nation's Health and Human Service Infrastructure and Workforce

Objective B: Ensure that the Nation's health care workforce can meet increased demands

The ATS agrees that in order to transform the nation's health care system, our health and human service infrastructure and workforce must be strengthened and we look forward to working with the Secretary to address workforce shortages in pulmonary, critical care and sleep medicine. Critical care intensivists and nurses care for the most seriously ill patients in hospital intensive care units (ICUs). In the U.S., patients in ICUs currently receive over 18 million days of care every year, with related health care costs estimated to be almost one percent of U.S. gross domestic product.^{vii} The increase in the U.S. elderly population is expected to cause the number of patients cared for in ICUs to grow rapidly during the next decade. According to recent studies, starting in 2007 and worsening through 2020, the U.S. will not have enough physicians to meet the needs of patients with respiratory disease and critical illness. The shortage of critical care specialists is particularly severe in rural areas.

According to the 2006 report by the Health Resources and Services Administration, *The Critical Care Workforce: A Study of the Supply and Demand for Critical Care Physicians*, the growth and aging of the population alone will increase demand for adult intensivist services by approximately 38 percent, from 1,900 to 2,600, between 2000 and 2020. The HRSA report also found that if the proportion of ICU patients whose care is directed by an intensivist were to increase from one third to a more optimal level of two thirds, then requirements would grow from a need for 3,100 Full Time Equivalent (FTE) intensivists in 2000 to 4,300 by 2020. This would translate to a shortage of about 1,200 intensivists in 2000, growing to 1,500 in 2020. These projections follow a 1998 study by the Committee on Manpower for the Pulmonary and Critical Care Societies (COMPACCS) that projected a growing shortfall of intensivists unless changes are made to increase the number of physicians trained in critical care. The ATS is concerned that the worsening shortage of critical care specialists will create an access barrier to critically ill patients and urges the Department to incorporate this important issue into programs to address healthcare workforce.

The COMPACCS study also predicts an growing shortage of pulmonologists over the next decade due to two competing factors: 1) rising demand from the aging population and; 2) an older workforce base of pulmonologists who will be retiring faster than can be replaced by new trainees.^{viii} There is also a shortage of pediatric pulmonologists and sleep specialists, who provide care for children with lung diseases and breathing disorders such as cystic fibrosis, asthma and sleep apnea. The ATS urges the Department to address workforce shortages as part of healthcare reform through initiatives including education incentives and expanded Graduate Medical Education (GME) to ensure that patients with respiratory disease, critical illness and sleep disorders have access to the healthcare services that they need.

Again, thank you for the opportunity to comment. Please contact Nuala S. Moore, Sr. Legislative Representative, in our Washington Office at 202.296.9770 or Nmoore@thoracic.org if you have any questions.

Sincerely,



Dean Schraufnagel, MD
President
American Thoracic Society

ⁱ Centers for Disease Control and Prevention (CDC). State-specific smoking attributable mortality and years of potential life lost – United States, 2000-2004. MMWR Morb Mortal Wkly Rep 2009;58:29-33.

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^{iv} NHLBI Fiscal Year 2009 Fact Book.

^v NHLBI Fiscal Year 2009 Fact Book.

^{vi} U.S. Department of Health and Human Services. Health Resources and Services Administration. Report to Congress: The Critical Care Workforce: A Study of the Supply and Demand for Critical Care Physicians. 2006.

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