

Secretary Designate Thomas A. Daschle  
451 Sixth Street, N.W.  
Washington, D. C. 20004

Dear Secretary Designate Daschle:

As members of the nation's broad patient and research advocacy communities, we believe one of the most important decisions facing the incoming Obama Administration is the appointment of a Commissioner of the Food and Drug Administration. We urge the early appointment of a Commissioner with impeccable qualifications in order to assure Americans prompt access to safe and effective medical products.

The number of Americans stricken with serious and life-threatening diseases stands at an all-time high. Those represented by our organizations will increase exponentially in the years ahead. Despite vast advances in basic understanding of the root causes of disease brought about by a doubling of biomedical research funding in recent years, a pipeline problem exists that is stifling innovation and denying patients access to the treatments they need. By the FDA's own admission novel therapies are not moving through development and to patients as quickly as they should. Recent studies confirm that the number of new medical therapies reaching the marketplace is the lowest in decades.

Over time, expanded regulatory responsibilities for drugs, medical devices, and food, without accompanied financial resources have put the FDA mission of promoting and protecting the public health at risk. The dire straits of the agency's scientific infrastructure have been documented by both the Institute of Medicine and FDA's own Science Advisory Board. The FDA's professional staff, which has a deep dedication to sound scientific decisions, is doing a remarkable job under these difficult circumstances. But in order to best equip FDA to regulate increasingly complex medical products and the rapidly evolving global marketplace, strong scientific leadership is needed.

Our organizations believe consistent and effective leadership at FDA during the Obama Administration can overcome many of FDA's current problems and can increase confidence in its ability to balance public safety with timely patient access to new therapies. A candidate with the right mix of diverse experience and specific leadership qualities can renew this vital health agency. We believe the following characteristics should be paramount:

- The Commissioner should have excellent scientific credentials. This individual should be science driven and have experience managing projects that are translational in nature.
- The Commissioner must have proven managerial and administrative experience with the ability to execute effectively a forward-looking vision for the agency.
- The Commissioner should have the capacity to build consensus around key issues related to the evaluation of products under review by engaging various stakeholder groups, including patients and their representatives.
- The Commissioner must be capable of rising above politics to elevate the science of FDA by taking an impartial approach to complex issues, despite pressure from elected and appointed officials and from the news media.

- The Commissioner must also have a vision for the advancement of evidence-based science in the drug development arena as well as the regulation of new and existing therapies.
- Candidates for Commissioner should not be excluded due to relationships with industry during the course of his/her career. In fact, diverse experience, including that with an FDA-regulated industry, should be viewed as positive a qualification.

By appointing a Commissioner possessing these qualities, the Obama Administration can demonstrate that it places a premium on meeting the urgent needs of Americans facing serious and life-threatening medical challenges. Our organizations feel there are a number of highly qualified individuals dedicated to public health who exemplify these principles. We respectfully ask the Obama transition team and President-elect Obama's choice for Secretary of Health and Human Services to consider such candidates for this important position. Our organizations are ready to discuss this matter further with transition officials if that would be helpful and productive.

Sincerely,

Alliance for Aging Research  
 ALS Association  
 Alzheimer's Foundation of America  
 American Association of Cancer Institutes  
 American Association for Cancer Research  
 American Association of Neurological Surgeons/  
 Congress of Neurological Surgeons  
 American Cancer Society-Cancer Action Network  
 American Society of Clinical Oncology  
 C3: Colorectal Cancer Coalition  
 FasterCures  
 Friends of Cancer Research  
 Intercultural Cancer Council Caucus  
 Kidney Cancer Association  
 Leukemia & Lymphoma Society  
 Lung Cancer Alliance  
 Marti Nelson Cancer Foundation  
 Men's Health Network

National Alliance on Mental Illness  
 National Coalition for Cancer  
 Research  
 National Health Council  
 National Minority Quality Forum  
 National Multiple Sclerosis Society  
 National Patient Advocate Foundation  
 Ovarian Cancer National Alliance  
 Parkinson's Action Network  
 Prevent Cancer Foundation  
 Research!America  
 RetireSafe  
 Sarcoma Foundation of America  
 Society for Women's Health Research  
 Society of Gynecologic Oncologists  
 Susan G. Komen for the Cure  
 Treatment Action Group  
 WomenHeart

Cc: John Podesta  
 R. Alta Charo  
 William Corr  
 Neera Tanden  
 Mark Childress