



November 24, 2008

President-Elect Barack Obama
451 6th Street N.W.
Washington, DC 20001

Dear President-Elect Obama:

The Alliance for a Stronger FDA represents more than 180 members, including leading consumer, patient, and industry groups, who have come together for a single purpose: to assure that the Food and Drug Administration (FDA) is adequately supported so that it can fulfill its public health and consumer protection functions.

Our Alliance congratulates you on your election as the forty-fourth President of the United States of America. As your transition begins, we write to stress the importance of a strong FDA to the health and well-being of all Americans.

FDA regulates products that represent about 25 percent of consumer spending in America. FDA's role in protecting the public health expanded greatly in recent years with the emergence of serious threats such as bioterrorism and avian flu, and with the increasing globalization of the products FDA regulates. The challenges facing the Agency have been well-documented through high-profile public health episodes that include contamination of FDA-regulated products such as tomatoes and leafy green vegetables, pet food ingredients, and the drug heparin. At a rising rate, imported products are implicated, though domestic concerns continue as well.

As our country faces increasing economic challenges, it is also important to point out that safe foods, drugs and devices are keystones of the American economy and FDA plays a pivotal role in getting appropriately safe and beneficial products to the market. The economy suffers when FDA does not have the resources to properly do its job. As an example, in each of the high profile produce contaminations, in excess of \$100 million in sales were lost.

The Alliance asks that you make FDA stronger by: (1) the timely nomination of an FDA Commissioner and (2) proper funding.

Importance of a Senate-Confirmed Commissioner

Appointment of the FDA commissioner is a vital component if the Obama administration hopes to hit the ground running, especially to address the potential for crisis to arise in these areas. A

Senate-confirmed FDA Commissioner can address safety concerns with the public, and also has the authoritative mandate to address the long-term and complex challenges facing the Agency. During the last 8 years, a confirmed FDA Commissioner was at the helm less than half the time. Since 1990, the transition period between confirmed Commissioners has always taken a minimum of more than one year. In two instances, the transition time was slightly less than two years. With the current challenges so compelling, the FDA can not wait for needed leadership.

While the FDA has the benefit of talented career scientists who carry out the core tasks, a Senate-confirmed Commissioner is needed to set the strategic agenda, and work within the Executive Branch and with Congress to establish the Agency's resource needs. As an example, in the coming year the Agency will respond to the globalization of regulated products through the establishment of its first overseas offices, and major policy decisions will need to be made regarding the process of overseas inspection and regulation. FDA also must establish the parameters around its information technology needs to make sure that new systems materially contribute to public health protection. Furthermore, as you know from your work on Personalized Medicine, FDA will play a major policy role in helping to prepare the regulatory pathway for the innovative tailored medicines of the future.

We strongly encourage the rapid nomination of an FDA Commissioner who will have your support to make the decisions needed to move the Agency forward and assure that FDA restores its position as the international gold standard of consumer protection based on sound science.

Importance of a Properly Funded FDA

We commend you for making increased funding for FDA a priority during your presidential campaign and for including additional funding for FDA as part of your health care reform proposal. The Alliance is grateful for your leadership on this critical public health issue and looks forward to working with you and your Administration to ensure that your commitment is fulfilled to increase FDA's funding.

Increased funding for FDA is needed to ensure that the Agency has the resources it needs to further fund its food science and inspection capacity, further fund drug and device regulation, and upgrade critical information technology systems. During 2008, Congress added to FDA's budget, especially in the 2008 supplemental appropriation, significant new resources. In the Continuing Resolution through March of 2009, Congress placed that increase into the base of the budget. These steps have allowed the FDA to hire additional inspectors across the U.S., establish new offices abroad, and begin to improve outdated information technology systems.

But more needs to be done, and we respectfully recommend that FDA have an appropriated budget for Fiscal Year 2010 of \$2.25 billion.

In November of 2007, an independent Science Board concluded that the FDA was woefully underfunded. The Science Board determined that the nation's public health is at risk, as are the regulatory systems that oversee the nation's food, drug and device products. The board attributed the deficiencies to soaring demands on the FDA and resources that have not increased in proportion to those demands. Providing for a well-funded FDA will allow your Administration an opportunity to make fundamental improvements to the public health.

As part of this transition document, we have attached the FDA Science Board report for your review.

Conclusion

As you plan your agenda during this transition, the FDA Alliance encourages you to make a stronger FDA an important step in your effort to ensure America's public health. The rapid appointment of an FDA commissioner and a properly funded FDA are needed to assure that Americans have safe foods and safe and effective medical products.

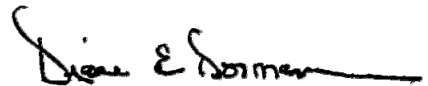
Sincerely,



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President, Alliance for a
Stronger FDA



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Center for Science in the
Public Interest



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