

**STATEMENT OF**  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**SUBMITTED TO THE**  
**COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM**  
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Introduction

Mr. Chairman and Members of the Committee, I am Jane E. Henney, M.D., Senior Vice President and Provost for Health Affairs at the University of Cincinnati and a Former Commissioner of Food and Drugs, United States Food and Drug Administration (“FDA” or the “Agency”). I appreciate the opportunity to discuss the work of the Agency and challenges and opportunities that the Agency faces today and in the future.

It has been my privilege to serve in the federal government both as a career and political appointee. From 1976 to 1985, I was a member of the United States Public Health Service and held a variety of positions at the National Cancer Institute (NCI), including 5 years as deputy director of NCI. From January 1992 until March 1994, I was a member of the Senior Executive Service and was the Deputy Commissioner for Operations of the FDA. In 1998, I was nominated by President Clinton and confirmed by the United States Senate as Commissioner of Food and Drugs. I was honored to serve in that capacity until January 2001.

The Food and Drug Administration has a broad mandate and its influence is far reaching as it executes its critical mission to safeguard the health of the public. From food to drugs to medical devices, from humans to veterinary medicine, the FDA touches people’s lives every day. Over the past one hundred years, the evolution of the agency has been driven by emergent public health threats and fraught with scientific, legal, and political complexity that has not diminished with time.

For nearly all of its 100 year history, it has set the gold standard for the world in regulation of food and medical products (drugs and devices) through scientifically based policy and product decision making. However, the FDA now finds itself in the spotlight with public confidence plummeting<sup>1</sup>, scientific staff turnover at what is potentially an all time high<sup>2</sup> and fiscal resources stretched beyond the Agency's ability to meet its mandates<sup>3</sup>.

### Leadership

Stable leadership is crucial to preserving and enhancing the Agency's credibility. Recently there have been Commissioners who serve for exceedingly short terms and there have been long periods when the Agency only has interim leadership. This is exceedingly destabilizing for the Agency. While I have confidence that product and enforcement decisions can still be made at the Agency, no institution – public or private – can do its best work if there is not a leader, a CEO in charge, setting direction and tone at the top of the organization and advocating on behalf of the organization and those it serves. One suggestion has been made to resolve this problem. Last year the Institute of Medicine issued a report entitled, "The Future of Drug Safety: Promoting and Protecting the Health of the Public,"<sup>4</sup> in which one of the specific recommendations was that Congress set a term of six years for the Commissioner of Food and Drugs to serve, following confirmation.

Of even greater concern is the allegation that the agency has become subject to the intrusion of political influence in its day to day operation. The position of Commissioner of Food and Drugs is nominated by the President with the advice and consent of the Senate. However, it is critical that the Commissioner, once confirmed, assure that the policy, product or enforcement decisions of the Agency are not subject to political review or influence. The American public expects and the industry needs decision making that is objective and credible. The agency must operate from a foundation of evidence-based decision making that is grounded in science.

### Resource Requirements

As the agency conducts its work, it must use its limited resources wisely and allocate these based on level of risk. With a hundred-year history of limited resources and numerous unfunded mandates, the agency has had to rely on its ability to gauge risk to the public health as its guide for resource allocation. This is the crux of another one of the major challenges facing the FDA.

The work of the Agency depends on having adequate numbers of highly skilled medical, scientific and legal staff. In the early 1990s, a shortage of medical and scientific reviewers resulted in a tremendous backlog in the pre-market approval of drugs. This backlog, coupled with the crisis of an inadequate number of treatment options for patients infected with

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<sup>1</sup> Cummings, J. (Ed.). *The FDA's Reputation with the General Public is Under Assault*. Wall Street Journal Health Care Poll (Harris Interactive). Vol. 5, Issue 9, May 26, 2006.

<sup>2</sup> Baciu, A, Stratton, K, & Burke, S (Eds.). *The Future of Drug Safety: Promoting and Protecting the Health of the Public*. Committee on the Assessment of the US Drug Safety System, Board on Population Health and Public Health Practice, Institute of Medicine of the National Academies. Washington, DC: The National Academies Press. 2006.

<sup>3</sup> *Ibid.*

<sup>4</sup> *Ibid.*

HIV/AIDS, led to the development of user fees provided by the Industry to subsidize the pre-market review of drugs and biologics. The funds were used to hire the additional staff needed by the Agency to reduce the backlog and provide reviews – positive or negative – to the industry in predictable time frames. This “experiment” was successful in demonstrating that review times could be shorter without lessening the quality of review and drugs that met the high standards set by the Agency would reach patients in need more quickly.

However successful the experiment, there have been drawbacks of the user fee program. The user fees were initially mandated almost exclusively for the pre-market approval process and other work fundamental to the Agency’s mission suffered as the Agency needed to shift resources from core functions to meet its obligations under the User Fee program. In drugs and biologics, the post-market review function and the regulatory research so critical to the Agency’s work, was eroded. In other parts of the Agency, inspections and enforcement activities in food, drugs, biologics, devices and veterinary products plummeted. These budget decisions taken by the Agency were largely imposed by Administrations and Congress who failed to provide the overall fiscal support the Agency needed.

The other drawback to the introduction of user fees has been the perception that the FDA has become unduly influenced by industry as the proportion of support for the Agency has become more dependent on user fees. Any hint or perception of this kind threatens the Agency’s credibility and, thus, its effectiveness.

Today, notwithstanding user fees, the FDA’s current appropriation is 36% less than the Agency’s actual cost of doing business. FDA’s needs should be paramount, in both the request, allocation and appropriation processes. Supporting the Agency, which is relied on by both individual patients and industry alike, is a concept that needs to be embraced and supported by the Administration, specifically the Department of Health and Human Services and the Office of Management and Budget, and Congress.

For the immediate future, I would urge you to appropriate sufficient funding for the FDA to execute its mission by increasing the FY08 budget to \$2.036 billion, not including the increase to user fees under the pending PDUFA reauthorization and additional appropriations under the Enhancing Drug Safety and Innovation Act of 2007. I would also urge you to consider a transition plan to increase the Agency’s appropriation so that it no longer depends on user fees.

### Looking Ahead

Finally, all of the Agency’s missions and mandates deserve support: food and drugs, biologics, blood and vaccines, devices, veterinary drugs, inspections and enforcement. Like any individual or institution reaching the ripe old age of 100, it is time to consider the reach and influence of this agency. It is time to consider not only providing it the financial resources it requires, but the legal and regulatory framework it needs to fulfill our vast expectations and today’s challenges. Much of the Agency’s legal/regulatory framework was developed based on conditions that no longer exist and is not adequate to meet today’s scientific or medical realities.

Today's science promises a revolution in personalized medicine and combination products that rely on aspects of biotechnology, information technology, and nanotechnology. The Agency must have the resources necessary to position itself to regulate the new drugs and devices that are just beginning to emerge from academic and industry laboratories. Due to the individually targeted nature of these products, the Agency will need to ensure that they are testing and evaluating the safety, efficacy and potential toxicity of the products in multiple patient groups. While dramatically increasing the quality of information available, this effort will stretch the Agency's already thin resources to the breaking point.

### Conclusion

Mr. Chairman, your review of the Agency and its challenges for the future comes at a critical time. As we move forward, we cannot permit this distinguished agency to fail in its mission. Nor can we allow the FDA to fall from its international position of prominence. Only through enhanced funding that supports improved drug safety, sufficient staffing and infrastructure, and rigorous attention to scientifically-based decision making can we ensure that the public is protected.

The FDA is the gateway through which the future of health care is passing. The FDA must be strong enough to deliver on the expectations that all of us have of this distinguished group of public servants.

I appreciate your continued interest in improving the Food and Drug Administration. Thank you again for the opportunity to submit this testimony. I will be happy to provide any additional information you may require.