FDA SCIENCE AND MISSION AT RISK

REPORT OF THE FDA SCIENCE BOARD'S SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY

ESTIMATED RESOURCES REQUIRED FOR IMPLEMENTATION

IN RESPONSE TO THE REQUEST OF REPRESENTATIVES DINGELL, WAXMAN, STUPAK AND PALLONE

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SUMMARY

In order to address the deficiencies detailed in our report the Subcommittee recommends that the FDA's appropriated (non-user fee) budget be:

- Increased by $375M in FY 2009
- Increased by an additional $450M in FY 2010
- Increased by an additional $460M in each of FY2011, 2012 and 2013.

The FDA's base budget in FY2008 was $1,494,896,000 (salary and expenses minus rent and facility costs). The comparable appropriations (non-user fee) levels we recommend:

FY2009:	$1,870,000,000
FY2010:	$2,320,000,000
FY2011:	$2,780,000,000
FY2012:	$3,240,000,000
FY2013:	$3,700,000,000

Implementation of our recommendations will require some additional rent costs above these levels. However, the Subcommittee has omitted rent and facility costs ($219M in FY 2008) because of our inability to project future needs and costs in this area. It should also be noted that in years 2010-2013 additional increases may be needed to address importation and inspection issues and optimization of the National Center for Toxicological Research (NCTR). Our subcommittee recommended a more in depth review of the Office of Regulatory Affairs and NCTR be undertaken by the FDA Science Board to identify scientific and technology gaps. It is anticipated that FDA will need a

substantial increase in the number of FTEs to significantly expand the field force to do food, drug, device and other inspections.

BACKGROUND

In December 2006, the FDA Commissioner requested that the FDA Science Board establish a Subcommittee to assess whether science and technology at the FDA can support current and future regulatory needs. The Subcommittee's charge was to identify the broad categories of scientific and technologic capabilities that FDA needs to support its core regulatory functions and decision making, throughout the product life cycle, today and during the next decade.

The Science and Technology Subcommittee (hereafter called the Subcommittee) was composed of three members of the Science Board and 30 other experts representing industry, academia and other government agencies, and included individuals with extensive knowledge of cutting-edge research. Most importantly, these experts possess a deep understanding of regulatory science and the core mission of the Agency.

The Subcommittee was asked to review gaps in science and technology and not to assess available resources. However, it rapidly became apparent that the gaps were so intertwined with two decades of inadequate funding that it was impossible to assess one without the other. The Subcommittee found that FDA's resource shortfalls have resulted in a plethora of inadequacies that threaten our society—including, but not limited to, inadequate inspections of manufacturers, a dearth of scientists who understand emerging new science and technologies, inability to speed the development of new therapies, an import system that is badly broken, a food supply that grows riskier each year, and an information infrastructure that was identified as a source of risk in every FDA Center and function. The Subcommittee concluded that FDA can no longer fulfill its mission without substantial and sustained additional appropriations.

The findings and recommendations of the Subcommittee were endorsed by all 33 members. On December 3, 2007 the Subcommittee officially transmitted their report ***FDA Science and Mission at Risk*** to the full Science Board. The Board unanimously accepted the report, accepted it as final, and dissolved the Subcommittee. Given the seriousness of the deficiencies noted and the urgency with which they need to be addressed, the Science Board was adamant that the report be broadly communicated to the public and to policy makers, including its posting in the *Federal Register* for public comment.

SUMMARY OF RATIONALE

The Subcommittee was in a unique position to develop reliable estimates of the resources required to implement the recommendations of its report. The Subcommittee membership had extensive experience in development and management of large R & D budgets and regulatory groups, including budget development and oversight for entire pharmaceutical companies (i.e. former CEO Merck; heads of research and development of Genentech, Abbott, Monsanto) and universities (Dean, Iowa State School of Agriculture; Dean, University of Texas Southwestern School of Medicine). The Subcommittee membership also included an economist with expertise in workforce issues, a former Assistant Secretary of Health and Human Services, and a former Chief Counsel of the FDA. In addition, despite the lack of access to internal data, the Subcommittee was able to review publicly available information and directly observe the overall stress within the Agency while conducting this review. Finally, as the Subcommittee became cognizant of the seriousness of the FDA's deficiencies and the magnitude of the crisis, the Subcommittee spent considerable effort garnering as much information as possible about the current roles and responsibilities of Agency staff and currently available resources.

The Subcommittee also had exceptional expertise in budget development and oversight with respect to developing budgets for emerging sciences, food safety and information technology. Members included leaders of relevant research institutes (founders and leaders of the Institute for Translational Medicine and Therapeutics at the University of Pennsylvania, the Institute for Systems Biology, the Broad Institute Harvard/MIT, Brown Institute of Molecular Medicine in the University of Texas Health Science Center Houston), research intensive departments in academic institutions (departmental chairs from Univ. Penn., Univ. of Alabama Birmingham, Univ. of Wisconsin), and other government agencies (i.e. HHS, NIH, CDC, USDA), a former Under Secretary for Food Safety, a VP of Information Technology of two major pharmaceutical companies, the Assistant Chief Information Officer for the Center for Infectious Diseases of the CDC and leader of the IT Influenza Pandemic preparedness team of CDC.

Based upon their best professional judgment and publicly available information, the Subcommittee budget estimates are summarized and linked to the major recommendations.

Of course, these estimates have several associated caveats. One is that the FDA, as part of the administration, is required to support the resource needs identified in the President's budget. As a result, the Subcommittee was unable to incorporate internal FDA estimates of what is needed to address the deficiencies noted. Another is a lack of data. The Agency does not have a historical budget data base, and as a result the Subcommittee was not in a position to conduct a zero-based budget analysis for FDA.

Of the information available from FDA, was FDA 's (and OMB's) acceptance of 5.8% as the core inflation rate for the Agency. The Agency needs that amount (currently $100 million) just to keep program and staffing levels constant with the previous year.

Although significant new resources are needed immediately, there is also need for a phased-in approach, which is why the Subcommittee is providing 5-year cost estimates. The Subcommittee recognizes that the timing of expenditures will depend on both institutional and market forces. The Subcommittee strongly recommends that a regulatory science business plan be developed within an upgraded science organization led by a new chief scientific officer and new scientific directors in each of the centers (as recommended in the Subcommittee's report). Recruitment of some of the new positions needs to follow the new, more centralized, planning the Subcommittee recommends. Similarly, some of the IT purchases and personnel should follow, not precede, the enterprise plan recommended. The Subcommittee feels strongly that the new External Advisory Committees for each Center be put in place immediately. The Subcommittee strongly recommends that an ongoing dialog take place between Subcommittee members and the Science Board and FDA leadership during the implementation process. The rebuilding of FDA science will be a long-term effort in the current budgetary environment. New resources must be targeted and wisely used for addressing priority gaps.

Another caveat is that while additional funding is essential, it must be accompanied by increased flexibility. Most critically, direct hiring authority must be returned to the Agency as opposed to being centralized within the Department of HHS. This is critical if the Agency is to be able to hire in a timely manner and be able to recruit top talent.

DETAILED RECOMMENDATIONS

There are many ways to allocate resources – whether by type of need, organizational structure, or overarching characteristic. The Subcommittee recommends that Congress and the FDA phase in the funding increases carefully, and refrain from arbitrarily allocating fixed percentages across each Center.

Year	2009	2010	2011	2012	2013
Food Supply	128	283	441	598	755

Biological Sciences with emphasis upon drug safety and full implementation of the IOM Report, the Critical Path, IIRIS, and external collaborations	136	301	468	634	800
Organization of Science	18	38	58	79	100
Scientific Capability, including development of robust training and visiting scientist program	18	38	58	79	100
Information Technology	75	165	260	355	450
Recommended Increase over 2008 Budget: by year and	375	450	460	460	460
cumulative	**375**	**825**	**1285**	**1,745**	**2,205**
Total Budget	1,870	2,320	2,780	3,240	3,700

Costs, linked to Findings and recommendations

Findings	Summary of Recommendations	Estimated 2013 Cost
The **capacity of science to support the FDA mission is dangerously constrained** from the effects of a long period of expanding Agency mandates and responsibilities, chronic under funding, and the extraordinary advance of scientific discoveries, the complexity of new products and claims submitted to the FDA for premarket approval, the emergence of challenging safety problems, and the globalization of the industries that FDA regulates.	Every part of FDA is in need of more resources. The committee's priorities fell into 5 categories: the nation's food supply, rapid development in biological sciences; overall organization of science; scientific capability and capacity; and information technology capability and capacity.	Sum of all elements: FDA Budget $3.7 Billion in 2013 (non-user fee, non-rent) Incremental Cost increase relative from 2008: $2.205 Billion
The **nation's food supply** is at risk due to lack of resources and technology to sufficiently monitor the tremendous volume of products manufactured domestically as well as exponential growth of imported products.	Develop risk-based approaches to the inspection of the nation's food supply, support the development of new technologies to automate sampling, and assure that the FDA works closely with other government agencies to identify and control outbreaks of corrupted, contaminated food, infected food supplies and to establish an integrated surveillance system. It is critical that FDA give more resources and attention to the challenges posed by nutritional supplements, cosmetics, and animal food.	**Increase FDA's base by $755M by 2013 (includes $350M to strengthen Imports and $100M to strengthen nutritional supplements, animal health, and cosmetics)**
Rapid developments in biological sciences are exceeding current science capacity to keep pace and adequately support the agency's safety mission.	Fully implement the Critical Path Initiative giving priority to those components likely to have the biggest impact. Be more aggressive in partnering with sister agencies, academia, and industry to access emerging science. Fully implement the Institute of Medicine's recommendations for improving the drug safety system giving highest priority to development of a modern active postmarked safety surveillance network for	**Increase FDA's base by $800M by 2013 (including $450M for IOM Drug Safety; $100M Critical Path; and $250M IIRIS and external collaborations)**

	drugs, biological products, and medical devices. Develop new quantitative methods to assess new products and guide sponsors to valid and informative study designs. Develop a program, i.e. IIRIS, to manage "emerging science" beginning with an integrative, cross-disciplinary program in systems biology and genomics. Initiate other programs in highest priority areas of emerging sciences; including nanotechnology, cell and tissue based therapies, and imaging. Emphasis should be placed upon external collaboration and partnering with sister agencies.	
The **overall <u>organization of science</u>** lacks a coherent structure and vision, and effective coordination and prioritization.	Strengthen the role and authority of the newly appointed Deputy Commissioner/Chief Medical Officer and recruit an outstanding Chief Science Officer (CSO) to lead the transformation of science infrastructure; create Deputy Directors for Science in each of the Centers with dotted line reporting to the CSO, establish Board of External Scientific Counselors for each Center, establish standardized processes to promote scientific excellence. Maximize opportunity for consolidation at White Oak and better integrate NCTR. Be more aggressive in partnering with sister agencies, academia, and industry to access emerging science.	**Increase FDA's base by $100M by 2013 (including funding for external collaborations)**
<u>Scientific capability and capacity</u> are inadequate to achieve the regulatory mandate. Recruitment, retention, and professional development programs are inadequate as well.	Put in place personnel systems which facilitate recruitment and retention of outstanding people as well as providing for termination of individuals whose work is of inadequate quality or productivity. Develop and implement a robust training program for visiting scientists and postdoctoral fellows.	**Increase FDA's base by $100M by 2013 (including $75 M for fellowship and visiting scientists program)**
FDA lacks **<u>information technology (IT) capability and capacity</u>** to support monitoring of drug and food safety and is	Develop and execute a comprehensive IT modernization plan driven by the regulatory mission and based on best IT	**Increase FDA's base by $450M by 2013**

particularly challenged in the regulation of products based upon new science. The FDA technology platform is outdated and unstable (>80% network servers beyond recommended service life and no continuity operations plan in the event of an infrastructure disaster). Inadequate communications platforms are significantly limiting FDA's ability to effectively communicate with consumers and industry stakeholders	practices that addresses the immediate regulatory science and services needs of FDA as well as the rapidly emerging IT needs required to support new technologies, scientific methodologies, products, and global business activities. Expand and improve risk communication with external scientific/medical community, the public, and policy makers.	