The FDA Alliance
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STATEMENT OF STEVEN A. GROSSMAN
EXECUTIVE DIRECTOR, THE FDA ALLIANCE
BEFORE THE
SUBCOMMITTEE ON HEALTH, HOUSE COMMITTEE ON ENERGY AND COMMERCE
WEDNESDAY, MAY 16, 2007

Chairman Pallone, Representative Deal and Members of the Subcommittee:

Thank you for this opportunity to testify on "Reauthorization of the Medical Device User Fee and Modernization Act" and related funding issues faced by the US Food and Drug Administration (FDA).

I am Steven Grossman, the Executive Director of The FDA Alliance. We are a broad-based, non-partisan coalition of consumers, patients, health care professionals, and industry. We have more than 100 members, including seven former FDA Commissioners. A list of members is at the end of my testimony.

FDA is America's premier consumer protection agency, yet the agency is **severely underfunded relative to the vast responsibilities given it by Congress and the justifiable expectations of the American people.** Appropriated funding (budget authority) is the agency's primary source of funds and needs to keep pace with the agency's mission and needs. Further, the FDA Alliance believes that:

- **The staff of the FDA are dedicated, hardworking and effective. They cannot keep up with the increasingly complex, growing workload without additional staff, improved information technology, and increased support for training, outreach, and scientific standards.** Over time, lack of support has made it difficult to recruit and retain the "best and brightest." It has eroded our nation's economically-valuable position as the "gold standard" for food, drug, and device regulation.

- **Strengthening FDA must be a priority for this Congress.** The funding shortfall affects every part of the agency, as well as its collective infrastructure. A five-year commitment is needed.

- **FDA should be fully funded through appropriations (budget authority) and augmented by the user fee programs that have become necessary to assure adequate funding for FDA.** Such fees cannot be allowed to substitute for sufficient levels of appropriated funds (budget authority).

Wholly apart from MDUFMA and other user fee revenue, **the FDA needs $2 billion in FY08 appropriated budget authority, an increase of about $450 million over this year's levels.** This higher level would restore FDA to the capabilities it had in FY03 and enable the agency to carry out the public health and safety program initiatives mandated by subsequent appropriations bills. **Of this $450 million increase, we recommend that the Center for Medical Devices and Radiological Health and its related field activities receive an increase of $72 million in appropriated funds (budget authority).**

Because devices are cutting-edge science, CDRH needs *these non-user fee monies* for additional staff to perform reviews, assure pre- and post-market safety, and facilitate innovative technology coming to market. An updated, modernized IT system is also essential to support the Center and its core and field staff.

Position of the FDA Alliance

The U.S. needs a strong FDA that is sized and modernized to carry out its responsibilities, now and in the future in a global economy with threats and opportunities that span the world. Instead, FDA is underfunded and understaffed despite responsibility for a quarter of all consumer spending. A weakened FDA undermines the agency's ability to carry out its dual roles: leading guardian of consumer health and safety and active leader in advancing global scientific and medical innovation.

FDA receives minimal new funds each year. Its ability to fulfill its mission is compromised by increasing costs, evolving missions, expanding science, and changing technologies. The American people and the Congress expect more from the FDA than it can deliver without additional funds.

User fees are an important component of the resources available to the FDA, but cannot substitute for significantly increased appropriations and a long-term commitment by Congress to assure that the FDA has the resources it needs.

The U.S. Food and Drug Administration needs $2 billion in FY08 appropriated budget authority in addition to any user fees. This increase would restore FDA to the capabilities it had in FY03 and would enable the agency to carry out the public health and safety program initiatives mandated by subsequent appropriations bills. Since FY03, FDA's budget has not kept up with inflation and has lost 20% of its buying power. An investment in FDA is imperative and long overdue. We need to preserve and sustain FDA's ability to protect Americans, advance innovation, and remain the regulatory "gold standard" worldwide. **Adding in user fee revenues, this would result in a total FDA budget of about $2.5 billion in FY 2008.**

Analysis done by FDA for stakeholder presentations last summer suggest that the agency appropriation is underfunded by $300 million to $800 million, compared to what is needed to accommodate its existing statutory program responsibilities and Congressional mandates. A version of this analysis is part of this testimony and demonstrates that $2 billion in FY 08 budget authority (with user fees additional) is an appropriate target for immediate reinforcement of FDA and its mission.

For example, $2 billion in FY08 appropriated funding (budget authority) is needed to sustain the public health and safety priorities given to FDA by Congress in such critical areas as:

- food safety
- counterterrorism/defense
- pandemic preparedness
- patient safety
- medical device reviews, as well as animal drug and generic drug reviews
- modernizing regulations to prepare for new technologies, such as nanotechnology.

Other key priorities include: improved and more capable information technology systems at FDA and restoring the field force that inspects foods, imports and manufacturing sites to post-9/11 staff levels.

Much of the historic underfunding of FDA can be attributed to a failure to fund the personnel costs required to fulfill the agency's mission. FDA spends more than 83% of its budget to support its workforce. The costs of maintaining and supporting staff have increased at a much faster rate than the agency's appropriated resources. By its own calculations, FDA needs inflation increases each year of at least 5.8% just to maintain its current service and staff level. Based on the MDUFMA proposal, this figure may actually be closer to 6.5%. Annual appropriations to FDA never include the full cost to the agency of pay and benefit increases or rising non-pay costs.

Currently, Congress appropriates just $4.94 per American per year (excluding user fees) to the FDA. At $2 billion in appropriated funds (budget authority) for FY08, this would still represent spending only $6.67 per American to help FDA keep pace with its vital missions and services. **Congress should make a long-term commitment to upgrade FDA's appropriated funding, so it can be more effective as the nation's premier consumer health and safety agency.**

A strong FDA is also vital to the nation's economy. Innovative companies need a cutting edge regulator to prepare the way for breakthroughs in medical devices and combination product regulation. As well, FDA must be strengthened to assess more sophisticated products and monitor the increasingly complex safety parameters in drugs, food, medical devices and veterinary products.

Providing $2 billion in appropriated funding in FY08 – and sustaining that level of budget authority and providing budget growth as needed for the next four fiscal years – will help the FDA fulfill its mandate and be innovative in its approach to regulation, oversight, inspections, approvals, and monitoring.

The following chart shows the FY 2006 appropriations, the FY 2007 final continuing resolution, the President's FY 2008 request and the FDA Alliance's request for FY 2008. The middle row—budget authority without user fees—is what sustains the bulk of the FDA's activities and is the focus of the FDA Alliance advocacy. A significant increase in budget authority appropriations is needed to strengthen FDA.

	FY 2006 Actual	FY 2007 CR	President's FY2008 Request	FDA ALLIANCE Request for FDA for FY 2008
Total program, incl. user fees	$1.876 billion	$1.965 billion	$2.085 billion	**$2.45 to $2.5 billion**
Budget authority (w/o user fees)	**$1.495 billion** includes $ 8 million For building and facilities	**$1.574 billion** Includes $ 5 million For building and facilities	**$1.641 billion** Includes $ 5 million For building and facilities	**$ 2.00 billion**
User fees	$ 382 million	$ 407.5 million	$ 444 million (FY07 plus inflation, not FDA user fee proposal of Feb. 2007) Includes proposed user fee: $ 16 million (generic drugs)	**$450 to $500 million (estimate)** **(assumes renewal of existing user fees at FDA's proposed higher levels)**

This table is subject to correction due to the nature of the sources used to compile the information. In addition, budget figures have been rounded for the purposes of this table.

Attachments:

1. Q&A: FDA Alliance Budget Recommendations for FY 2008
2. List of 108 FDA Alliance Members, as of May 11, 2007

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Q & A: FDA Alliance Budget Recommendations

What is the FDA Alliance Recommendation?

- ✓ $2 billion in FY 2008 budget authority/appropriations *(user fees would add about $500 million to this)*
- ✓ This is an increase of $450 million in BA appropriations compared to the FY 2007 CR level

How did the FDA Alliance derive its recommendation?

As shown in the chart on the next page, our $2 billion budget recommendation represents that amount of funding needed to bring FDA appropriations back up to its FY2003 funding level:

- ✓ FY 2003 appropriated funding, increased by 5.8% per year (the amount FDA's costs increase each year) for FY2004-FY2007; and
- ✓ Including program mandates as directed by the appropriations committee since 2003

Can FDA absorb $450 million in new budget authority/appropriations in one fiscal year?

Funding of this scale is necessary to assure the public health and support US economic growth. The FDA Alliance has consulted a variety of sources familiar with FDA's needs and capacity. They agree that:

- ✓ Upfront investment requirements are large (*e.g.* for adverse events data bases)
- ✓ A substantial number of new hires are needed (*e.g.* to restore personnel levels to at least FY03 levels)
- ✓ FDA has the ability to enter into contracts and hire personnel to use $450 million effectively

How would FDA Alliance allocate the $450 million among FDA's various missions?

- ✓ The FDA Alliance recommends that each center's percentage of a $430 million increase be equal to the center's percentage of non-rent budget authority appropriations over the last 5 years.
- ✓ The remaining $20 million is allocated to rent costs for increased staff at the proposed level

Recommended FY08 Budget Authority Increases by Center				
(based on 5-year historical FDA budget allocation of non-rent, non-user fee appropriations)				
Center/Major Function	**FY 2007 Appropriations *(budget authority w/o user fees)***	***% of Non-Rent BA Approp.***	**FDA Alliance : Recommendations for Budget Authority/Appropriations**	
			FY 2008	**Increase Over FY 2007**
Foods	$457,105,000	33%	$597,105,000	+$140,000,000
Drugs	$315,138,000	23%	$413,138,000	+$98,000,000
Biologics	$144,547,000	11%	$191,547,000	+$47,000,000
Animal Drugs& Feed	$94,749,000	7%	$124,749,000	+$30,000,000
Devices & Radiol. Health	$230,683,000	17%	$302,683,000	+$72,000,000
NCTR	$42,056,000	3%	$55,056,000	+$13,000,000
Other Activities	90,541,000	7%	$120,541,000	+$30,000,000
SUBTOTAL	**$1,374,819,000**		**$1,804,819,000**	**+$430,000,000**
Rent & Facility-Related Costs	$199,375,000		$219,375,000	+20,000,000
TOTAL	**$1,574,194,999**		**$2,024,194,000**	**+$450,000,000**

Note: FDA Alliance recommendations and allocations do not include any new authorities that may result from pending legislation and do not include user fee revenue.

Total FDA Appropriated S&E Budget Authority, If…

1. Appropriated Budget Authority had increased at 5.8% per year over FY 2003 level, and
2. All funds for program increases had really been added to the Appropriation

UNDER THESE ASSUMPTIONS,

THE FY 2008 BUDGET AUTHORITY SHOULD BE $2 Billion,

WITH USER FEES SEPARATE AND ADDITIONAL

	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008
Amt if 2003 increased by 5.8% per year	**$ 1,373**	**$ 1,453**	**$ 1,537**	**$ 1,626**	**$ 1,720**	**$ 1,820**
Additions Shown in Budget, and then increased in Subsequent years at 5.8%						
1) Food Safety Counterterrorism/Defense		$ 20.5	$ 83.7	$ 94.4	*See Discussion Below Regarding FY 2007 Funding*	*See Discussion Below Regarding FY 2008 Funding*
2) Patient Safety		$ 3.0	$ 3.2	$ 3.4		
3) OTC Drugs		$ 0.7	$ 0.7	$ 0.7		
4) Generic Drugs		$ 8.0	$ 8.5	$ 9.0		
5) BPCA		$ 3.5	$ 3.7	$ 3.9		
6) Medical Device Review		$ 1.0	$ 26.6	$ 34.2		
7) Orphan Product Grants			$ 1.2	$ 1.3		
8) Influenza (transfer from OC)			$ 0.3	$ 0.3		
9) Medical Product Countermeasures			$ 5.0	$ 5.3		
10) BSE/Mad Cow Disease			$ 8.0	$ 8.5		
11) Drug Safety				$ 10.0		
12) Critical Path				$ 0.8		
13) DTC Advertising				$ 0.9		
14) Pandemic Preparedness				$ 20.0		
Total Additions		**$ 37**	**$ 141**	**$ 192**	**$ 203**	**$215**
What would have been:	**$ 1,373**	**$ 1,489**	**$ 1,678**	**$ 1,819**	**$ 1,924**	**$ 2,035**
Actual Appropriation: [1]	**$ 1,373**	**$ 1,379**	**$ 1,450**	**$ 1,487**	**$ 1,574**	
Difference (shortfall)		**$ (110)**	**$ (228)**	**$ (332)**	**$ (366)**	
Percent Difference (shortfall)		**-7%**	**-14%**	**-18%**	**-19%**	

[1] From S&E Budget Authority in All Purpose Tables in Congressional Budget Justifications

FY2007:

FY 2007 is calculated as a 5.8% increase over 2006, including prior year program additions

$1.819 billion X 1.058 = $1.924 billion

FY2008:

Using the above calculation as a baseline and assuming no further program additions, FY 2008 would be calculated as a 5.8% increase over 2007

$1.924 billion X 1.058 = $2.036 billion

Based on analysis done by Frank Claunts for FDA, with revisions, updates and annotations by the FDA Alliance March 13, 2007

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FDA ALLIANCE MEMBERS—as of 5/11/07: 108 members

HONORARY MEMBERS—Former FDA Commissioners

Charles C. Edwards, MD
Jere E. Goyan, PhD (deceased)
Frank E. Young, MD
Lester M. Crawford, DVM, PhD
Donald Kennedy, PhD
Arthur Hull Hayes, Jr., MD
Jane E. Henney, MD

NON-PROFITS

Academy of Managed Care Pharmacy
Accelerate Cure/Treatments for Alzheimer's Disease (ACT-AD)
Allergy and Asthma Network/Mothers Of Asthmatics
Alliance for Aging Research
American Celiac Disease Alliance
American Dietetic Association
American Porphyria Foundation
American Society for Clinical Pharmacology and Therapeutics
American Society for Pharmacology and Experimental Therapeutics
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists
Aplastic Anemia and MDS International Foundation
Celiac Sprue Association
Center for Science in the Public Interest
Children's Tumor Foundation
The Critical Path Institute
Elizabeth Glaser Pediatric AIDS Foundation
FasterCures
Foundation for Allergy and Immunology Research
GBS/CIDP Foundation International
Hemophilia Federation of America
Hydrocephalus Association
Institute for African-American Health
Institute for Alternative Futures
International Foundation for Anticancer Drug Discovery
International Foundation for Functional Gastrointestinal Disorders
Jefferson County (AR) Industrial Foundation
Minority Physicians Research Alliance
National Alliance for Hispanic Health
National Consumers League

National Foundation for Celiac Awareness
National Hemophilia Foundation
National Kidney Foundation
National MPS Society
National Organization for Rare Disorders
National Research Center for Women & Families
Neurofibromatosis, Inc.
Parent Project Muscular Dystrophy
Patient Safety Institute
Prevent Blindness America
RetireSafe
Society for Women's Health Research
Sturge-Weber Foundation
TMJ Association
US Pharmacopeia
Wilson's Disease Association

TRADE ASSOCIATIONS

Consumer Healthcare Products Association
Cosmetic, Toiletry, and Fragrance Association
Massachusetts Medical Device Industry Council
Medical Device Manufacturers Association
National Association of Chain Drug Stores
Pharmaceutical Research and Manufacturers of America

COMPANIES

Allergan	AstraZeneca	Cephalon
Ligand Pharmaceuticals	Merck	Ovation Pharma
Pfizer	ResVerlogix	Sanofi Aventis
Schering-Plough	UCB	

LAW FIRMS/CONSULTING FIRMS

Bedard & Associates Consulting	Catalyst Healthcare Consulting
Chesapeake Research Review, Inc.	ECG, Inc.
Engage Health	Garvey Associates
HealthPolCom Consulting	HillCo Partners
HPS Group	Immel Resources
International Regulatory Affairs Group	Resolute Regulatory Consulting
Rx Development	SciWords
Strategic Health Policy International	TeleMedicine & Medical Informatics Webster and Webster Associates

INDIVIDUALS

Ronald Alexander	Anthony Celeste	Frank Claunts	Richard Cooper
J. Richard Crout	Donna R. Cryer	James Dickinson	Mary H. Hager
Ron Hammerle	Pamela Jones	Sandra Kamisar	John Kamp
Bruce Mackler	Gerry F. Meyer	Art Norris	Stuart Pape
Wayne Pines	Ted Roumel	William Schultz	Bert Spilker
Michael R. Taylor			