Food and Drug Administration FY2011 Budget and Appropriations

name redacted
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Summary

The President's budget request for FY2011 included $4.032 billion for the Food and Drug Administration (FDA). The total is made of $2.508 billion in direct appropriations (which FDA calls budget authority) and $1.523 billion in user fees. Overall, the request is 22.8% more than the enacted FY2010 total appropriation, with budget authority up 6.2% and fees up 65.2%. Most of the increase would come from proposed new user fees to support generic drug activities, food export certification, reinspection, and food inspection and facility registration. For continuing user fee programs (prescription drug, medical device, animal drug, animal generic drug, tobacco product, mammography quality standards, export certification, and color certification), the $1.233 billion request is 33.7% above FY2010.

Budget justification documents describe FY2011 agency initiatives in food safety, medical product safety, and regulatory science. They also show the program-level budget request (both budget authority and user fees) and describe activities in each of FDA's program areas: human drugs, biologics, animal drugs and feeds, devices and radiological health, tobacco products, and toxicological research.

The Commissioner of Food and Drugs has testified to the subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of both the Senate and House Committees on Appropriations. On June 30, 2010, the House subcommittee approved Chair Rosa DeLauro's mark, copies of which were not made public. It included, for FY2011, $2.571 billion in budget authority for FDA. It recommended a total FDA program level, including user fees, of $3.773 billion. The Senate Committee on Appropriations reported S. 3606 on July 15, 2010. It would provide FDA with $2.516 billion in budget authority and $1.233 billion in user fees for a total FY2011 program level of $3.75 billion.

On September 29, 2010, neither the full Senate nor the full House had approved an agriculture appropriations bill for FY2011, nor had Congress passed any other of the regular FY2011 appropriations bills. The Senate amended and approved H.R. 3081, the Continuing Appropriations Act, 2011, which would allow federal operations, including the FDA, to continue at FY2010 levels from October 1, 2010, the start of FY2011, through December 3, 2010. The House passed the continuing resolution early on September 30, 2010, and the President signed it that day as P.L. 111-242.

Updates to this report will track legislative activity.

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Introduction

The Food and Drug Administration (FDA) regulates the safety of foods (including animal feeds) and cosmetics, and the safety and effectiveness of drugs, biologics (e.g., vaccines), and medical devices. With new authority that began in FY2010, FDA also regulates tobacco products according to their impact on public health.[1]

The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill provides FDA's annual funding. The total amount that FDA can spend, its program level, consists of direct appropriations (which FDA calls budget authority) and other funds, most of them user fees.[2] An appropriations bill specifies both the budget authority and user fee amounts each year. It dictates the total for each of FDA's major program areas (foods, human drugs, biologics, devices and radiological health, animal drugs and feeds, tobacco products, and toxicological research) and several agency-wide support areas (Office of the Commissioner and other headquarter offices, rents to the General Services Administration, and other rent and rent-related activities). Traditionally, the appropriations committees have used report language to recommend, urge, or request specific activities within major programs.

The standard appropriations procedure involves congressional passage of 12 annual regular appropriations acts, of which agriculture (including FDA) is one.[3] For 7 of the previous 11 fiscal years, Congress had not completed that standard process and had passed omnibus or consolidated appropriations legislation, as shown in **Table 1**. Recent examples include FY2009, when Congress acted in the final days of FY2008 to provide appropriations for the start of FY2009 as part of the larger Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (P.L. 110-329, signed on September 30, 2008), and passed an omnibus FY2009 appropriations bill that included FDA (P.L. 111-8) in March 2009. The FY2010 agriculture appropriations (P.L. 111-80) followed the standard process except that final passage occurred after the start of the fiscal year. The process for FY2011 began on February 1, 2010, when the President released his budget request.

[1] The Family Smoking Prevention and Tobacco Control Act (enacted June 22, 2009, as Division A of P.L. 111-31, Family Smoking Prevention and Tobacco Control and Federal Retirement Reform) gave authority to the Food and Drug Administration to regulate the manufacture, marketing, and distribution of tobacco products. CRS Report R40475, *FDA Tobacco Regulation: The Family Smoking Prevention and Tobacco Control Act of 2009*, by (name redac ted) and (name redacted), describes the development of this new FDA authority and discusses how it differs from traditional FDA responsibilities based on safety and effectiveness.

[2] It also authorizes collections and spending from several specific other funds (relating to mammography quality standards, and color and export certification). For historical information on FDA's budget and statutory authorities, and descriptions of the responsibilities of FDA program areas, see CRS Report RL34334, *The Food and Drug Administration: Budget and Statutory History, FY1980-FY2007*, coordinated by (name redacted); CRS Report R40792, *Food and Drug Administration Appropriations for FY2010*, by (name redacted); and CRS Report RS22946, *Food and Drug Administration (FDA): Overview and Issues*, by (name redacted).

[3] "Congress has developed certain rules and practices for the consideration of appropriations measures, referred to as the congressional appropriations process.... Regular appropriations bills provide most of the funding that is provided in all appropriations measures for a fiscal year, and must be enacted by October 1 of each year. If regular bills are not enacted by the deadline, Congress adopts continuing resolutions to continue funding generally until regular bills are enacted" (CRS Report 97-684, *The Congressional Appropriations Process: An Introduction*, by (name redacted)).

Table 1. Legislative Vehicle for Final FDA Appropriations, FY1999-FY2010

Fiscal Year	Final Appropriations Bill	Public Law and Date Enacted
2010	*Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2010*	P.L. 111-80, October 21, 2009
2009	Omnibus Appropriations Act, 2009	P.L. 111-8, March 11, 2009
2008	Consolidated Appropriations Act, 2008	P.L. 110-161, December 26, 2007
2007	Revised Continuing Appropriations Resolution, 2007	P.L. 110-5, February 15, 2007
2006	*Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006*	P.L. 109-97, November 10, 2005
2005	Consolidated Appropriations Act, 2005	P.L. 108-447, December 8, 2004
2004	Consolidated Appropriations Act, 2004	P.L. 108-199, January 23, 2004
2003	Consolidated Appropriations Resolution, 2003	P.L. 108-7, February 20, 2003
2002	*Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2002*	P.L. 107-76, November 28, 2001
2001	*Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2001*	P.L. 106-387, October 28, 2000
2000	*Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2000*	P.L. 106-78, October 22, 1999
1999	Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999	P.L. 105-277, October 21, 1998

Notes: Cells in italics indicate "regular" agriculture appropriations bills, rather than consolidated or omnibus bills. None of these bills were enacted before the beginning of the fiscal year to which they applied.

FDA Budget and the President's Request for FY2011

In February of each year (except for when a new President has taken office the month before), the President presents a budget request to Congress. The annual *Food and Drug Administration Justification of Estimates for Appropriations Committees* contains program-level details of the President's request, while also highlighting successes, needs, and special initiatives for the coming year. Because the topics selected for discussion vary over the years, analysts cannot use this information to track exact changes over time. The program-level detail, however, provides a window into the priorities and activities of the agency.

Budget Authority and User Fees

Table 2 displays the President's FY2011 request by major program area. For historical context, the table also has columns for FY2009-enacted appropriations, FY2009 actual appropriations (as of February 2010), and FY2010-enacted appropriations.

The FY2011 request—$4.032 billion—is 22.8% higher than FY2010-enacted appropriations. The increase would be mostly in user fees. The request for $2.508 billion in budget authority (BA) is 6.2% higher than the FY2010 appropriations.

For continuing user fee programs (prescription drug, medical device, animal drug, animal generic drug, tobacco product, mammography quality standards, export certification, and color

certification fees), the requested $1.233 billion is 33.7% above FY2010. Tobacco product fees account for much of this increase as FDA ramps up the regulatory authority that Congress gave it in 2009.[4] The requested increase in continuing user fee programs excluding tobacco product fees is 14%.

The FY2011 request includes an additional $290 million in proposed new user fees that Congress has not yet authorized.[5] These are generic drug user fee authority ($38 million), food export certification fees ($4 million), reinspection fees ($27 million), and food inspection and facility registration fees ($220 million). The total user request is for $1.523 billion, a 65.2% increase over FY2010.

Budget Justification Description of Activities

In addition to program-specific descriptions, which coincide with the program-specific funding shown in **Table 2**, the budget justification documents describe major initiatives planned for the upcoming year.

Initiatives. The budget justification documents describe major initiatives planned for FY2011 with all the requested funds. The three major initiatives cut across program areas. The first described is *Transforming Food Safety*. The agency outlines its plans to set standards for safety; establish an integrated national food safety system; enhance surveillance and improve risk analysis and research for food and feed safety; expand laboratory capability; increase inspection capacity; pursue pilot studies with industry using track and trace technology; and increase inspections of domestic and foreign facilities.

In the *Protecting Patients* initiative FDA would seek to invest in new scientific tools and partnerships, modernize the agency's approach to supply chain safety for medical products, and expand its capacity to conduct medical product safety assessments. This would include launching an electronic drug registration and listing system to stop illegal drug imports and expanding foreign inspections. The third initiative, *Advancing Regulatory Science for Public Health*, involves FDA plans to build its scientific infrastructure, develop standards for new and emerging technologies, modernize the standards for evaluating products, and accelerate the development of essential medical therapies.

Programs. The program-specific narratives highlight elements of these initiatives along with other activities. For the *Food* program, these include more closely integrating with state and local governments; working with public health organizations in foreign countries to shift burden of assuring imported food safety from the FDA to the foreign production/processing environment; developing tools to identify, evaluate, prioritize, and communicate risks; enhancing the reportable food registry and the consumer complaint reporting system; participating in the nanotechnology initiative; and hiring additional laboratory staff.

[4] The June 2009 enactment of the legislation authorizing FDA to regulate tobacco products allowed a prorated amount of authorized tobacco product user fees for FY2009. In fact, no tobacco product fees were collected in FY2009. The FY2010 appropriations bill set the amount at $235 million; the FY2011 request is for $450 million.

[5] For the past few years, the President's request has included these proposed fees. In the FY2010 request, they totaled $141 million. Neither the House nor the Senate appropriations committees included the proposed and unauthorized fees in its reported bill.

For the *Human Drugs* program, the budget justification narrative includes expanding involvement with the science of nanotechnology and developing new biomarkers; implementing a quantitative risk-based program to target clinical site inspections; increasing inspections; improving human subject protection; completing and validating a new electronic drug registration and listing system, allowing information about specific drug products, specific ingredients, and specific facilities around the world; working with other countries' regulatory authorities; targeting high risk manufacturing facilities for inspections; continuing implementation of the National Sentinel System Network, a public-private collaboration; and staffing the Safe Use Initiative.

Biologics program activities in FY2011 would include increasing outreach to improve industry practices and performance; building capacity to reduce the risk of disease transmission caused by infected tissues; evaluating the use of nanoparticles in analytic tests; developing analytic tests with stem cells to facilitate clinical translation of therapies; hiring and training investigators to conduct complex medical product inspections; and developing biological markers and other approaches to evaluate the safety of vaccines and vaccine components.

For the *Animal Drugs and Feeds* program, the budget justification describes hiring and training scientific staff to build expertise to regulate new animal biotechnology products; expanding the National Antimicrobial Resistance Monitoring System, which would allow FDA to make more informed science based decisions; establishing an Integrated National Food Safety System with Strengthened Inspection and Response Capacity; and coordinating and increasing surveillance of state activities and data-sharing.

The FDA-listed activities for the *Devices and Radiological Health* program include participating in the development and implementation of a national strategy for the best public health use of health-related electronic data; systematically integrating all available internal and external data involving the pediatric population; broadening targeted surveillance; building infrastructure to analyze pediatric postmarket device information; increasing oversight of foreign manufacturing facilities; developing standards for safe and effective CT scanners and fluoroscopes; and recruiting scientists in fields such as biostatistics, epidemiology, modeling, and risk sciences.

FY2011 will be the second year of the *Tobacco Products* program at FDA. It is funded solely by user fees. Planned activities include conducting research and evaluation programs to better understand how the FDA regulations and tobacco control and prevention programs protect the public from the adverse health consequences of tobacco use; implementing a comprehensive framework for a research and testing program to support tobacco product standards development and other activities; developing comprehensive education and communications programs designed to reach the public; and contracting with states and territories to conduct inspections.

The narrative for the *National Center for Toxicological Research* describes developing and deploying rapid detection tests; developing and training scientific staff; and engaging in collaborative and interdisciplinary research.

To carry out these initiatives, as well as continue standard FDA activities, the agency would rely on direct congressional appropriations and user fee revenue.

Table 2. FDA FY2011 Appropriations: Administration Request, and House Subcommittee and Senate Committee Recommendations

(dollars in millions)

Program area	Funds	FY2009 Enacted[a]	FY2009 Actual[b]	FY2010 Appropriations	FY2011 President's Request	% change FY2010 Approp. to FY2011 Request	House Subcommittee Referred[d]	Senate Full Committee Reported[e]
Foods	BA	646	713	784	848	8.2		856
	Fees	—	—	—	194	—		
	Total	646	713	784	1,042	32.9		
Human drugs	BA	410	437	465	484	4.2		489
	Fees	364	365	415	516	24.3		
	Total	774	802	880	1,000	13.6		
Biologics	BA	182	195	206	215	4.2		215
	Fees	88	93	99	114	15.1		
	Total	270	287	305	329	7.7		
Animal drugs and feeds	BA	115	122	135	141	3.8		141
	Fees	18	14	20	34	70.4		
	Total	133	135	156	175	12.4		
Devices and radiological health	BA	279	299	315	326	3.3		326
	Fees	49	47	53	59	11.6		
	Total	328	345	368	385	4.5		
Tobacco products	BA	5	5	0	0	0		0
	Fees	22	0	217	421	94.7		
	Total	27	5	217	421	94.7		
National Center for Toxicological Research (NCTR)	BA	52	56	59	61	3.8		61
	Fees	—	—	—	[c]	[c]		
	Total	52	56	59	61	4.5		

Program area	Funds	FY2009 Enacted[a]	FY2009 Actual[b]	FY2010 Appropriations	FY2011 President's Request	% change FY2010 Approp. to FY2011 Request	House Subcommittee Referred[d]	Senate Full Committee Reported[e]
Headquarters and Office of the Commissioner	BA	118	130	144	162	12.5		157
	Fees	41	29	57	95	67.3		
	Total	159	159	200	256	28.0		
GSA rent	BA	134	134	146	154	5.5		154
	Fees	25	23	26	40	56.6		
	Total	159	156	172	194	13.1		
Other rent and rent-related activities (including White Oak consolidation)	BA	102	101	91	105	15.4		105
	Fees	18	18	26	40	52.8		
	Total	120	119	117	145	23.8		
Export and color certification funds	BA	—	—	—	—	—		
	Fees	10	9	10	10	0		10
	Total	10	9	10	10	0		
Subtotal, Salaries & Expenses	BA	2,039	2,190	2,346	2,496	6.4		2,504
	Fees	636	589	922	1,523	67.1		1,233
	Total	2,675	2,779	3,268	4,019	23.1		3,737
Subtotal, Buildings & Facilities	BA	16	6	16	12	-22.0		12
	Fees	—	—	—	—	—		
	Total	16	6	16	12	-22.0		
FDA Total, Budget Authority	**BA**	2,055	2,196	2,362	2,508	6.2	2,571	2,516
FDA Total, User Fees	**Fees**	636	598	922	1,523	65.2		1,233
FDA Total, Program Level	**Total**	2,691	2,794	3,284	4,032	22.8	3,773	3,750

Sources: Department of Health and Human Services, *Fiscal Year 2011, Food and Drug Administration, Justification of Estimates for Appropriations Committees (Justification)*, http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/ucm202301.htm;
"Statement of Chairwoman Rosa DeLauro, Subcommittee Markup: Fiscal Year 2011 Agriculture, Rural Development, FDA Appropriations Bill," Press Release, June 30, 2010, http://appropriations.house.gov/images/stories/pdf/ardf/Delauro_Opening_Statement.6.30.10.pdf; and
S.Rept. 111-221 to accompany S. 3606, submitted by Mr. Kohl from the Committee on Appropriations, July 15, 2010, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_reports&docid=f:sr221.111.pdf.

Note: Data for FY2009, FY2010, and the FY2011 President's Request come from the FY2011 *Justification*, as follows:
BA figures from All Purpose Table–Budget Authority, page 60.
Total figures from All Purpose Table–Total Program Level, page 59.
User fee figures for FY2011 request calculated from information provided in All Purpose Table–User Fees, page 61.
User fee figures for FY2009 and FY2010 are calculated as Total minus BA.

a. The FDA FY2011 *Justification* labeled this as "Enacted."

b. The FDA FY2011 *Justification* labeled this as "Actual."

c. The FDA FY2011 *Justification* indicated that the request for NCTR includes $414,000 in proposed user fees.

d. DeLauro statement (June 30, 2010 press release) gave only FDA totals http://appropriations.house.gov/images/stories/pdf/ardf/Delauro_Opening_Statement.6.30.10.pdf.

e. S.Rept. 111-221 provided program-level budget authority figures but only an FDA total for user fees http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_reports&docid=f:sr221.111.pdf.

Congressional Action on Appropriations

The appropriations committees in the House and the Senate each have subcommittees that parallel the 12 annual appropriations bills. The subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies consider FDA appropriations.[6] The textbook order of activity is as follows:

- In each chamber, the subcommittee considers the issues, perhaps holds hearings, and marks up a bill for the full committee's consideration.
- In each chamber, the full committee considers the subcommittee-marked bill or a version that the full committee chair presents, and reports a bill, perhaps with committee amendments, to the full House or the full Senate for consideration.
- The full House considers the House Committee on Appropriations-reported bill, perhaps amending it on the floor, and passes the bill; the full Senate considers the Senate Committee on Appropriations-reported bill, perhaps amending it on the floor, and passes the bill.
- If the House-passed and Senate-passed bills are not identical, each chamber assigns Members to meet in conference to work out one acceptable bill. Each chamber must vote to approve the conference bill; the second chamber that passes the conference bill sends it to the President for signing.

Current Status

The annual appropriations process began in February 2010 with the President's submission of his proposed budget for FY2011. The budget justification documents for the Food and Drug Administration, available online through the White House Office of Management and Budget and the FDA Web sites,[7] describe the agency's programs, provide some funding history, and outline plans for the use of the requested funding.

On September 29, 2010, neither the full Senate nor the full House had approved an agriculture appropriations bill for FY2011, nor had Congress passed any other of the regular FY2011 appropriations bills. The Senate amended and approved H.R. 3081, the Continuing Appropriations Act, 2011, which would allow federal operations, including the FDA, to generally continue at FY2010 levels from October 1, 2010, the start of FY2011, through December 3, 2010. The House passed the continuing resolution early on September 30, 2010, and the President signed it later that day as P.L. 111-242. **Table 3** presents the action taken thus far this appropriations cycle. The next steps for FDA's FY2011 appropriations will likely occur within

[6] For coverage of the entire agriculture appropriations bills for FY2009 and FY2010, see CRS Report R40000, *Agriculture and Related Agencies: FY2009 Appropriations*, coordinated by (name redacted), and CRS Report R40721, *Agriculture and Related Agencies: FY2010 Appropriations*, coordinated by (name redacted).

[7] Office of Management and Budget, The President's Budget, FY 2011 Budget, http://www.whitehouse.gov/omb/budget/Overview/; and Department of Health and Human Services, Fiscal Year 2011, Food and Drug Administration, Justification of Estimates for Appropriations Committees, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM199447.pdf.

congressional negotiations either for an omnibus, government-wide appropriations bill for the remainder of FY2011 or in incremental continuing resolutions.

House

The Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the House Committee on Appropriations held a hearing on March 10, 2010, on the President's FY2011 Request for FDA.[8] FDA Commissioner Margaret Hamburg testified[9] and responded to questions.

On June 30, 2010, Chair Rosa DeLauro held a markup of a bill distributed to committee Members but not to the public. Representative DeLauro stated that the bill would include $2.571 billion in budget authority for FDA; including user fee revenue, the total FDA program level would be $3.773 billion for FY2011,[10] as shown in data column 6 of **Table 2**. She said that the bill differed from the President's request by including, for example, additional money for the Office of Generic Drugs ($15 million), review of direct-to-consumer ads ($3 million), review of communications to medical professionals ($2 million), Center for Devices and Radiological Health ($7 million), and food safety activities ($16 million). DeLauro also said that the report to accompany the bill (neither of which are yet available) would mention the "need to create an independent office of post-market drug evaluation." It would also direct FDA to provide a status report on its work on track-and-trace technologies for improving drug supply chain safety.

Neither subcommittee Chair DeLauro nor the Committee on Appropriations has released bill text of the mark.

Senate

The Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies of the Senate Committee on Appropriations held a hearing on March 9, 2010, on the President's FY2011 budget request for FDA. FDA Commissioner Margaret Hamburg testified[11] and responded to questions.

On July 15, 2010, the Senate Committee on Appropriations reported S. 3606. For FY2011, the bill would provide $2.516 billion in budget authority and $1.233 billion in user fees for a total

[8] "DeLauro Welcomes Commissioner Hamburg Before Agriculture Appropriations Subcommittee," http://appropriations.house.gov/images/stories/pdf/ardf/Delauro_Opening_Statement.3.10.10.pdf.

[9] Statement of Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, Food and Drug Administration, Department of Health and Human Services, before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, U.S. House of Representatives, March 10, 2010, http://appropriations.house.gov/images/stories/pdf/ardf/Margaret_Hamburg.3.10.10.pdf.

[10] "Statement of Chairwoman Rosa DeLauro, Subcommittee Markup: Fiscal Year 2011 Agriculture, Rural Development, FDA Appropriations Bill," Press Release, June 30, 2010, http://appropriations.house.gov/images/stories/pdf/ardf/Delauro_Opening_Statement.6.30.10.pdf; and "Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Appropriations Summary—FY 2011," http://appropriations.house.gov/images/stories/pdf/ardf/AG_FY2011_Summary_for_Subcommittee_-_for_press.pdf.

[11] Statement of Margaret A. Hamburg, M.D., Commissioner of Food and Drugs, Food and Drug Administration, Department of Health and Human Services, before the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, U.S. Senate, March 9, 2010, http://appropriations.senate.gov/ht-agriculture.cfm?method=hearings.view&id=c308f381-4a15-4724-8f1e-be37c58c9f7c.

FDA program level of $3.75 billion. The accompanying S.Rept. 111-221,[12] submitted by subcommittee Chair Herb Kohl, noted that the committee did not include $290 million in Administration-requested user fees for which Congress has not passed authorizing legislation (for generic drug review, reinspection, export certification, and food inspection and facility registration). Data column 7 of **Table 2** shows the committee-reported amounts.

S.Rept. 111-211 described the committee's rationale for its recommendations, in agreement with the President's request, to increase FY2010 amounts for food safety ($83 million); drug, device, and biologics safety ($43 million); and regulatory science ($20 million). Repeating concerns it had raised in its FY2010 appropriations report,[13] the committee strongly encouraged FDA to develop a program, with states, for increasing the inspection of imported shrimp for banned antibiotics. Regarding antibiotic development, it directed FDA to report on its progress toward the committee's request last year for development of guidance on clinical trials. It specified that the report cover the guidance on community-acquired bacterial pneumonia, FDA plans for guidances on multi-drug and pan-resistant organisms, and progress regarding development and appropriate use of antibacterial drugs for humans. The committee recommended several FDA activities relating to antimicrobial resistance, specifically regarding use of antibacterial drugs in animals.

The committee directed that the agency use $22 million for its critical path initiative, with $6 million of that going to partnerships. Of the $6 million, at least $2 million must be used to support research in prevention, diagnosis, and treatment of tuberculosis. It directed FDA to report on critical path spending semi-annually. The committee recommended $3 million for demonstration grants for improving pediatric device availability. Regarding the drug supply chain (e-pedigrees), it directed FDA to report on the status of its work with electronic track-and-trace and authentication technologies. The committee stated its support of an Administration-requested $1.4 million increase for studies to develop a modernized food label. It recommended $97 million for the generic drugs program, of which $56 million is for the Office of Generic Drugs ($4 million more than FY2010 and $2 million more than the Administration's request).

The committee directed FDA to report on Emergency Use Authorizations to include an assessment of whether the authority is sufficient. It recommended that $7 million in appropriated funds, as well as the $19 million in user fees, be used for Mammography Quality Standards Act activities; supported the expansion of nanotechnology research; recommended $16 million for orphan product development grants ($2 million more than the budget request); recommended $6 million for the Office of Women's Health; and recommended a $1 million increase to hire staff "facilitating the development of drugs to treat rare diseases."

The committee reiterated its encouragement for FDA to work with states to more aggressively combat fraud in the seafood industry; it supported FDA's work with the National Oceanic and Atmospheric Administration on seafood safety and encouraged sharing information with the Federal Trade Commission regarding fraud in seafood marketing and labeling. It again directed FDA to respond to a proposed standard of identity to prevent the misbranding and adulteration of honey. Finally, the committee directed FDA to initiate traceability projects on food products or ingredients linked to foodborne disease outbreaks.

[12] S.Rept. 111-221 to accompany S. 3606, submitted by Mr. Kohl from the Committee on Appropriations on July 15, 2010, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_reports&docid=f:sr221.111.pdf.

[13] S.Rept. 111-39 to accompany S. 1406, Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bills, 2010, submitted by Mr. Kohl July 7, 2009, http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_reports&docid=f:sr039.111.pdf.

Table 3. FY2011 Appropriations Timeline Regarding FDA

Group	Document	Action and Date
The Administration	FDA Justification of Estimates for Appropriations Committees, FY2011	Released, February 1, 2010
Senate Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, Committee on Appropriations	Commissioner of Food and Drugs hearing testimony	March 9, 2010
House Subcommittee on Agriculture, Rural Development, FDA, and Related Agencies, Committee on Appropriations	Commissioner of Food and Drugs hearing testimony	March 10, 2010
House Subcommittee	Chairman's mark (DeLauro) not released to public (summary table and press release available)	Marked up, June 30, 2010
Senate Committee on Appropriations	S. 3606 and S.Rept. 111-221(Kohl)	Reported, July 15, 2010
Senate	H.R. 3081, the Continuing Appropriations Act, 2011	Passed, September 29, 2010
House	H.R. 3081, the Continuing Appropriations Act, 2011	Passed, September 30, 2010
The President	P.L. 111-242, the Continuing Appropriations Act, 2011	Signed, September 30, 2010

Updates to this report will track legislative activity.

Author Contact Information

(name redacted)
Specialist in Drug Safety and Effectiveness
/redacted/@crs.loc.gov, 7-....