FY 2003 and FY 2004 Unit Costs for the Process of Medical Device Review

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I. BACKGROUND

A. What is MDUFMA?

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) was enacted "in order to provide FDA with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier time, and to ensure that reprocessed medical devices are as safe and effective as original devices."[1] This law has four particularly important features:

- *User fees* are assessed for the review of certain medical device premarket submissions. These fees provide additional resources to make FDA reviews more timely, predictable, and transparent to applicants. MDUFMA fees, and linked increases in appropriations for the medical device program, help FDA expand available expertise, modernize its information technology (IT) infrastructure, provide new review options, and provide more guidance to prospective applicants. The ultimate goal is to approve and clear safe and effective medical devices more rapidly, benefiting applicants, the health care community, and most importantly, patients.

- *Performance goals* for many types of premarket reviews provide FDA with a roadmap to achieving review improvements. These quantifiable goals become more demanding each year and include FDA decision goals and cycle goals (cycle goals refer to FDA actions prior to a final action on a submission). Under MDUFMA, FDA must also meet a variety of *commitments*, such as to develop performance goals for modular PMAs and to improve pre-approval inspection timeliness.

- *Establishment inspections may be conducted by accredited persons* (third-parties), under carefully prescribed conditions. These inspections will augment FDA inspections and will provide U.S. firms

[1] *Medical Device User Fee and Modernization Act of 2002*, Report 107-728 (October 7, 2002), p. 21.

that compete in international markets greater flexibility in meeting FDA, foreign, and standards requirements.

- *New regulatory requirements for reprocessed single-use devices*, provide FDA strengthened authority to help ensure reprocessed devices are safe and effective for their intended uses.

The user fees authorized by MDUFMA are intended to add $25.1 million to FDA's medical device budget authority during FY 2003, rising each year until fee revenues amount to $35 million in FY 2007, plus adjustments for inflation and fee revenue shortfalls. These sums, together with additional appropriations that are also specified in the law, were agreed to by FDA, Congress, and industry stakeholders as being essential to high-quality, timely medical device reviews, and to postmarket surveillance and other activities that support reviews.

MDUFMA created user fees for the review of several types of medical device applications, specified exclusion of user fees for others, set formulas for discounts and waivers, and specified the activities included in the MDUFMA review process. MDUFMA provides for fee discounts and waivers for small businesses. Small businesses make up a significant proportion of the medical device industry, and these discounts and waivers help ensure that these businesses remain economically healthy and innovative.

User fees, as specified in MDUFMA, are not cost-based. Furthermore, the user fee is a relatively small supplement to, rather than a replacement for, appropriations. The following table shows that fees collected as a percentage of program cost have risen from 16% in fiscal year 2003 to 18% in fiscal year 2004.

	Fiscal Year 2003	Fiscal Year 2004
Fees Collected	$21.6M	$27.2M
MDUFMA Cost	$140.4M	$147.4M
Fees as a % of Cost	16%	18%

B. What is the MDUFUMA Unit Cost Study?

Other user fee programs (Prescription Drug User Fee and Animal Drug User Fee Programs) differ from MDUFMA in several significant aspects. They created user fee pricing mechanisms that resulted in lower fees per application because the majority of fee revenue is collected from other mechanisms. Two-thirds of Prescription Drug user fee revenues come from annual fees paid for by manufacturing establishments and products while three-quarters of Animal Drug user fee revenues are derived from annual establishment, product, and sponsor fees.

MDUFMA user fees differ in that they are totally derived from applications. The MDUFMA legislation also sets increased revenue targets adjusted for inflation and workload, each of the first three years. The fee structure in the legislation, combined with reduced numbers of fee-paying applications, led to sharp increases in the fee per application over the last two years. In response to requests from segments of the medical device industry for additional information about FDA's costs to review medical device applications, the Commissioner directed FDA staff to develop unit cost estimates for MDUFMA, similar to information developed for other user fee programs. These unit costs are, in effect, the average costs for FDA to review various types of medical device applications during a particular period of time. This document presents the unit cost estimates that were developed for fiscal years 2003 and 2004.

MDUFMA was built on an assumption of a steady state workload and substantially increasing resources over the 5-year period from 2003 to 2007. It should have been an expectation of both industry and FDA that costs per completed review would rise each year over this period as the program added resources and became appropriately funded. For that reason the costs per completed application that are developed for FY 2003 and 2004 must be looked at in this context—a beginning point that is expected to increase until the program is appropriately funded in FY 2007.

FDA contracted with Dr. Dale R.Geiger to provide assistance in developing unit costs. Work started in the fall of 2004. This report summarizes the calculation of the unit costs and discusses the methodology and assumptions used in developing these unit cost estimates.

Note concerning the enactment of the Medical Device User Fee Stabilization Act of 2005 (MDUFSA): This report was substantially completed prior to the enactment of MDUFSA, which occurred on August 1, 2005. In those places where the report describes requirements under MDUFMA, the report should be read as summarizing requirements that were in effect prior to August 2005.

II. METHODOLOGY AND ASSUMPTIONS

A. Allowable and Excluded Costs

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by MDUFMA, defines the process for the review of medical device applications and the costs that may be included in that process. The Agency has identified costs for the following activities for inclusion in their annual financial report to Congress.[2] This section and the next are included in that annual financial report as appendices D and E.

[Section 737(5)(A)] The activities necessary for or in anticipation of the review of premarket applications, premarket reports, supplements, and premarket notification submissions, including, but not limited to, the following:

- 510(k)s -- Traditional/Supplements/Abbreviated/Specials (third party and non-third party)
- Evaluation of Automatic Class III Designations
- Traditional and Expedited PMAs (includes amendments, supplements, and annual reports)
- Modular PMAs (shell, modules, amendments, supplements, and annual reports)
- PDPs (including amendments, supplements, and annual reports)
- Premarket Reports (amendments, supplements, annual reports)
- Reclassification Petitions
- Class II Exemption Petitions
- BLAs and BLA Supplements (Applications subject to 351 of the PHS Act)
- Recruitment and use of outside experts during the review process
- Obtaining advisory committee input (e.g., convened meetings, homework assignments)
- Resolution of product jurisdictional issues
- Dispute resolution/appeals
- Information Technology (IT) support for review activities
- Recruitment of review staff, support staff, and project managers

[2] Each fiscal year FDA is required to submit a financial report to Congress. The 2003 and 2004 MDUFMA Financial Reports are attached as Appendices B and C.

[Section 737(5)(B)] The issuance of action letters that allow marketing of devices or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to place them in condition for approval. This includes activities such as the issuance of deficiency letters, meetings with applicants to discuss such letters, and review of the responses.

[Section 737(5)(C)] The inspection of manufacturing establishments and facilities undertaken as part of the review of pending premarket applications, premarket reports, and supplements, including activities such as the review of manufacturing information submitted in premarket applications, pre-approval GMP inspections, and resolution of any identified GMP issues.

[Section 737(5)(D)] Monitoring of research conducted in connection with the review of such applications, reports, supplements, and submissions. For the types of applications identified above, this would include monitoring activities such as:

- Conduct of bioresearch monitoring inspections (both "for cause" and pre-approval) of sponsors, institutional review boards, and clinical investigators
- Adverse event and complaint investigations related to on-going clinical trials
- GLP inspections (21 CFR Part 58)

[Section 737(5)(E)] Review of device applications subject to section 351 of the Public Health Service Act for an investigational new drug application (IND) under section 505(i) or for an investigational device exemption (IDE) under section 520(g) and activities conducted in anticipation of the submission of such applications under section 505(i) and 520(g). This would include the review of IDEs (original, amendments, and supplements) and INDs (amendments, supplements, and safety reports). Also included are pre-IDEs (review of the submission and any meetings or correspondence), significant/non-significant risk determinations, and Determination/Agreement meetings.

[Section 737(5)(F)] The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, premarket reports, supplements, and premarket notification submissions, including activities such as the development of device-specific, cross-cutting, special control, and program-related guidances, as well as "Blue Book Memoranda" and Standard Operating Procedures.

[Section 737(5)(G)] The development of voluntary test methods, consensus standards, or mandatory performance standards under section 514 in connection with the review of applications listed above. This would include national and international standards development and coordination related to the review of premarket applications.

[Section 737(5)(H)] The provision of technical assistance to device manufacturers in connection with the submission of such applications, reports, supplements, or submissions, including activities such as:

- Informal consultation via phone, meetings, e-mail, and facsimile
- Meetings between FDA and applicants, such as pre-submission meetings, Determination/Agreement meetings, and meetings to discuss deficiencies in premarket applications
- Use of outside experts in the review of premarket applications
- Review of labeling prior to approval of a premarket application or supplement
- FDA sponsored conferences/workshops related to premarket submissions
- Staff participation at non-FDA meetings related to such applications

[Section 737(5)(I)] Any activity undertaken under section 513 or 515(i) in connection with the initial classification or reclassification of a device or under section 515 (b) in connection with any requirement for approval of a device, including activities such as the review of requests for information submitted under section 513(g) and the "call" for PMAs for pre-amendment devices.

[Section 737(5)(J)] Evaluation of post-market studies required as a condition of approval of a premarket application or premarket

report under section 515 or section 351 of the PHS Act. This would include activities such as the review of:

- Protocols for the post-market studies
- Modifications to such protocols
- Data collected under the protocol
- Labeling changes (instructions for use, warnings, precautions, etc.), if needed as a result of the review of the data.

[Section 737(5)(K)] Compiling, developing, and reviewing information on relevant devices to identify safety and effectiveness issues for devices subject to premarket applications, premarket reports, supplements, or premarket notification submissions, including activities such as:

- Epidemiology studies
- Post-marketing problem identification/resolution, including reports filed under the Medical Device Report regulation

Training related to premarket and post-market approval activities. This would include the following types of training:

- Scientific, clinical, and statistical training
- Managerial or other administrative training
- Policy/regulatory training
- Professional development (coursework, attendance at professional meetings, library resources)
- "Vendor Days"
- Site Visit Program for premarket reviewers

User Fee Act implementation, including activities such as:

- Guidance/regulation development
- Stakeholder outreach for educational and comment purposes
- Training of Agency staff
- IT support for implementation

Section 737(6) of the Act defines the "costs of resources allocated for the process for the review of medical device applications" as the expenses incurred in connection with this process for:

(A) Officers and employees of the FDA, contractors of the FDA, advisory committees, and costs related to such officers, employees, committees and contracts;
(B) Management of information, and the acquisition, maintenance, and repair of computer resources;
(C) Leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies; and
(D) Collecting user fees and accounting for resources allocated for the review of premarket applications, premarket reports, supplements, and submissions.

FDA interprets this provision as excluding:

- Enforcement policy and regulation development
- Third-party inspection program
- Post-approval compliance actions and activities unrelated to PMA Conditions of Approval and investigations of safety and effectiveness issues for devices subject to FDA regulation
- Post-approval activities relating to:
  - Promotion and advertising
  - International coordination/Mutual Recognition Agreement work
  - International standard development
  - Liaison/outreach and manufacturing assistance
  - Device tracking
- Inspections unrelated to the review of covered applications
- Export/Import activities unrelated to the conduct of a clinical trial
- Research related to future products
- All activities conducted under the Mammography Quality Standards Act, radiation safety authorities of the Federal Food, Drug, and Cosmetic Act (Sections 531 et. seq.), and the Clinical Laboratories Improvement Act.

B. General Methodology

The costs estimates for the process for the review of device applications are based on obligations recorded within FDA's Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER), Office of Regulatory Affairs (ORA), and the Office of the Commissioner (OC). These organizations contribute to the cost categories used in the study as follows:

Cost Category	Contributing FDA Organization
Review of Premarket Applications (PMAs), Product Development Protocols (PDPs), Premarket Reports (PMRs), Modular PMAs, PMA Supplements, and 510(k)s	CDRH, CBER
Review of Biologic License Applications (BLAs) and Supplements, and 510(k)s	CBER
Field Inspection and Investigation Costs	ORA
Agency General and Administrative Costs	OC

The costs were identified and estimated using a variety of methods. Using the definitions of costs and activities included in the "Process for the Review of Device Applications" in the Act, a portion of the costs within each of the four organizations listed above was identified as part of the device review process.

Center Costs

CDRH and CBER costs are incurred in organizational components throughout the Centers. Most components perform a mixture of activities--some included in the process for the review of device applications, and some not included. These components were assigned to three categories: 1) direct review and laboratory components; 2) indirect review and support components; and 3) Center-wide costs. Costs are accumulated by cost

centers (usually organization components at the division level). The allocation of costs for the categories is discussed below.

Direct Review and Laboratory Components

Employees in CDRH and CBER, other than those noted below as Center indirect review and support components, report their time in categories that can be used to differentiate between time spent on the process for the review of device applications and other efforts.

Both CDRH and CBER have time reporting systems in place. These time reporting systems were modified after the enactment of MDUFMA, so that time could be reported in categories that could be separated into allowable and excluded activities with respect to the process for the review of device applications, as defined in MDUFMA and as further defined in Appendix D of FDA's MDUFMA Financial Report to Congress. This process is further explained below.

CDRH had a time reporting system that has been used to gather information about how employees spend their time for a two-week period one or two times each year for the past 10 years. After the definitions of allowable and excluded costs for the process for the review of device applications under MDUFMA were further refined, as presented in Section A, the time reporting categories in the CDRH time-reporting system were modified so that all data captured fit into either allowable or excluded costs. These modifications to the system were completed in mid-June, 2003.

Once these modifications were completed, CDRH employees other than management and administrative personnel reported all of the time they worked against these revised categories for a period of eight consecutive weeks, from June 29 through August 23, 2003. Whether time categories were counted as allowable or excluded was not apparent to employees as they reported their time.

FDA Centers are payroll-intensive organizations. In most years, over 60 percent of all FDA funds go to pay for employee salaries and benefits. Almost all other costs directly support these employees. Therefore, it is reasonable to use the time reporting as the basis of distributing all costs incurred for that cost center for the entire FY 2003.

For FY 2004, all CDRH employees, other than management and administrative personnel, reported all of the time they worked for one two-week period during each quarter of the fiscal year. The results from the eight weeks of time reporting data were then averaged and extrapolated to the entire year. This served as the basis for measuring CDRH costs for the device review process for FY 2004 for direct review and laboratory components, and the same pattern will be followed in future years.

A similar procedure was used in CBER's direct review and laboratory components to measure costs for the device review process. CBER was able to use the time reporting system it has had in place for over 10 years, and which was validated by studies done just after PDUFA was initiated. That system collects time reports from all employees other than management and administrative support personnel for four different two-week periods in each of FY 2003 and FY 2004.

CBER's existing system was also modified to ensure that categories against which time was reported could be clearly divided into those that were either allowable or excluded in the MDUFMA-defined process for device application review. Management and administrative support personnel is then assumed to follow the same pattern between process and non-process costs as the average time of those employees who reported their time. CBER's time reporting data are collected during two weeks each quarter and a quarterly report is extrapolated from the two weeks data. Each separate quarterly report is then added together to produce an annual report. A similar process will take place each future fiscal year. The results from the eight weeks of time reporting data were then added and extrapolated to the entire year.

This process for determining allowable and excluded costs for MDUFMA direct review and laboratory costs is identical to the process for the review of human drug applications as measured by Arthur Andersen under PDUFA for 1992 and 1993.

Center Indirect Review and Support Components

Indirect review and support components provide the infrastructure for the review process. In CDRH, these are the Office of the Center Director and the Office of Management and Operations. In CBER, these components include the Office of the Center Director, Office of Management, Office of

Information Management, and the Office of Communications, Training, and Manufacturers Assistance.

In both CDRH and CBER, the allowable costs for these indirect review and support components were determined by multiplying the average percent of allowable costs for all direct review and laboratory components by the total costs of each of these indirect review and support components.

Center-wide Expenses

A number of Center-wide expenses are paid for centrally from agency funds each year rather than from funds allocated to the centers. These costs include rent, utilities, some computer equipment, facilities repair and maintenance, and some extramural and service contracts. Many of these costs, such as rent, can be traced back to the specific organization component that generated the cost and were assigned the user fee related percentage calculated for the division to which the expenditure related. For the costs that benefited the Center as a whole and could not be traced to a specific organization, a weighted average user fee percentage was calculated based on the level of user fee costs to total costs in the Center.

Field Inspection and Investigation Cost

All field inspection and investigation costs are incurred by FDA's Office of Regulatory Affairs (ORA). ORA costs are incurred in both district offices (the "field") and headquarters support offices. In FY 2002, the Agency began tracking accumulated ORA costs through the use of the Field Accomplishment and Compliance Tracking System (FACTS). FACTS is a time and activity tracking system which captures time in a variety of categories, including pre-approval inspections of manufacturing facilities, investigations of clinical studies, and analytical testing of samples--which are included in the process for the review of device applications.

Total direct hours reported in FACTS are used to calculate the total number of staff-years required by ORA to perform activities in the process for the review of device applications as defined in MDUFMA. In addition to the direct time, an allocation of support time is also included to represent the work done by the ORA administrative and management personnel. The Agency then applies the total number of user fee related staff years to the average salary cost in ORA to arrive at the ORA user fee related salary costs. The final step is to allocate

ORA obligations for operations and rent to the device review process based upon the ratio of user fee related staff years to total ORA staff years. The following table summarizes the calculation for the FYs 2003 and 2004, respectively.

Food and Drug Administration
Office of Regulatory Affairs
Costs of the Process for the Review of Device Applications
As of September 30, 2003 and 2004

Cost Component	FY 2003	FY 2004
Staff Years Utilized	59	60
ORA Average Salary & Benefits	$79,696	$86,376
Salary and Benefits	$4,702,043	$5,182,556
Operations and Rent	$2,969,792	$2,844,744
Total	**$7,671,835**	**$8,027,300**

The ORA costs for the process for the review of device applications described above include total process costs, including costs paid from appropriations and costs paid from fee revenues.

Agency General and Administrative Costs

The Agency general and administrative costs are incurred in the FDA's Office of the Commissioner (OC).

The OC costs applicable to the process for the review of device applications were calculated using a method prescribed by the Division of Cost Determination Management, Office of Finance, Office of the Secretary, Department of Health and Human Services. The method uses the percentage derived by dividing total Office of the Commissioner (including Office of the General Counsel, Office of Financial Management, and Office of Policy) costs by the total salary obligations of the Agency, excluding the Office of the Commissioner. That percentage is then multiplied by the total salaries (excluding benefits) applicable to the process for the review of devices in CDRH, CBER, and ORA to arrive at the total General and Administrative Costs.

Using this process, $10,293,297 and $10,671,593 in general and administrative obligations were dedicated to the device review process in FYs 2003 and 2004, respectively. These are total costs, including funds obligated both from appropriations and from fees. The Agency general and administrative obligations in FY 2004 accounted for about 7.2 percent of the total FY 2004 cost of the process for the review of device applications. This is down slightly from 7.3 percent in FY 2003.

At the beginning of FY 2004, FDA implemented a major reorganization and streamlining of its administrative support activities. Many functions and resources from all FDA Centers, ORA, and from components of the Office of the Commissioner were consolidated into an Office of Shared Services under the Office of Management—a component of the Office of the Commissioner. This was done in an effort to achieve greater efficiency in the provision of these services. For reporting comparability purposes, however, resources expended by the Office of Shared Services in FY 2004 supporting the device review process are shown as having been incurred by CDRH, CBER, ORA, or OC, in proportion to the resources transferred from each these components to the Office of Shared Services.

The included costs for the purposes of this study are the same as defined above and reported to Congress annually. The source of these costs is the FDA accounting system that is audited annually by an external third party. In summary, the resources obligated for the review of medical device applications, were:

FDA Component	FY 2003	FY 2004
Center for Devices and Radiological Health (CDRH)	$111,499,009	$115,537,033
Center for Biologics Evaluation and Research (CBER)	$10,970,557	$13,161,145
Field Inspection and Investigation Costs (ORA)	$7,671,835	$8,027,300
Agency General and Administrative Costs (OC)	$10,293,297	$10,671,593
Total Costs	**$140,434,698**	**$147,397,071**

The purpose of the following cost model is to develop a logical approach to distribute these costs to different review programs: technically referred to as "cost objects."

C. Determination of Cost Objects

The first task in any cost analysis is the determination of what is to be costed: the cost objects. There are four generic categories of applications for medical device review received by CDRH and CBER. These categories are:

Review of Investigational Products (IDE and IND): CDRH receives and reviews original applications, amendments, and supplements for Investigational Device Exemptions (IDEs). CBER receives IDEs as well as Investigational New Drug (IND) applications. Reviews of IDEs and INDs generate no user fees, but consume significant resources.

Once an IDE or IND is reviewed and an investigation has begun, much additional work, some of it quite lengthy, often occurs. Numerous supplements can be submitted and Agency review and interaction with sponsors often occurs for years. Clinical investigations that yield promising results can lead to marketing application submissions.

Review of Premarket Notification Submissions (510(k)s): Both CDRH and CBER receive many 510(k) applications. This category of review is generally faster than other marketing reviews. 510(k)s seek marketing clearance for a device "substantially equivalent" to one already in the marketplace that does not require premarket approval.

Review of Premarket Applications (PMAs) and Biologic Licensing Applications (BLAs): CDRH and CBER both receive PMAs and CBER also receives device BLAs. Within CDRH and CBER, there are several types of PMAs: modular and traditional, either one of which may also be expedited. Furthermore, complex supplement requests know as "panel-track supplements" and devices that qualify for a humanitarian device exemption (HDE) also fall in the PMA category. In general, PMA and BLA reviews take considerably more time and resources than 510(k) reviews. FDA receives far fewer PMAs and BLAs than 510(k)s.

Review of PMA Supplements (Multiple Types): CDRH has three categories of supplements: 180-Day, Real-Time, and Other, although MDUFMA fees are applicable only to the first two. CBER also has these categories and two others. This cost object does not include panel-track supplements or HDE supplements.

The original plan for the unit cost proposed that fifteen unit costs be developed as follows:

1.	IDE	CDRH and	CBER
2.	IND		CBER only
3.	510(k)	CDRH and	CBER
4.	Traditional PMA	CDRH and	CBER
5.	Expedited PMA	CDRH only	
6.	Modular PMA	CDRH only	
7.	Panel Track Supplement	CDRH only	
8.	HDE	CDRH only	
9.	BLA		CBER only
10.	Efficacy Supplement		CBER only
11.	BLA Manufacturing Supplement		CBER only
12.	Changes Being Effected Supplement		CBER only
13.	180-Day Supplement	CDRH and	CBER
14.	Real-Time Supplement	CDRH only	
15.	Other Supplement	CDRH and	CBER

Lack of data quickly showed the impracticality of the original plan. For example, time reporting in both CDRH and CBER combined the efforts spent on six of the supplement areas above. No sound method existed to re-create two-year old time reporting in the desired categories.

Furthermore, analysis of time reporting data for subsets of PMA reviews revealed that the time for these subsets may not have been fully and accurately captured.

Another deficiency of the original plan was the combination of CDRH and CBER efforts in five of the cost objects. Combination obscures differences and transparency.

After an initial feasibility assessment, a plan was recommended and approved to develop estimated unit costs for the following eight cost objects:

1. CDRH IDE
2. CDRH 510(k)
3. CDRH PMA
4. CDRH Supplements

5. CBER IDE/IND
6. CBER 510(k)

7. CBER PMA/BLA
8. CBER Supplements

This cost object set enabled development of unit costs for each of four general categories of applications separately for each Center.

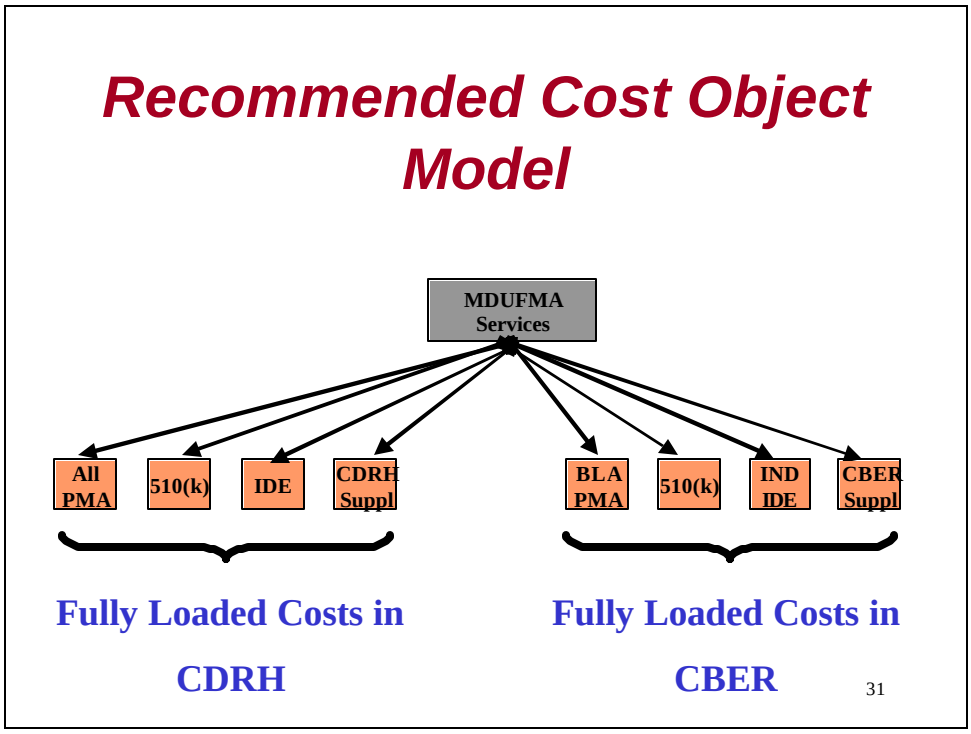

Figure 1 Cost objects identified for unit cost analysis.

D. CDRH Cost Distribution Process

In simple terms, the job of the cost model is to distribute CDRH's cost to its four cost objects and then add an appropriate amount from the Office of Regulatory Affairs and the Office of the Commissioner. The key to beginning this distribution is the time reporting done within the Center.

CDRH surveys its staff for a two-week period each quarter to develop its time reporting. Time reporting in CDRH consists of 32 different categories related to device application review processes. Some of these categories are exclusively related to one of the cost objects, but many of the time reporting categories support one or more cost objects.

The table below lists all 32 CDRH time reporting categories and the cost object/objects each supports.

Table 1 CDRH time reporting categories and their associated CDRH cost objects.

	time reporting category	510(k)	IDE	PMA	Supplements
1	510(k)	X			
2	eval class III	X			
3	Ide		X		
4	ide supplements		X		
5	determine meetings		X		
6	original pmas			X	
7	expedited pma			X	
8	mod pma			X	
9	pma supplements non panel				X
10	pma suppl panel tract			X	
11	product develop protocol			X	
12	petitions	X	X	X	X
13	class II exemption petitions	X			
14	review standards	X	X	X	X
15	bioresearch monitoring		X	X	
16	reg/pol devl premarket	X	X	X	X
17	premarket mfg assist	X	X	X	X
18	premarket liaison	X	X	X	X
19	FOI	X	X	X	X
20	Intl review stnd devl	X	X	X	X
21	Intl coordination	X	X	X	X
22	Fda/eu mra	X	X	X	X
23	Intl harmonization training	X	X	X	X
24	premarket eval training	X	X	X	X
25	513(g)	X			
26	post market surv studies			X	
27	adverse experience rpt	X		X	
28	prob ident/resolution	X		X	
29	epidemiology study			X	
30	dom stnds development	X	X	X	X
31	lab based studies	X	X	X	X
32	science base training	X	X	X	X

Directly Associated Costs

Some categories show very simple, direct relationships. For example, the first category above called “510(k)” represents effort spent exclusively on 510(k) reviews. The following table summarizes the simple, direct relationships. They are fairly straightforward with the exception of

"bioresearch monitoring." CDRH management estimated that one third of this function was directly associated with IDE and the balance was support cost for PMA processes discussed below.

Table 2 CDRH time reporting categories that are directly related to cost objects.

	time reporting category	510(k)	IDE	PMA	Supplements
1	510(k)	X			
2	eval class III	X			
3	ide		X		
4	ide supplements		X		
5	determine mtgs		X		
6	original pmas			X	
7	expedited pma			X	
8	mod pma			X	
9	pma suppl non panel				X
10	pma suppl panel tract			X	
11	product devl protocol			X	
13	class II exemption petitions	X			
15	bioresearch monitoring		1/3		
25	513(g)	X			

General Support Costs

Other categories, however, like #12 in Table 1, "petitions," are not uniquely associated with cost objects. According to CDRH management, work on petitions could be part of 510(k) cost, IDE cost, PMA cost, or Supplements cost. Since the model builder is not an expert in the medical device review, management knowledge was sought to understand how each labor category relates to cost objects. In this case, CDRH management described the "petitions" function as one of a general support nature.

Thirteen other time reporting categories were similarly deemed general support in nature. These can be thought of as part of the infrastructure used by all application review processes. As shown in Table three these general support functions consist of the review of standards, regulation and policy development, premarket manufacturing assistance, premarket liaison, Freedom of Information Act requests, international review standards development, international coordination, FDA/European Union Mutual Recognition Agreements, international harmonization training, premarket evaluation training, domestic standards development, laboratory-based studies, and science based training.

Table 3 CDRH time reporting categories that provide support to all cost objects.

	time reporting category	510(k)	IDE	PMA	Supplements
12	Petitions	X	X	X	X
14	review standards	X	X	X	X
16	reg/pol devl premarket	X	X	X	X
17	premarket mfg assist	X	X	X	X
18	premarket liason	X	X	X	X
19	FOI	X	X	X	X
20	intl review stnd devl	X	X	X	X
21	intl coordination	X	X	X	X
22	fda/eu mra	X	X	X	X
23	intl harmonization training	X	X	X	X
24	premarket eval training	X	X	X	X
30	dom stnds devl	X	X	X	X
31	lab based studies	X	X	X	X
32	science base training	X	X	X	X

Distribution of the cost of general support functions to cost objects requires making an assumption. The goal in cost accounting and analysis is to make reasonable assumptions using knowledgeable people's input. General support costs are typically prorated to cost objects proportionately to those cost objects' directly associated costs as defined in Table 2. The distribution of these costs to cost objects is shown in Table 4.

Table 4 Distribution of general support functions for FY 2003 and FY 2004.

		510(k)	IDE	PMA	Supplements
2003	All General Support Functions	41.3%	26.0%	23.2%	9.5%
2004	All General Support Functions	40.7%	27.6%	22.3%	9.4%

PMA Support Costs

Three time reporting categories were deemed to be support in nature: but not generalized support. Post market surveillance studies, epidemiology studies and two thirds of bioresearch monitoring were considered supportive only of the PMA cost object. The cost model distributes 100% of the cost of these functions to the PMA cost object.

Table 5 CDRH time reporting categories that exclusively support PMA.

	time reporting category	510(k)	IDE	PMA	Supplements
15	bioresearch monitoring			2/3	
26	post market surv studies			X	
29	epidemiology study			X	

Unique Support Costs

The remaining two time reporting categories were thought to require special handling. Adverse experience reporting and problem identification and resolution do not provide support to the IDE and Supplements review processes. Furthermore, CDRH management estimated that the support from these time reporting categories should be directed 80% to 510(k) and 20% to PMA.

Table 6 CDRH time reporting categories with unique distribution to cost objects.

	time reporting category	510(k)	IDE	PMA	Supplements
27	adverse experience rpt	X		X	
28	prob ident/resolution	X		X	

Summary of 510(k) Cost Elements

Table 7 shows all time reporting codes (and the percentage of the cost of that time reporting code) associated with the 510(k) review process for FY 2003 and FY 2004.

Table 7 CDRH time reporting categories that drive 510(k) cost.

	time reporting category	510(k)-03	510(k)-04
1	510(k)	100%	100%
2	eval class III	100%	100%
12	Petitions	41%	41%
13	class II exemption petitions	100%	100%
14	review standards	41%	41%
16	reg/pol devl premarket	41%	41%
17	premarket mfg assist	41%	41%
18	premarket liason	41%	41%
19	FOI	41%	41%
20	intl review stnd devl	41%	41%
21	intl coordination	41%	41%
22	fda/eu mra	41%	41%
23	intl harmonization training	41%	41%
24	premarket eval training	41%	41%
25	513(g)	100%	100%
27	adverse experience rpt	80%	80%
28	prob ident/resolution	80%	80%
30	dom stnds devl	41%	41%
31	lab based studies	41%	41%
32	science base training	41%	41%

Summary of IDE Cost Elements

Table 8 shows all time reporting codes (and the percentage of the cost of that time reporting code) associated with the IDE review process for FY 2003 and FY 2004. Note the slight difference (from 26% to 28%) shown for the general support labor categories as slightly more effort was spent here in 2004.

Table 8 CDRH time reporting categories that drive IDE cost.

	time reporting category	IDE-03	IDE-04
3	ide	100%	100%
4	ide supplements	100%	100%
5	determine mtgs	100%	100%
12	petitions	26%	28%
14	review standards	26%	28%
15	bioresearch monitoring	33%	33%
16	reg/pol devl premarket	26%	28%
17	premarket mfg assist	26%	28%
18	premarket liason	26%	28%
19	FOI	26%	28%
20	intl review stnd devl	26%	28%
21	intl coordination	26%	28%
22	fda/eu mra	26%	28%
23	intl harmonization training	26%	28%
24	premarket eval training	26%	28%
30	dom stnds devl	26%	28%
31	lab based studies	26%	28%
32	science base training	26%	28%

Summary of Supplements Cost Elements

Table 9 shows all time reporting codes (and the percentage of the cost of that time reporting code) associated with the Supplements review process for FY 2003 and FY 2004.

Table 9 CDRH time reporting categories that drive Supplements cost.

	time reporting category	Supplements-03	Supplements-04
9	pma suppl non panel	100%	100%
12	petitions	9%	9%
14	review standards	9%	9%
16	Reg/pol devl premarket	9%	9%
17	premarket mfg assist	9%	9%
18	premarket liason	9%	9%
19	FOI	9%	9%
20	Intl review stnd devl	9%	9%
21	Intl coordination	9%	9%
22	Fda/eu mra	9%	9%
23	Intl harmonization training	9%	9%
24	premarket eval training	9%	9%
30	dom stnds devl	9%	9%
31	Lab based studies	9%	9%
32	science base training	9%	9%

Summary of PMA Cost Elements

Table 10 shows all time reporting codes (and the percentage of the cost of that time reporting code) associated with the PMA review process for FY 2003 and FY 2004.

Table 10 CDRH time reporting categories that drive PMA cost.

	time reporting category	PMA-03	PMA-04
6	original pmas	100%	100%
7	expedited pma	100%	100%
8	Mod pma	100%	100%
10	Pma suppl panel tract	100%	100%
11	product devl protocol	100%	100%
12	petitions	23%	22%
14	review standards	23%	22%
15	bioresearch monitoring	67%	67%
16	reg/pol devl premarket	23%	22%
17	premarket mfg assist	23%	22%
18	premarket liason	23%	22%
19	FOI	23%	22%
20	intl review stnd devl	23%	22%
21	intl coordination	23%	22%
22	fda/eu mra	23%	22%
23	intl harmonization training	23%	22%
24	premarket eval training	23%	22%
26	post market surv studies	100%	100%
27	adverse experience rpt	20%	20%
28	Prob ident/resolution	20%	20%
29	epidemiology study	100%	100%
30	Dom stnds devl	23%	22%
31	lab based studies	23%	22%
32	science base training	23%	22%

E. CBER Cost Distribution Model

CBER has fewer time reporting categories. These are shown below by cost object.

Table 11 CBER cost objects and their associated time reporting categories.

	time reporting category	510(k)	IDE/IND	BLA/PMA	Supplements
1	ind activity		X		
2	bla activity			X	
3	bla supplements				X
4	other applications - pma			X	
5	other applications - 510(k)	X			
6	research		X	X	
7	control laboratory			X	
8	surveillance & enforcement	X	X	X	X
9	misc other	X	X	X	X

Note that 510(k), IDE/IND, BLA/PMA, and Supplements all have time reporting categories that exclusively support those cost objects, leaving only three areas that require distribution to multiple cost objects.

CBER management determined that “research” supported only the IDE/IND and BLA/PMA processes and furthermore, that 25% of the “research” effort supported IDE/IND and the balance of 75% supported BLA/PMA.

“Surveillance and enforcement” and “miscellaneous other” were described as more general support function and management estimated their relative consumption as 20% 510(k), 15% IND/IDE, 50% PMA/BLA, and 15% Supplements.

Distribution of time reporting categories in CBER can be shown in a single matrix given its simplicity.

Table 12 CBER cost objects and their proportion of each time reporting category.

	time reporting category	510(k)	IDE/IND	BLA/PMA	Supplements
1	ind activity		100%		
2	bla activity			100%	
3	bla supplements				100%
4	other applications - pma			100%	
5	other applications - 510(k)	100%			
6	research		25%	75%	
7	control laboratory			100%	
8	surveillence & enforcement	20%	15%	50%	15%
9	Misc other	20%	15%	50%	15%

F. Office of Regulatory Affairs Cost Distribution Model

The Office of Regulatory Affairs conducts field inspections as part of the medical device review process. ORA maintains records of field trips made for eight different reasons related to medical device application review.

Table 13 ORA actiivity counts for 2003 and 2004.

	2003	2004
42boo3 pma pre approval insp	0	3
83001 premarket inspections	91	94
83003 510(k) premarket inspect	5	0
83808 good lab practice	14	19
83809 review board	99	73
83810 sponsor org program	83	107
83811 clinical investigations	170	187
total	462	483

CDRH management provided guidance as to the cost objects supported by each type of inspection as shown below. ORA cost was distributed on this basis.

Table 14 Distribution of ORA activities by MDUFMA cost object.

ora activity distribution	cdrh 510(k)	cdrh ide	cdrh pma	cdrh supl	cber 510(k)	cber ide/ind	cber bla/pma	cber supl
42boo3 pma pre approval insp			100%					
83001 premarket inspections			83%				17%	
83003 510(k) premarket inspect	97%				3%			
83808 good lab practice		31%	43%	13%		2%	9%	2%
83809 review board		62%	22%	6%		5%	5%	1%
83810 sponsor org program		62%	22%	6%		5%	5%	1%
83811 clinical investigations		62%	22%	6%		5%	5%	1%

G. Office of the Commissioner Cost Distribution Model

OC Support Pool: FDA administrative costs were distributed to cost objects on the basis of the sum of all other direct, indirect, and ORA cost accumulated by that cost object. This is a commonly used approach for higher-level support cost that is often referred to as "process sustaining." The general assumption is that top management efforts are proportional to the dollars spent in their sub-organizations and sub-activities.

H. Determination of the "Units" Denominator for Unit Costing

Unit cost is the ratio of a cost numerator determined in the models described above to a denominator representing a quantity of applications related to the costs expressed in the numerator. Choice of the denominator is an important consideration.

The last study of Prescription Drug unit costs used the number of received applications as the denominator. This denominator can distort unit cost in situations such as where period-to-period fluctuations occur in receipts while the workload and cost remains constant. The impact of fluctuation seems greatest in application categories where quantities are relatively small and cycle times long. These situations apply primarily in the CDRH PMA and CBER PMA/BLA cost objects.

There are also some theoretical considerations in specifying the denominator. For unit cost to represent a performance measurement, it

makes sense for the denominator to reflect a measure of performance achieved through the expenditure of the numerator's dollars. In other words, an output-related denominator provides a better, performance-based measure of the unit cost of producing units. In most cases it was felt that "final actions" represented a good measure of process output. This measure usually represents application clearances/approvals, although withdrawals are also counted as final actions.

Consider the following data for 510(k):

Table 15 CDRH 510(k) in process status and activity.

510(k) CDRH	2003	2004
Beginning In Process	1276	1377
510(k)s Received	4225	3634
510(k)s Clearances	3518	3460
510(k)s Other Decisions	606	459
Ending In Process	1377	1092

Final actions in FY 2004 (3,460 clearances and 459 other decisions) numbered roughly 10% more than receipts. A unit cost calculated with receipts as the denominator would therefore be roughly 10% higher than the same cost divided by the larger (in this case) final actions denominator.

While an output related denominator is superior to input receipts, it should be noted that this is not a perfect measure. Significant differences in complexity exist between different 510(k) applications. For example, there are some 510(k) applications with clinical data that approach the complexity, cycle time, and resource consumption of a lengthy PMA review.

Using "final actions" also provides a less than ideal measure for the reviews of IDEs and INDs. These reviews initially last a few weeks, but because investigations can remain open and active for years, they have supplements that consume considerable review resources. For internal management purposes, a denominator that included final actions for supplements would provide an additional useful view. However, for the purpose of this report and given the limitations of the time reporting data, a "final actions" definition that considers only the original application was used.

Denominator determination for PMA Supplements is also problematic due to the fact that costs represent several distinctly different types of supplements.

For example, the CDRH unit cost for supplements can be thought of as a weighted average of the unit costs for 180-Day Supplements, Real Time Supplements, and Other Supplements. Since these are non-homogeneous processes, mix changes in the relative proportions of each supplement can drive apparent changes in unit cost.

Table 16 CDRH PMA Supplements final actions by category.

Supplements CDRH	2003	2004
Real Time	177	193
180 Day	238	129
Other	230	324
Total	645	646

For FYs 2003 and 2004, CDRH PMA Supplements data illustrates the problem. The total is practically identical, while 180-Day Supplements significantly declined and Other Supplements significantly increased. Care must therefore be taken in interpreting results until such time as time reporting permits the development of unit cost for each type of supplement.

Not unexpectedly, the same issues apply in PMA applications. Mix changes between traditional, modular, panel-track supplements, and HDEs as well as differences in the number of expedited requests make evaluation of unit cost problematic.

Furthermore, the long cycle time involved in PMA reviews poses another confounding problem. It is possible; in fact likely, that significant progress can be made that does not result in a “final action” within a given fiscal year. This would not be a big issue if progress of the work in process were the same every year. In that case, “final actions” would correctly capture all process output. The danger exists, however, that year-end levels of progress could be significantly more (or less) than the beginning of year levels.

III. ESTIMATED UNIT COSTS

Based on the methodology discussed above and the use of "final actions" as the denominator the following unit costs were estimated.

Two years of data were available to develop these estimates. Combining data from both FY 2003 and FY 2004 provides a total of 16 weeks of time reporting data: dampening the impact of any time reporting period that might have been abnormally skewed one way or another.

Developing final actions data for the two-year period similarly improves quality of the denominator in two ways. First, the distortion of year-to-year mix change is avoided. Second, a larger base of final actions diminishes the impact of in process status change.

Estimated unit costs per unit based on "final actions" are summarized below.

Fiscal Years 2003 & 2004 Combined Costs

CDRH	$M	final actions	$K/unit
IDE	61.6	467	131.9
510(k)	107.7	8043	13.4
PMA	71.5	127	563.0
Supplements	19.0	1291	14.7

CBER	$M	final actions	K/unit
IDE/IND	4.4	35	126.3
510(k)	4.2	139	30.4
PMA/BLA	16.2	13	1244.2
Supplements	3.2	877	3.7

CDRH management offered the following thoughts on the study findings:

> **"This reports presents findings concerning the unit costs for the review of device applications performed during FYs 2003 and 2004. Because these unit**

costs reflect the resources and workloads available during this particular timeframe, they should not be viewed as "true" costs, but rather as benchmarks for future comparisons. This is, FDA resources and workloads fluctuate from year to year and so may unit cost estimates."

CBER management offered the following thoughts on the differences between CDRH and CBER unit costs:

"The results of this initial cost study may raise the question of the comparability of unit costs for applications between CDRH and CBER. One major difference is the restricted nature of the device applications that are reviewed in CBER. While CDRH deals with the full gamut of complexity seen in devices, CBER handles only a relative few types of devices, which tend to be similar to the more complex types reviewed in CDRH. This is likely to be reflected as a higher average resource requirement for reviews. Another factor that might contribute to a higher unit cost for applications reviewed in CBER is the use of "average loaded reviewer cost" to assess the dollar amount of resources spent on the program. Due to its other product areas and funding from the Prescription Drug User Fee Act, CBER has a higher infrastructure cost and a higher average base salary for reviewers than does CDRH. Thus the same review effort would generate a higher unit cost. One factor that cannot be discounted is what might be termed the "energy of activation" for the program in CBER. Since device review performance in CBER had lagged considerably, a great effort had to be made to bring performance up to the appropriate levels. What is not clear is the degree to which the small numbers of applications handled in CBER affect the determination of unit cost. It will be important to see how the unit cost changes as the program progresses so that we can properly interpret it and use it as a management tool."

IV. FUTURE STUDIES

Future unit cost studies will benefit from the significant changes that are already occurring in the time reporting process within CDRH. New thinking and new categories promise to better capture process costs and allow an expanded cost object portfolio in FY 2005.

More importantly, the time reporting process itself has assumed greater importance, and there is now a greater appreciation of the value added from time reporting. This change in attitude has already led to a serious effort on the part of Center management to re-educate time reporters and reemphasize the importance of correct reporting.

Awareness has also increased in the area of evaluating the in-process status of PMA and BLA applications. The relatively long cycle times of these reviews means that significant work could be accomplished, but unit cost is overstated simply because final actions did not occur in that fiscal year. (The opposite is just as likely: where final actions occurred in a fiscal year that did not contain the bulk of work and cost.)

One solution to this problem is an "equivalent units" analysis. This analysis estimates the number of equivalent, fully completed units in-process at the beginning and end of the year. The difference is then added (if the ending status of in-process work exceeds the beginning of period status) or subtracted (if the ending status of in-process work is less than the beginning of period status) from "final actions."

It should be recognized, however, that the equivalent units analysis depends on management judgment and that judgment can be flawed or biased. Furthermore, it may be very difficult to estimate the percentage complete on applications where problems, issues, and likely prognoses are unknown. Nevertheless, these judgmental adjustments are likely to be much more reflective of output (and therefore yield a better unit cost) than precise, mechanical approaches that do not consider fluctuation in the state of in-process work. Greater management attention to percentage completion may also yield operational benefits in project management and control.

APPENDIX A

Insert MDUFMA Act here

http://www.fda.gov/cdrh/mdufma/MDUFMA2002.pdf

APPENDIX B

Insert 2003 MDUFMA Financial Report to Congress here
http://www.fda.gov/oc/mdufma/finreport2003/financial-fy2003.html

APPENDIX C

Insert 2004 MDUFMA Financial Report to Congress here
http://www.fda.gov/oc/mdufma/finreport2004/financial-fy2004.html

APPENDIX D

Biography of Dr. Dale R. Geiger

Dr. Geiger brings a unique combination of academic study, government management research, and corporate management experience to the problem of improved performance in government. He holds three degrees from MIT and earned his Doctorate from the Harvard Business School earned after a seventeen-year career that included several significant controllership positions.

Now a retired, tenured faculty at California State University, a frequent visitor at George Washington University, and an associate of Georgetown University's Center for Professional Development, Dr. Geiger writes extensively and exclusively on the motivation, role, and development of cost management and managerial cost accounting systems in government. He has researched, trained, and consulted at numerous organizations including the U. S. Army, Air Force, and Navy, the General Accounting Office, the National Academy of Public Administration, the Treasury Department, the Department of Agriculture, the National Forest Service, the Internal Revenue Service, the Bureau of Engraving and Printing, the National Institutes of Health, the Public Building Service, the Bureau of Land Management, the Federal Deposit Insurance Corporation, the Food and Drug Administration, and California's Department of Justice, Franchise Tax Board, and State Comptroller's Office.

Dr. Geiger served on the task force that wrote FASAB's managerial costing standard. He has published a five-part series on managerial cost accounting at the request of the Government Accountants Journal and a book entitled Winning the Cost War. The Association of Government Accountants recognized Dr. Geiger's contributions with its National Author's Awards in 1995 and 2001, its Education and Training Award in 1996, and its Career Contributions to Research Award in 2000. The citation for the later award read:

"Dr. Geiger's research proposes innovative and practical responses to the 'cost war' fought by government organizations struggling with lower budget levels. His sustained research contributions into the measurement and management of cost in government organizations promise to improve government's mission effectiveness by improving its mission efficiency."