IMPLEMENTING USER FEES IN THE FOOD AND DRUG ADMINISTRATION

A CASE STUDY

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INTRODUCTION

PURPOSE

In the past, the Office of Inspector General (OIG) has conducted audits of existing user fee systems and conducted analyses for the President's Council on Integrity and Efficiency on establishing and implementing user fee systems in the U.S. Department of Health and Human Services (HHS).

Over the past several years, HHS budget proposals have included provisions for user fees to support various program activities previously funded through general appropriations. In connection with these proposals, the Office of Management and Budget has suggested that the Department develop an analytic framework for discussing and considering additional user fees in HHS. The purpose of this report is to provide such a framework using the Food and Drug Administration as the case study.

BACKGROUND

User fees are charges directed at specific beneficiaries of specific governmental activities. The HHS currently charges user fees for a variety of purposes. Additional fees will become effective soon, including user charges to States (who are expected to recover the charge from end users) for using the Federal Parent Locator Service in certain cases, and user charges to laboratories conducting medical testing to recoup the cost of regulating those laboratories under the Clinical Laboratories Improvement Amendments of 1988 (CLIA).

The Food and Drug Administration (FDA) currently imposes user fees for several activities, including color certification, reconditioning of products, and imported tea inspections. Previous work by the Office of Inspector General has examined the implementation of these user fees and the estimated costs that might be incurred and recovered for proposed new fees.[1]

General statutory authority for imposing user fees is found in title V of the Independent Offices Appropriation Act of 1952 (IOAA), currently codified at 31 U.S.C. § 9701. Under this statute, "[t]he head of each agency...may prescribe regulations establishing the charge for a service or thing of value provided by the agency." Executive guidance on this subject is provided in Office of Management and Budget Circular A-25, which outlines general policy for assessing and collecting fees. Circular A-25 states in part,

> A user charge...will be assessed against each identifiable recipient for benefits derived from Federal activities beyond those received by the general public....[S]pecial benefit will be considered to accrue and a user charge will be imposed when a Government service: (a) enables the beneficiary to obtain more immediate or substantial gains or values...than those that accrue to the general public...; or (b) provides business stability or contributes to public confidence in the business activity of the beneficiary...; or (c) is performed at the request of or for the convenience of the recipient, and is beyond the services regularly received by other members of the same industry or group, or of the general public....

The Congress has also required agencies to impose user fees through specific authorizing legislation mandating collection of user fees for certain activities. Legislation directed HHS to charge users for use of the Federal Parent Locator System and regulating medical laboratories under CLIA. All user fees currently in place at the FDA are assessed in accordance with specific legislative guidance. For color certification and antibiotic certification, the Congress directed FDA to assess fees "as may be necessary to provide, maintain, and equip" the service. (21 U.S.C. § 357(b) and 376(e).) For tea imports, the Congress prescribed that "no tea...shall be examined for importation into the United States...unless the importor or consignee of such tea or merchandise, prior to such examination, has paid for deposit into the Treasury of the United States as miscellaneous receipts, a fee of 3.5 cents for each hundred weight or fraction thereof of such tea and merchandise." (21 U.S.C. § 46a.) For imports, Congress also directed the FDA to charge the owner or consignee for expenses incurred by the agency with respect to refused articles (e.g., travel, per diem or subsistence, and salaries of officers or employees involved in destruction or relabeling). (21 U.S.C. § 381(c).)

For several years, budgets proposed by the Administration have included provisions for expanded user fees in FDA. Such proposals have never been enacted into law by the Congress. Nevertheless, the President's 1991 budget includes a provision for collection of $152 million in new user fees by FDA.

OBJECTIVES AND METHODOLOGY

The FDA was chosen as our case study because it is frequently suggested and debated as a program area that might be funded through a system of user fees and because it provides a rich background against which to explore the complexities of the arguments for and against imposing user fees. To conduct this study, the OIG:

- synthesized previous work done on user fees, especially as it relates to FDA and other regulatory environments, through an extensive literature review and analysis;

- assessed the experiences of selected Federal agencies and programs with established user fees, through interviews with officials in those agencies and review of relevant documents; and

- assessed the views of program officials, affected industry representatives, and others in regard to possible user fees in FDA.

FINDINGS

User fees are imposed on individuals and businesses by the Federal, State and local governments for a variety of purposes and programs. Some of the Federal activities for which user fees are imposed are similar to activities undertaken in the Food and Drug Administration and paid for through general appropriations.

User fees are collected for a wide range of governmental activities at the Federal, State and local levels. Examples of these activities are listed in Exhibits 1 and 2.

EXHIBIT 1.
STATE/LOCAL ACTIVITIES FOR WHICH USER FEES ARE IMPOSED

- License applications: professional licenses, business licenses, liquor licenses
- Engineering and building safety plan review and inspection
- Fire permits, inspections, and plan review
- Recreational facility use
- Water and sewage supply
- Emergency and police services necessitated by negligence or illegal behavior

EXHIBIT 2.
FEDERAL ACTIVITIES FOR WHICH USER FEES ARE IMPOSED

- Certain types of inspections performed by the Department of Agriculture
- Patent and trademark services provided by the Department of Commerce
- Pesticide registration at the Environmental Protection Agency
- Fingerprinting services of the Federal Bureau of Investigations
- Broadcast licenses from the Federal Communications Commission
- Applications to acquire commercial rights processed by the Interstate Commerce Commission
- Inspection services of the Immigration and Naturalization Service
- Rulings, determination letters, and opinion letters from the Internal Revenue Service
- Copyright registration by the Library of Congress
- Administration of pipeline safety programs by the Department of Transportation
- Freedom of Information requests from various agencies

Over time, various studies have found that the Federal Government is not recovering appropriate costs through user fees. In 1982, the President's Private Sector Survey on Cost Control concluded that recovering the full costs of Federal programs benefitting specific beneficiaries would save taxpayers $21 billion over 3 years.[2] Assessing policies and practices regarding user fees in six executive departments in

1989, the President's Council on Integrity and Efficiency found that the agencies have not "maximized the opportunity to establish and collect user charges as a method of recovering costs incurred in providing benefits to identifiable recipients."[3]

However, as Exhibit 2 demonstrates, numbers of Federal agencies do impose user fees--some of them for regulatory functions similar to those performed by FDA. Their experience is of special interest in examining the feasibility and method of instituting fees in FDA. (For a more complete description of these agencies' user fees systems, see appendix A.)

The Environmental Protection Agency

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) is responsible for regulating pesticides. In 1972, EPA was charged with the task of reregistering all pesticides in order to assess safety and environmental impact based on current scientific data and analysis. After numerous deadlines passed for completing the reregistration effort, the Congress established a 9-year program with user fees to supplement the reregistration effort. The EPA charges a one-time reregistration fee for reviewing an active ingredient and charges a maintenance or annual fee to product registrants, which is based on number of registrations held.

Apart from this program, manufacturers are required to register their products with EPA prior to marketing. The EPA had developed a fee schedule to charge manufacturers for processing applications for registering a pesticide product and asssessed these charges for a short time prior to the enactment of the accelerated reregistration program. These fees were suspended until 1997 by FIFRA of 1988. Once the reregistration effort is complete, EPA will again charge these fees. Applications are categorized as new chemical registrations, new biochemical and microbial registrations, new use pattern registrations, old chemical registrations, amendments and experimental use permits. Registration fees (based on 1988 costs) range from $184,500 for a new chemical review to $700 for an amendment review, submitted at the time of filing.

The Federal Communications Commission

The Federal Communications Commission (FCC) charges fees for processing applications for broadcast licenses based on authority granted the agency under the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). The COBRA established numerous categories and amounts of fees to be assessed and collected by FCC in support of its application processing responsibilities.

The Federal Energy Regulatory Commission

The Federal Energy Regulatory Commission (FERC) assesses fees to regulated gas, oil, electric and hydroelectric companies. Fees are charged for the following activities, among others: changes in producer rate schedules, producer certificates, applications, pipeline certificate applications, and changes in electric rates. The general authority for collecting fees is found in the IOAA and the Omnibus Budget Reconciliation Act of 1986. Fees are assessed at the time of filing.

In addition to specific user charges for its review of various filings, FERC charges hydroelectric licensees annual charges to recover the costs of regulating the hydroelectric industry in accordance with the Federal Power Act. The FERC recovers the remainder of its budget through annual charges levied on regulated oil, gas and electric firms based on broad authority granted the agency in the Omnibus Budget Reconciliation Act of 1986.

The Nuclear Regulatory Commission

The Nuclear Regulatory Commission (NRC) charges fees to its licensees for license reviews and inspections based on the general authority in IOAA. In addition, NRC assesses annual charges on operating nuclear power reactors based on authority granted the agency in the Consolidated Omnibus Budget Reconcilation Act of 1985, as amended. These IOAA and annual COBRA fees together are to amount to 45 percent of the NRC budget.

User fees represent an application of the "benefit principle" of taxation: those who benefit from governmental provision of a service or good should be required to pay for it. To appropriately determine what programs within the Food and Drug Administration could be funded, partially or in whole, through user charges, it is necessary to first ask: who benefits from FDA regulation?

User fees are generally imposed when two basic conditions exist. First, certain identifiable individuals or businesses--as distinct from the general public--benefit from the service or function. Second, the service or good is exclusionary in nature. In other words, someone who has not paid for the service or good can be excluded from obtaining it.

According to the benefit principle of taxation, those who benefit from governmental activity should be required to pay for it. Governmental functions which benefit the "common good" and which are indivisible in nature (national defense is the most obvious example) are to be funded through general taxation; special services or benefits conferred on select groups or individuals (mail delivered by the U.S. Postal Service, for example) are paid for by those select groups or individuals (the "users").

The principle itself is generally accepted as a valid premise on which to base revenue decisions. The Congress formally indicated its agreement with this principle in the early 1950s when it expressed concern that "the Government is not receiving full return from many of the services for which it renders to special beneficiaries"[4] and enacted the provision in IOAA to allow agency heads to impose user fees for various services or products or value so long as the charge was (1) fair; (2) based on governmental costs, value of the service or product, public benefit, and other "relevant facts"; and (3) not prohibited by statute.

Agreement in principle has not prevented controversy concerning the application of the principle to specific governmental functions and beneficiaries. A prime example is the disagreement which exists as to whether FDA should impose user fees for its regulatory activities.

According to one view, FDA's regulatory activities in ensuring the safety of drugs, devices, cosmetics and food entering the marketplace serve the public interest rather than commercial firms regulated under the Food, Drug and Cosmetic Act.[5] For example, the Pharmaceutical Manufacturers Association, in testimony before Subcommittee on Rural Development, Agriculture, and Related Agencies on the President's 1991 budget, stated:

> The FDA product review activities for which this tax would be imposed are not voluntary--a basic requirement to justify user fees under current Federal policy. Instead, they are required by law for the public benefit. The only private benefit--the second criterion for allowing user fees to be charged--that is received by regulated companies in the approval of health products premarking applications is that they are allowed to remain in business.
>
> Meanwhile, the alleged benefit of a so-called "seal of approval" by FDA on these products is discounted by the reality that the law prohibits any indication of such "approval." Morever, FDA approval has not provided a defense, on the whole, from State product-liability laws to a manufacturer based on compliance with Federal Government standards of safety and efficacy.

According to this view, regulatory activities do not constitute a benefit to commercial firms but rather a cost of doing business: to pay for the "liberty" of marketing a product is to pay tribute to the agency in a distorted variation of the privilege theory of taxation (those who exercise a privilege should pay for it).[6]

Others make an opposite case. While they may agree that FDA serves the public interest, they also see private benefits accruing to the regulated industry and the consumers of their products. They point to the wide range of functions at the local,

State and Federal level supported in whole or in part by user fees; some of the agencies charging user fees are, like FDA, expressly constituted to protect the public from harm. Further, they suggest that the fact that regulation is mandatory does not constitute prima facie evidence that regulated firms derive no benefit from FDA activities; nor does the fact that FDA product review activities are mandatory prevent imposition of user fees (even under the strict rules of IOAA), because firms voluntarily enter a regulated business.[7]

In this view, the beneficiaries of FDA's regulatory activities include commercial firms and the consumers of their products. While public benefits accrue in the form of general improvement in health and safety, psychological reassurance regarding the availability of safe and effective drugs and devices, and protection from the spread of communicable disease controlled through FDA-approved drugs, the consumers of such products and firms which manufacture the products derive special private benefit from FDA's regulatory activities. Consumers get safe and effective products; and while attaching a user fee to consumers of such products may not be practical, charging the manufacturer "provides a convenient, though admittedly imperfect, conduit for passing through some or all of the costs of the regulatory agency forward to consumer beneficiaries."[8] In addition, a regulated firm reaps certain benefits from FDA's review, approval, inspection and enforcement activities: permission to market a product, increased consumer confidence in industry's products, reduced exposure (and potential liability) for businesses that

WHO BENEFITS?

The FDA is not the only agency where disagreement has evolved over "who benefits" from its regulatory activities.

The Nuclear Regulatory Commission successfully defended its fee schedule in cases brought before the courts by petitioners arguing they derived no private benefit from NRC activities. The courts agreed with NRC's contention that regulated firms do indeed derive a private benefit from their activities. In Mississippi Power & Light Co. v. NRC, the Fifth Circuit Court of Appeals rejected the argument that the NRC benefits only the general public and does not confer private benefits on licensees. The court's opinion stated that, "In National Cable [Television Association, Inc. v. FCC] the Court recognized the authority of the FCC to assess a fee even though 'the main function of the Commission is to safeguard the public interest.' 415 U.S. at 341, 94 S.Ct. at 1149. The Court thus acknowledged the FCC's authority to assess against applicants a fee for services rendered nothwithstanding the strong public interest served in providing the service....

"...A license from the NRC is an absolute prerequisite to operating a nuclear facility, and as such, is a benefit 'not shared by other members of society.' Aside from the benefit of being able to operate a business, the petitioners are recipients of other benefits flowing from the grant of a license or permit...[R]outine inspections conducted by the NRC could uncover hazardous conditions which, if allowed to continue, would jeopardize the safe operation of a licensee's facility. In short, we are not impressed by the petitioners' argument that they receive no benefit from the conferral of an NRC license. Even so, to accept petitioners' argument would mean that *no* federal agency could assess any fees, since all public agencies are constituted in the public interest."

The First Circuit Court of Appeals continued this line of reasoning in holding in New England Power Company, et al. v. NRC that "review work performed by the NRC at the request of an applicant constitutes a sufficiently substantial and particularized benefit to the applicant to justify the imposition of fees" even where the application is voluntarily withdrawn.

might have marketed a less-than-safe product except for FDA's oversight, improved products resulting in better sales, and protection from unfair competition.

The act of imposing a user fee creates certain benefits and costs, which may by themselves provide the primary impetus or impediment to the charge. These benefits and costs may accrue to the agency or program instituting the fee, to the users themselves, and to the general public. Exhibits 3 and 4 list the possible benefits and costs to these groups.

EXHIBIT 3.
POTENTIAL BENEFITS OF USER FEES

To the Agency	*To the Users*	*To the Public*
Peripheral benefits of cost accounting	Can challenge agency on service, costs	Relieved of cost burden unless a user or direct beneficiary
Revenues act as "demand signals" which allow the agency to allocate resources efficiently; improves governmental efficiency	More rapid, effective service	"Opportunity" benefit; allows existing resources to be used for other, more public goods, products and services
Increased revenues which could be used for expansion of services or improvement in existing services		
"Opportunity" benefit; allows existing resources to be used for other, more public goods, products and services		
Allows for recoupment of costs from those outside direct tax base		
Controls use of service or good; discourages misuse; encourages economy		

The primary benefit of imposing user fees is generally considered the increased revenue they generate, which might be used to continue, expand or improve existing service. For some, these increased revenues might be important enough to override other objections to the imposition of fees. However, it has been suggested that other benefits can accrue to the agency imposing the fee, the general public, and even the users themselves, when user fees are imposed. For example, the agency may become more aware of the costs of its activities, better able to identify needed system improvements, and more motivated to make those improvements. If fees are related to both intensity and type of service, the agency can use the fees as a measurement of resource requirements and a way of meeting those same resource demands, and users are more responsible for the use of resources.

EXHIBIT 4.
POTENTIAL COSTS OF USER FEES

To the Agency	*To the Users*	*To the Public*
Revenues may not exceed the costs of administration or collection, may not raise funds to warrant the effort, or may be too small to have an effect	Less affluent users at a disadvantage	Increase in concentration of users
Public will not accept the fees	Discourages use	Users may adjust their behavior in socially undesirable ways
Discourages use	Paying for a basic service	Costs passed on to consumers
Fees drive the process and thereby compromise it		
Encourages "gaming"		
Reduces regular budget appropriations		
Legal challenges		

Users themselves benefit from increased efficiency and accountability in agency operations, as well as from system maintenance and expansion made possible as a result of collected revenues. In addition, users directly charged for services are better able to document and challenge agency activities affecting their industry or business.

At the same time, user fees have certain costs beyond the fee which the user must pay. As a practical matter, fees might be difficult to administer and may be too small to warrant the effort of assessment and collection. Further, the collection of fees may result in a reduction in agency appropriations in the amount of expected collections through fees, a significant concern to program officials worried about possible "shortfalls."

The public may not respond positively to the imposition of fees, even where it relieves them of cost burdens, based on their fears that agency or user behavior might be adversely or inappropriately affected. Regulatory officials might be particularly concerned that the agency's role in protecting the public from undue health risks might be compromised by user fees; firms might charge that the agency is conducting inspections only to increase revenues, or that it is reluctant to impose severe penalties on firms because such firms represent the funding source for the agency. Firms might be discouraged from or delay applying for agency approval to engage in various activities because of the user fee.

The possibility of legal challenge to the fee represents another possible cost of imposing a charge. Federal agencies have been challenged on their authority to institute fees and method for assessing fees.[9]

Numerous considerations should be taken into account when developing the pricing and fee structure of a user charge. Some of these considerations are listed in Exhibit 5.

EXHIBIT 5.
CONSIDERATIONS FOR PRICING USER FEES

- Cost of providing the service or product
- Marginal cost of providing the service or product
- Externalities, e.g., public benefits
- Effect on user behavior
- Demand for service or product
- Intensity of demand
- Value of service or product/benefit received from the service or product
- Horizontal equity
- Vertical equity
- Ability of the user to pay

The degree to which each of these considerations is taken into account would significantly affect how fees might be structured in FDA. If we synthesize various approaches to developing fee schedules based on possible application to FDA activities, the following range of options emerges:

Consideration	*Application*
Cost	Fees based on actual or estimated costs to the agency of processing applications, conducting inspections and surveillance. Firms applying for FDA approval or market clearance or being inspected would be charged for the cost of providing that service.
Equity	Fees based on ability of firms to pay charges. Total agency costs for various functions might be allocated among regulated firms based on sales, profits, market share, or other indices.
Industry Benefit	Fees based on benefit of FDA regulatory activities. Fees discriminate among activities based on anticipated benefit to the firm, e.g., user charges might be applied to approved drug applications but not for nonapproved drug applications.
Social Benefit	Fees based on social benefit of various industry activities, e.g., full or partial waivers might be instituted for applications for important new drug therapies and applications for drugs to treat contagious diseases (one example might be AIDS drugs).

Competition	Fees based on market factors, e.g., larger firms might be charged at a higher rate than smaller firms to encourage new competitors in the market; firms requiring more frequent inspections because of past violations might be charged more than firms in continuous compliance to reflect comparative costs of oversight, and to provide incentives for improved compliance performance.
Acceptance	Fees based on expediency and past success of similar user charges, e.g., fees might be developed to ensure acceptability to the Congress and the courts, industry, agency officials, and consumers.
Administration	Fees based on ease of administration, e.g., flat fees reflecting average agency costs for processing certain types of applications; firms must include payment along with applications rather than being billed.

In practice, user fee systems reflect consideration of many of these concepts. User fee schedules at EPA, FCC, FERC, and NRC are based primarily on cost to the agency. But the agencies have also instituted waiver systems to take into account social or public benefit and effect of the fee on competition. For example, FERC bases user fees on costs to the agency, but allow waivers for certain licensees (municipalities and firms in financial difficulty); they recover the remaining portion of their budget through annual charges which are assessed based on the market standing of licensees. A somewhat similar system is in place at NRC and EPA and, with the exception of annual charges, at FCC.

Administrative feasibility is also an important consideration. Complex systems which seek to impose user charges based on precise calculations of costs and complicated waiver criteria are difficult to administer and resource-intensive. Agencies typically try to strike a balance between such precision and administrative simplicity.

Little consideration is given to industry benefit (although at EPA, registration for pesticides with "minor use" are exempt from the fee schedule to take effect in 1997; the equivalent exemption at FDA might be for orphan drugs). No system among the four agencies bases any of its charges on whether the agency ultimately makes a decision that is favorable or unfavorable to the applicant. Officials thought that developing charges based on benefit to industry would be more difficult to develop and defend in court than charges based solely on costs, as well as creating larger conflict-of-interest problems for the agency.

Administering and collecting fees can represent a substantial investment of agency resources and time.

Officials at the four agencies we visited agreed that "user fees are work." Fee schedules must be developed; regulations published in the Federal Register outlining the fee schedule (if not detailed in legislation) and the collection mechanism; public comments received and considered; procedures developed to account for incoming funds, returned checks, insufficient amounts included with filings, and billing; and procedures instituted for adjusting the fees on a periodic basis. Because of these complexities, officials estimated that FDA would require at least 1 year to implement a user fee system.

IMPROVING ADMINISTRATIVE EFFICIENCY

To improve administrative efficiency and reduce administrative costs for the collection of user fees, the FCC has entered into an agreement with a lock-box operator. Firms send their applications, payment and payment form to the lock-box operator who deposits the fees in the U.S. Treasury. For especially large filings, the payment form and payment are sent to the lock-box operator while the application is deposited directly with the FCC. The operation of the lock-box operator is funded by the Treasury. The FCC has implemented this approach to collection and accounting based on past experience, which was not positive, of maintaining a collection and accounting operation within the Commission. The FCC found this internal operation to be difficult to manage and to staff, and experienced significant processing backlogs of 2 to 3 weeks. The FCC estimates that the average time for applications to be processed by the lock-box operator and received by FCC Bureaus for substantive processing will be 2 to 3 days.

Officials at NRC and FERC, which have annual charges to supplement specific processing and inspection fees, suggested that annual charges are easier to administer. At FERC (though not at NRC) officials thought annual charges were better accepted by industry because they are based on a measure of "ability to pay," even though such charges can result in firms which have not received a particularized benefit from the agency's activities (for example, those that have not made a filing with the agency during the year) being charged to support those activities. But not all annual fees are easy to administer--EPA reported difficulty in assessing its reregistration fees because the Congress required the agency to prorate charges in certain cases based on market share. This approach requires the agency to maintain records of market share, an index constantly in flux and requiring continual adjustment.

Questions for policymakers considering FDA user fees include: (1) determining the activities to be included or supported by the fee; (2) determining the timing of assessment; (3) setting the fee; (4) deciding where the fee should be deposited; and (5) relating the fee to the process.

Determining the activities to be included or supported by the fee

One of the first decisions to be considered is what activities should be included in the user fee schedule. For example, to regulate new drug products, FDA requires submission of investigational new drug (INDs) and new drug applications (NDAs). Once a product is approved, the agency conducts inspections of facilities producing approved drug products, collects and analyzes reports of adverse drug reactions associated with approved drug products, and requires submission of NDA supplements when certain changes in manufacturing or labeling take place. (A similar set of activities takes place for generic drug and device clearance and approval.) Some proposals have focused on assessing fees for processing NDAs, rather than the whole spectrum of activities associated with regulating new drug products. This approach has the advantage of administrative simplicity; it has the disadvantage of either limiting cost recovery for regulatory activities or of subsidizing these activities by charging higher fees for NDAs. While firms which submit NDAs for FDA approval may "use" more FDA services in the way of IND review and consultation, inspection and other surveillance activities, this relationship is imperfect. Some firms may submit numerous INDs for which an NDA is never submitted; some NDAs may not be approved, so no inspection or surveillance activity is required for that specific product.

The most complex system is one is which each discrete function or type of activity performed by the agency is charged to a specific user. However, this is not always feasible, equitable, or necessary. For many FDA functions, especially those other than premarket approvals and inspections, FDA would face a formidable task to identify the right firm to charge. In such cases, one manufacturer might initiate an action with benefits to a larger group of manufacturers (device reclassifications, OTC switches) or the identity of the manufacturer is obscure (e.g., standard setting, research, over-the-counter review, postmarketing surveillance reports).

As a result of congressional authorization, other agencies have moved to a combination of user fees and annual fees which alleviates this difficulty. The NRC bills for application processing and inspections while recovering an additional portion of regulatory costs of generic activities through annual charges. The FERC and EPA have also moved to a combination of user fees and annual charges to more fully recover total agency costs.

Determining the timing of assessment

Another key decision for policymakers developing a fee system is when to actually assess a fee. For example, a user fee for NDAs might be assessed at the time of filing or at the time of approval. Assessing the charge at the time of filing more fully recovers agency costs, encourages manufacturers to submit only those applications with a reasonable chance of approval, and reduces possible conflicts of

interest (agency incentives to approve products in order to increase revenues). Assessing a charge at the time of approval has the advantage of more clearly linking the fee to particularized benefits to the manufacturer. The Federal agencies which we visited all assess charges at the time of filing, even though, like FDA, they may take months or years to complete a review and make a determination that may ultimately be unfavorable. As discussed earlier, NRC successfully defended its practice of charging a fee even when a firm voluntarily withdraws its application on the basis that even applications which are withdrawn incur costs to the agency. Thus, EPA, FERC, FCC and NRC all assess fees based on agency costs rather than a favorable agency decision. Officials believe that this approach, in addition to following the requirements of Circular A-25 (which indicates that costs should be recovered rather than the monetary equivalent of private benefits when Federal activities have incidental public benefits) is also easier to defend in court.

Setting the fee

What are the agency costs to process various types of applications, inspect facilities and goods, and meet other regulatory obligations? The sidebar describes the approaches NRC, FERC, EPA, and FCC have taken to answer this question.

WHAT DOES IT COST?

At NRC and FERC, fees are based on strict tracking and documentation of costs by agency employees. Employees supply information on time spent on various categories of activities; that information is entered into time accounting systems. Average costs by category of activity are determined by tabulating the number of employee hours spent on the activity, determining the workload for that activity (e.g., number of completed filings), and developing an average hourly cost per employee. Hours are divided by workload and multiplied by the hourly cost to figure average costs for activities within that category. The fee schedule is updated annually based on the new year's data on employee hours and rates (FERC is starting to average costs over a 3-year period).

At EPA, costs of the registration program were documented using information from the agency's time accounting, tracking, management, and financial systems, along with input from program officials. The FCC used a more general approach to develop estimated costs for processing various types of filings and conducting inspections. The FCC schedule, while very detailed, is based primarily on its budget and cost allocations within its bureaus.

Ideally the agency should consider, in setting fees, the economic adjustments that will occur based on the fee amount and placement. Rational consumers make economic adjustments on the basis of anticipated benefit and cost. Such decisions may work in favor of efficient use of service, but underuse or overuse may also occur. Set too high, a fee can discourage manufacturers from producing drugs and devices. Too low a fee induces overuse of agency resources and services. In the case of FDA, although manufacturers incur costs to prepare applications, the absence of a fee or too low a fee may nevertheless induce submission of applications that the manufacturer consideres to hold little prospect for success. (Such "overuse" of FDA resources

might be indicated by the volume of withdrawn applications or approved applications yielding no marketed product.)

Regardless of where the fee is set, some degree of economic adjustment will occur. The net effect of these economic adjustments may be either positive or negative. Where a fee is charged for a previously "free" service, some reduction in demand can be expected to occur, although in a regulated industry with fees imposed on profit-making firms, the effect may be muted (especially if marginal costs are relatively low). Firms may also merge capital and resources in order to reduce marginal costs. While officials at FERC and NRC saw little to no effect on industry as a result of their fee systems, EPA officials did report that smaller businesses were adversely affected by their reregistration fees; a number left the pesticide market, resulting in a smaller number of fee payers and higher charges for those remaining.

Waivers may be one solution to correct undesirable economic adjustments, although a waiver system increases administrative complexity. Waivers can be based on the characteristics of the applicant (e.g., small businesses, nonprofit businesses) or on the nature of the activity (e.g., products with substantial "benefit spillovers" to the general public, such as drugs or devices representing important new therapies or drugs to prevent the spread of communicable disease). Waivers will also tend to encourage the activity to which they are applied: higher fees for certain activities will encourage firms to move resources towards those activities for which lower charges are assessed.

Generally it is assumed that FDA user fees would result in consumers paying higher costs for products regulated by the agency. To the extent that fees assessed by FDA raise a firm's overall costs, the firm may increase prices. (Price increases and fees would not likely be linked product-by-product when a firm sells a line of products.) To some extent any additional costs passed on to the consumer would be offset by a reduced tax burden. However, this shifting of costs might prove troublesome to those already concerned about the high price of drugs and medical devices, or who are concerned about trading a progressive (income-based) funding source for a regressive (flat) funding source. The higher price would also induce consumers to reduce purchases or substitute out of the higher-priced products. If fees were to become a significant part of overall costs, affected products would be placed at a disadvantage in competition with substitute products not burdened by significant fee expenses, and consumers might be made worse off as a result of having to make substitutions in the face of higher prices.

Deciding where the fee should be deposited

Revenues from user fees can be deposited as miscellaneous receipts in the general fund of the U.S. Treasury, to reduce the budget deficit or to offset agency appropriations, or can be directed to the agency for general or specific use, as

through a special revolving fund. Earmarking the revenues for use by the agency for specific purposes (e.g., to fund improvements and expansions in existing service areas for which the user fee is imposed) may increase the likelihood of their acceptance by industry and others. Fungibility of funds may be such that earmarking is largely cosmetic. Special arrangements have been devised to improve credibility that earmarked funds will be used in a particular way. The EPA's arrangement (see sidebar) for the disposition of fees is unique, and EPA officials considered this element of the user fee system to be critical in obtaining the necessary industry support for the fee program.

EPA'S REVOLVING FUND

Funds collected through EPA's user fee charges for reregistration processing and maintenance fees are deposited in a newly created "reregistration and expedited processing fund" in the U.S. Treasury, "available to the Administrator, without fiscal year limitation, to carry out reregistration and expedited processing of similar applications." This singular legislation requires that collected funds are earmarked to support the activities for which they were collected and allows the agency flexibility in using the funds throughout the reregistration period as it needs them. The EPA is using some of these funds to improve its data management systems and internal processes and procedures and the bulk of the monies to expand the agency's scientific expertise and staff.

Relating the fee to the process

Another key consideration is how the user fee will affect and reflect how FDA does its business. For example, some drug manufacturers, in a previous study conducted by the Office of Inspector General, criticized the FDA for inconsistency in reviewing and approving applications for new and generic drugs.[10] An audit conducted by the OIG confirmed that there is significant variation in elapsed time to approval for applications submitted by different manufacturers to different reviewers for the same generic drug product.[11] If such variability is due to differences among FDA reviewers in workload, skill level, and requirements they impose, then it is more defensible to develop a fee which represents the average cost of processing a category of application. Thus, manufacturers whose applications are assigned to less experienced reviewers, reviewers who have more applications to review, or reviewers with more stringent standards, are not unfairly penalized by the assignment. On the other hand, if the differences in review times are attributable to differences in the adequacy of applications submitted by manufacturers, it might be more defensible to charge a fee based on actual costs so that manufacturers which prepare better applications are not subsidizing those firms which submit less than adequate applications.

As experts review FDA's mission and performance, procedures and protocols might be altered. Significant changes in FDA functions or procedures might affect the advisability of charging a fee for a particular function, and might create a greater or lesser case for imposition of a fee. For example, some manufacturers have suggested that FDA reduce its involvement in the IND stage of product development while

others want increased FDA involvement at this stage.[12] One possible response is for FDA to make its involvement at the IND stage voluntary. Manufacturers who wanted to consult with FDA at this stage in order to better ensure that their NDA would pass muster could do so, while those that felt they had sufficient in-house knowledge could proceed without FDA oversight. Under such a system, a user fee for IND review and consultation would appear to be very appropriate: manufacturers who feel they need and benefit from FDA advice and guidance would be charged a fee for that consultation.

User fees to recover the costs of inspection activities represent another area where process is an important consideration. The amount of variability and discretion in how inspections are conducted leads to a set of questions similar to those we raised in regard to drug application review. Further, if routine inspections are conducted randomly, with some facilities never or infrequently visited by FDA, charging the establishment under review a fee for the cost of inspection unfairly penalizes the firm randomly selected for review. However, if every manufacturing or processing site is inspected within a certain period (even if the period is one of years, as with drug and device manufacturing inspections), an equitable fee may be more easily assessed. For some of these areas where the nature of the activity precludes easy assessment of a fee, annual charges spread throughout industry might be the preferred solution.

SUMMARY

The question of whether to assess user fees in Federal programs is a contentious one. Considering user fees as a method of funding for a particular program or agency precipitates debate which continues as any legislation and implementing regulations take form. Because imposition of fees involves charging users for services previously funded through general appropriations, questions of equity, efficiency, and externalities naturally arise.

Based on our review, we believe that user fees in the Food and Drug Administration (FDA), properly instituted, represent a legitimate method to recover regulatory costs. Such fees would be consistent with fee systems in other Federal regulatory environments. However, as this report demonstrates, developing a fee system at FDA is not a simple matter. Even so, while time and resource intensive, the process of developing a fee system might have its own benefits, including increased scrutiny of procedures and tasks and the costs of doing business.

In all four cases we examined, the Environmental Protection Agency (EPA), the Federal Communications Commission (FCC), the Federal Energy Regulatory Commission (FERC), and the Nuclear Regulatory Commission (NRC), the Congress has passed and the President has signed into law specific components of their user fee systems. While such legislation can range from the more general (authorizing agencies to collect annual charges, as with FERC and NRC) to the more specific (delineating an actual fee schedule, as with FCC) it is generally considered preferable to sole reliance on the general authority in the Independent Offices Appropriations Act. Specific authorizing legislation allows for expanded authority, more flexibility, and greater protection from legal challenge.

While we have not attempted to examine exhaustively how user fees might be implemented in FDA, our review does suggest a number of issues for consideration. One of these is possible use of a hybrid system of annual charges and specific user fees. Annual fees at EPA, NRC, and FERC have worked well, especially in concert with specific user charges. Such a hybrid system has increased cost recovery without requiring detailed assessment of charges for every agency activity.

The framework provided by this report might be used by other agencies within the U.S. Department of Health and Human Services (HHS) as they consider implementing user fees in other areas. While this report is specifically tailored toward examination of our case study, FDA, the structure of considerations and questions may remain much the same for any HHS program.

APPENDIX A

SUMMARIES OF USER FEE SYSTEMS IN OTHER FEDERAL REGULATORY AGENCIES

ENVIRONMENTAL PROTECTION AGENCY (EPA) (1)

Type of fee	Reregistration fees and maintenance (annual) fees.
Amount of fee	Reregistration fees are variable, and based on characteristics of the pesticide such as the number and type of active ingredients and end use. Fees are paid collectively by all registrants of the pesticide. One-time reregistration fees range from $50,000 to $150,000. Maintenance fees are based on number of product registrations held. Maintenance fees in FY 1990 are $650 for the first product and $1,300 for additional registrations, with caps on the total fee for any one party holding registrations.
Legal authority	Public Law 100-532, enacted October 25, 1988 and effective 60 days later. Authority terminates in 1997.
Disposition of fee	Reregistration and expedited processing fund in the U.S. Treasury, "available to the Administrator, without fiscal year limitation, to carry out reregistration and expedited processing of similar applications" (e.g., so-called "me-too" applications). Pub. L. 100-532 s 102(k)(2).
Waivers	For reregistration of pesticides for minor use and partial waivers for small businesses.
Adjustments	Fees subject to adjustment by EPA Administrator in order to collect $14,000,000 each fiscal year, except that maximum maintenance fee for a registrant with 50 or less registrations is $20,000, and for a registrant with more than 50 registrations, $35,000.

ENVIRONMENTAL PROTECTION AGENCY (EPA) (2)

Type of fee — A pending fee schedule (to be implemented in 1997) will establish registration fees for (1) new chemical registration reviews; (2) new biochemical and microbial registration reviews; (3) new use pattern registration reviews; (4) old chemical registration reviews; (5) amendment review; (6) experimental use permit reviews. [This fee schedule was in effect for a period of 5-6 months prior to its suspension under FIFRA of 1988.]

Amount of fee — The pending fee schedule establishes the following charges (1988 costs): $184,500 for new chemical registration reviews; $64,000 for new biochemical and microbial registration review; $33,800 for new use pattern registration review; $4,500 for experimental use permit review; $4,000 for old chemical registration review; $700 for amendment review.

Legal authority — 31 U.S.C. 9701 and Public Law 100-202. Proposed rules implementing the fee schedule were published citing the authority under 31 U.S.C. 9701. Subsequently, EPA's FY 1988 appropriation (Public Law 100-202) authorized EPA to collect not more than $25 million for its regulatory activities. The final rule implementing EPA's fee schedule cited both 31 U.S.C. 9701 and Public Law 100-202 as its authority. EPA's proposed rule was published November 1986; the final rule was published May 1988. Public Law 100-532, FIFRA of 1988, postponed implementation of the fee schedule until September 1997.

Disposition of fee — Under Public Law 100-202, fees for the agency's regulatory activities will be deposited in a special fund available for appropriation to carry out the agency's activities in the programs for which the charges are made.

Waivers — The agency may waive the fee when (1) it initiates the amendment; (2) the anticipated revenues from the uses described in the application are insufficient to cover the fee; (3) the applicant will experience severe economic hardship; and (4) applications are for pesticides serving significant public interests (e.g., "pesticides offering unique advantages for reducing public health risks, those that significantly reduce a current environmental risk, or a product with extraordinary utility in use

in Integrated Pest Management"). Firms must submit a waiver request, and pay a fee for the review of the request. If the waiver is granted, the fee is refunded; if the waiver is denied, the agency retains the fee.

Adjustments

Based on periodic review of agency costs. New fees will be established through rulemaking.

FEDERAL ENERGY REGULATORY COMMISSION (FERC)

Type of fee	Filing fees for applications, petitions, requests for review and certifications. The FERC has established 31 different categories of filings for which fees are assessed. Annual charges for the cost of operating FERC which have not been recovered through processing fees are assessed against companies that hold hydroelectric licenses, natural gas pipeline companies, public utilities, and oil pipeline companies.
Amount of fee	1990 filing fees range from $26,260 for a pipeline certificate application to $80 for review of jurisdictional agency determinations.
Legal authority	For collection of filing fees, 31 U.S.C. 9701. Annual charges are authorized by the Federal Power Act, Part I (16 U.S.C. s 991-828(e) and Pub. L. 99-509, s 3401(a)(1), Omnibus Budget Reconciliation Act of 1986.
Disposition of fee	Credited to FERC's Proprietary Fund. Any revenues in excess of FERC's appropriation are credited to the General Fund of the U.S. Treasury.
Waivers	If applicant is suffering severe economic hardship at the time of filing, a petition for a waiver may be filed. State, municipalities and anyone engaged in the official business of the Federal government are exempt and may file a petition requesting such exemption.
Adjustments	Updated annually in the Federal Register.

FEDERAL COMMUNICATIONS COMMISSION (FCC)

Type of fee	Applications for broadcast licenses.
Amount of fee	The COBRA of 1985 established 80 fee categories. Fees range from as low as $20 for renewal of a cellular system license to as high as $18,000 for an application to launch and operate a space station.
Legal authority	Consolidated Omnibus Budget Reconciliation Act of 1985, Public Law 99-272, Section 5002(e) and (f), codified at 47 U.S.C. s 158.
Disposition of fee	General fund of the U.S. Treasury "to reimburse the United States for amounts appropriated for use by the Commission in carrying out its functions..." 47 U.S.C. s 158(e).
Waivers	No charges to radio services of local government, police, fire, highway maintenance, forestry-conservation, public safety and special emergency radio, or other government entities. No charges for good cause in the public interest.
Adjustments	Schedule to be reviewed every 2 years and adjusted to reflect changes in the Consumer Price Index.

ENDNOTES

1. Office of Inspector General, "Analysis of Costs Included in Current Food and Drug Administration User Fees and the Potential for Additional User Fees," December 1987, A-01-87-02522.

2. J. Peter Grace, Chairman, President's Private Sector Survey on Cost Control, War on Waste (New York: MacMillan Publishing Company, 1984.)

3. Audit Committee, President's Council on Integrity and Efficiency, "Audit of the Establishment and Collection of User Charges," p. 3.

4. House Report 82-384, p. 2-3.

5. At one time this view was widely held; as evidence, the 1959 version of OMB Circular A-25 which provides executive guidance on Federal user charges explicitly used FDA approval of new drugs as an example of an activity particularly ill-suited for user fees. The latest version of OMB Circular A-25, circulated in draft July 1987, uses the same example to demonstrate appropriate application of user fees. 52 Fed. Reg.

6. See Milton Kafoglis, "User Fees as a Regulatory Tool," in Thomas D. Hopkins, Federal User Fees: Proceedings of a Symposium, Administrative Conference of the United States, Washington, D.C., 1988, p. 18.

7. In National Cable Television Assn. v. U.S. the Supreme Court distinguished taxes which are levied by Congress, from fees which are levied by Federal agencies based on authority contained in IOAA by developing this distinction: A fee "is incident to a voluntary act, e.g., a request that a public agency permit an applicant" to do something. Hence the Court took the view that applicants enter a regulated industry voluntarily, and thus amounts collected to support the activities of the regulating agency are "fees" rather than "taxes."

8. Kafoglis, in Hopkins, p. 15.

9. *See*, for example, National Cable Television Asso. v Federal Communications Com. (1976) 180 App DC 235, 554 F2d 1094; Mississippi Power & Light Co. v United States Nuclear Regulatory Com. (1979, CA5) 601 F2d 223, 51 ALR Fed 571, cert den 444 US 1102 62 L Ed 2d 787, 100 S Ct 1066; and Skinner v. Mid-America Pipeline Co. (1986) 87-2098, 57 LW 4458-4462.

10. Office of Inspector General, Office of Evaluation and Inspections, "Perspectives of Drug Manufacturers: Investigational New Drug and New Drug Applications," and "Perspectives of Drug Manufacturers: Abbreviated New Drug Applications," 12-90-00770 and 12-90-00771, February 1990.

11. Office of Inspector General, Office of Audit, "Management Advisory Report: Vulnerabilities in the Food and Drug Administration's Generic Drug Approval Report," August 1989, A-15-89-00051.

12. Office of Inspector General, Office of Evaluation and Inspections, "Perspectives of Drug Manufacturers: Investigational New Drug and New Drug Applications," p. 12.

SELECTED REFERENCES

During the course of the OIG's literature review on user fees, the following references proved most helpful. Readers interested in more detail on Federal user fees should consult these sources.

Eastern Research Group Inc., "Federal User Fees: Data Compilation with Addendum" (prepared for the Administrative Conference of the United States, symposium on user fees), Washington, DC, May 3, 1988.

Clayton P. Gillette and Thomas D. Hopkins, "Federal User Fees: A Legal and Economic Analysis," Boston University Law Review, Volume 67, Number 5, November 1987, 795-874.

Thomas D. Hopkins, editor, "Federal User Fees: Proceedings of a Symposium," Administrative Conference of the United States, Washington, DC, 1988.

President's Council on Integrity and Efficiency, "Audit of the Establishment and Collection of User Charges," February 1989.

United States Congress, Congressional Budget Office, "Charging for Federal Services," December 1983.

U.S. Department of Health and Human Services, Food and Drug Administration, Office of Planning and Evaluation, "User Charge Study," August 1983.

U.S. Department of Health and Human Services, Office of Inspector General, Office of Audit, "Analysis of Costs Included in Current Food and Drug Administration User Fees and the Potential for Additional User Fees," A-01-87-02522, December 1987.