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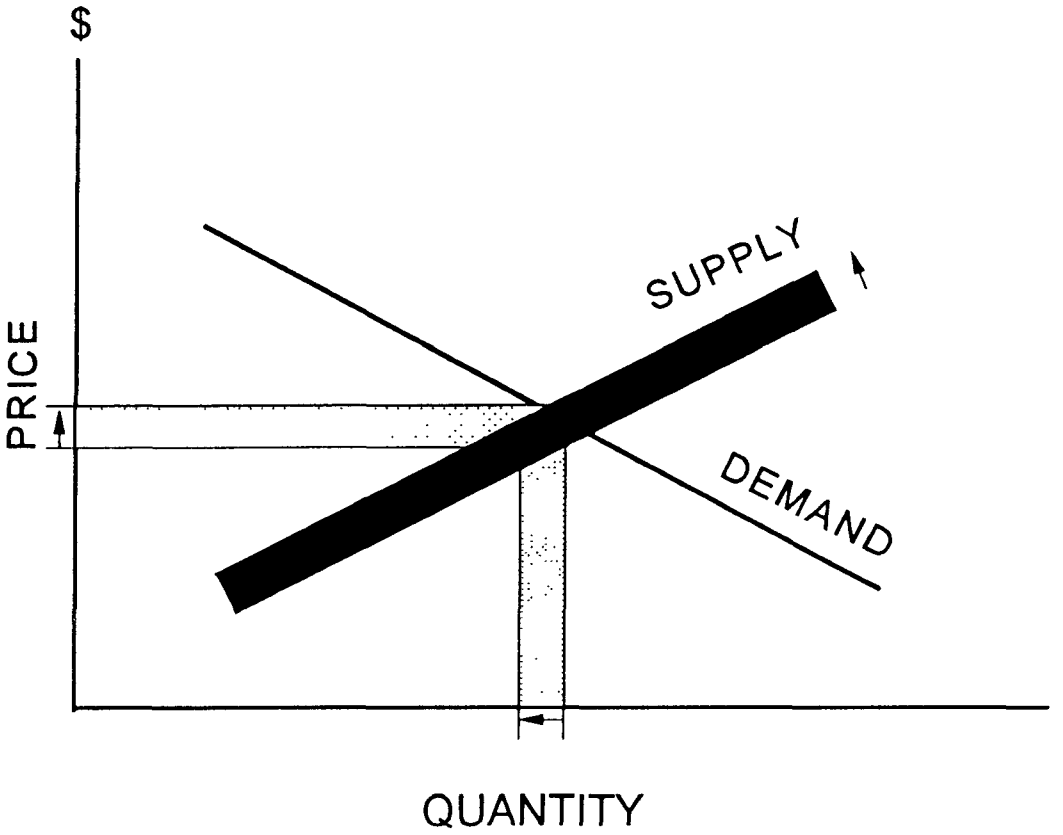

Economic Impact and Regulatory Flexibility Analysis of Proposed Effluent Guidelines for the Pharmaceutical Manufacturing Industry

Final Report

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Office of Water
U.S. Environmental Protection Agency
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SECTION ONE

EXECUTIVE SUMMARY

This economic impact analysis (EIA) examines compliance costs and economic impacts resulting from the U.S. Environmental Protection Agency's (EPA's) proposed revisions to effluent guidelines for the U.S. pharmaceutical industry. The EIA estimates the economic effects of compliance with the proposed regulation in terms of annualized costs; facility closures; changes in rate of return on assets and the interest coverage ratio at the firm level; and profitability effects at the firm level. In addition, impacts on employment and affected communities, foreign trade, specific demographic groups, and new sources also are considered. Finally, a Regulatory Flexibility Analysis detailing the impacts on small businesses within the pharmaceutical industry is included in the EIA.

1.1 OVERVIEW

The remainder of this section follows the general outline of the EIA. Section 1.2 summarizes the primary data sources used for the EIA and Section 1.3 profiles the pharmaceutical industry. Section 1.4 presents an overview of the methodology used in the EIA, focusing on the cost annualization model. Section 1.5 presents the facility-level analysis, which focuses on facility closures, and Section 1.6 investigates firm-level impacts. Sections 1.7 and 1.8 analyze employment and community-level and foreign trade impacts, respectively. Section 1.9 presents the regulatory flexibility analysis and Section 1.10 investigates distributional impacts associated with the regulation. Finally, Section 1.11 explores impacts on new sources.

1.2 DATA SOURCES

Data sources are discussed in detail in Section Two of this EIA. The primary data source used in the EIA was the Pharmaceutical Survey, which was conducted under the authority of

Section 308 of the Clean Water Act. Through the survey, EPA obtained detailed technical and financial information from a sample of pharmaceutical establishments that potentially would be affected by EPA's proposed effluent guidelines. The industry was stratified into the following five groups, based on type of operations conducted: A) fermentation, B) biological and natural extraction, C) chemical synthesis, D) formulation and mixing/compounding, and E) research. EPA censused the facilities in most of these categories, for a total of 202 facilities. EPA sampled 42 facilities in the following categories: stand-alone facilities in group D that use solvents and discharge indirectly and Group D facilities with onsite research facilities (i.e., group D/E) that use solvents and discharge indirectly.

Another major data source used to supplement the survey data in the EIA is data from the U.S. Department of Commerce. Commerce collects a wide range of data, such as number of establishments, number of employees, volume of shipments, exports, imports, value added, apparent consumption, and manufacturing costs. Other data sources used include the U.S. Food and Drug Administration (FDA), Bureau of Labor Statistics (BLS), Dun & Bradstreet (D&B), Robert Morris Associates (RMA), the Pharmaceutical Manufacturers Association (PMA), and various journal articles.

1.3 PROFILE OF THE PHARMACEUTICAL INDUSTRY

1.3.1 Overview of the Pharmaceuticals Industry

More than 110,000 pharmaceutical products currently are on the market. These products can be divided into three categories: new drugs (patented, branded drugs); generic drugs (equivalent versions of previously patented drugs), and over-the-counter (OTC) drugs (available without prescription). Drugs are manufactured using an array of complex batch-type processes and technologies that occur in three main stages: research and development (R&D); fermentation, extraction, and chemical synthesis, which covers the conversion of organic and chemical substances into bulk active ingredients; and formulation, which refers to the combining of bulk active ingredients with other substances to produce proper dosages.

1.3.2 Facility, Owner Company, and Parent Company Characteristics

According to U.S. Department of Commerce data, 1,343 facilities involved in pharmaceutical production existed in 1990. These facilities employed 183,000 people. Smaller facilities (i.e., those with less than 100 employees) dominate the pharmaceutical industry, although a higher percentage of facilities in the pharmaceutical industry have more than 250 employees than in the manufacturing sector overall. EPA estimates that approximately 286 of the 1,343 pharmaceutical facilities are either direct or indirect effluent dischargers and might be affected by the revised effluent regulations. The Section 308 Survey obtained data from 244 of these establishments.

U.S. Department of Commerce data indicate that the value of shipments for the drug industry were $64.1 billion in 1992. In real terms, growth has averaged 2 to 4 percent annually for the pharmaceutical industry. The Section 308 Survey data indicate that pharmaceutical facility revenues average approximately $100 million per facility per year, while average revenues for owner companies are approximately $600 million. The U.S. pharmaceutical industry also has consistently maintained a positive balance of trade, with a trade surplus of $961 million in 1991. According to the Section 308 Survey, the mean pharmaceutical export rate for sample facilities was 8.8 percent in 1990.

Manufacturing costs for the pharmaceutical industry from 1988 to 1990 rose from $7.4 billion to $9.6 billion at the facility level, from $58.7 billion to $63.8 billion at the owner-company level, and from $149.1 billion to $177.3 billion at the parent company level. In addition, the research and development expenditures for the pharmaceuticals industry are more than 16 percent of sales, one of the highest proportions for any U.S. industry, while promotional expenditures account for approximately 22 percent of the industry's revenues.

Data from the Section 308 Survey indicate that the median rate of return on assets at the facility level from 1988 to 1990 ranged from approximately -3 percent to 10 percent. The interest coverage ratios vary from approximately -1 percent to 51,267 percent. In addition, the profitability of the pharmaceutical industry appears to be above average among U.S. industries.

1.3.3 Industry Structure and the Pharmaceutical Market

Although the number of pharmaceutical facilities has grown over the past several decades, it is likely that competition would have been greater in the industry if high R&D costs, FDA regulations, and other factors did not serve as barriers to entry into the industry. In addition, concentration ratios in the pharmaceutical industry, as well as exit and entry into the industry, are quite high. There also is some indication that pharmaceutical companies are vertically integrated as discussed further in Section Three. These factors all affect entry of new firms into the pharmaceutical market.

Demand conditions vary significantly among specific drug markets. In the prescription drug market, demand is complicated by the role of health care providers and the presence of health insurance, which reduce the competitive nature of the market. The lack of price sensitivity among consumers, however, is partly offset by increasing sensitivity among insurers. Demand for OTC drugs, on the other hand, conforms more readily to standard models of consumer demand.

The degree of substitutability among pharmaceuticals varies. Patented drugs in the United States enjoy ostensible protection from bioequivalent drugs for a number of years, which limits direct substitutability. The increase in generic drugs, however, increases substitutability once the patent for a drug expires. For OTC drugs, the market is much like other competitive commodity markets, with a high degree of substitutability causing demand to be relatively sensitive to price changes. In addition, pharmaceuticals are not a very close substitute for most other forms of medical treatments, although they might act as complements.

These factors seem to lead to price inelasticity for pharmaceuticals as a whole. Available studies indicate that the demand for pharmaceuticals as a group may be quite inelastic (i.e., between 0 and -1.0). Demand for specific drug products, however, may be relatively elastic (i.e., less than -1.0). The absence of close substitutes for drug therapies in general and the presence of health insurance probably explains that inelasticity of demand for pharmaceuticals. The existence of close substitutes for individual drugs and the pressure to control health care costs, on the other hand, probably explains the relative elasticity of demand for specific drugs.

Because regulatory costs associated with new effluent standards can affect a large portion of the pharmaceutical industry, the industry as a whole might be able to pass through regulatory costs to consumers in the form of higher drug prices. Individual companies, however, will have less latitude in passing through costs, although many specific companies do appear to have sufficient market power to pass through regulatory costs. Throughout most of the EIA, however, the conservative assumption that manufacturers cannot pass through compliance costs is used.

1.4 OVERVIEW OF THE EIA METHODOLOGY AND COMPLIANCE COST ANALYSIS

A number of regulatory options have been developed by EPA and are analyzed in this EIA. These options are divided into those for direct dischargers and those for indirect dischargers. In addition, A and C industry subcategories (representing facilities that use fermentation or biological and chemical synthesis) are distinguished from B and D industry subcategories (representing facilities that use biological and natural extractive processes or that are formulators of pharmaceutical products). For direct dischargers, the technologies are further broken down into Best Practicable Control Technology Currently Available (BPT), Best Conventional Pollutant Control Technology (BCT), Best Available Technology Economically Achievable (BAT), and New Source Performance Standards (NSPS) options; for indirect dischargers, Pretreatment Standards for Existing Sources (PSES) and Pretreatment Standards for New Sources (PSNS) technology options are examined.

Table 1-1 presents the regulatory options addressed in this analysis and defines the technologies associated with each option. Although a total of 37 options are evaluated in the EIA, EPA has selected the following options for inclusion in the proposed regulation:

- For direct discharging A/C facilities, BPT-A/C#2 is selected for conventional pollutants and BAT-A/C#2 is required for nonconventional pollutants.
- For direct discharging B/D facilities, BPT-B/D#2 is selected for conventional pollutants and BAT-B/D#1 is required for nonconventional pollutants.
- NSPS-A/C#1 is selected for new A/C facilities that are direct dischargers (this option is identical to BAT-A/C#3).

TABLE 1-1

REGULATORY OPTIONS CONSIDERED IN THE ECONOMIC IMPACT ANALYSIS

Type of Option	Name	Description
Direct Dischargers		
Best Practicable Technology	BPT-A/C#1	Current biological treatment
	BPT-A/C#2	Advanced biological treatment + cyanide destruction
	BPT-A/C#3	Advanced biological treatment + cyanide destruction + effluent filtration
	BPT-A/C#4	Advanced biological treatment + cyanide destruction + polishing pond
	BPT-A/C#5	Advanced biological treatment + cyanide destruction + effluent filtration + polishing pond
	BPT-B/D#1	Current biological treatment
	BPT-B/D#2	Advanced biological treatment
	BPT-B/D#3	Advanced biological treatment + effluent filtration
Best Conventional Technology*	BCT-A/C#1	Advanced biological treatment + effluent filtration
	BCT-A/C#2	Advanced biological treatment + polishing pond
	BCT-A/C#3	Advanced biological treatment + effluent filtration + polishing pond
	BCT-B/D#1	Advanced biological treatment
	BCT-B/D#2	Advanced biological treatment + effluent filtration
Best Available Technology	BAT-A/C#1	Advanced biological treatment + cyanide destruction with nitrification where necessary
	BAT-A/C#2	Advanced biological treatment + cyanide destruction + in-plant steam stripping
	BAT-A/C#3	Advanced biological treatment + cyanide destruction + in-plant steam stripping/distillation
	BAT-A/C#4	Advanced biological treatment + cyanide destruction + in-plant steam stripping/distillation + activated carbon
	BAT-B/D#1	Advanced biological treatment
	BAT-B/D#2	Advanced biological treatment + in-plant steam stripping

TABLE 1-1 (cont.)

Type of Option	Name	Description
Best Available Technology (Cont.)	BAT-B/D#3	Advanced biological treatment + in-plant steam stripping/distillation
	BAT-B/D#4	Advanced biological treatment + in-plant steam stripping/distillation + activated carbon
New Source Performance Standard	NSPS-A/C#1	Advanced biological treatment + cyanide destruction + in-plant steam stripping/distillation
	NSPS-A/C#2	Advanced biological treatment + cyanide destruction + in-plant steam stripping/distillation + activated carbon
	NSPS-B/D#1	Advanced biological treatment + in-plant steam stripping/distillation
	NSPS-B/D#2	Advanced biological treatment + in-plant steam stripping/distillation + activated carbon
Indirect Dischargers		
Pretreatment Standards for Existing Sources	PSES-A/C#1	In-plant steam stripping + cyanide destruction
	PSES-A/C#2	In-plant steam stripping/distillation + cyanide destruction
	PSES-A/C#3	In-plant steam stripping/distillation + cyanide destruction + end-of-pipe advanced biological treatment
	PSES-A/C#4	In-plant steam stripping/distillation + cyanide destruction + end-of-pipe advanced biological treatment + activated carbon
	PSES-B/D#1	In-plant steam stripping
	PSES-B/D#2	In-plant steam stripping/distillation
	PSES-B/D#3	In-plant steam stripping/distillation + activated carbon
Pretreatment Standard for New Sources	PSNS-A/C#1	In-plant steam stripping/distillation + cyanide destruction
	PSNS-A/C#2	In-plant steam stripping/distillation + cyanide destruction + end-of-pipe advanced biological treatment
	PSNS-A/C#3	In-plant steam stripping/distillation + cyanide destruction + end-of-pipe advanced biological treatment + activated carbon
	PSNS-B/D#1	In-plant steam stripping/distillation
	PSNS-B/D#2	In-plant steam stripping/distillation + activated carbon

*In the Development Document (EPA, 1995), BCT-A/C#1, 2, and 3 in this table actually correspond to Options 3, 4, and 5, and BCT-B/D#1 and 2 in this table correspond to #2 and #3. The options not listed in this table were never considered in this report because they are equal to or less stringent than the requirements of the selected BPT option, and thus no incremental costs are incurred over BPT.

- NSPS-B/D#1 is selected for new B/D facilities that are direct dischargers (this option is identical to BAT-B/D#3).
- PSES-A/C#1 is selected for A/C facilities that are indirect dischargers.
- PSES-B/D#1 is selected for B/D facilities that are indirect dischargers.
- PSNS-A/C#1 is selected for new A/C facilities that are indirect dischargers (this option is identical to PSES-A/C#2).
- PSNS-B/D#1 is selected for new B/D facilities that are indirect dischargers (this option is identical to PSES-B/D#2).

The selected BAT options include all of the processes mandated in the selected BPT options.

Section Four also presents the overview of the EIA methodology and describes the principle economic and financial models used. Figure 1-1 shows how these principle models (the cost annualization model, the facility closure model, and the owner company model) operate.

The cost annualization model estimates the annual compliance cost to the facility of new pollution control equipment and operations. This model provides the data necessary for the facility-level analysis. Annualizing costs is a technique that allocates the capital investment over the lifetime of the equipment, incorporates a cost-of-capital factor to address the costs associated with raising or borrowing money for the investment and the tax-reducing effects of expenditures (i.e., depreciation allowances allowed on corporate income tax), and includes annual operating and maintenance (O&M) costs. The resulting annualized cost represents the average annual payment that a given company will need to make to upgrade its facility.

The annualized costs for the selected regulatory options are given in Table 1-2 in 1990 dollars. The average annualized costs per facility are $1.1 million ($1.3 million, 1994 $) for BAT-A/C#2, $51 thousand ($58 thousand, 1994 $) for BAT-B/D#1, $0.4 million ($0.4 million, 1994 $) for PSES-A/C#1, and $52 thousand ($59 thousand, 1994 $) for PSES-B/D#1. The aggregate annualized costs are $26.8 million ($30.6 million, 1994 $) for BAT-A/C#2, $0.7 million ($0.8 million, 1994 $) for BAT-B/D#1, $34.6 million ($39.5 million, 1994 $) for PSES-A/C#1, and $7.9 million ($9.1 million, 1994 $) for PSES-B/D#1, for a total aggregate cost of $70.0 million ($80.0 million, 1994 $). EPA is also soliciting comments on an alternative regulatory scenario

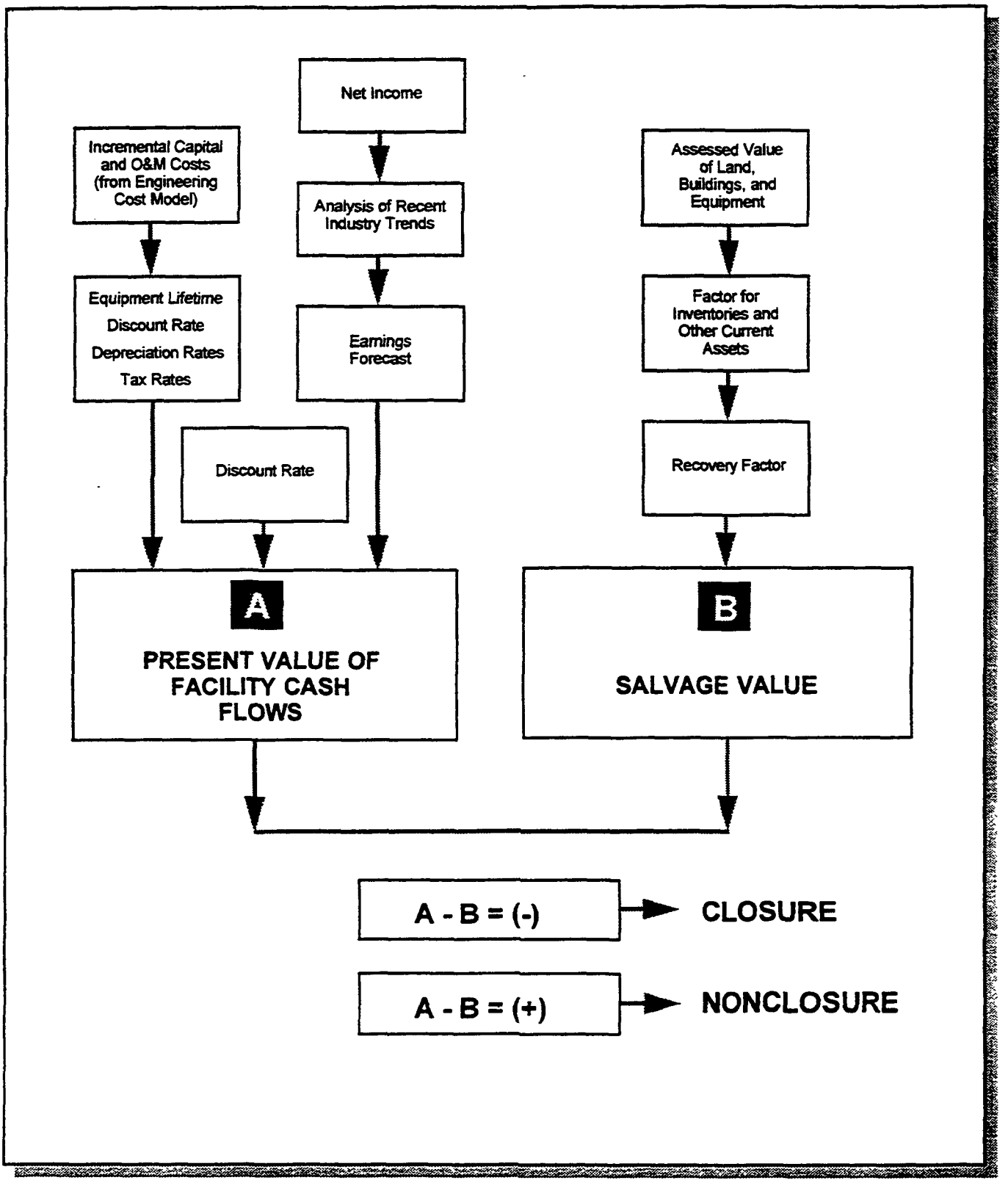

Figure 1-1. Basic facility closure analysis methodology.

TABLE 1-2

COMPLIANCE COSTS FOR SELECTED REGULATORY OPTIONS (1990 $)

Option Number	Total Capital Costs	Total O&M Costs	Total Posttax Annualized Costs	Average Annual Cost per Facility*
BAT-A/C#2	$56,392,127	$35,689,088	$26,779,144	$1,115,798
BAT-B/D#1	$644,446	$1,104,801	$708,758	$50,626
PSES-A/C#1	$70,795,915	$46,441,499	$34,564,845	$392,782
PSES-B/D#1	$25,160,649	$8,956,179	$7,922,101	$51,778
Total**	$152,993,137	$92,191,568	$69,974,848	$250,806

* Total Posttax Annualized Costs divided by the total number of facilities for each subcategory.
** Total number of facilities includes seven nondischarging facilities.

Note: These numbers are for all facilities and do not reflect closures predicted by the analyses in this report.

Source: ERG estimates based on Radian Corp. capital and operating costs estimates for pollution control equipment.

comprising BAT-A/C#3, BAT-B/D#1, PSES-A/C#2, and PSES-B/D#2 (the in-plant steam stripping/distillation regulatory scenario; see Appendix C). Under this scenario, the total compliance costs are $111.9 million ($127.9 million 1994 $).

1.5 FACILITY-LEVEL ANALYSIS

This section discusses the impacts on 282 facilities in the survey universe.[1] Of these 282 facilities, 148 facilities are not directly considered by the facility closure model. These 148 facilities comprise two groups: certifying facilities and single-facility firms. These groups and the reasons they are not directly considered by the model are described below.

EPA exempted facilities from providing facility-level data if the company owners certified that the regulation would have no economic impact on the facility (i.e., the rulemaking will be economically achievable for the company and its certified facilities). Sixty-five facilities (which represent 72 facilities in the survey universe) certified no impact. Another 76 facilities in the survey universe indicated that their owner firm and the facility are the same entity (i.e., the firm owns only one facility). In these cases, the firm-level analysis in Section Six was determined to be the appropriate level at which to evaluate impacts at these facilities. These 76 "firm/facilities," as well as the 72 certifying facilities, are placed automatically in the "no-closure" category by the facility closure model. This approach avoids double counting of impacts at both the firm and facility level. Results of the analysis show impacts relative to all 282 facilities in the analysis.

Facility closures are estimated by comparing the facility's "salvage value" (the expected amount of cash the owner would receive if the facility were closed permanently and liquidated) to the present value of its future earnings (the value in current dollars of the expected stream of earnings that the facility can generate over a specified period of time). If the salvage value is greater than what the facility is expected to generate in earnings, then it is assumed that the owner would liquidate the facility. Salvage value includes the value of current (i.e., short-term)

[1]A total of 286 facilities are represented by 244 facilities in the Section 308 survey. Three survey facilities (representing four facilities in the survey universe) provided insufficient data in the Section 308 survey and are not included in this analysis.

assets and fixed (i.e., long-term) assets. Data for the facility-level analysis are either taken directly from the 308 Pharmaceutical Survey or estimated based on Section 308 data.

The baseline facility-level analysis indicates that 38 facilities (in the survey universe), or 13 percent of the total number of facilities, will close in the baseline. The results of the postcompliance facility-level analysis for selected regulatory options are given in Table 1-3. The analysis predicts that no facilities will close as a result of any of the selected regulatory options. The same result is obtained when the alternative regulatory scenario (steam stripping/distillation) is considered.

1.6 FIRM-LEVEL ANALYSIS

The firm-level analysis evaluates the effects of regulatory compliance on companies owning one or more affected pharmaceutical facilities and identifies other impacts not captured in the facility analysis. The analysis assesses the impacts of facility closures on each firm and the impact of compliance costs at all facilities owned by the firm that do not close. These impacts are assessed using ratio analysis, which employs two indicators of financial viability: the rate of return on assets (ROA)[2] and the interest coverage ratio (ICR)[3]. The ratio analysis simulates the analysis an investor and/or creditor would employ in deciding whether to finance a treatment system, or make any other investment in the firm. In the baseline ratio analysis, the company's financial viability before the investment is made is evaluated. This analysis includes the effects of any baseline facility closures that might reduce net income and assets. In the postcompliance analysis, the company's financial condition following the investment is predicted. Data from the Section 308 survey and engineering costs analyses are used to calculate baseline and postcompliance ROAs and ICRs. ROA and ICR are computed with the survey data in the baseline analysis. In the postcompliance analysis, the relevant survey data (net income, net income and earnings before interest and taxes [EBIT], total assets, and interest expenses) are

[2]Net income divided by total assets.

[3]Earnings before interest and taxes divided by interest expense.

TABLE 1-3

FACILITY CLOSURES FOR SELECTED OPTIONS: POSTCOMPLIANCE ANALYSIS

Facility Subcategory	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total
Direct Discharge															
A/C	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
B/D	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
Indirect Discharge															
A/C	0	3	0%	0	27	0%	0	23	0%	0	22	0%	0	75	0%
B/D	0	12	0%	0	41	0%	0	53	0%	0	22	0%	0	128	0%
Zero Discharge															
A/C	0	0	0%	0	2	0%	0	1	0%	0	0	0%	0	3	0%
B/D	0	1	0%	0	1	0%	0	1	0%	0	0	0%	0	3	0%
All Facilities															
TOTAL	0	18	0%	0	78	0%	0	95	0%	0	53	0%	0	244	0%

* These facility numbers reflect those facilities projected to remain open following the baseline analysis.

Note:
1. Analysis assumes certified facilities do not close.
2. Analysis excludes four facilities (one A/C direct discharger, two B/D indirect dischargers, and one A/C zero discharger) because of lack of financial data.

Source: ERG estimates.

adjusted to reflect annual compliance costs estimated at the facility level as well as losses in income caused by postcompliance facility closures, if any.

To evaluate the baseline viability of the companies analyzed, the baseline ROA and ICR values are compared against the lowest quartile (25th percentile) values for the pharmaceutical sector (SIC 283). Those companies for which the value of either the ROA or the ICR is less than the first quartile value from RMA and D&B are judged to be vulnerable to financial failure. The baseline analysis indicates that out of 187 firms in the survey universe, 54 (29 percent) are likely to fail even before the impact of the effluent guideline requirements is considered.

The standard postcompliance analysis, referred to as Postcompliance Analysis 1, evaluates impacts on companies that are not found to be vulnerable in the baseline analysis. For these healthier companies, if either of the postcompliance ROA and ICR values fall below the first quartile benchmarks, then the company is judged to be vulnerable to financial failure as a consequence of regulatory compliance; these companies are determined to sustain a "significant impact" as a result of the regulation. Table 1-4 presents the results of Postcompliance Analysis 1. Postcompliance Analysis 1 indicates that only two firms with A/C indirect discharging facilities and one firm (a firm/facility) that is a B/D indirect discharging facility[4] are expected to experience significant impacts as a result of compliance costs associated with the selected regulatory options. Overall, these firms represent 3.8 percent of all firms with A/C indirect discharging facilities, 1.4 percent of firms with B/D indirect discharging facilities, and 2.3 percent of all regulated firms that do not fail in the baseline. These results are the same under the alternative regulatory scenario (in-plant steam stripping/distillation).

Postcompliance Analysis 2 examines the relative percentage change in ROA or ICR as a result of compliance costs or facility closures associated with the selected regulatory options for firms that have positive net income and/or EBIT, but whose ROA or ICR fall below benchmarks. This analysis determines the severity of impact, assuming these firms do not close in the baseline. A percentage change in ROA or ICR of more than 5 percent is considered a major impact. The results of the Postcompliance Analysis 2, which are presented in Table 1-5, indicate that a total

[4]This firm/facility is counted as a facility closure in later analyses.

TABLE 1-4

POSTCOMPLIANCE ANALYSIS 1*

	Total Number of Firms	No Significant Impact		Significant Impact		
		# of Firms	% of Group	# of Firms	% of Group	% of All Firms**
Firms with A/C Direct Facilities	15	15	100.0%	0	0.0%	0.0%
Firms with B/D Direct Facilities	7	7	100.0%	0	0.0%	0.0%
Firms with A/C Indirect Facilities	53	51	96.2%	2	3.8%	1.5%
Firms with B/D Indirect Facilities	72	71	98.6%	1	1.4%	0.8%
All Firms+	133	130	97.7%	3	2.3%	2.3%

* This scenario analyzes impacts from regulating A/C Direct facilities under options BAT-A/C#2 and BPT-A/C#2, B/D Direct facilities under options BAT-B/D#1 and BPT-B/D#2, A/C Indirect facilities under option PSES-A/C#1, and B/D Indirect facilities under option PSES-B/D#1.
** Out of all firms in the postcompliance analysis (133 firms).
+ Number of firms for All Firms might be less than the total firms by subcategory because some firms have more than one type of facility. Total number of All Firms includes firms that have nondischarging facilities

Note: Analysis excludes three firms because of lack of financial data.

Source: ERG estimates.

TABLE 1-5

POSTCOMPLIANCE ANALYSIS 2

Range of Change	Percent Change in ICR*		Percent Change in ROA**	
	# Firms	% of Total	# Firms	% of Total
0	9	31.0%	6	30.0%
>0 - <=5	11	37.9%	3	15.0%
>5 - <=10	2	6.9%	3	15.0%
>10 - <=20	0	0.0%	2	10.0%
>20 - <=50	5	17.2%	2	10.0%
>50	2	6.9%	4	20.0%
Total # Firms	29	100.0%	20	100.0%

* Firms that failed the baseline analysis are analyzed here if [(base EBIT and net income>0)and(base ICR or ROA<bench)]or[(base net income<=0)and(base EBIT>0)]. Because only firms with positive EBIT can be analyzed here, those with negative EBIT are analyzed for percent decline in EBIT in Table 1-6.

** Firms that failed the baseline analysis are analyzed here if [(base EBIT and net income>0)and(base ICR or ROA<bench)]or[(base EBIT<=0)and(base net income>0)]. Because only firms with positive net income can be analyzed here, those with negative net income are analyzed for percent decline in net income in Table 1-6.

Source: ERG estimates.

of nine firms, or about 31 percent of marginal firms with positive EBIT, are expected to incur substantial impacts measured as percent change in ICR (i.e., greater than 5 percent change) if they do not fail for other reasons. In addition, 11 firms (55 percent of the marginal firms with positive ROA), are expected to incur substantial impacts measured as percent change in ROA (i.e., greater than 5 percent) if these firms do not fail for other reasons.

Postcompliance Analysis 3 evaluates firms with negative ROA or ICR ratios. Although changes in ROA or ICR ratios that already are negative are difficult to present meaningfully, the proportion of the postcompliance net income or EBIT loss attributable to compliance costs provides a qualitative sense of impact. As in Postcompliance Analysis 2, a change of more than 5 percent is considered a major impact. The Postcompliance Analysis 3 results, which are presented in Table 1-6 indicate that six firms (24 percent of firms with negative EBIT) will incur substantial impacts if they do not fail for other reasons. For firms with negative net income in the baseline, only five firms (or about 15 percent) are expected to incur substantial impacts if they do not fail for other reasons.

All firms identified as potentially experiencing a major impact in Postcompliance Analyses 2 and 3 are investigated further to determine the likelihood of baseline failure, looking at several measures that might indicate the firm is healthier than the baseline analysis might indicate. These measures include substantial increases in net income and working capital, high research and development expenditures, etc. Any facilities not identified as highly likely to fail in this analysis are determined to be a potential upper bound on overall impacts from the proposed effluent guidelines.

Many of the firms in Postcompliance Analysis 2 and 3 overlap in these counts, thus only 16 firms identified as likely to fail in the baseline are considered likely to incur major impacts if they do not actually fail. Of these 16 firms, only one is considered to have indications that its financial situation is better than the baseline analysis indicates, and thus might not fail in the baseline. The firm showed outstanding growth in net income over a 3-year period. If the last year (1990) of financial data is assumed to be representative of its future performance, this firm not only would not fail in the baseline but also would not fail in the postcompliance analysis.

TABLE 1-6

POSTCOMPLIANCE ANALYSIS 3

Range of Change	Percent Change in EBIT*		Percent Change in Net Income**	
	# Firms	% of Total	# Firms	% of Total
0	12	48.0%	15	44.1%
>0 - <=5	7	28.0%	14	41.2%
>5 - <=10	1	4.0%	1	2.9%
>10 - <=20	1	4.0%	2	5.9%
>20 - <=50	1	4.0%	1	2.9%
>50	3	12.0%	1	2.9%
Total # Firms	25	100.0%	34	100.0%

* Firms that failed the baseline analysis are analyzed here if (base EBIT<=0).
** Firms that failed the baseline analysis are analyzed here if (base net income<=0).

Source: ERG estimates.

Thus, the results of Postcompliance Analysis 1 are considered the upper bound estimate of major firm-level impacts from the selected regulatory options.

Finally, the Profitability Analysis determines impacts on profitability among firms estimated to have no significant impact from compliance costs in Postcompliance Analysis 1. This analysis investigates the percentage change in ROA among the financially healthy firms to assess impacts on profitability. Again, a change of more than 5 percent is considered a major impact. Table 1-7 presents results from the Profitability Analysis, which indicate that 15 firms (not including those projected likely to fail postcompliance) will experience major impacts short of firm failure from the selected regulatory options. When the 36 firms that certified that they would experience no impacts from any effluent guideline are included in the count of financially healthy firms, only 11 percent of firms in the postcompliance analysis are expected to experience major impacts short of firm failure.

1.7 EMPLOYMENT AND COMMUNITY-LEVEL ANALYSIS

The employment and community-level analysis investigates employment losses, community-level impacts, and employment gains resulting from compliance with the effluent guidelines. Primary and secondary employment losses, which are the primary indicator of community-level impacts, are measured as a direct result of facility and firm closures. Primary employment losses are based on employee layoffs associated with the facility closures estimated in the facility-level and company-level analyses. These job losses are estimated from survey data on annual employment hours, which are then converted into fulltime equivalents (FTEs). The significance of facility employment losses on the community then is measured by their impact on the community's overall level of employment. An increase in the community unemployment rate equal to or greater than 1 percent is considered significant. Secondary impacts are assessed through multiplier analysis, which measures the extent of impacts in other industries as a function of impacts in the primary industry.

The baseline impacts from the analysis on primary employment include 14,381 jobs that are estimated to be lost, out of a total employment of 147,804 workers (9.7 percent of total

TABLE 1-7

PERCENTAGE DECLINE IN ROA, BY TYPE OF FACILITY

Employment Size of Firm	Number of Firms						
		Percent Change in ROA					
	Total	0	>0 - <=5	>5 - <=10	>10 - <=20	>20 - <=50	>50
Firms with A/C Direct Facilities	10	1	8	0	0	1	0
Firms with B/D Direct Facilities	3	0	3	0	0	0	0
Firms with A/C Indirect Facilities	36	8	22	3	0	3	0
Firms with B/D Indirect Facilities	53	22	23	3	1	3	1
All Firms*	97	35	47	6	1	7	1

*Number of firms for All Firms might be less than the total firms by subcategory because some firms have more than one type of facility. Total number of All Firms includes firms that have nondischarging facilities.

Note:
1. This table analyzes firms that passed the baseline analysis, excluding the 36 firms that only have certified facilities.
2. Analysis excludes three firms because of lack of financial data.

Source: ERG estimates.

employment in the affected segment of the pharmaceutical industry). The baseline analysis also predicts that secondary job losses will total 85,567 FTEs, using the industry-specific multiplier of 5.95. Under the postcompliance analysis, no employment losses are projected to occur as a result of regulatory options for direct dischargers. For A/C and B/D indirect dischargers, however, total projected primary employment losses are estimated to be 91 out of the 133,423 FTEs estimated to remain following the baseline analysis, which is 0.07 percent of total baseline employment in the affected segment of the industry. Secondary losses are predicted to be 541 FTEs, again using the multiplier of 5.95. The actual change in area unemployment rates associated with these closures is estimated at less than 1 percent for all affected communities. These results are the same under the alternative regulatory scenario (in-plant steam stripping/distillation).

Employment gains are also computed. Additional employment is likely to be needed to account for the increase in demand for pollution control equipment, the need to install the equipment and the need to operate the equipment. On an annual basis, 68 FTEs are expected to be added due to the need to manufacture pollution control equipment, 10 FTEs are expected to be added annually as a result of the need to install equipment, and 889 FTEs are expected to be added to maintain the equipment, for a total of 967 FTE primary employment gains.

Total primary and secondary employment gains are calculated as a range. The lower end of the range assumes that FTEs added to maintain equipment will not materialize but that losses in production hours resulting from the proposed rule that could not be estimated because of lack of data would be absorbed by this increase in labor hours. The low end of the range also uses the lower range of secondary effect multipliers. The high end of the range uses all labor gain components (manufacturing, installation, and operation) with the high end of the range for secondary employment multipliers. Total primary and secondary labor gains therefore are estimated to range between 218 and 2,890 FTEs. The net effect on primary and secondary employment is estimated to range from a loss of 323 FTEs to a gain of 2,349 FTEs. The net employment impact is negligible when compared to national level employment and will have no impact on national-level employment rates.

Gains are slightly greater under the alternative regulatory scenario (in-plant steam stripping/distillation) because of the greater equipment and installation expense. Overall, under the alternative regulatory scenario, net employment impacts would range from 272 FTEs lost to 2,421 FTEs gained.

1.8 FOREIGN TRADE IMPACTS

Pharmaceutical products are traded in an international market, with producers and buyers located worldwide. Changes in domestic pharmaceutical production due to the effluent guidelines can therefore affect the balance of trade. Consequently, the EIA includes a foreign trade impact analysis. Using data from the Section 308 Survey, the value of 1990 pharmaceutical exports is estimated for facilities expected to close. These values are summed across facilities to obtain an estimate of the total value of U.S. pharmaceutical exports that would no longer be produced. This value is then compared to the total value of U.S. pharmaceutical exports produced in 1990.

The resulting impact of effluent guidelines on pharmaceutical exports and the U.S. balance of trade is negligible. The one firm/facility that is predicted to close as a result of the effluent guidelines has pharmaceutical exports totaling $76 thousand ($87 thousand, 1994 $). The loss of these exports will have virtually no effect on U.S. pharmaceutical exports, which, according to the U.S. Department of Commerce, totalled $5.7 billion in 1991 (1991 $). The results are the same under the alternative regulatory scenario (steam stripping/distillation).

1.9 REGULATORY FLEXIBILITY ANALYSIS

A regulatory flexibility analysis has been conducted to ensure that small entities potentially affected by the new effluent guidelines will not be disproportionately burdened by the regulation. In the regulatory flexibility analysis, pharmaceutical firms are defined as small if they employ fewer than 750 persons.

1.9.1 Financial Profile of Small Firms

Median total assets and liabilities at the affected pharmaceutical firms rise with size, as does median net income. On average, small firms tend to have lower ROA than large firms, although the 500 to 750 employees size group has a considerably higher ROA than firms with over 750 employees. The poorest performing groups are the 19 to 99 and 100 to 499 employees size groups, which have a median ROA of 4 percent.

Average pharmaceutical costs and revenues tend to rise with the size of the firm. Pharmaceutical revenues comprise 60 percent of total revenues in large firms, whereas in small firms the proportion rises to as high as 87 percent in the 500 to 750 employees site group, indicating that these firms hold fewer diverse interest than large firms, making them more vulnerable to impacts from the proposed effluent guidelines.

The proportion of value of shipments exported does not tend to increase with size. The 19 to 99 employees size group exports the largest portion of the reported value of shipments. The average percentage for small firms is approximately the same as that for large firms.

1.9.2 Impacts on Small Firms

Impacts on small firms measured as firm failure are as follows. Two of the three firms that were projected to fail in the firm-level analysis under the selected regulatory options have fewer than 750 employees. Consequently, two-thirds of the significant firm impacts will be among small firms, although only 2 percent of small firms are affected in this manner. In addition, 14 out of the 15 firms found to experience a significant decline in ROA (over 5 percent) have fewer than 750 employees. These firms represent about 14 percent of all small firms.

When cash flow is analyzed, however, impacts seem less disproportionate. Except in the 19 to 99 employees category, the total present value of compliance costs as a percentage of the present value of net income is on average smaller among small firms than among large firms. It

is not surprising that the 19 to 99 employees size group is more heavily affected since it is the weakest group financially. The median small firm's percentage is lower overall than that for large firms (0.04 percent vs. 0.25 percent). Overall, for all firms the present value of compliance costs is less than 1 percent of the present value of net income on average. Under the alternative regulatory scenario, these percentages are 0.1 percent for small firms and 0.5 percent for large firms.

The above analyses indicate that although small firms do bear a large portion of the impacts such as firm failures, these impacts are felt by a very small percentage of all small firms. Additionally, the percentages of the present value of compliance costs to the present value of net income are expected to be no larger, on average, among small firms than among large firms. Thus, overall EPA finds that impacts on small firms are not disproportionate to those on large firms. This finding would also apply to the alternative regulatory scenario (in-plant steam stripping/distillation).

1.10 PROJECTED DISTRIBUTIONAL IMPACTS

For the distributional analysis, the zero cost passthrough assumption is not used. Instead, it is assumed that manufacturers will raise pharmaceutical prices in response to increased regulatory costs. To determine upper bound impacts, it is further assumed that all cost increases can be passed through to consumers.

The extent to which drug prices can rise assuming perfectly inelastic demand is determined as the ratio of total compliance costs to total cost of pharmaceutical production in the affected facilities and in the pharmaceutical industry as a whole. The results of this analysis are presented in Table 1-8. The average ratio for the selected regulatory options ranges from 0.2 to 3.4 percent. For all the selected regulatory options, the ratio of compliance costs to total pharmaceutical costs is 1.6 percent. Most facilities will incur compliance costs of less than 1 percent of total pharmaceutical costs. A total of 41 facilities (20 percent of all facilities included in this analysis) will incur compliance costs greater than 1 percent of total pharmaceutical costs. Only three facilities (1 percent of all facilities) will incur compliance costs greater than 10

TABLE 1-8

COMPLIANCE COSTS AS A PERCENTAGE OF TOTAL PHARMACEUTICAL PRODUCTION COSTS, BY FACILITY

Regulatory Option	Compliance Costs/Total Costs										
	0.0%		>0.0% - 0.1%		>0.1% - 1.0%		>1.0%- 10.0%		>10%		Average Ratio*
	# Facilities	% Total	# Facilities	% Total	# Facilities	% Total	# Facilities	% Total	# Facilities	% Total	
BAT-A/C#2	0	0%	1	7%	5	36%	7	50%	1	7%	3.4%
BAT-B/D#1	0	0%	4	44%	5	56%	0	0%	0	0%	0.2%
PSES-A/C#1	14	23%	6	10%	21	34%	19	31%	1	2%	1.6%
PSES-B/D#1	43	36%	28	24%	34	29%	12	10%	1	1%	0.6%
All Facilities											
All	57	28%	39	19%	65	32%	38	19%	3	1%	1.6%

* Average Ratio does not include those facilities with zero option costs.

Note:
1. Analysis excludes certified facilities and zero dischagers.
2. Analysis also excludes six additional facilities (one A/C direct discharger, two A/C indirect dischargers, and three B/D indirect dischargers) because of lack of financial data.

Source: ERG estimates.

percent of total pharmaceutical costs. Finally, approximately 28 percent of all facilities in this analysis will experience no increase in total pharmaceutical production costs as a result of the effluent guidelines. Under the alternative regulatory scenario (in-plant steam stripping/distillation) the average percentage of compliance costs to total costs is 2.5 percent with five facilities incurring compliance costs greater than 10 percent of total costs.

In this analysis, the impacts of increased drug prices on various demographic groups is evaluated. The demographic groups considered include the elderly, the population living under the poverty level, disadvantaged minorities, the uninsured, and state and federal governments.

When possible uses for products produced by a sampling of highly affected facilities (those where compliance costs exceed 10 percent of total pharmaceutical costs) were investigated, it appeared that children, women, and the elderly were likely to be the major consumers of many of these products. According to Health Insurance Association of America (HIAA), the groups least likely to have health insurance are hispanics, young adults, and African Americans; African Americans, hispanics, and children are most likely to be covered by government insurance, and African Americans, hispanics, and the elderly are least likely to have insurance related to employment. Government insurance programs tend to spend less on drugs and other medical nondurables than do private insurers, according to this same source, and about 93 percent of people with work-related medical insurance have some type of drug insurance. Thus those who lack any health insurance, those who are covered by government insurance, and those who are covered by nonwork-related medical insurance might be least likely to have drug coverage. When the predominant consumers of the products expected to be affected by potentially sizeable cost increases are compared to the groups most likely to lack drug insurance, young adult women, children, and the elderly are likely to be the most heavily affected by potential cost increases, if such increases can be passed through to consumers.

Because, on average, any potential price increases are likely to be very low (1.6 percent on average), impacts on mass consumers of drugs such as HMOs, governments, and, indirectly, third-party insurers, should be minimal.

1.11 IMPACTS ON NEW SOURCES

The selected options for new sources are NSPS-A/C#1, NSPS-B/D#1, PSNS-A/C#1, and PSNS-B/D#1. In all cases, the requirements for new sources are more stringent than those for existing sources. However, the difference in cost between new source requirements and existing source requirements for typical facilities are relatively small when compared to the average facility costs of production. In most cases, existing facilities would be required to retrofit in-plant steam stripping systems, whereas new sources would have to install in-plant steam stripping/distillation systems. Because designing in pollution control equipment in a new source is typically less expensive than retrofitting the same equipment in an existing source, the cost differential between the selected requirements for existing sources and those higher existing source options that are technically equivalent to new source requirements should be an upper limit on the differential annual cost faced by new sources. Where this differential is not substantial relative to the typical costs of doing business in this industry, no significant barrier to entry is likely to exist.

The average per-facility compliance costs were investigated to determine what the cost differentials would be between proposed new source and existing source requirements. The average per-facility cost differentials ranged from about a $34 thousand to a $590 thousand difference (for A/C direct dischargers), depending on the type of facility. The maximum $590 thousand ($674 thousand 1994 $) difference generates the highest percentage of compliance cost differential to pharmaceuticals manufacturing cost—about 1.4 percent of total manufacturing costs and about 3.0 percent of pharmaceutical manufacturing costs. Since this cost differential is likely to be less than that assumed here, this small premium estimated to be paid by new sources is not likely to have much impact on the decision to enter the market. Furthermore, these same options, when applied to existing sources, were found to have nearly identical impacts on existing sources as the selected options for existing sources. Thus no significant barriers to entry are estimated to result from the proposed new source requirements.

Under the alternative regulatory scenario (in-plant steam stripping/distillation) only the requirements for existing BAT-B/D direct dischargers are less stringent than those for equivalent new sources. The cost differential between BAT and NSPS requirements is estimated to be $53 thousand ($61 thousand 1994 $), or about 0.1 percent of pharmaceutical or total manufacturing costs.

SECTION TWO

DATA SOURCES

The EIA relies on a variety of data sources including the Section 308 Pharmaceutical Survey conducted specifically for this regulatory development effort, the U.S. Department of Commerce, the U.S. Food and Drug Administration (FDA), Bureau of Labor Statistics (BLS), Dun & Bradstreet (D&B), Robert Morris Associates (RMA), the Pharmaceutical Manufacturers Association (PMA), and various journal articles. Most of the analysis conducted in Sections Four through Eleven make extensive use of the data collected from the Section 308 Pharmaceutical Survey. Other data sources were used primarily in the development of the industry profile in Section Three. Data gathered in the profile, however, provides the foundation for much of the analysis in later sections.

The following sections describe the two principal data sources for this EIA: the Section 308 Pharmaceutical Survey and sources available through the U.S. Department of Commerce. Other data sources are described, as necessary, in Sections Three through Eleven.

2.1 THE SECTION 308 PHARMACEUTICAL SURVEY

The Section 308 Pharmaceutical Survey obtained detailed technical and financial information from a sample pharmaceutical establishments potentially affected by EPA's proposed effluent guidelines. EPA stratified the industry into five groups based on type of operation:

- A) Fermentation
- B) Biological and natural extraction
- C) Chemical synthesis
- D) Formulation and mixing/compounding
- E) Research

The stratification permitted EPA to census (i.e., survey all facilities) facilities within some subcategories and sample facilities within others. EPA took a census of all facilities that (1) manufacture active ingredients (subcategories A, B, C) and directly discharge process wastewater and (2) perform formulating and mixing/compounding (subcategory D) and directly discharge or directly and indirectly discharge process wastewater. EPA judged that a census of these facilities was necessary to achieve statistical accuracy because the overall universe was small, few facilities were in the same combination of subcategories, and each facility was expected to have wastewater generated by proprietary processes that would make their effluent significantly different from other facilities in the same subcategory. Overall, EPA conducted a census of 202 facilities in these four subcategories (EPA, 1990).

EPA also censused subcategory D stand-alone facilities that use solvents and discharge indirectly and subcategory D facilities with onsite research facilities (i.e., subcategory D/E) that use solvents and discharge indirectly and have less than 19 employees or more than 747 employees. For subcategory D indirect discharging facilities with between 19 and 168 employees and between 169 and 747 employees, EPA used a sampling methodology. The sampling methodology stratified these facilities by flow rates and employee size using a linear regression between the log of the number of employees and log of the flow rate. Employee and flow rate data were available from EPA's *Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Point Source Category* (1983). Overall, EPA sampled 42 pharmaceutical facilities in subcategories D and D/E (EPA, 1990). Survey results used throughout the EIA are weighted according to the sampling plan. Subcategory D and D/E facilities with between 19 and 747 employees received a weight of 2 (because only about half of these facilities were surveyed). (All subcategory D facilities are grouped with subcategory B facilities for the purpose of this analysis, which is discussed in Section Four.) All other facilities received a weight of 1. The coefficient of variation in any particular strata (i.e., combination of subcategory and flow group) is no greater than 15 percent.

EPA determined that no information was needed from three groups of pharmaceutical facilities:

- Facilities that do not discharge wastewater

- Facilities that do not use solvents and whose only source of process wastewater is from formulation and mixing/compounding
- Stand-alone research facilities

These facilities do not require effluent guidelines because their impact on water quality and POTW operations is considered to be negligible.

The survey data were used extensively in the development of BPT, BCT, BAT, NSPS, PSES, and PSNS regulations for the industry. Surveyed facilities provided technical information on pharmaceutical products; compound and chemical usage and disposition; waste minimization and pollution prevention activities; wastewater generation, collection, and conservation; wastewater treatment; steam stripping; and wastewater characteristics. The survey also collected financial data such as number of employees; ownership structure; discount rate; market value of land, buildings, and equipment; value of shipments; manufacturing costs; assets; liabilities; and net income. Financial data were collected at the facility, owner-company, and parent company levels.

All surveyed facilities were given the option to legally certify that the facility would incur no significant economic impact as a result of the effluent guidelines. These facilities gave up their right to challenge aspects of the effluent guidelines based on economic achievability so long as the cost of compliance of the guidelines ultimately promulgated by EPA does not exceed the compliance cost estimated in the survey. Certifying facilities were excused from completing the bulk of the financial questionnaire. Sixty-five of the 244 surveyed facilities certified no significant economic impact and thus did not provide financial data.

2.2 U.S. DEPARTMENT OF COMMERCE DATA

The EIA supplements financial data collected in the Section 308 Pharmaceutical Survey with data from the U.S. Department of Commerce. Commerce divides the pharmaceutical industry into four 4-digit Standard Industrial Classifications (SICs):

- *SIC 2833 Medicinal and Botanical.* Establishment primarily engaged in : (1) manufacturing bulk organic and inorganic medicinal chemicals and their derivatives and (2) processing bulk botanical drugs and herbs.

- *SIC 2834 Pharmaceutical Preparations.* Establishments primarily engaged in manufacturing, fabricating, or processing drugs in pharmaceutical preparations for human or veterinary use. The greater part of the products of these establishments are finished in the form intended for final consumption, such as tablets, capsules, liquids, etc. These pharmaceutical preparations are promoted to the medical profession (prescription drugs) and the general public (over-the-counter (OTC)).

- *SIC 2835 In Vitro and In Vivo Diagnostic Substances.* Establishments engaged in the manufacturing chemical, biological, and radioactive substances used in diagnosing or monitoring human and animal health by identifying and measuring normal and abnormal constituents of body fluids or tissues.

- *SIC 2836 Biological Products, Except Diagnostic Substances.* Establishments engaged primarily in the production of bacterial and virus vaccines, toxoids, and analogous products, serums, plasmas, and other blood derivatives for human and veterinary use.

Commerce collects a wide range of data at the 4-digit SIC level including number of establishments, number of employees, volume of shipments, exports, imports, value added, apparent consumption, manufacturing costs, and other data. Commerce further segments the pharmaceutical into 14 5-digit and hundreds of 7-digit SIC codes. Comprehensive financial data at the 5 and 7-digit levels, however, is available only under SIC 2834 Pharmaceutical Preparations. Commerce data are reported in publications such as the *Census of Manufactures*, *County Business Patterns*, and *U.S. Industrial Outlook*. The EIA uses the most current available data from these sources in the development of the industry profile in Chapter Three.

Numerous other data sources employed by the EIA also are organized by SIC code. For example, price indices generated by BLS are reported according to SIC code. Financial ratio data reported by D&B and RMA also are organized by SIC.

A major difficulty with using data organized by SIC, however, is its inability to capture all establishments engaged in the production of pharmaceuticals. Commerce classifies facilities by their primary line of business. Thus, only establishments that garner at least 50 percent of their revenues from pharmaceutical-related business are classified in the four pharmaceutical SIC

codes. Facilities that manufacture pharmaceuticals but list some other line of business (e.g., chemical production) as their primary SIC are not captured in the four pharmaceutical SICs. facilities that manufacture pharmaceuticals but whose primary business is classified in some other SIC code. Thus, Commerce data do not provide a complete picture of the U.S. pharmaceutical industry.

The Section 308 Pharmaceutical Survey data cover only a subset of the pharmaceutical industry. The five categories used to segment the pharmaceutical industry in the survey do not correspond with the four pharmaceutical SICs. Moreover, surveyed facilities were not asked to report their SIC. Thus, no direct comparison can be made between Commerce and survey data.

2.3 REFERENCES

U.S. EPA. 1990. U.S. Environmental Protection Agency. Supporting Statement for OMB Review: Detailed Questionnaire for the *Pharmaceutical Manufacturing Industry*. Washington, D.C.: Office of Water Regulations and Standards.

U.S. EPA. 1983. U.S. Environmental Protection Agency. Development Document for Effluent Guidelines, New Source Performance Standards, and Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category. Washington, DC: U.S. EPA.

SECTION THREE

PROFILE OF THE PHARMACEUTICAL INDUSTRY

This profile of the U.S. pharmaceutical industry provides statistical and descriptive information necessary for developing the EIA methodology presented in Section Four and for interpreting its results. This section is organized into six subsections that address the principal determinants of supply and demand for U.S. pharmaceuticals and present key industry statistics. The section begins with an introduction to the pharmaceutical industry—its products, regulatory environment, and manufacturing processes. Section 3.2 presents basic facility, owner company, and parent-level statistics including number of facilities, employment, value of shipments, international trade, production costs, and baseline financial conditions. Finally, Section 3.3 discusses market structure and demand in the pharmaceutical industry. Key topics such as barriers to entry, vertical integration, industry concentration, and the price elasticity of pharmaceutical demand are covered. The section concludes with an analysis of the industry's ability to raise prices in response to increased regulatory costs.

3.1 OVERVIEW OF PHARMACEUTICAL PRODUCTS, REGULATIONS, AND MANUFACTURING PROCESSES

The EIA will rely on three principal schemes for segmenting the pharmaceutical industry. As explained in Chapter Two, much of the available EIA data is categorized by either U.S. Department of Commerce's SIC code (SICs 2833, 2834, 2835, and 2836) or by EPA's five manufacturing subcategories representing the industry's principal manufacturing processes. In addition, the industry can be segmented according to major drug types and the regulations that govern their manufacture and sale. This section introduces the reader to the industry's products and regulatory environment (Section 3.1.1) and provides a synopsis of the industry's principal manufacturing processes (Section 3.1.2).

3.1.1 Pharmaceutical Products and Regulations

One of the more convenient means for categorizing the more than 110,000 pharmaceutical products currently on the market is by using regulatory definitions. The pharmaceutical industry is regulated by a variety of state and federal agencies that play a major role in nearly all aspects of pharmaceutical production from drug research and development to manufacturing and marketing. At the core of pharmaceutical regulation is the FDA, which is charged with ensuring the safety and effectiveness of drugs intended for human and animal use. To this end, FDA reviews drugs before they reach the market, monitors clinical trials, dictates labeling requirements, specifies acceptable manufacturing practices, and conducts postmarket surveillance. The industry also is directly regulated by other federal and state agencies such as the Occupational Safety and Health Administration (OSHA) and EPA. Other federal and state governments, acting through the Medicare and Medicaid programs as major third-party payers of prescription drugs, also have considerable influence on the industry (see Section 3.4.3). In addition, federal and state governments (1) purchase large quantities of pharmaceutical products through the U.S. Public Health Service and the Veterans Administration (VA), (2) sponsor pharmaceutical research and development (R&D) through the National Institutes of Health (NIH), and (3) influence product development through tax policy.

Pharmaceutical manufacturers must obtain FDA approval before marketing a drug in the United States. For review purposes, FDA groups drug marketing applications into one of three categories—new drugs (i.e., patented, branded drugs), generic drugs, and over-the-counter (OTC) drugs—according to the following guidelines:

- A new drug can be either an entirely new molecular entity (NME); a new ester, salt, or other noncovalent derivative; a new formulation; for a new indication; or a new combination (see Figure 3-1 for definitions of these terms).
- Generic drugs are equivalent versions of previously marketed, patented prescription drugs and generally appear on the market several years after patent expiration.
- OTC drugs are available without a prescription and generally undergo a less rigorous review process. Examples include aspirin, cough medicines, and home pregnancy tests.

New molecular entity (NME). A drug for which the active moiety (either as the unmodified base compound or an ester, salt, clathrate, or other noncovalent derivative of the base compound) has not been previously approved or marketed in the United States for use in a drug product, either as a single ingredient or as part of a combination product, or as part of a mixture of stereoisomers.

New ester, salt, or other noncovalent derivative. A drug for which the active moiety has been previously approved or marketed in the United States, but for which the particular ester, salt, clathrate, or other noncovalent derivative, or the unmodified base compound is not yet approved or marketed in the United States, either as a single ingredient, part of a combination product, or part of a mixture of stereoisomers.

New formulation. A new dosage form or formulation, including a new strength, where the drug has already been approved or marketed in the United States by the same or another manufacturer. The indication may be the same as for the already marketed drug product or may be new.

New combination. A drug product containing two or more active moieties that have not been previously approved or marketed together in a drug product by any manufacturer in the United States. The new product may be a physical or a chemical (ester or noncovalent) combination of two or more active moieties.

New indication. The product duplicates a drug product (same active moiety, same salt, same formulation, or same combination) already approved or marketed in the United States by the same or another firm except that it provides for a new use.

Figure 3-1. New drug definitions.

Source: FDA, 1992.

As can be seen in Figure 3-2, new drugs accounted for the majority (53.3 percent) of industry sales in 1991. OTC drugs accounted for 34.1 percent of sales and generic drugs made up the remaining 12.6 percent.[1]

Each of these three major drug types face differing market conditions. The presence of patents and other barriers to market entry create monopolistic conditions in the sales of branded, patented drugs, whereas in other markets, the presence of generics create classic competitive conditions. Competition among and within these drug groups and other issues concerning market structure in the pharmaceutical industry are discussed in detail in Sections 3.4 and 3.6. The following three subsections introduce the reader to the major drug types and regulations that affect their manufacturing and sale.

3.1.1.1 New Drugs

FDA has classified approximately 90 percent of all drugs marketed since 1938 as "new drugs," requiring manufacturers to submit New Drug Applications (NDA) to FDA containing clinical and other data demonstrating the drug's safety and effectiveness. Because they have never been marketed before, new drugs receive the most scrutiny from FDA and undergo a lengthy review process to determine whether the drug is safe and effective in its intended use.

According to FDA data, the agency has approved an average of 90 new drugs each year since 1982 (see Figure 3-3). Approximately 26 percent of the new drugs approved each year are NMEs. The agency also approves, on average, some 1,207 new drug supplements, which represent a change to an already approved drug such as adding a new indication (approved use), revising an approved indication, and other changes. FDA approves approximately 60 percent of all new drug applications (NDAs) and supplements received each year (FDA, 1992). Figure 3-4 presents a breakdown of new drugs approved between 1987 and 1992 by major therapeutic category.

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[1]For the purposes of this analysis, biologics and veterinary drugs, which undergo separate review processes, will be considered subsets of new drugs and generics. In 1990, they accounted for 8.5 percent of the U.S. pharmaceutical market.

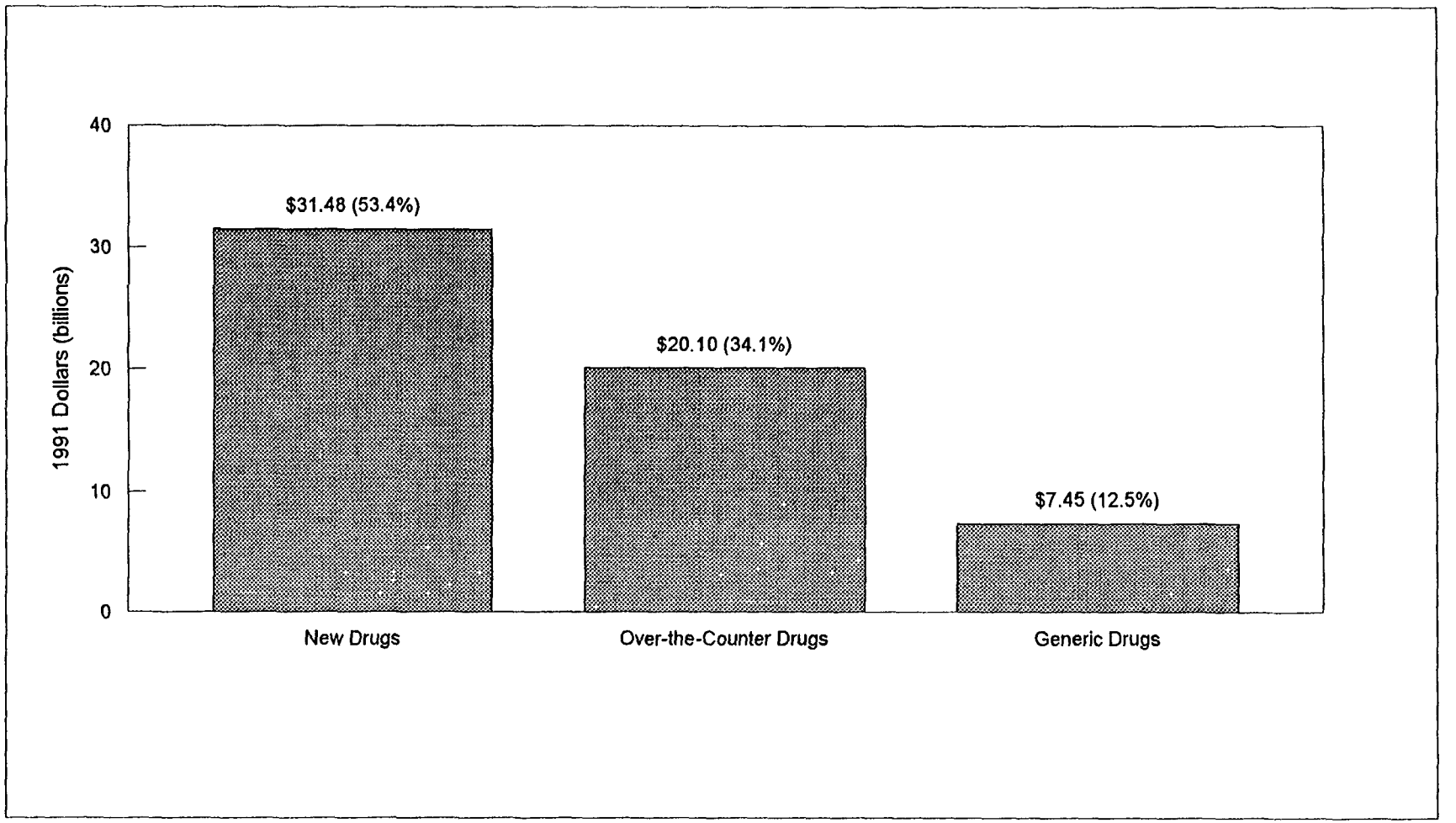

Figure 3-2. U.S. drug sales by major drug type: 1991 ($billions).

Source: NatWest, 1992; U.S. Department of Commerce, 1993.

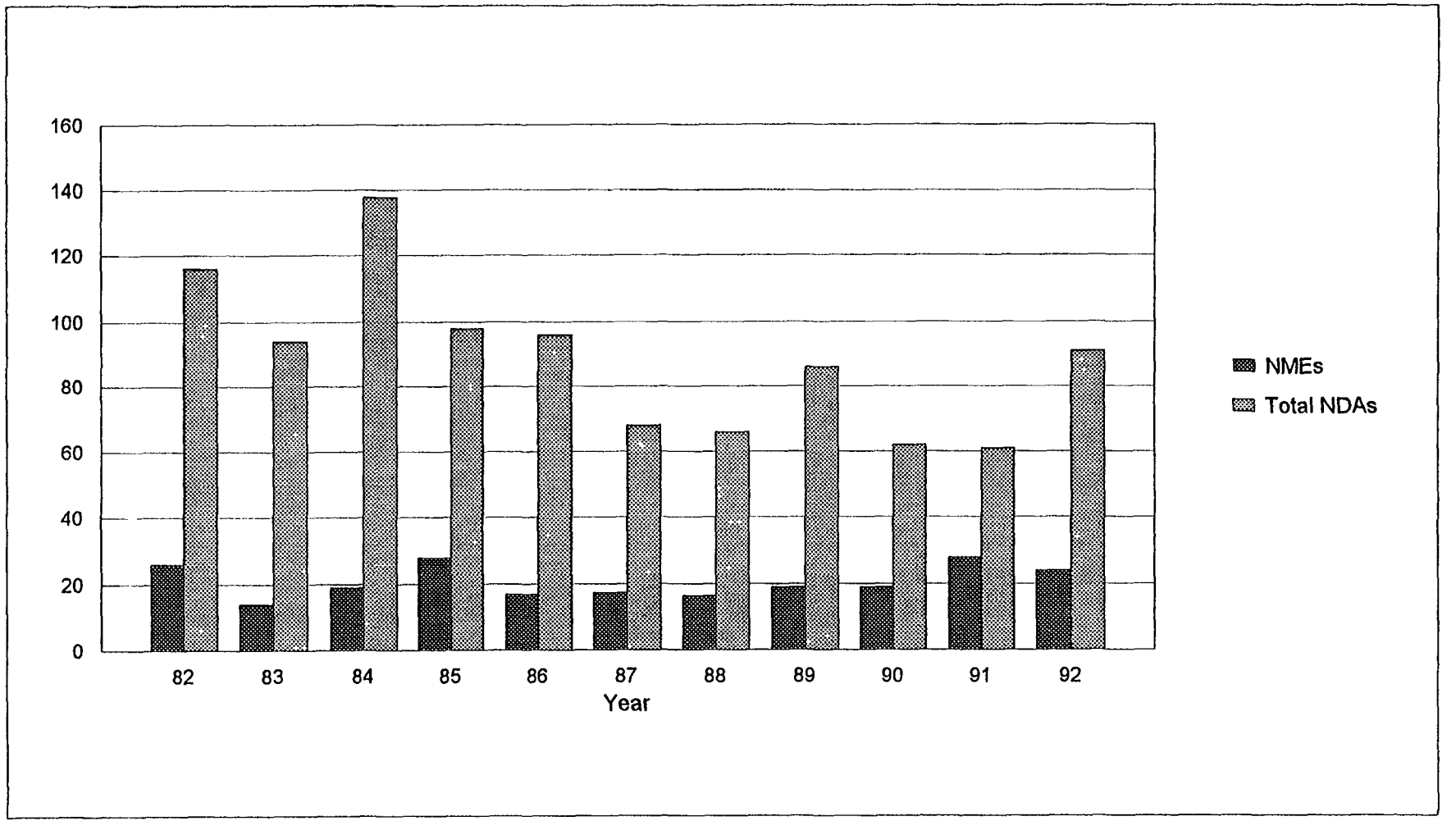

Figure 3-3. Number of approved New Drug Applications (NDAs) and New Molecular Entities (NMEs): 1982-1992.

Source: FDA, 1992.

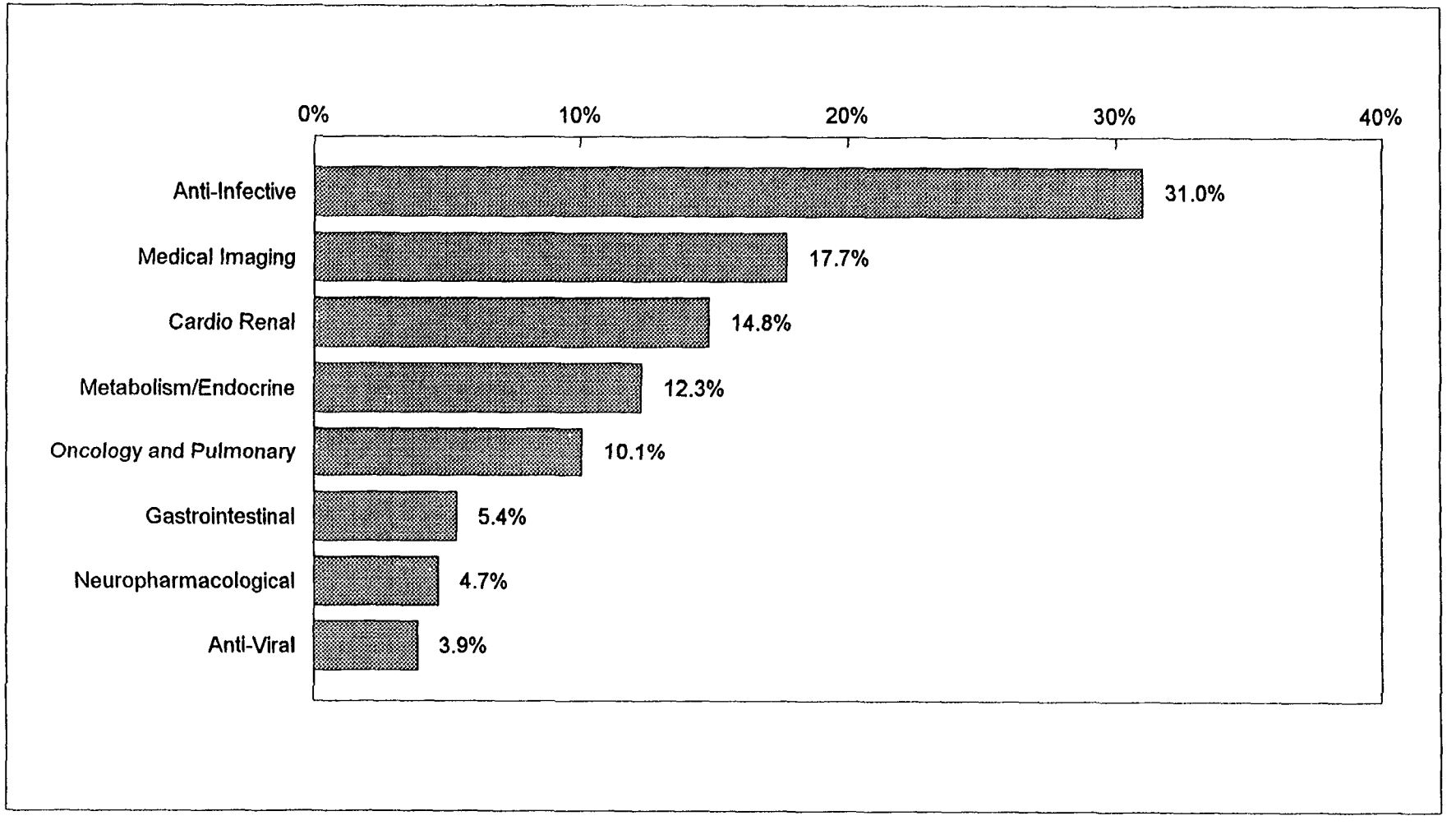

Figure 3-4. Approved NDAs by therapeutic category: 1987-1992.

Source: FDA, 1992.

To prioritize NDAs for review, FDA classifies new drugs according to their potential therapeutic importance. Type A drugs represent drugs that might provide effective therapy or diagnosis for a disease that is not adequately treated or diagnosed by any marketed drug. Type B drugs have modest advantages over currently marketed drugs such as greater patient convenience and fewer side effects. Type C drugs have substantially equivalent therapeutic benefits as already marketed drugs. Approximately 22 percent of the new drugs approved by FDA between 1987 and 1992 were classified as either Type A or B, representing potentially significant therapeutic gains (FDA, 1992).

3.1.1.2 Generic Drugs

When the patent on a prescription drug runs out, other manufacturers often enter the market with a generic version of the drug. To gain market approval, manufacturers of generic drugs must prove to FDA through an abbreviated NDA (ANDA) that their product is "bioequivalent" to a previously marketed drug. FDA defines bioequivalent drugs as drugs with identical active chemical ingredients and that enter the bloodstream at the same rate and levels. Because demonstrating bioequivalence is generally much easier than proving the overall safety and effectiveness of a drug (FDA assumes that bioequivalency implies identical safety and effectiveness), generic drugs are generally approved much more quickly than new drugs.[2] Nonetheless, bioequivalence testing may take several years to complete. Currently, FDA is averaging about 240 ANDA approvals per year (Sherwood, 1993).

Although generic drugs accounted for 12.6 percent of total pharmaceutical sales in 1991, they accounted for 34 percent of all prescriptions filled (NatWest, 1992). Since 1980, generic drugs have captured an increasing share of the prescription drug market. As shown in Figure 3-5, generic drugs accounted for 19.1 percent of prescription drug sales in 1991, almost double their

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[2]Before 1984, manufacturers of generic drugs would often need to duplicate many of the original manufacturer's clinical tests to gain market approval. The 1984 Drug Price Competition and Patent Term Restoration Act (the 1984 Price Act) rescinded these strict controls for generics, stipulating that generic drug manufacturers need only demonstrate bioequivalence to a previously marketed drug. It is generally agreed that the 1984 Price Act has greatly facilitated the entry of generics into the pharmaceutical market.

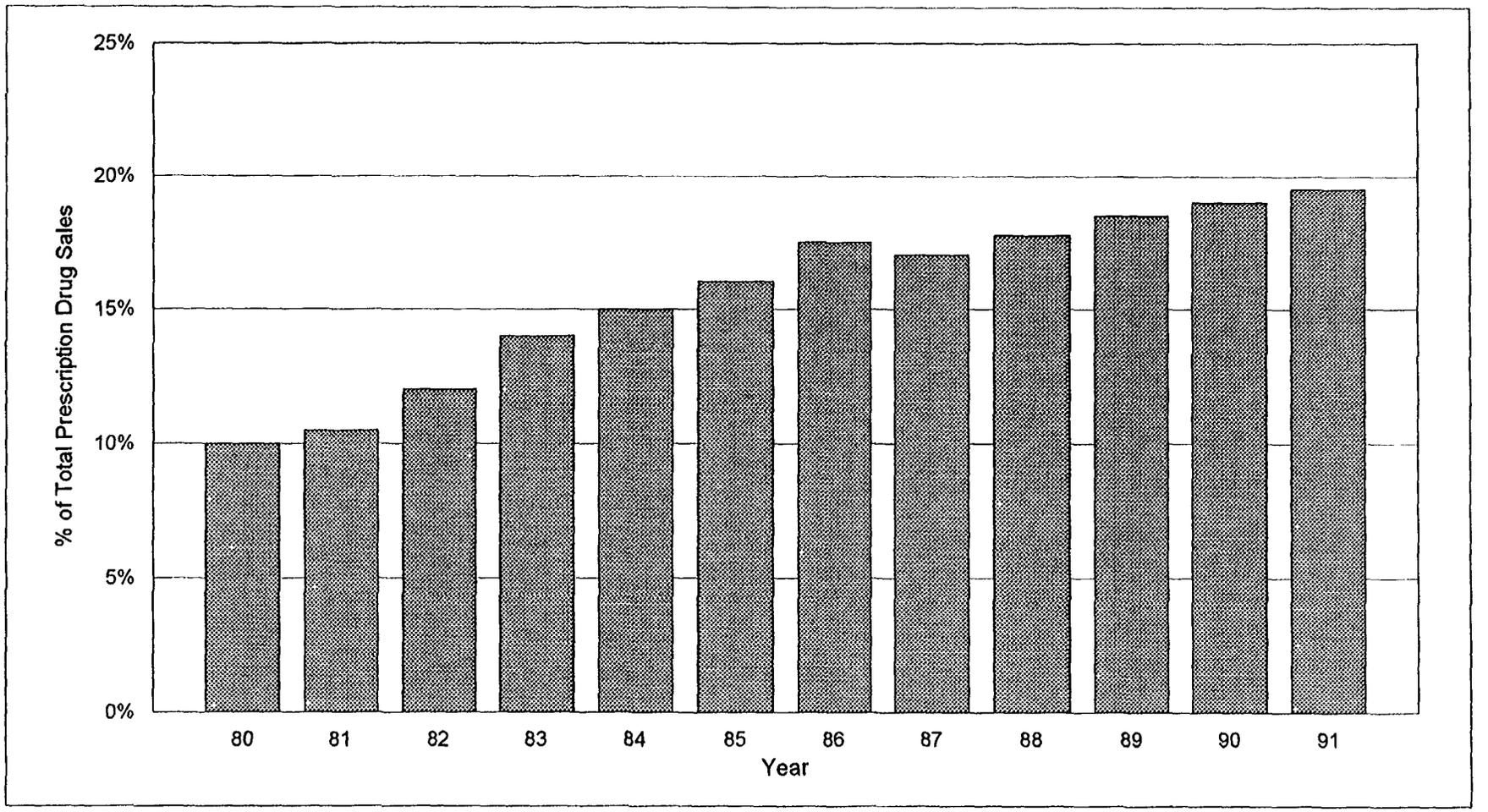

Figure 3-5. Generic prescription drug sales as a percentage of total prescription drug sales: 1980-1991.

Source: NatWest, 1992.

market share in 1980. With rising health care costs, public and private insurers have put increasing pressure on health care providers to use less expensive generic drugs when available. According to industry analysts, the generic drug industry is poised to accumulate even greater market share over the next decade as brand-named drugs representing current annual sales of over $20 billion lose patent protection between now and 1996 (NatWest, 1992).

3.1.1.3 OTC Drugs

FDA treats OTC drugs somewhat differently than other regulated pharmaceutical products. Before 1976, OTC drugs were not subject to the same NDA requirements. In 1976, however, FDA revised its OTC policy, calling for more rigorous regulation of the OTC market. In the same year, FDA embarked on an extensive review of all FDA approved ingredients of OTC drugs. FDA divided the previously broad grouping of OTC drugs into distinct therapeutic categories (e.g., sleeping aids, cough suppressants), each with its own monograph standard requiring specific labeling and dosages. In its review of OTC ingredients, FDA has removed many previously approved ingredients from the list of approved OTC ingredients. Once FDA's review is complete, new OTC drugs that have not been monographed will have to submit safety and effectiveness data to FDA, much like that required in an NDA.

Like generics, OTC drugs are a growing segment of the overall pharmaceutical market. OTC trade organizations expect the OTC market share to increase over the next decade as FDA increasingly grants OTC status to prescription drugs and as the move to control health care costs leads to greater use of less expensive OTC products. Within the OTC market itself, analgesics account for approximately 39 percent of total sales, cold medications 19 percent, and antacids 14 percent. Other OTC products such as antinausea drugs and cough medicines make up the remainder of the OTC market.

3.1.2 Manufacturing Processes

The pharmaceutical industry uses an array of complex batch-type processes and technologies in the manufacture of its products.[3] In general terms, the production of pharmaceuticals occurs in three main stages: R&D; fermentation, extraction, and chemical synthesis; and formulation (see Figure 3-6 for a schematic diagram of these three stages). These manufacturing processes correspond to EPA's subcategorization scheme (see Section Two).

3.1.2.1 Stage I

Stage I—R&D—encompasses several fields, including chemical, microbiological, and pharmacological research. A typical pharmaceutical company employs specialized personnel with expertise in medicinal, organic, and analytical chemistry; microbiology; biochemistry; physiology; pharmacology; toxicology; chemical engineering; and pathology. The development of a new drug involves innumerable laboratory processes and years of experimental testing. The entire R&D process can take as long as 12 years to complete.[4]

3.1.2.2 Stage II

Stage II—Fermentation, Extraction, and Chemical Synthesis—covers the conversion of organic and chemical substances into bulk active ingredients. Three of EPA's pharmaceutical industry categories (subcategories A, B, and C) correspond to these three conversion processes. The processes are defined as follows:[5]

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[3]For a detailed discussion of pharmaceutical manufacturing processes, please refer to EPA's 1982 and 1983 proposed and final development documents (U.S. EPA, 1982; U.S. EPA, 1983). These sources are the basis for much of the discussion in Section 3.1.2.

[4]See Section 3.2.3 for a more detailed discussion of pharmaceutical R&D.

[5]The following definitions are adapted from *Guides to Pollution Prevention: The Pharmaceutical Industry*. U.S. EPA, 1991.

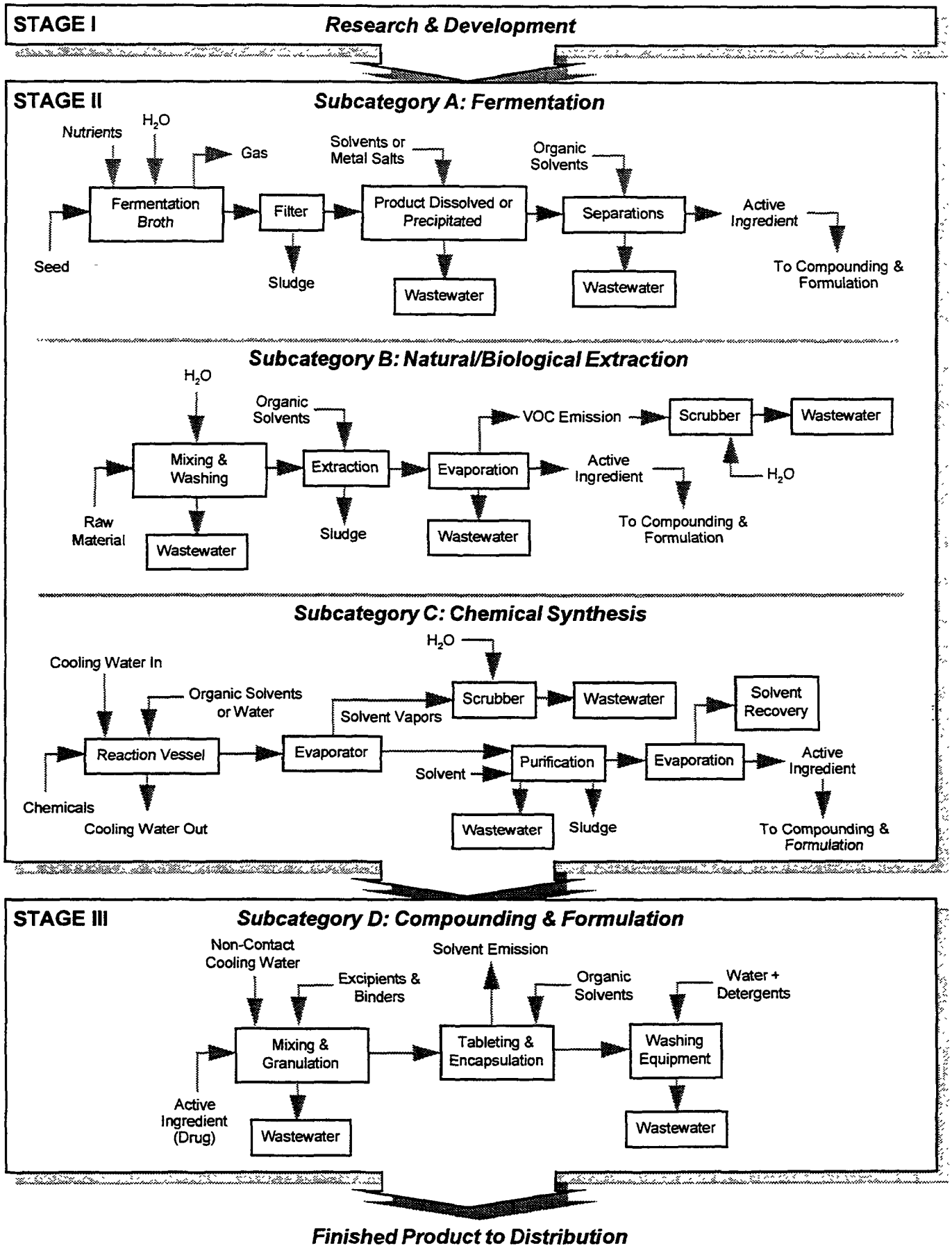

Figure 3-6. The three stages of pharmaceutical production.
Source: Adapted from EPA, 1992.

- ***Fermentation (Subcategory A).*** Fermentation processes consist of two major steps: inoculation (the introduction of a pathogen into a living organism to stimulate the production of antibodies) and seed preparation and fermentation, followed by crude product recovery and purification. The process begins in the lab with a carefully maintained population of a microbial strain. A few cells from this culture are matured into a dense suspension and then transferred to a seed tank designed for maximum cell growth. Material from the seed tank is then transferred to a vessel for fermentation. Following cell maturation, the fermenter broth is filtered to remove solid residues. The filtrate is then processed to recover the desired product using solvent extraction, precipitation, and ion exchange or adsorption chromatography. Steroids, Vitamin B_{12}, and antibiotics are typically produced using a batch fermentation process.

- ***Extraction (Subcategory B).*** Biological, or natural, extraction produces pharmaceuticals from natural material sources such as roots, leaves, and animal glands. Product recovery and purification processes include precipitation and solvent extraction. The amount of finished drug product is quite small compared with the volume of natural source material used. During each process step, the volume of material worked greatly diminishes to the point where final purification might occur on volumes of less than one-thousandth of the initial volume. Anticancer drugs, insulin, morphine, and hormones are examples of drugs manufactured using natural extraction processes.

- ***Chemical Synthesis (Subcategory C).*** Chemical synthesis takes place in a series of reaction, separation, and purification steps. Numerous types of chemical reactions, recovery processes, and chemicals are used to produce drugs through chemical synthesis. Chemicals used in chemical synthesis operations range widely and include organic and inorganic reactants and catalysts and a variety of solvents listed as priority pollutants by EPA. Most drugs today are produced by chemical synthesis. Examples include aspirin and acetaminophen.

A substance that is fermented, naturally extracted, or chemically synthesized might require no further processing to become a bulk active ingredient. Alternatively, additional chemical synthesis might be necessary before the desired active ingredient is formed. Of the facilities included in the Section 308 survey, 59 percent were engaged in one or more of the above processes.

3.1.2.3 Stage III

Stage III—Formulation—refers to the combining of bulk active ingredients with other substances to produce dosage forms suitable for human or animal intake. Formulation

corresponds to EPA subcategory D and can be defined as the preparation of dosage forms into tablets, capsules, liquids, parenterals (introduced otherwise than by way of the intestines), and creams and ointments. Tablets account for 90 percent of all medications taken orally and are produced by blending active ingredients with fillers such as starch or sugar and binders such as corn starch. Hard and soft capsules consist of gelatin capsules that are filled with an active ingredient. Liquid dosage forms include syrups, elixirs, suspensions, and tinctures, all of which are prepared by mixing solutes with a selected solvent in a glass-lined or stainless steel vessel. Parenterals are injected into the body and are prepared as solutions, dry solids, suspensions, dry insoluble solids, and emulsions. Ointments and creams are semisolid dosage forms prepared for topical use. Approximately 68 percent of the surveyed facilities had formulating operations.

Following formulation, finished drugs are distributed to hospital formularies, health maintenance organizations (HMOs), retail pharmacies, and directly to consumers.

3.2 FACILITY, OWNER COMPANY, AND PARENT COMPANY CHARACTERISTICS

This section presents facility, owner company, and parent company data for the pharmaceutical industry garnered from the U.S. Department of Commerce and the Section 308 Pharmaceutical Survey. The data cover numbers of establishments and employees, value of shipments, international trade, production costs, and baseline financial conditions. For the purposes of this EIA, a facility is defined as an individual location where pharmaceutical products are manufactured and/or formulated. An owner company might control one or several individual facility locations. Owner companies might, in turn, be owned by a parent company. The U.S. Department of Commerce collects data only at the facility level; the Section 308 Pharmaceutical Survey, however, collected financial data at all three levels. As discussed in Section Two, U.S. Department of Commerce data is more representative of the industry as a whole, whereas the survey data are more representative of the potentially regulated community. Each of the following sections begins by discussing U.S. Department of Commerce data, where available, and then follows with parallel survey data.

3.2.1 Number of Establishments and Employees

3.2.1.1 U.S. Department of Commerce Data

In 1990, the U.S. Department of Commerce classified some 1,343 establishments (i.e., facilities) involved in producing SIC 283 drugs (see Table 3-1).[6] Approximately half of these establishments (51 percent) were producing SIC 2834 drugs (pharmaceutical preparations), with the remaining establishments divided among SICs 2833, 2835, and 2836. These pharmaceutical establishments employed 183,000 people in 1990, an increase of 6.1 percent over 1987 employment levels (see Table 3-2). A little less than half of the industry's workforce is involved in production. As with the number of establishments, industry employment is heavily concentrated in SIC 2834, with nearly 80 percent of total industry employment concentrated in pharmaceutical preparation. As seen in Table 3-2, employment continued to grow in SIC 2834 in 1991 and 1992.

Smaller establishments (less than 100 employees) dominate the pharmaceutical industry, accounting for 78 percent of all establishments in SIC 283 in 1990. Almost half of all establishments employ fewer than 20 people. The industry, however, does have an unusually high percentage of establishments with more than 250 employees (11 percent) when compared to the manufacturing sector overall, in which only 4 percent of establishments have more than 250 employees. As discussed in Section 3.5, the presence of an unusually high percentage of large firms in the industry can be attributed to the enormous financial commitment necessary to develop and market new products and the existence of economies of scale in pharmaceutical manufacturing.

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[6]In reality, there are probably more establishments manufacturing pharmaceuticals than are indicated by U.S. Department of Commerce data. Because U.S. Department of Commerce classifies facilities by their primary line of business, the four pharmaceutical SIC codes do not capture facilities that manufacture pharmaceuticals but whose primary business is classified in some other SIC code.

TABLE 3-1

NUMBER OF PHARMACEUTICAL ESTABLISHMENTS
BY EMPLOYEE SIZE: SIC 283 DRUGS
(1990)

SIC Code	Total Number of Establishments	Number of Employees			
		1-19	20-99	100-249	>250
283 Drugs	1,343	632	416	141	154
2833 Medicinals and Botanicals	266	133	68	13	12
2834 Pharmaceutical Preparations	680	288	202	78	112
2835 Diagnostic Substances	161	60	56	26	19
2836 Biological Products, Except Diagnostics	220	97	88	24	11

Source: U.S. Department of Commerce, 1990.

TABLE 3-2

TOTAL NUMBER OF EMPLOYEES AND PRODUCTION WORKERS
SIC 283 DRUGS
(1987-1992)

SIC Code	1987	1988	1989	1990	1991*	1992*
Total Employment						
SIC 283 Drugs	172,000	175,000	184,000	183,000	NA	NA
SIC 2833 Medicinals and Botanicals	11,600	11,300	11,400	10,900	NA	NA
SIC 2834 Pharmaceutical Preparations	132,000	133,000	142,000	144,000	148,000	152,000
SIC 2835 Diagnostic Substances	15,400	16,200	16,100	14,900	NA	NA
SIC 2836 Biological Products, Except Diagnostics	13,300	13,700	14,500	13,300	NA	NA
Production Workers						
SIC 283 Drugs	79,600	81,000	82,800	81,400	NA	NA
SIC 2833 Medicinals and Botanicals	6,100	6,200	6,600	6,500	NA	NA
SIC 2834 Pharmaceutical Preparations	59,900	60,800	62,400	61,500	63,400	64,200
SIC 2835 Diagnostic Substances	6,800	7,500	6,800	6,600	NA	NA
SIC 2836 Biological Products, Except Diagnostics	6,800	6,500	7,000	6,800	NA	NA

* Estimated
NA = Not Available

Source: U.S. Department of Commerce, 1993.

3.2.1.2 Section 308 Pharmaceutical Survey Data

EPA estimates that approximately 286 of the industry's 1,343 establishments are either direct or indirect dischargers and therefore potentially would be affected by revised effluent regulations. The Section 308 survey censused or sampled 244 of these establishments to represent the 286 facilities. Of the 286 facilities 73 percent are owned by other companies. Only 27 percent of the surveyed facilities indicated that they were independently owned. In 1990, 69 parent companies owned 56 percent of the surveyed establishments.

Employment data were collected at the facility level only (see Table 3-3). According to the survey data, only 6 percent of all establishments had fewer than 20 employees. This pattern is in contrast to U.S. Department of Commerce data, which indicates that almost half of all pharmaceutical establishments employ fewer than 20 employees. Conversely, where U.S. Department of Commerce reports that only 11 percent of pharmaceutical establishments have more than 250 employees, nearly 55 percent of the surveyed establishments reported employment of over 250 people. Approximately 70% of manufacturing employment is concentrating in pharmaceutical manufacturing among the surveyed facilities. Over 50% of the surveyed facilities reported no employment in nonpharmaceutical related activities.

3.2.2 Value of Shipments

3.2.2.1 U.S. Department of Commerce Data

According to the U.S. Department of Commerce, drug industry shipments increased more than 8 percent in 1992 to $64.1 billion, an estimate that includes all products shipped by establishments classified in SICs 2833 through 2836. Shipments of drug products alone totaled $48.3 billion in 1991. In current dollars, drug industry shipments have grown at a rate of 9 to 12 percent since 1987. In real terms, growth has averaged 2 to 4 percent annually. Table 3-4 lists total industry shipments (1987 $) and drug product shipments between 1987 and 1992. The data indicates that the industry performed well despite the recent recession.

TABLE 3-3

SURVEYED FACILITIES BY NUMBER OF EMPLOYEES

Number of Employees	Number of Facilities	Percentage of *All* Facilities
1-19	18	6%
20-99	57	20%
100-249	55	19%
250-500	54	19%
501-999	57	20%
>1000	45	16%
Total	286	100%

Source: Section 308 Pharmaceutical Survey.

TABLE 3-4

VALUE OF SHIPMENTS: SIC 283 DRUGS ($1987 Millions)

SIC Code	1987	1988	1989	1990	1991*	1992*	1993**
Industry Shipments†							
SIC 283 Drugs	$39,263	$40,942	$41,998	$42,773	$43,723	$44,751	$46,881
SIC 2833 Medicinals and Botanicals	$3,350	$3,960	$4,213	$4,274	$4,359	$4,406	$4,538
SIC 2834 Pharmaceutical Preparations	$32,094	$32,988	$33,581	$34,144	$34,998	$35,872	$37,737
SIC 2835 Diagnostic Substances	$2,205	$2,237	$2,275	$2,282	$2,316	$2,362	$2,432
SIC 2836 Biological Products, Except Diagnostics	$1,614	$1,757	$1,929	$2,073	$2,050	$2,111	$2,174
Product Shipments††							
SIC 283 Drugs	$35,283	$36,939	$37,753	$38,649	$39,499	NA	NA
SIC 2833 Medicinals and Botanicals	$4,224	$4,721	$4,781	$5,030	$5,141	NA	NA
SIC 2834 Pharmaceutical Preparations	$26,610	$27,214	$27,443	$27,264	$27,864	NA	NA
SIC 2835 Diagnostic Substances	$2,683	$3,030	$3,396	$3,924	$4,101	NA	NA
SIC 2836 Biological Products, Except Diagnostics	$1,765	$1,974	$2,132	$2,431	$2,484	NA	NA

* Estimated.
** Forecast.
† Value of all products and services sold by establishments in the pharmaceutical industry.
†† Value of products classified in the pharmaceutical industry produced by all industries.

Source: U.S. Department of Commerce, 1993.

Table 3-5 presents value of shipment data by size of establishment (i.e., by number of employees). As might be expected, the industry's sales are concentrated in larger establishments. In 1987, for example, the 70 establishments with more than 500 employees accounted for 54 percent of the industry's value of shipments. Conversely, the 696 establishments with fewer than 20 employees accounted for only 2 percent of total industry shipments. Shipments per employee increased across size classes, indicating the possible presence of economies of scale (see Section 3.5.2).

The bulk (80 percent) of industry shipments is attributed to SIC 2834 Pharmaceutical Preparations, which in 1992 had sales totaling $35.9 billion (see Table 3-4). For SIC 2834, the U.S. Department of Commerce further breaks down shipments into five-digit SIC codes representing individual therapeutic categories. Table 3-6 presents value of shipments data for nine therapeutic categories within SIC 2834. As can be seen, approximately 71 percent of SIC 2834 shipments are for prescription drugs, 24 percent for OTC drugs, and 5 percent for bulk shipments. OTC drugs account for the greatest portion of shipments in SICs 28349, pharmaceutical preparations for veterinary use; 28346, pharmaceutical preparations acting on the skin; and 28344, pharmaceutical preparations acting on the respiratory system.

3.2.2.2 Section 308 Survey Data

The Section 308 survey collected data on pharmaceutical and nonpharmaceutical revenues at the facility, owner company, and parent company levels.[7] Only 212 facilities reported revenues for all 3 years surveyed.[8] As shown in Table 3-7, these 212 facilities generated $21.2 billion in revenues in 1990, an average of approximately $100 million per facility. Pharmaceutical revenues accounted for over 80 percent of total revenues. Table 3-8 shows the distribution of facilities by pharmaceutical, nonpharmaceutical, and total revenues. Over 62% of the facilities reported having no nonpharmaceutical revenues at all.

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[7]Unless otherwise noted, all revenue data is reported in 1990 dollars.

[8]It has not been determined why so many of the surveyed facilities failed to report revenues for all three years surveyed.

TABLE 3-5

VALUE OF SHIPMENTS BY EMPLOYEE SIZE OF ESTABLISHMENT: SIC 283
(Millions of 1987 $)

Employee Size	Number of Establishments	Number of Employees	Value of Shipments	Value of Shipments Per Employee
<20 employees	696	4,800	$757.4	$0.16
20-99 employees	390	17,200	$2,620.8	$0.15
99-500 employees	200	43,200	$12,136.1	$0.28
>500 employees	70	104,700	$23,748.0	$0.28

Source: U.S. Department of Commerce, 1991a.

TABLE 3-6

VALUE OF PRODUCT SHIPMENTS BY PRESCRIPTION/NON-PRESCRIPTION: SIC 2834 PHARMACEUTICAL PREPARATIONS ($ Millions)

SIC Code	Product Description	1990				1991			
		Total	Prescription Legend	Nonpre-scription	Bulk Shipments	Total	Prescription Legend	Nonpre-scription	Bulk Shipments
28341	Pharmaceutical preparations affecting neoplasms, endocrine system, and metabolic diseases, for human use.	$2,743	$2,638	$24	$81	$3,341	$3,205	$27	09
28342	Pharmaceutical preparations acting on the central nervous system and the sense organs, for human use.	$7,219	$4,908	$2,265	$46	$7,820	$5,489	$2,278	$53
28343	Pharmaceutical preparation acting on the cardiovascular system, for human use.	$4,815	$4,680	$3	$132	$5,009	$4,868	$5	$137
28344	Pharmaceutical preparations acting on the respiratory system, for human use.	$3,724	$1,653	$1,977	$95	$3,758	$1,826	$1,893	$39
28345	Pharmaceutical preparation acting on the digestive or the genito-urinary systems, for human use.	$4,840	$3,566	$1,253	$22	$5,606	$4,221	$1,359	$26
28346	Pharmaceutical preparations acting on the skin, for human use.	$1,558	$470	$1,057	$31	$1,621	$500	$1,085	$37
28347	Vitamin, nutrient, and hemantic preparations, for human use.	$2,588	$1,267	$151	$170	$2,597	$1,194	$1,234	$179
28348	Pharmaceutical preparations affecting parasitic and infective diseases, for human use.	$5,411	$4,593	$745	$73	$5,731	$4,846	$836	$49
28349	Pharmaceutical preparations for veterinary use.	$1,057	$362	$612	$83	$1,163	$481	$634	$48

Prescription Legend: A drug product that, by federal law, is available only by prescription by a licensed physician.
Nonprescription: A drug product that is sold over the counter, whether advertised or otherwise promoted to the professions or the general public.
Bulk Shipments: Represents the value of dosage forms shipped in bulk to other plants of the same company or other companies.
Source: U.S. Department of Commerce, 1991b.

TABLE 3-7

FACILITY, OWNER COMPANY, AND PARENT COMPANY REVENUES (Billions of 1990 $)

Production Cost Category	1988		1989		1990	
	Total	Average	Total	Average	Total	Average
Facilities (n = 212)						
Revenues from sales of pharmaceutical products (domestic and international)	$13.4	$0.06	$14.6	$0.07	$17.0	$0.08
Nonpharmaceutical sales	$3.4	$0.02	$4.0	$0.02	$4.2	$0.02
Total revenues*	$16.8	$0.08	$18.6	$0.09	$21.2	$0.10
Owner Companies (n = 157)						
Revenues from sales of pharmaceutical products (domestic and international)	$42.6	$0.3	$44.4	$0.3	$48.8	$0.3
Nonpharmaceutical sales	$42.6	$0.3	$48.2	$0.3	$48.9	$0.3
Total revenues*	$86.9	$0.6	$94.4	$0.6	$99.8	$0.6
Parent Companies (n = 68)						
Revenues from sales of pharmaceutical products (domestic and international)	$73.3	$1.1	$80.6	$1.2	$80.7	$1.2
Nonpharmaceutical sales	$213.7	$3.1	$215.1	$3.2	$218.7	$3.2
Total revenues*	$292.3	$4.3	$295.7	$4.3	$305.2	$4.5

*Pharmaceutical revenues and nonpharmaceutical revenues might not add to total revenues because of inconsistencies in survey reporting.

Source: Section 308 Pharmaceutical Survey.

TABLE 3-8

DISTRIBUTION OF SURVEYED FACILITIES BY VALUE OF SHIPMENTS: 1990
($ Millions)

Value of Shipments	Pharmaceutical Shipments		Nonpharmaceutical Shipments		Total Shipments	
	Number	%	Number	%	Number	%
0	3	1%	132	62%	3	1%
>0-1	2	1%	15	7%	11	5%
>1-5	29	14%	9	4%	17	8%
>5-25	64	30%	25	12%	65	31%
>25-100	50	24%	21	10%	62	29%
>100-250	31	15%	8	4%	36	17%
>250	15	7%	2	1%	18	8%

Source: Section 308 Pharmaceutical Survey.

Company-level pharmaceutical revenues in the sample totaled $42.6 billion in 1988, $44.4 billion in 1989, and $48.8 billion in 1990 (see Table 3-7).[9] Total company-level revenues in the sample (including nonpharmaceutical revenues) totaled $86.9 billion in 1988, $94.4 billion in 1989, and $99.8 billion in 1990. Average revenues remained essentially flat over the period at approximately $600 million per owner company. Owner companies in the sample generated close to 50 percent of total revenues from pharmaceuticals.[10]

Parent company pharmaceutical revenues in the sample totaled $73.3 billion in 1988, $80.6 billion in 1989, and $80.7 billion in 1990. Total revenues reported by parent companies included in the survey came to $292.3 billion in 1988, $295.7 billion in 1989, and $305.2 billion in 1990. In 1990, parent companies generated 27 percent of their revenues from the sale of pharmaceuticals.

Table 3-9 shows the distribution of surveyed owner companies and parent companies by total revenues. Approximately one-third of the owner companies reported revenues of less than $25 million, one-third reported between $25 and $200 million, 21 percent between $200 million and $1 billion, and the remaining 13 percent over $1 billion. Approximately one third of the parent companies sampled reported revenues of less than $250 million, 16 percent between $250 million and $1 billion, 35 percent between $1 billion and $10 billion, and 16 percent over $10 billion.

3.2.3 Production Costs

The following section presents manufacturing, research and development, and promotional cost data for the pharmaceutical industry.[11] Research and development and

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[9]Approximately 42 percent of the owner companies surveyed derive 100 percent of their revenues from pharmaceutical sales.

[10]Company-level revenues from the survey and U.S. Department of Commerce are not directly compared because foreign revenues are treated differently.

[11]Unless otherwise noted, all cost data is presented in 1990 dollars.

TABLE 3-9

NUMBER OF SURVEYED OWNER COMPANIES AND PARENT COMPANIES BY TOTAL REVENUES: 1990
($ Millions)

Owner Companies		Parent Companies	
Total Revenues	Number of Companies	Total Revenues	Number of Companies
$0-$25	50	$0-$250	23
≥$25-$200	50	≥$250-$1,000	11
≥$200-$1,000	33	≥$1,000-$10,000	24
≥$1,000	24	≥$10,000	10

Source: Section 308 Pharmaceutical Survey.

promotional costs are considered separately because of the critical role they play in realizing long-term gains in the industry.

3.2.3.1 Manufacturing Costs

The most current data on costs of production in the pharmaceutical industry are available from the Section 308 Pharmaceutical Survey. Table 3-10 presents cost data at the facility, owner company, and parent company levels for the sampled entities. Costs are broken down into the cost of pharmaceutical products and nonpharmaceutical products (including the cost of labor, capital, materials, and overhead), total operating expenditures (e.g., energy, depreciation), and research and development.

Product and operating costs rose from 1988 to 1990 in real terms at all three levels. Excluding research and development expenditures, the total cost of production at the facility level rose from $7.4 billion in 1988 to $9.6 billion in 1990, from $58.7 billion to $63.8 billion at the owner company level, and from $149.1 billion to $177.3 billion at the parent company level. The cost of pharmaceutical production as a percentage of the total cost of goods sold was approximately 67 percent at the facility level, 33 percent at the owner company level, and 17 percent at the parent company level in 1990.

3.2.3.2 Research and Development

The cost of researching, developing, and obtaining market approval for a new drug is a significant component of total production costs. According to the U.S. Department of Commerce, the pharmaceutical industry spent approximately $11 billion in 1992 on R&D (U.S. Department of Commerce, 1993). These expenditures amounted to more than 16 percent of sales, one of the highest proportions for any U.S. industry. FDA estimates that 9 percent of all U.S. industrial R&D is in pharmaceuticals (FDA, 1990).

TABLE 3-10

COST OF PHARMACEUTICAL PRODUCTION IN SURVEYED POPULATION
(Billions of 1990 $)

Production Cost Category	1988		1989		1990	
	Total	Average	Total	Average	Total	Average
Facility Level (n = 204)						
Cost of pharmaceutical products	$6.1	$0.03	$6.3	$0.03	$6.4	$0.03
Cost of nonpharmaceutical products	$1.3	$0.01	$3.1	$0.02	$3.2	$0.02
Total cost of goods sold	$7.4	$0.04	$9.4	$0.05	$9.6	$0.05
Company Level (n = 98)						
Cost of pharmaceutical products	$19.7	$0.2	$20.0	$0.2	$21.3	$0.2
Cost of nonpharmaceutical products	$39.0	$0.4	$43.0	$0.4	$42.5	$0.4
Total cost of goods sold	$58.7	$0.6	$63.0	$0.6	$63.8	$0.7
Total operating cost (not including cost of goods)	$35.6	$0.4	$40.0	$0.4	$40.0	$0.4
Research and development expenditures	$9.8	$0.1	$10.3	$0.1	$10.9	$0.1
Parent Company Level (n = 63)						
Cost of pharmaceutical products	$25.3	$0.4	$27.6	$0.4	$29.7	$0.5
Cost of nonpharmaceutical products	$123.8	$2.0	$134.8	$2.1	$145.6	$2.3
Total cost of goods sold	$149.1	$2.4	$162.4	$2.6	$177.3	$2.8
Total operating cost (not including cost of goods)	$67.7	$1.1	$77.1	$1.2	$86.0	$1.4
Research and development expenditures	$14.3	$0.2	$15.6	$0.2	$17.4	$0.3

Source: Section 308 Pharmaceutical Survey.

Section 308 survey data indicated a similar level of research and development expenditures by the sampled owner and parent companies. Research and development cost data were not available at the facility level. In 1990, research and development costs among the surveyed firms amounted to $10.9 billion at the company level (an average of $100 million per owner company) and $17.4 billion at the parent company level (an average of $300 million) (see Table 3-10). R&D costs averaged approximately 20 percent of the cost of goods sold over the 3 years reported in both owner and parent companies. The reported expenditures include nonpharmaceutical research and development expenditures as well.

The research required to discover and develop NMEs is central to pharmaceutical R&D, because manufacturers of generics and chemically similar products build on the knowledge produced in the course of developing NMEs. NMEs are discovered either through screening existing compounds or designing new molecules. Once synthesized, NMEs undergo rigorous preclinical testing in laboratories and in animals and then clinical testing in humans to establish the compounds' safety and effectiveness. Further clinical studies might be conducted following market approval.

The primary component of R&D cost is labor. Pharmaceutical R&D draws on the expertise of a diverse array of biological, chemical, and physical scientists to discover NMEs with potential therapeutic benefits. Also of importance in pharmaceutical R&D is the opportunity cost of capital, which can be quite high given the risk and time involved. By some estimates, for every 9,999 compounds on which research is conducted, only one drug product is introduced to the market. A typical pharmaceutical company will require 9 to 12 years to bring an NME to market (OTA, 1993).

Tuft's Center for the Study of Drug Research, a research institute specializing in the pharmaceutical industry, recently estimated that it costs an average of $231 million ($1990) to bring an NME to market. Approximately half of this total is the cost of capital (DiMasi, 1991). In a recent study of the costs of pharmaceutical R&D, OTA estimated that the aftertax R&D cash outlay for each NME that reached the market in the 1980s was about $65 million ($1990). The full aftertax cost of these outlays, compounded over 12 years to the day of market approval was approximately $194 million ($1990) (OTA, 1993). Moreover, these costs include R&D

expenditures for unsuccessful as well as successful product development efforts. OTA points out that the cost of pharmaceutical R&D is highly sensitive to changes in science and technology and in the regulatory environment, both of which are continuously evolving. Consequently, the study warns that one cannot predict future R&D costs from current estimates, which are based on R&D costs for drugs that went into development more than 10 years ago. Some evidence exists that pharmaceutical R&D is becoming more expensive over time as firms devote greater resources to hiring scientists, investing in new technology, and submitting their products to more extensive preclinical and clinical testing.

3.2.3.3 Marketing

Promotional expenditures account for approximately 22 percent of the industry's revenues (Day, 1993). Promotional expenditures tend to decline as a percentage of total sales over the life of the drug. For example, OTA estimates that in the second year following market approval, promotional expenditures account for 50 percent of sales. By the product's tenth year, however, promotional expenditures will have declined to only 6.5 percent of sales (OTA, 1993). Many view these high promotional expenditures as evidence that the industry does not compete on the basis of price and instead devotes excessive resources to product differentiation through advertising. Others contend that these promotional expenditures serve to educate physicians and allow new competitors to enter specific drug markets (see Section 3.5.1).

3.2.4 International Trade

3.2.4.1 U.S. Department of Commerce Data

The U.S. pharmaceutical industry has consistently maintained a positive balance of trade in international markets. In 1991, the industry's trade surplus totaled $961 million, and the U.S. Department of Commerce estimates that it exceeded $1.3 billion in 1992. Exports totaled $5.7 billion in 1991 compared to $4.8 billion in imports. Nearly 47 percent of the industry's exports were to the European Community in 1991. With $947 million in U.S. drug purchases, Japan

represented the greatest single-country importer of U.S. pharmaceuticals. On the import side, the United States purchased $831 million in pharmaceuticals from the United Kingdom. Figure 3-7 show U.S. pharmaceutical exports and imports for 1991.

The United States holds a dominant position in many international pharmaceutical markets. In Europe, for example, U.S. pharmaceutical companies account for 25 percent of total pharmaceutical sales. The United States also has a strong presence in Japan with 10 percent of the market. Worldwide (including the United States), U.S. companies account for 33 percent of total pharmaceutical sales (FDA, 1990). In important markets such as the United States, the United Kingdom, and France, U.S. companies have introduced the largest percentage of new drugs. Even in Japan, the United States is second only to Japan in new drug introductions.

As in many U.S. industries, foreign investment in U.S. pharmaceutical companies subsided in 1992 after peaking in the late 1980s. In 1990, foreign investment in U.S. pharmaceutical companies totaled $10 billion, while U.S. investment in foreign pharmaceutical companies totaled $10.6 billion.

The U.S. Department of Commerce expects the United States to maintain its strong position in international markets over the next decade. Nearly 33 percent of worldwide pharmaceutical R&D is conducted by U.S. firms, thus providing the United States with a competitive edge for developing new drug products. The North American Free Trade Agreement (NAFTA), the advent of an economically unified Europe, and the increasing recognition of U.S. patent laws in China, Mexico, and Latin America, all suggest continued strength in international markets for the U.S. pharmaceutical industry. Greater political stability in the former Soviet Union and other Eastern Block countries also will create new trading opportunities for the U.S. pharmaceutical industry.

3.2.4.2 Survey Data

According to the Section 308 survey data, international sales account for a significant proportion of the total revenues of surveyed facilities, owner companies, and parent companies.

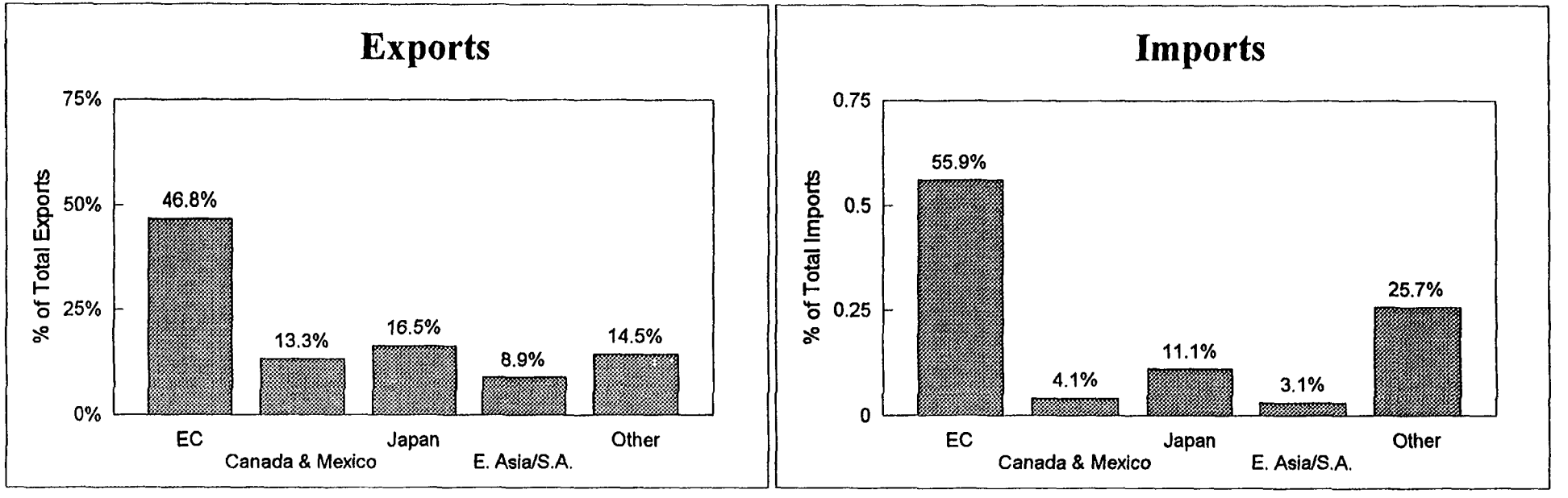

Figure 3-7. U.S. pharmaceutical exports and imports: 1991.

Source: U.S. Department of Commerce, 1993.

This finding is not surprising given the multinational character of the pharmaceutical industry (nearly 50 percent of the parent companies of surveyed facilities are headquartered in foreign countries). At the company level, international sales accounted for over 25 percent of all pharmaceutical revenues generated in 1990. Nearly 50 percent of all pharmaceutical sales made by parent companies in 1990 were to foreign countries. International sales are an important component of overall pharmaceutical sales at the facility level as well. Table 3-11 presents the distribution of surveyed facilities by percentage of pharmaceutical shipments accounted for by international sales. Although a substantial number (44 percent) of the surveyed facilities reported no international pharmaceutical sales, over 20 percent of the facilities reported receiving more than 10 percent of their pharmaceutical revenues from international sales in 1990. The mean pharmaceutical export rate for sample facilities was 8.8 percent in 1990.

3.2.5 Financial Conditions

The Section 308 Pharmaceutical Survey collected data on company costs, revenues, liabilities, earnings, and other financial statistics. These data allow key financial ratios to be calculated. The ratios are measures of a company's ability to meet short- and long-term obligations and to generate a sufficient return on investments. This section presents baseline data on two financial ratios: (1) rate of return on assets (ROA), and (2) interest coverage or times interest earned ratio. These ratios will be used in Section Five to assess economic impacts at the owner company level.

Financial ratios are calculated at the owner company level only, where firm impacts are most direct and substantial. The ratios are also compared with industry benchmarks obtained from Dun & Bradstreet Information Services. As explained in greater detail in Section 3.4, baseline ratio data are used to identify firms whose financial condition, independent of regulatory action, is sufficiently poor as to jeopardize their ability to make investments in wastewater treatment systems. These firms are at risk of financial failure even without regulatory impacts.

A variety of financial ratios are available for measuring the financial health of pharmaceutical companies, including ratios addressing liquidity, asset management, debt

TABLE 3-11

NUMBER OF FACILITIES BY PERCENTAGE OF PHARMACEUTICAL SHIPMENTS EXPORTED

Percentage of Pharmaceutical Shipments Exported	1989		1990	
	Number	%	Number	%
0%	82	46.9%	77	44.0%
>0%-2.5%	33	18.9%	36	20.6%
>2.5-5%	13	7.4%	13	7.4%
>5%-10%	11	6.3%	10	5.7%
>10%	36	20.6%	39	22.3%

Note: Only 175 facilities reported export data.

Source: Section 308 Pharmaceutical Survey.

management, profitability, and market value. The appropriate ratio choice depends on the purpose of the analysis. This analysis focuses on measuring the possibility of facility closure or firm financial failure because of regulatory impacts. To attract the financing for a wastewater treatment system, a firm must demonstrate or project financial strength both before and after the regulation-induced investment. Financial strength is often assessed on the basis of whether a firm can incur debt associated with a capital investment while continuing to generate a return on investment that will attract further investment. Thus measures of debt levels and profitability are critical to the analysis of financial strength.

The two ratios judged most important to the financial analysis of potential creditors and investors are the rate of return on assets and the interest coverage ratio. The sections below define these ratios and discuss their value for this research. Additionally, the discussion reviews the overall profitability of the industry, which helps to provide background for the remainder of the financial analysis.

3.2.5.1 Return on Assets

A firm's financial performance determines the willingness of creditors and investors to provide the capital necessary to sustain or expand operations. If performance is poor, investors will not provide capital or will seek higher returns in the form of higher interest rates on debt or higher returns on equity to compensate for above-average levels of risks. The higher cost of capital might in turn limit the ability of a given company to invest in improved wastewater treatment.

Financial performance will be measured in terms of the pre-tax return on assets (ROA). ROA is computed as the ratio of net income to assets:

$$ROA = \frac{Net\ Income}{Total\ Assets}$$

ROA is a measure of profitability of a firm's capital assets, independent of the effects of taxes and financial structure. It is perhaps the most comprehensive measure of a firm's financial performance. ROA provides information about the quality of a firm's management, the competitive position of a firm within its industry, and, on an aggregate level, the economic condition of an industry overall. In addition, ROA incorporates information about a firm's operating margin and asset management capability: the ratio of net income to sales (operating margin), multiplied by the ratio of sales to assets (asset turnover), equals ROA. If a firm cannot sustain a competitive ROA, it will probably have difficulty financing new investments. This is true regardless of whether the financing is obtained through debt or equity financing.

Table 3-12 presents baseline ROA data for companies included in the survey sample. The ratio data are presented by quartile (i.e., with values given that denote the ratios for lowest 25 percent of firms, the median, and the highest 25 percent of firms) for firms grouped by annual revenues. The mean and standard deviation for each group of firms also is presented.

The return on assets over the years 1988 to 1990 varied from a first quartile of approximately -3 percent to an upper quartile of 10 percent for the smallest size class of firms (those with $25 million or less in annual revenues), to between 4 and 9 percent for the largest firms (those with over $1 billion in revenues). The data indicate that the lower quartile of firms in the smallest size class, on average, generated negative net income between 1988 and 1990. These firms appear to be the most vulnerable by the ROA measure. Long-term performance at this level would threaten these firms' ability to stay in operation. All other ROA values given in the table were positive.

Table 3-13 presents industry ROA ratios reported by Dun & Bradstreet for each SIC of the pharmaceutical industry. As can be seen, the results are more or less consistent with those drawn from the survey sample. Dun & Bradstreet's results reflect data for 266 companies overall. It should be noted that differences in the organization of data makes the comparison of ratio results only approximate.

TABLE 3-12

BASELINE RETURN ON ASSETS (ROA) AND
INTEREST COVERAGE (ICR) RATIOS, BY ANNUAL REVENUES

Annual Revenues ($millions)	Number of Observations	Mean	Lower Quartile	Median	Upper Quartile
ROA					
0-25	60	-2%	-3%	5%	10%
26-200	55	5%	1%	5%	12%
201-1,000	33	15%	2%	7%	26%
>1,000	26	7%	4%	6%	9%
ICR					
0-25	60	Infinity	-1%	578%	51,267%
26-200	55	Infinity	201%	464%	8,470%
201-1,000	33	Infinity	272%	2,043%	Infinity
>1,000	26	1,111%	372%	677%	1,130%

Source: Section 308 Pharmaceutical Survey.

TABLE 3-13

COMPARISON OF SAMPLE RATIOS WITH PUBLISHED INDUSTRY AVERAGES

Source	Number of Observations	Quartile		
		Lower	Median	Upper
ROA				
Survey Sample (1988-1990 average)	174*	-3% to 4%	5% to 7%	9% to 26%
Dun & Bradstreet Information Services (1990)				
SIC 2833	34	-2%	2%	11%
SIC 2834	167	3%	10%	21%
SIC 2835	29	NA	4%	7%
SIC 2836	34	0%	4%	10%
ICR				
Survey Sample (1988-1990 average)	174*	-1% to 372%	464% to 2,043%	1,130% to Infinity
Robert Morris Associates (1991-1992)				
SIC 2833	113	180%	440%	1,110%

*Out of 177 firms, only 174 responded with data for computing ROA and ICR.

Sources: Section 308 Pharmaceutical Survey data; Robert Morris Associates (1992); and Dun & Bradstreet Information Services (1993).

3.2.5.2 Interest Coverage Ratio

The second general area of concern to creditors and investors is the extent to which the firm can be expected to manage its financial burdens without risk of financial failure. In particular, if a firm's operating cash flow does not comfortably exceed its contractual payment obligations (e.g., interest and lease obligations), the firm is vulnerable to a decline in profits or an increase in costs because in either case its ability to continue meeting interest obligations would be in jeopardy. Either scenario may (1) sharply reduce or eliminate returns to equity owners of the firms, and/or (2) prevent the firm from meeting its contractual obligations.

The ability to manage financial commitments is expressed as the ratio of earnings before interest and taxes (EBIT) to interest obligations, or the interest coverage ratio (ICR):

$$ICR = \frac{EBIT}{Interest}$$

A low ICR indicates vulnerability of the firm to financial failure and the potential for difficulty in obtaining financing for wastewater treatment capital investments.

As shown in Table 3-12, the interest coverage ratios vary from approximately -1 percent to 51,267 percent for the smallest firms to 372 percent to 1,130 percent for the largest firms in the Section 308 sample of firms. A number of firms reported no or negative interest burdens over the specified time period. These firms were assigned ICRs of infinity. Only the lowest quartile of companies in the smallest size class showed negative interest coverage ratios.

Robert Morris Associates reported data on the interest coverage ratios for 113 firms. As for ROA, these data are approximately consistent with those reported by the survey sample (see Table 3-13). The median value in the Robert Morris sample is 440 percent. Median values for the survey sample by size class ranged from 464 percent to 2,043 percent.

3.2.5.3 Overview of Profitability in the Pharmaceutical Industry

This section presents additional evidence on profitability in the pharmaceutical industry. If the pharmaceutical industry were found to be relatively unprofitable overall, then investment levels in the industry would be declining and industry benchmarks might underestimate the extent of vulnerability among industry firms.

Profitability in the pharmaceutical industry has been extensively studied, and a recent Office of Technology Assessment (OTA) research report, *Pharmaceutical R&D: Costs, Risks and Rewards,* summarizes this work (OTA, 1993). OTA compared the pharmaceutical industry's rate of return with that of other industries. OTA also considered whether the higher rates of return in the pharmaceutical industry were caused by a higher cost of capital in the industry. Elements of the OTA research are summarized here.

OTA compiled recent literature on the profitability and internal rates of return (IRR) for the pharmaceutical industry. The IRR is the interest rate at which the net present value of all cash flows into and out of the company equals zero. It provides a generally reliable method of calculating the return on investments. OTA identified a number of studies conducted between 1975 and 1991 that measured the profitability of the industry, including three studies that compared the pharmaceutical industry to others. These studies were designed to improve on the measurements possible with publicly available reports of industry profits. Accounting measures of profitability can be flawed because:

- Accounting standards require firms to record R&D, advertising, and promotion outlays as current expenditures, whereas they are generally investments with a future return. The value of the "intangible assets" represented by these expenditures is too uncertain for use in accounting statements but, nevertheless, represents assets that should be factored in.

- Financial statements report income and expenses as they are accrued and not necessarily as they are realized, which can distort the timing of revenues and investments and misrepresent the rate of return.

- Even if the other distortions are corrected, the accounting rate of return could still depart from the IRR because accounting profits do not adjust properly for

the time profile of cash flows from various investments and are further distorted by growth or decline in investment over time (OTA, 1993).

The studies identified by OTA used various techniques to develop more accurate estimates of the rate of return for the companies studied, such as incorporating information about the timing of investments in R&D, correcting for the effect of inflation, incorporating depreciation rates for investments in R&D and advertising, and other changes. The various studies produced estimates of the IRR.

Three studies compared the corrected pharmaceutical industry IRR estimates with similarly adjusted profit figures for other industries. The study results should be interpreted cautiously because they covered very small samples of companies. Further, the studies tended to focus on larger (and presumably more successful) firms. Nevertheless, the studies showed that the adjusted rate of return for the pharmaceutical industry was found to be consistently higher than that in the other industries examined.

Table 3-14 summarizes the elements of the most recent of the studies reviewed by OTA, a study by Megan and Mueller of 10 pharmaceutical firms between 1975 and 1988. Megan and Mueller compared the IRR for the pharmaceutical industry with that of other industries that have similarly large investments in R&D and advertising, including the toy, distilled beverages, and cosmetics industries. These authors used various assumptions about the depreciation of R&D and advertising to measure the true profitability impact of these investments. This study found that 10 pharmaceutical firms had an IRR of 12.15 percent. The other industries, with similarly adjusted depreciation estimates, produced rates of return of 6.6 percent (toys), 11.44 percent (distilled beverages), and 11.5 percent (cosmetics).

OTA also commissioned its own report on the relative level of pharmaceutical industry profits. This study, authored by Baber and Sok-Hyon, used a recently developed technique for converting accounting data into an IRR estimate. This study compared rates of return for 54 research-intensive pharmaceutical firms with samples of companies in other industries. The authors found that the pharmaceutical industry had IRRs that were consistently 2 to 3

TABLE 3-14

SUMMARY OF PHARMACEUTICAL INDUSTRY PROFITS STUDY

Study Description	Study Characteristics	Comment
Pharmaceutical industry sample (Year of Data)	10 major firms, 1975 to 1988.	
Other industries sample	Selected firms in advertising or R&D-intensive industries; 6 firms in toy industry; 4 in distilled beverage firms; 9 in cosmetic firms.	Selected firms with similar large investments in R&D and advertising.
R&D capitalization assumptions	R&D depreciation rates estimated for each firm by regressing sales on lagged R&D. Maximum 8-year life for investment.	Capitalization rate assumptions are necessary to improve accuracy of rate of return estimates over normal accounting measures.
Advertising capitalization assumptions	Same depreciation estimation technique as for R&D with a maximum 4-year life for investment.	Capitalization rate assumptions are necessary to improve the accuracy of rate of return estimates over normal accounting measures.
Rate-of-return estimates—pharmaceutical industry	12.15 percent	None
Rate-of-return estimates—other firms	Toy industry - 6.66 percent Distilled beverages - 11.44 percent Cosmetics - 11.51 percent	Other industries showed lower rates of return, using consistent adjustments to the accounting data.

Source: OTA, 1993.

percentage points higher, under various alternative calculation methodologies, than those for nonpharmaceutical companies.

The question remains whether the observed differences in IRR resulted from differences in the cost of capital. If pharmaceutical investments are riskier, then investors would require higher IRR and the cost of capital for the industry would be higher. OTA estimated the average cost of capital for the industry and for two control groups. OTA found that the pharmaceutical industry's cost of capital was slightly higher than that for one group of control firms and lower than that for another group. OTA recognized the potential errors and biases in its measurement techniques, but nevertheless concluded that the higher rates of return found for the pharmaceutical industry could not be explained by differences in the relative costs of capital.

Overall, the profitability of the pharmaceutical industry appears to be above average among U.S. industries. This suggests that the overall baseline viability of the industry is equivalent to, if not better than, that of other industries.

3.3 INDUSTRY STRUCTURE AND THE PHARMACEUTICAL MARKET

Information concerning market structure, the demand for pharmaceuticals, and pricing behavior provides much of the basis for reaching conclusions about the industry's ability to "pass through" additional regulatory costs via higher drug prices and thereby predicting which entities bear what portions of regulatory impacts. The first section of the following discussion (Section 3.3.1) examines evidence of market structure as defined by barriers to entry, industry concentration ratios, and vertical integration patterns. Market structure data must be complemented by other information on the pharmaceutical industry as well. Subsequent sections examine the characteristics of pharmaceutical demand (Section 3.3.2) and market conduct and performance (Section 3.3.3). Section 3.3.4 presents conclusions about the likelihood that manufacturers can pass through regulatory costs to consumers of pharmaceuticals.

3.3.1 Market Structure

The more barriers to entry that exist in a given market, the more likely it is that monopolistic or oligopolistic conditions will prevail in that market. Such conditions allow firms greater latitude in setting prices and hence the ability to pass regulatory costs along to consumers. Barriers to entry and concomitant factors of concentration and vertical integration are discussed in the following sections.

3.3.1.1 Barriers to Entry

Critics of the pharmaceutical industry often blame barriers to entry (i.e., economic, social, and regulatory factors that prevent or discourage new firms from entering a given market) for limiting competition in the pharmaceutical industry and thereby creating inefficiencies in the supply of a socially desirable product. One major barrier to entry is the high cost of pharmaceutical R&D. Raising the necessary capital to finance pharmaceutical R&D can be difficult for new firms that have no capital resources of their own and must attract investors that can tolerate long-term, high-risk investments. Investors might be more inclined to invest in established firms that have demonstrated that they can bring a drug to market, recover R&D expenditures, and produce reasonable returns on investment capital. Investors also might be wary of new firms that have not demonstrated that they can clear FDA regulatory hurdles. For example, new firms might be less capable of producing well-documented and organized NDAs, which can extend the regulatory review process and thus delay returns on investments.

The prevalence of patents also serves to prevent new firms from entering particular drug markets. By law, patented drugs in the United States enjoy ostensible protection from bioequivalent drugs for a period of 17 years (OTA, 1993). This protection gives the drug manufacturer a monopoly over its particular product for the life of the patent. Several factors, however, act to reduce the effective patent life of drugs. The greatest threat to the effective patent protection for a drug is the delay between patent issuance and FDA approval, which can be as much as 10 years. Drug companies obtain patents during the R&D phase, and many years can elapse before the company can take advantage of its monopoly power. OTA estimates that

the effective patent life (i.e., the time between drug approval and patent expiration) on new drugs averages 11 years (OTA, 1993). Moreover, patents do not provide complete protection from competition because competitors might be able to offer other drugs with similar therapeutic benefits.

Once patents expire, manufacturers of bioequivalent, or generic, drugs can enter the market. Evidence suggests that over the past decade, introduction of generic versions of branded products is becoming more common. Today, nearly 34 percent of all prescription drug orders are filled by generics rather than branded, or "pioneer" drugs, an 11 percent increase since 1986. As noted earlier, the passage of the 1984 Price Act made it easier for generics to gain market approval from FDA, and both public and private insurers have become more adamant about the use of less expensive generics.

High promotional expenditures in the pharmaceutical industry also can serve as a barrier to entry. Traditionally, the economic literature has viewed high promotional expenses as an indication of an imperfect competitive environment. In a market characterized by oligopoly (i.e., the domination of a given market by a small number of firms), firms will use advertising rather than price competition to differentiate products. New firms might be at a disadvantage with respect to more established firms if they must compete on the basis of reputation rather than price. The high promotional expenses required to compete in drug markets also add to the capital demands on new entrants.

Despite the high cost of promotion, several economists in the late 1970s determined empirically that industry promotional expenditures were positively related to market entry. Thus, new entrants use their promotional campaigns to achieve market entry. In a study of 17 therapeutic markets over the period 1969 to 1972, Tessler concluded that promotional expenditures actually facilitate entry because new products could not compete with existing products without being able to distinguish themselves through advertising. Hornbrook found similar results and concluded that promotional expenditures serve more as a market penetration tool for new pharmaceutical manufacturers than as a barrier to entry (Feldstein, 1988).

On balance, patent protection and long regulatory lead times for approval of new pharmaceuticals represent barriers to entry. Although it is extremely difficult to quantify the impact of such barriers on market competition, it is likely that established pharmaceutical companies have a degree of market power because of their regulatory experience, established R&D operations, and patent protection. Although the number of pharmaceutical establishments, particularly generics manufacturers, has grown over the past several decades, it is likely that competition in the industry would have been greater in the absence of high R&D costs, FDA regulations, and other barriers to entry discussed above.

3.3.1.2 Concentration and Vertical Integration

The degree of concentration and vertical integration in a given industry is often used as an indicator of barriers to entry. Concentration is generally measured in terms of the percentage of value of shipments accounted for by a given number of firms in a particular industry. The U.S. Department of Commerce calculated 4-, 8-, 20-, and 50-firm concentration ratios for all 4-digit SIC industries through 1987 (see Table 3-15). The higher the concentration ratio in a given industry, the easier it is for manufacturers to set prices or to collude to set prices. Industrial economists have proposed that when the leading four firms control 40 percent or more of a given market, the market may be characterized by oligopolistic conditions that present significant barriers to entry.

Table 3-15 lists the 4-, 8-, 20-, and 50-firm concentration ratios for SICs 2833, medicinal and botanicals; 2834, pharmaceutical preparations; and 2836, biological products, as reported by the U.S. Department of Commerce. As can be seen, the four leading firms in SIC 2833 controlled 72 percent of sales of SIC 2833 products in 1987. This situation contrasts to the four-firm concentration ratio of 22 percent in SIC 2834 and 45 percent in SIC 2836. There are almost three times as many companies in SIC 2834 as in SIC 2833. The relatively low four-firm concentration ratio of 22 percent in SIC 2834 and the relatively large number of companies suggests that barriers to entry in the pharmaceutical preparations sector of the industry are relatively insignificant compared with barriers to entry in the medicinals and botanicals sector.

TABLE 3-15

4-, 8-, 20-, and 50-FIRM CONCENTRATION RATIOS:
SICs 2833, 2834, AND 2836: 1954-1987

SIC Code	Year	Percent of Total Value of Shipments			
		4 Largest Companies	8 Largest Companies	20 Largest Companies	50 Largest Companies
2833 Medicinals and Botanicals	1987	72	80	89	95
	1982	62	75	85	94
	1977	65	78	89	96
	1972	59	75	90	98
	1970	64	74	NA	NA
	1967	74	81	91	98
	1966	70	81	NA	NA
	1963	68	79	91	99
	1958	64	77	89	98
	1954	72	84	93	NA
2834 Pharmaceutical Preparations	1987	22	36	65	88
	1982	26	42	69	90
	1977	24	43	73	91
	1972	26	44	75	91
	1970	26	43	NA	NA
	1967	24	40	73	90
	1966	24	41	NA	NA
	1963	22	38	72	89
	1958	27	45	73	87
	1954	25	44	68	NA
2836 Biological Products, Except Diagnostics	1987	45	65	80	93

NA = Not Available.

Source: U.S. Department of Commerce, 1991a.

Nevertheless, concentration ratios calculated for such large industry segments are of limited value. The overall drug market is fragmented into a number of separate, noncompeting therapeutic markets. Manufacturers of antibiotics, for example, do not compete with manufacturers of muscle relaxants. Thus, concentration ratios should be calculated and analyzed within the specific therapeutic markets in which manufacturers do compete. Only one study was identified in the economic literature of concentration ratios by therapeutic category. The study, conducted by Vernon (1971), divided the prescription drug market into 19 therapeutic markets according to the degree of demand-side substitutability between different drugs (i.e., relatively close drug substitutes were placed in the same general therapeutic market). The four-firm concentration ratios calculated by Vernon in the 19 therapeutic markets are presented in Table 3-16. As can be seen, all of the concentration ratios are quite high; the lowest ratio in a therapeutic market is 46 percent. Several concentration ratios are in the 90 percent range, and the unweighted average is 68 percent. Vernon's study suggests that a relatively small number of companies dominate sales in the individual therapeutic markets.

Even therapeutic market-specific concentration ratios might not present an accurate picture of competitive conditions in the pharmaceutical industry, however. According to Feldstein (1988), concentration ratios are a static measure of market power. Feldstein notes that although a particular therapeutic market can be characterized by high concentration at a given point in time, market shares in that therapeutic market can change radically over time. Instability in market shares over time indicates intense competition among firms through new product innovation. One study in the early 1970s noted that of the 20 industries investigated, only the petroleum industry possessed a higher degree of market instability than the pharmaceutical industry. Moreover, exit from and entry to the pharmaceutical industry seems to be quite high. In a study of 17 therapeutic markets between 1963 and 1972, 15 markets had five or more new entrants. Market exit occurred in 16 of the 17 markets (Feldstein, 1988).

A high level of vertical integration might also indicate the presence of barriers to entry in a given industry. Vertical integration refers to the extent to which production inputs and services are produced and transferred within a given company, rather than procured from other companies. In the pharmaceutical industry, a vertically integrated firm might engage in research and development, several stages of manufacturing (i.e., extraction and formulation), and

TABLE 3-16

CONCENTRATION RATIOS IN THE U.S. PRESCRIPTION DRUG INDUSTRY, BY THERAPEUTIC MARKET: 1968

Therapeutic Market	Four-Firm Concentration Ratio
Anesthetics	69
Antiarthritics	95
Antibiotics-penicillin	55
Antispasmodics	59
Ataractics	79
Bronchial dilators	61
Cardiovascular hypertensives	79
Coronary-peripheral vasodilators	70
Diabetic therapy	93
Diuretics	64
Enzymes-digestants	46
Hematinic preparations	52
Sex hormones	67
Corticoids	55
Muscle relaxants	59
Psychostimulants	78
Sulfonamides	79
Thyroid therapy	69
Unweighted average	68

Source: Vernon, 1971.

distribution. In the pharmaceutical industry, the principal advantage of vertical integration is in achieving economies of scope, which occur when production inputs can be used to produce several different outputs. For example, cumulative drug R&D and promotional expenditures might be used jointly in the production of more than one drug product. Economies of scope might serve as a barrier to entry in the pharmaceutical industry to the extent that the high costs associated with pharmaceutical R&D and promotion raise start-up costs and reduce the ability of new firms to raise sufficient capital to profitably enter the industry.[12]

Evidence from the Section 308 Pharmaceutical Survey provides some indication that pharmaceutical companies are vertically integrated. Of the 139 parent companies for which survey data are available, 129 have operations spanning all four of the industry's major production processes: fermentation (process A), biological and natural extraction (process B), chemical synthesis (process C), and formulation (process D). Three of the parent companies own facilities involved in processes A or C only, and 7 own facilities involved in processes B or D only. At the facility level, 150 of the 244 facilities surveyed engage in only one production process (101 of these firms engage only in formulation), 70 perform two production processes, 16 perform three production processes, and 8 engage in all four major production processes. Nearly 85 percent of the owner and parent companies reported R&D expenditures in the 3 years surveyed.

Thus, many pharmaceutical companies have chosen to integrate vertically. Companies that engage in research and development, production of active ingredients, and formulation take advantage of natural economies of scope that reduce the costs associated with developing and marketing new drugs. The evidence indicates a degree of vertical integration in the industry. The effect of this factor on market structure and market performance cannot be quantified, but the data suggest that major pharmaceutical companies have a degree of market power.

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[12]Vertical integration also can lead to economies of scale where the existence of fixed factors of production such as physical capital can cause unit costs to fall as output rises. It is generally assumed, however, that unit costs are constant across output levels in the pharmaceutical industry. Other advantages of vertical integration might include the ability to capture monopoly/monopsony inefficiency loses and engage in price discrimination (RTI, 1993).

3.3.2 The Characteristics of Demand for Pharmaceuticals

Demand conditions for pharmaceutical manufacturers will help to determine the impact of regulation-induced costs on market prices and outputs. This section examines various characteristics of demand, including the market demographics, the primary market outlets, and the effect of health insurance on the market.

Demand conditions vary significantly among specific drug markets. Differences in regulatory requirements and payment mechanisms are particularly important in determining demand. For example, in the prescription drug market (i.e., new drugs and generics), demand is complicated by the role of health care providers and the presence of health insurance. Unlike most consumer markets, consumers of prescription drugs are not directly involved in purchasing decisions; that is, they do not decide which drugs to take, for how long, and at what dosages. Health care providers act on the patient's behalf in deciding which medical treatment is most appropriate given the patient's health status, financial condition, and insurance coverage. These topics are discussed further below.

The demand for OTC (i.e., nonprescription) drugs, on the other hand, conforms more readily to standard models of consumer demand. OTC drugs are relatively easy to market, available without physician consent, and sold in a relatively competitive environment. As for the demand for other nondurables, the demand for OTC drugs is thought to be positively correlated with income and negatively correlated with price. Consumers identify a specific health need, such as relief from minor pain or cold symptoms, and then search for a product to satisfy that need. Because in most cases a variety of OTC products will meet a given need, demand is heavily influenced by advertising and price.

3.3.2.1 Market Demographics

Like the demand for health care generally, the demand for pharmaceuticals is derived from the demand for good health. A pharmaceutical is both a consumption commodity, since it makes the consumer feel better in the present, and an investment commodity, since it may

extend the life of the consumer. Given this view of pharmaceutical demand, one would expect, all other things being equal, that the demand for pharmaceuticals will be dependent on factors such as the incidence of illness and sociodemographic factors like age, education, and income. Other factors such as perceptions of the seriousness of medical conditions and belief in the efficacy of medical treatment also influence pharmaceutical demand.

Among individuals, pharmaceutical demand is heavily concentrated in the segment of the population that includes people of age 65 and older. In fact, today between 30 and 40 percent of all pharmaceuticals are consumed by persons 65 years old and older (NatWest, 1992). This finding is not surprising given the strong correlation between age and health. As the U.S. population ages over the next several decades, the demand for pharmaceuticals will presumably rise. Since 1980, the number of people age 65 and older has increased at a rate more than twice that of the general population. By 1996, the U.S. Census Bureau predicts that 13 percent of the U.S. population will be over 65 years of age. The U.S. Department of Commerce cites the aging of the U.S. population as one of the main reasons it expects pharmaceutical sales to grow at more than 5 percent annually over the next 5 years (U.S. Department of Commerce, 1993).

3.3.2.2 Major Market Outlets

According to a 1991 study of the pharmaceutical market, retail pharmacies and hospital formularies (i.e., internal pharmacies) dispense over 84 percent of all pharmaceuticals sold in the United States (see Figure 3-8). Direct mail order establishments and HMOs, however, are capturing an increasing share of the market. Pharmaceutical purchases by hospitals have fallen by 6 percent since 1983. This drop is credited, in part, to changes in the Medicare system that have created incentives for hospitals to reduce inpatient services. Drugs once prescribed on an inpatient basis are now more likely to be prescribed on an outpatient basis and thus dispensed through retail pharmacies (OTA, 1993).

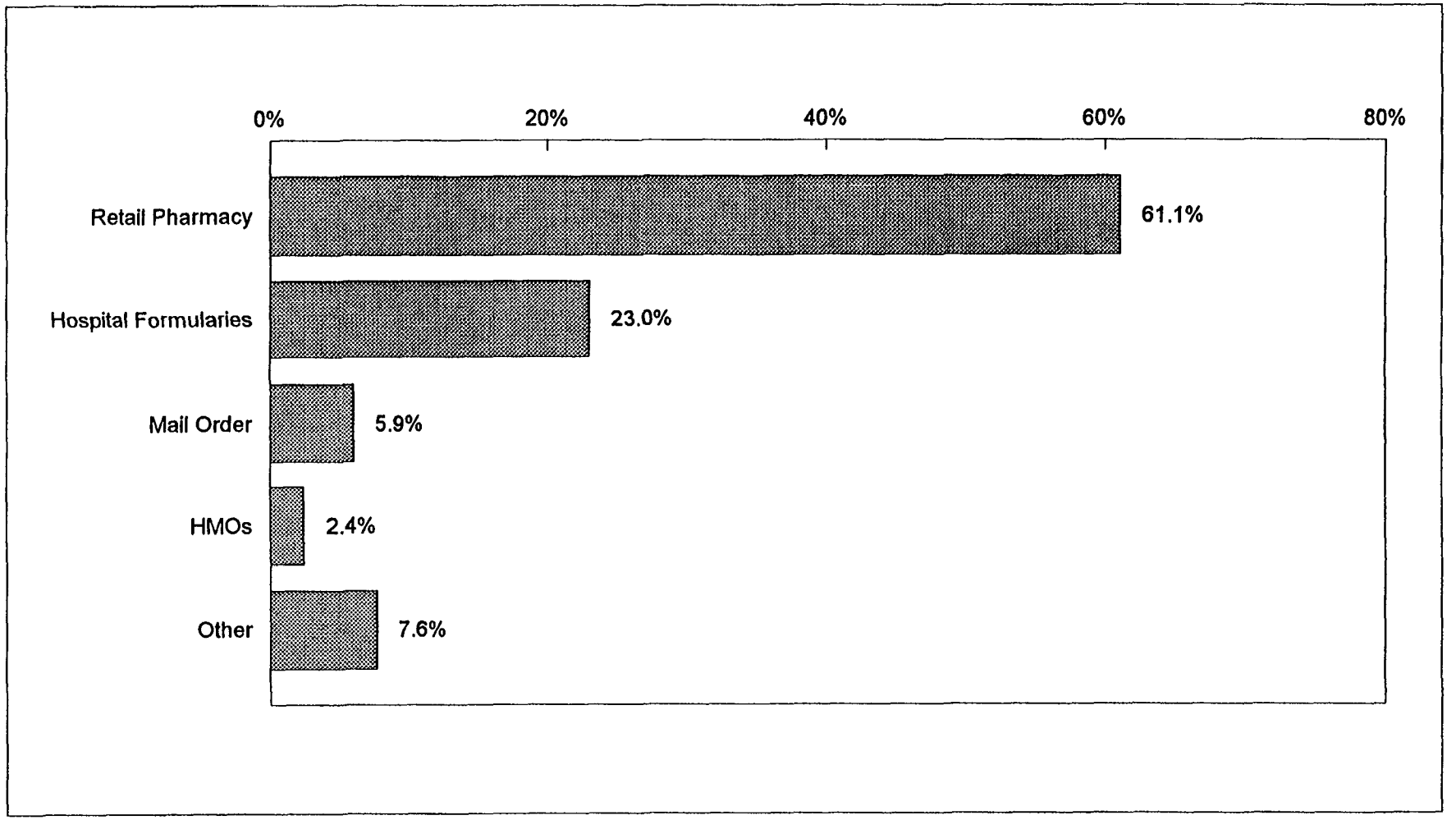

Figure 3-8. U.S Pharmaceutical sales by retail component: 1991.

Source: OTA, 1993.

3.3.2.3 The Role of Health Insurance and Health Care Providers

The demand for prescription drugs is influenced by the complex structure of health insurance and health care provision. It is generally believed that the presence of health insurance makes consumers relatively insensitive to the price of health care. Although not empirically measured, this relationship is expected to apply to the demand for pharmaceuticals as well. The full impact of health insurance on prescription demand is somewhat muted by deductibles and copayments; nonetheless, health insurance almost certainly makes consumers less sensitive to drug prices. Many privately insured Americans are protected from extraordinary medical costs and, thus, have little incentive to limit health care expenditures, including the use of prescription drugs. According to OTA, in 1987, 28 percent of all prescribed drug expenditures were paid for by private insurance, 10 percent by Medicaid, 6 percent by other insurers such as Medicare and Worker's Compensation, and 57 percent by individuals.[13]

The percentage of Americans with public or private health insurance has risen steadily over the past decade to 86 percent today (OTA, 1993). Virtually all health insurance plans cover hospital services, including prescription drugs administered at the hospital. As noted earlier, however, hospitals account for a declining share of total pharmaceutical sales in the United States, dropping from 29 percent in 1983 to 23 percent in 1991 (OTA, 1993). This drop can be attributed to a shift toward a greater reliance on outpatient services, which are often less expensive than hospital care.

Outpatient prescription drug insurance, although less common than inpatient coverage, covers an increasing proportion of Americans. The proportion of outpatient prescription drug purchases paid for by insurers increased from 27 to 43 percent between 1977 and 1987 (OTA, 1993). OTA estimates that in 1987, between 70 and 74 percent of the noninstitutionalized population had at least some outpatient prescription drug coverage. Very few health insurance plans cover 100 percent of prescription drug costs, however. Full coverage is most common in HMOs. Most health insurance plans rely on copayments to limit prescription drug use, although

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[13]Insurance coverage of pharmaceutical expenditures is less than that for health care generally. Approximately 75 percent of all health care expenditures are paid for by insurance.

copayments are generally in the range of $5 or less (OTA, 1993). Private insurers generally cover all drugs approved for market by FDA.[14]

The lack of price sensitivity among consumers is partly offset by increasing sensitivity among insurers. To control rising health care costs, many private and public insurers have moved to limit pharmaceutical expenditures. Many private insurers have created incentives for physicians and consumers to substitute generic drugs for branded drugs. OTA reports that in 1989, 14 percent of all employer-based health insurance plans offered lower copayments for generic drugs than for branded drugs. HMOs are particularly well suited to encourage generic drug utilization because they control physicians more directly than fee-for-service plans. Some HMOs require that their formularies automatically substitute generic drugs for branded drugs unless the physician explicitly instructs otherwise. HMOs and other insurers also try to reduce drug costs by negotiating with manufacturers for volume discounts and relying on direct mail-order pharmacies for drugs that patients need refilled on a regular basis. Medicaid, the nation's major public health insurer, also creates incentives to keep drug costs low.

3.3.2.4 Substitutability among Pharmaceuticals and with Other Medical Services

The availability of close substitutes plays an important role in determining competitive conditions in various drug markets. Generally, the greater the availability of close substitutes in a given market, the more difficult it is to raise prices without losing market share. Substitution occurs within specific drug markets or within the overall health care market (i.e., pharmaceuticals can substitute for other forms of health care), and both of these are discussed below.

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[14]Insurance does not always cover uses of prescription drugs not explicitly approved by FDA. OTA reports that insurers are generally willing to reimburse for "off-label" uses that have been documented as effective in one of three major medical compendia or in multiple published studies. The so called off-label use of prescription drugs is common in many branches of medicine, especially in the treatment of cancer (OTA, 1993).

Substitutability among Pharmaceuticals

The degree of substitutability within or across specific drug markets varies considerably among the patented drug market, the generic drug market, and the OTC drug market.

Patented Drug Market. Patented drugs in the United States enjoy ostensible protection from bioequivalent drugs for a number of years. Effective patent life, however, reflects only the period of time in which a particular compound is formally protected from bioequivalent competitors. Manufacturers of patented drugs may enjoy market exclusivity for many years after patent expiration because of the time needed to approve generic competition, or because the particular market is too small to entice generic competitors.[15] In addition, manufacturers of patented drugs may be able to extend their monopoly power after patent expiration by developing new dosage forms for the same drug. The 1984 Price Act automatically grants a 3-year period of market exclusivity, regardless of patent status, to any drug for which an additional full NDA or NDA supplement has been submitted. With a new dosage form that makes a drug easier to administer or causes fewer side effects, the "pioneer" manufacturer can retain effective monopoly power because its competitors can only market the earlier, and presumably inferior, generation of the product.

The availability of close substitutes for many patented drugs, however, erodes the monopoly power enjoyed by these manufacturers. Drugs of different molecular structure often can compete in the same therapeutic market. For example, calcium channel blockers, angiotensin-converting enzyme inhibitors, beta-blockers, and diuretics all compete in the antihypertension drug market. Between 1987 and 1992, 78 percent of the new drugs approved by FDA were deemed substantially equivalent to already marketed drugs in terms of medical importance and therapeutic usage (FDA, 1992). Thus, it would seem that although patents certainly reduce the availability of identical substitutes during the life of the patent, physicians in many cases can choose from more than one drug therapy to treat a given ailment.

[15]U.S. patent law prohibits companies from conducting commercially valuable research using patented products.

Generic Drug Market. The ascendancy of generic competitors in the prescription drug market has greatly increased the availability of substitutes in the nonpatent drug market. Prior to the 1984 Price Act, generics accounted for a low percentage of total prescriptions given their relatively low price and FDA-guaranteed bioequivalence. Brand loyalty, strict FDA regulation, and state antisubstitution laws that prevented pharmacies from making generic substitutions not specifically requested by a physician all acted to reduce the ability of generics to compete with branded prescriptions. Over the past decade, however, generic competition has increased dramatically, and today generics account for 34 percent of all prescriptions written.

The rise in generic competition is the result of several factors. Perhaps most importantly, both private and public insurers (i.e., Medicaid/Medicare) encourage, if not require, physicians to prescribe generic drugs when available (virtually all states have repealed their antisubstitution laws). Many HMO formularies now automatically prescribe generic drugs unless the physician makes a handwritten request for a branded drug. As mentioned earlier, the 1984 Price Act made it easier for generics to obtain FDA approval as well. In a recent study of 18 drugs whose patents expired in 1983, Grabowski found that nearly all of the manufacturers lost about half of their market share to generic competition within 2 years after initial entry of generic competitors (Grabowski, 1992).

OTC Market. As discussed earlier, the OTC market is much like other competitive commodity markets where there is a high degree of substitutability and demand is relatively sensitive to changes in price. OTC drugs do not face the same regulatory hurdles as prescription drugs and generally do not require such large R&D expenditures. Unlike many prescription drug markets, most OTC drug markets are quite large and thus capable of sustaining many manufacturers of the same product.

Substitutability with Other Medical Services

Physicians typically can serve the patient in the hospital setting or they can provide ambulatory (i.e., outpatient) services, such as prescription medicines. For certain conditions, pharmaceuticals might be a very close substitute for inpatient services (e.g., hospitalization,

surgery). For example, instead of performing surgery, a doctor might prescribe antibiotics to treat infected tonsils. Also, the use of vaccines reduces the prevalence of certain medical conditions such as polio, diptheria, and hepatitis. Some argue that pharmaceuticals can provide a relatively low-cost alternative to other available medical treatments. The Pharmaceutical Manufacturers Association (PMA) estimates that between 1976 and 1985 a new drug therapy for ulcers reduced the cost of treating ulcers by $5.8 billion (PMA, 1989).

Nevertheless, pharmaceuticals are not a very close substitute for most other forms of medical treatments. Certain surgical procedures could be less expensive than drug therapy. For example, minor outpatient surgery at the onset of disease might be less costly than chronic drug treatment. Pharmaceuticals might, in fact, act more as complements to other forms of health care than as substitutes. Many surgical procedures are accompanied with pharmaceutical use both during and after surgery. Pharmaceuticals are used to diagnose certain diseases, which then might be treated through surgery or other medical procedure.

Overall, the extent of substitutability is fairly low. Few pharmaceuticals can be replaced by nonpharmaceutical products and services, although more than one pharmaceutical product is often available to treat a given ailment. Nevertheless, substitutability is limited in the patented drug market where pharmaceutical products are protected from direct competition. The degree of substitution in the prescription drug market increases over time as patents expire and generic equivalents enter the market. Substitution is highest in the OTC market where market entry is relatively easy.

3.3.2.5 Price Elasticity of Demand

Few econometric studies have attempted to measure empirically the effect of price on the demand for pharmaceuticals (i.e., the price elasticity of demand). Four such studies (Reekie, 1978; Lavers, 1989; O'Brien, 1989; and Johnston, 1991) have been published, although only one was conducted in the United States. Their elasticity estimates are presented in Table 3-17, and the results are discussed below.

TABLE 3-17

ESTIMATES OF THE PRICE ELASTICITY OF DEMAND FOR PRESCRIPTION DRUGS

Study Author	Elasticity Estimates	Study Time Frame	Comments
Reekie (1978)	-1.03 to -2.83	1958-1975	Study of individual pharmaceutical products within 25 therapeutically competitive markets. Price of close substitutes included in regression estimate. Calculated separate estimates for therapeutically significant and insignificant drugs.
Lavers (1989)	-0.15 to -0.20	1971-1982	Study of increases in prescription charges for a wide range of pharmaceuticals in the U.K.
O'Brien (1989)	-0.23 -0.64	1969-1977 1978-1986	Study of increases in prescription charges for a wide of range of pharmaceuticals in the U.K.
Johnston (1991)	-0.5	NA	Study of increases in prescription charges for a wide range of pharmaceuticals in Australia.

NA = Not Available.

In separate studies, O'Brien (1989) and Lavers (1989) estimated the effect on demand for a wide range of prescription drugs given an increase in the copayment demanded by Great Britain's National Health Service (NHS). Between 1969 and 1986 the charge for prescription drugs increased substantially in Great Britain from 0.125£ per prescription in 1969 to £2.20 in 1986 (£1986), an increase in real terms by a factor of 17.6. The ratio of patient charges to actual drug cost also has more than doubled over that same time period from 0.21 in 1969 to 0.43 in 1986. The patient charge is a fixed rate and does not vary by prescription type. Men over the age of 65, women over the age of 60, children under 16, and low income groups are exempt from the prescription charges. Approximately 24 percent of the 323 million prescription items dispensed in 1986 included an associated charge.

Both O'Brien and Lavers found a negative relationship between prescription charges and the volume of nonexempt prescription items dispensed. O'Brien's study estimated a price elasticity of demand over the entire period of -0.33, indicating that a 1 percent increase in patient charges leads to a 0.33 percent decrease in prescription drug use. O'Brien also discovered that there has been a gradual change in time in the elasticity. For the period 1969 to 1977, O'Brien calculated a price elasticity of -0.23. Elasticity increased in his study, however, to -0.64 between 1978 and 1986. This finding suggests that prescription drug use became more responsive to price between the study periods. Using similar data, Lavers found an elasticity of demand between -0.15 and -0.20 for the period 1971 to 1982, remarkably close to O'Brien's 1969-1978 estimate.

Johnston (1991) studied a similar situation in Australia where federal policies led to a doubling of prescription charges for a large group of pharmaceuticals in the 1970s. Johnston's estimate of -0.5 indicates slightly more elastic demand than indicated by studies conducted by O'Brien and Lavers.

The studies conducted by O'Brien, Lavers, and Johnston do not consider the possibility of substitution among drug products within specific therapeutic markets, and thus do not provide a complete measure of demand elasticity for individual drug products. Reekie (1978) accounts for product substitution by including the price of therapeutically competing drugs in the estimating equations for individual prescription drugs within therapeutic categories. Using this method, Reekie found more elastic demand responses than either O'Brien, Lavers, or Johnston. Reekie's

estimates ranged from -1.03 to -2.83, depending on the therapeutic significance of the drug and how many years the drug had been on the market. Predictably, Reekie's estimates were most elastic for drugs that had been on the market for a number of years and offered only modest therapeutic gains, and most inelastic for recently introduced drugs that provided important therapeutic gains.

Although these empirical studies are hardly conclusive regarding price elasticity, they do indicate that the demand for pharmaceuticals as a group may be quite inelastic (i.e., between 0 and -1.0), whereas the demand for specific drug product may be relatively elastic (i.e., less than -1.0). The absence of close substitutes for drug therapies in general and the presence of health insurance leads one to expect that the overall demand for pharmaceuticals would be inelastic. Conversely, given the existence of close substitutes for individual drugs (e.g., generics and other therapeutically similar drugs) and the pressure to control health care costs, the demand for specific drugs may be relatively price elastic.

3.3.3 Market Conduct and Performance

To predict regulatory impacts, it is necessary to examine not only how the pharmaceutical industry is structured, but how it behaves. The pharmaceutical industry has been under attack for its seemingly uncompetitive pricing tactics, for having excessive market power related to patent protection advantages, and for other potential barriers to entry discussed above. This section explores the numerous factors pharmaceutical manufacturers consider when setting drug prices, examines the evidence on drug price inflation, and discusses some of the recent actions taken by both industry and government to control drug prices.

A basic element of market performance is the rate of price inflation. The price of drugs has outpaced the rate of general inflation over the last several decades. Table 3-18 presents producer price indices (PPI) for selected drug categories including all drugs, single-source drugs, and multiple-source drugs for selected years between 1981 and 1988. As can be seen in the table, the rate of increase in the PPI for almost all drug types outpaced inflation (i.e., the change in PPI for all commodities) in the seven years studied. Price inflation in the drug industry, however,

TABLE 3-18

CHANGE IN PRODUCER PRICE INDEX FOR PHARMACEUTICALS: 1981-1988

Commodity	Percent Change in PPI 1981-1988	Average Annual Percent Change in PPI	Annual Percent Change in PPI						
			1982	1983	1984	1985	1986	1987	1988
All commodities	9.1	1.3	2.0	1.3	2.4	-0.5	-2.9	2.6	4.0
All drugs	83.5	9.1	7.3	9.5	9.6	9.6	8.7	8.7	10.1
Single-source drugs	78.1	8.6	7.6	7.3	9.8	10.2	8.1	7.3	9.9
Multiple-source drugs	85.8	9.3	7.2	10.4	9.5	9.3	9	9.4	10.1
Originator	105	10.8	8.9	12.9	11.5	10.5	10.4	10	10.9
Non-originator	20	2.7	2.1	0.7	-0.5	3.3	2.1	4.7	6.3

Source: HCFA, 1992.

has not been as severe as for medical care generally. Table 3-19 lists consumer price indices (CPI) for medical care generally, prescription drugs, hospital rooms, and physician services between 1950 and 1985. According to this data, the CPI for drugs rose 187 percent between 1950 and 1985, in contrast to the much larger CPI increases in medical care (651 percent) and hospital rooms (2,245 percent) over the same time period. Interestingly, between 1950 and 1985, the CPI for drugs rose less than the rate of inflation (i.e., the change in CPI for all goods and services). In more recent years (i.e., between 1980 and 1985), however, the CPI for drugs increased twice as much as the general rate of inflation.

3.3.3.1 Patterns of Price Competition

Manufacturers have considerable latitude to set prices according to factors other than marginal cost, such as reputation, demand conditions in different markets (e.g., hospital v. retail), and the company's long-run financial goals.[16] Ultimately, the prescription drug manufacturer must establish a price that can recover the long-run costs associated with pharmaceutical research and development. Typically, manufacturers of patented drugs will set initial price well above marginal cost with the understanding that demand for the product will most likely be fairly inelastic at least until the patent expires and close substitutes become available. The manufacturer uses the time between market launch and patent expiration to recoup R&D costs and generate sufficient profits to finance new product development. The prescription drug manufacturer will devote considerable resources to promoting its product during this period, convincing physicians and patients of the drug's therapeutic benefits and establishing itself as the preeminent supplier of the drug in anticipation of generic competition.

Once the patent expires for a given prescription drug, price-competition becomes a greater consideration. Because patented drugs will have garnered a certain level of brand loyalty from physicians, generic drug manufacturers must enter the market with a relatively low price to establish market share. According to NatWest Investment Banking Group, which monitors the

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[16]Evidence suggests that because of the wide availability of close substitutes in the OTC drug market, OTC drug manufacturers generally act as price takers. It is assumed, therefore, that OTC prices approximate marginal cost.

TABLE 3-19

CHANGE IN CONSUMER PRICE INDEX FOR PHARMACEUTICALS AND SELECTED HEALTH CARE SERVICES: 1950-1985

Year	Percent Change from Previous Year				
	All Goods and Services (%)	**Prescription Drugs (%)**	**Medical Care (%)**	**Hospital (Semiprivate Room) (%)**	**Physician Services (%)**
1950	NA	NA	NA	NA	NA
1955	9.4	9.7	20.7	39.6	18.5
1960	10.4	13.5	22.1	35.5	17.7
1965	6.4	-11.5	13.1	32.5	14.7
1970	23.2	-0.8	34.7	91.6	37.5
1975	38.7	8.0	39.8	62.4	39.5
1980	53.2	41.6	57.7	77.4	59.0
1985	30.6	71.5	51.6	69.6	48.1
1950-1985	**339.2**	**186.7**	**650.7**	**2,244.9**	**622.5**

NA = Not Applicable

Source: Feldstein, 1988.

generic industry, the first generic manufacturer to enter a given market generally prices its drug around 30 percent below the brand-name drug and realizes a gross margin of about 55 percent. The second generic manufacturer to enter a market usually prices its product at about a 40 percent discount, and the third entrant at about a 50 percent discount. NatWest estimates that by the time the fourth generic manufacturer enters a market, generic prices are half of brandname prices and gross margins will have fallen to 30 percent or less (NatWest, 1992). The advantage of being the first generic entrant in a given market is clear.

Contrary to expectations, manufacturers of branded drugs do not attempt to deter entry into their markets by competing with generics on the basis of price. Rather, studies show that in most cases pioneer firms continue to increase prices following entry at the same rate as before patent expiration. Some industry experts believe that brand-name drug manufacturers do not have the same force or the breadth of product line to compete with the major generic manufacturers on the basis of price (NatWest, 1992). Branded manufacturers trust that despite the relatively high price of their drug, physicians will continue to prescribe their drug over generic drugs because they are familiar with it and because many question the quality of generic drugs even though they have been deemed bioequivalent by FDA. Nonetheless, studies show that branded drugs lose market share rapidly following patent expiration. According to one study, brand-name drug market share declines to only 40 percent within 5 years following patent expiration (Grabowski, 1992). Within 6 years, brand name drugs command only 20 percent of the market. In its study of the industry, OTA made various market analyses using an assumption that within 10 years brand name drugs will have left the market altogether (OTA, 1993).

3.3.3.2 Government Actions to Limit Pharmaceutical Price Increases

In the last several years, industry as well as state and federal governments have taken measures to control drug price inflation. For example, in 1990, 10 companies with over 40 percent of the U.S. pharmaceutical market share agreed to keep drug prices in line with inflation (Solomon, 1993). The PMA, which has spearheaded the effort, continues to enlist new companies in the price control program. Today, 16 pharmaceutical companies in all have agreed to keep increases in the price of their products at or below the rate of inflation.

Federal and state governments have recently taken steps to control drug prices through the Medicaid system. Medicaid provides health insurance for U.S. citizens of limited financial means and is funded jointly by states and the federal government. Medicaid currently covers outpatient prescriptions in 49 states and the District of Columbia, and accounts for nearly 15 percent of all outpatient prescription drug expenditures in the U.S. today (OTA, 1993). Retail pharmacies dispense prescriptions at little or no cost to Medicaid recipients. State Medicaid agencies then reimburse pharmacies according to specified price tables. Some 22 states require copayments ranging between $0.50 and $3.00 per prescription (OTA, 1993). States must cover all drugs approved by the FDA.

The 1990 Omnibus Budget Reconciliation Act (PL 101-508) altered state Medicaid reimbursement policies. Prior to 1990, state Medicaid agencies reimbursed pharmacies according to the pharmacy's acquisition cost plus a reasonable markup for single-source drugs, at no more than 150 percent of the lowest published price for multiple-source drugs.[17] In 1990, however, Medicaid instituted a new reimbursement scheme whereby pharmaceutical manufacturers must give state Medicaid agencies a rebate on their drug purchases. The rebate is designed to keep the cost of Medicaid drugs at or below the rate of inflation. Beginning in 1994, Medicaid will institute more stringent reimbursement policies that will create strong disincentives for manufacturers to introduce drugs at above-average prices. The law will effectively reduce revenues for manufacturers in the Medicaid segment of the pharmaceutical market. The mechanics of the new reimbursement policy are still being developed, and its effect on drug prices is not yet known. National health care reform could alter Medicaid drastically and might include its new incentives for controlling health care costs generally and drug costs in particular.

The general trend toward cost-containment in the health care field could ultimately increase the level of price competition in the prescription drug market. Thus, administrative actions as well as consumer and market behavior combine to determine pricing patterns in the industry.

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[17]Single-source drugs are those available from only one manufacturer (i.e., a patented name-brand drug). Multiple-source drugs are available from several manufacturers (i.e., generics).

3.3.4 Conclusions about EIA Assumptions on Cost Passthrough Potential

Because regulatory costs associated with effluent guideline limitations for the pharmaceutical industry can affect a large portion of the industry, the industry as a whole might be able to pass through regulatory costs to the consumer in the form of higher drug prices. Individual companies (especially those marketing generic and OTC drugs), however, will have less latitude to raise prices to the extent that their competitors do not face the same regulatory costs. Nevertheless, many companies appear to have sufficient market power to pass through regulatory costs.

The price elasticity data also suggests that at least some of the regulatory costs can be passed on to consumers. The price elasticity studies indicate that demand is highly inelastic in the case of patented drugs with no substitutes (in the range of -0.2 to -0.4), mildly inelastic for generic drugs (-0.6 to -0.8), and elastic for OTC drugs (less than -1.0). Thus, if the EIA distinguished among these three market segments, regulation-induced price increases in each component of the industry could be examined. Unfortunately, product-specific cost and price data were not available from the Section 308 Pharmaceutical Survey, and so the EIA can examine impacts only on the drug market as a whole.

Despite the evidence relating to market power and price elasticities, the EIA primarily will use the conservative assumption that manufacturers cannot pass through compliance costs except when impacts on consumers are investigated. In this latter case a 100 percent cost passthrough assumption is used. The assumption of no cost passthrough maximizes the potential regulatory impacts on manufacturers, whereas an assumption of 100 percent cost passthrough maximizes the potential regulatory impacts on consumers.

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SECTION FOUR

ECONOMIC IMPACT ANALYSIS METHODOLOGY OVERVIEW AND COMPLIANCE COST ANALYSIS

The economic impact analysis (EIA) of effluent guidelines and standards for the pharmaceutical industry covers several components necessary for identifying and characterizing the potential impact of regulatory compliance costs at the facility and owner company levels, as well as other secondary impacts. The fundamental component of the methodology is the facility-level analysis, which identifies facilities likely to close because of incremental compliance costs. This analysis is performed in Section Five. Results of the facility analysis, combined with additional firm-level and other data, provide the basis for determining the extent of secondary impacts on owner companies (Section Six), employment (Section Seven), foreign trade (Section Eight), small businesses (Section Nine), and specific demographic groups (Section Ten).

Together, the impact analyses offer a comprehensive assessment of economic impacts at all relevant levels of economic activity. Figure 4-1 shows how the three principle individual models (the cost annualization model, the facility closure model, and the owner company model) relate to one another, the inputs required for these models, and the outputs they generate. At the heart of the EIA is the cost annualization model, which uses facility-specific cost data and other inputs to determine the annualized capital and operating and maintenance (O&M) costs of improved wastewater treatment. Annualized cost data feed into the facility analysis, which investigates the economic impacts on individual manufacturing facilities irrespective of ownership. The company-level analysis examines the possible effects of increased regulatory costs and facility closures on companies that own one or more affected pharmaceutical establishments. The EIA then explores the impact of facility and owner company closures on employment and other measures of community welfare. Additional analyses explore how increased compliance costs will affect the balance of trade and whether small businesses and certain demographic groups will experience disproportionate impacts.

Ideally, the EIA methodology would include an analysis at the product-line level of detail. Higher compliance costs could be expected to cause product-line closures at some facilities that

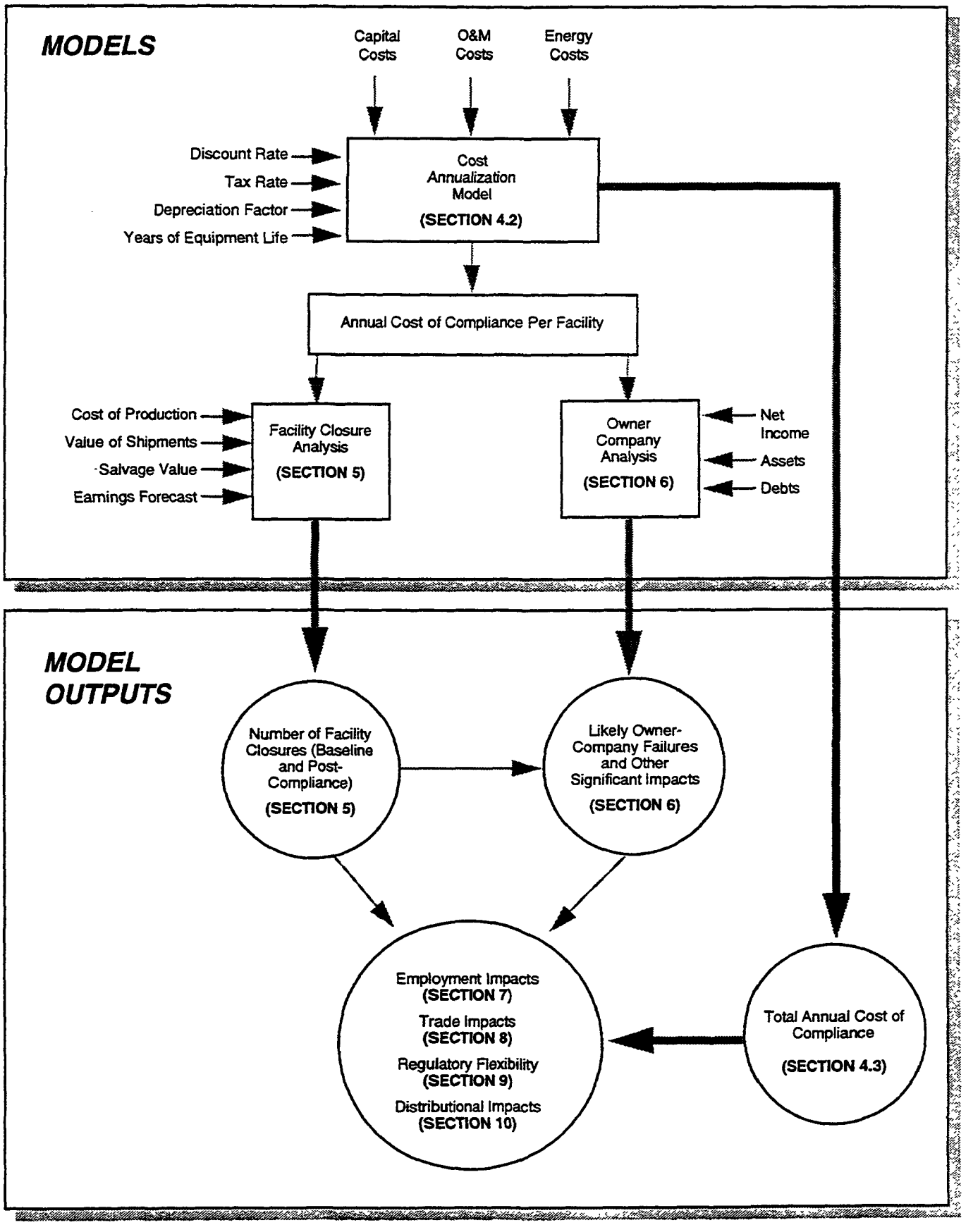

Figure 4-1. Interrelationship of EIA methodology components.

remain in operation. An analysis of product-line closures, however, is not possible because the Section 308 Pharmaceutical Survey did not collect financial information on individual product lines. The facility closure and owner company-level analyses, however, are expected to be adequate for evaluating impacts on this industry.

The remainder of this section describes the cost annualization model (Section 4.1) and employs the model to calculate the total annualized cost of compliance for the pharmaceutical industry as a whole (Section 4.2).

4.1 COST ANNUALIZATION MODEL

4.1.1 Purpose of Cost Annualization

The cost annualization model estimates the annual compliance cost to the facility of new pollution control equipment and operation. Cost annualization calculations consider the annual cash outflow for the facility given the tax-reducing effects of expenditures (i.e., depreciation allowances allowed on corporate income tax). The cost of additional pollution control equipment can be divided between two components: the initial capital investment to purchase and install the equipment, and the annual cost of operating and maintaining such equipment (O&M costs). Capital costs are a one-time expense incurred only at the beginning of the equipment's life, and O&M costs are incurred every year of the equipment's operation. The engineering cost model used to estimate facility compliance cost defines both capital and O&M costs.[1]

To determine the economic feasibility of upgrading a facility, the costs must be compared against the facility's income statement and its capital structure. The initial capital outlay should not be compared against the facility's income in the first year because this capital cost is incurred only once. Additionally, it reflects the common practice of financing capital expenditures. This

[1]Cost data from Radian Corp.'s engineering cost model are reported for capital costs, O&M costs, and energy costs. For simplicity, the cost annualization model treats energy costs as part of O&M costs.

initial investment, therefore, should be spread out over the equipment's life. Annualizing costs is a technique that allocates the capital investment over the lifetime of the equipment, incorporates a cost-of-capital factor to address the costs associated with raising or borrowing money for the investment, and includes annual O&M costs. The resulting annualized cost represents the average annual payment that a given company will need to make to upgrade its facility. The annualized cost is analogous to a mortgage payment, which spreads the one-time investment in a home into a series of constant monthly payments.

4.1.2 Inputs and Assumptions

4.1.2.1 The Regulatory Options

The engineering cost estimates that feed into the cost annualization model are based on a set of regulatory options developed by EPA. The following section summarizes these options. The derivation of the initial engineering cost estimates under each option is discussed in the Development Document (EPA, 1995).

The pollution control options are divided into those for direct dischargers and those for indirect dischargers. Within each discharger category, additional distinctions are made. First, all technology options are divided between industry subcategories, with A and C industry subcategories (representing facilities that use fermentation or biological and chemical synthesis processes) being distinguished from B and D industry subcategories (representing facilities that use biological and natural extractive processes or that are formulators of pharmaceutical products). For direct dischargers, the technologies are then further broken down into Best Practicable Control Technology Currently Available (BPT), Best Conventional Pollutant Control Technology (BCT), Best Available Technology Economically Achievable (BAT), and New Source Performance Standards (NSPS) options; for indirect dischargers, Pretreatment Standards for Existing Sources (PSES) and Pretreatment Standards for New Sources (PSNS) technology options are examined.

Table 4-1 presents the regulatory options addressed in this analysis and defines the technologies associated with each option. The abbreviations used to briefly identify the options (e.g., BAT-A/C#1, which represents the BAT control technology option 1 for the industry subgroup consisting of facilities using the A and/or C production processes) are introduced in this table. In all, there are 37 separate options, 21 for A/C facilities and 16 for B/D facilities. None of these options is a zero-discharge option. Zero discharge options were eliminated because EPA determined that they were not technologically feasible.

As Table 4-1 shows, five BPT options were evaluated for A/C facilities that are direct effluent dischargers. BPT-A/C#1 consists of current biological treatment, while BPT-A/C#2 is based on advanced biological treatment along with cyanide destruction. BPT-A/C#3 includes the same processes as BPT-A/C#2, plus effluent filtration. BPT-A/C#4 also includes the same processes as BPT-A/C#2, but adds a polishing pond. Finally, BPT-A/C#5 also includes BPT-A/C#2 processes, along with both effluent filtration and a polishing pond. Only three BPT options are proposed for the direct discharging B/D facilities. BPT-B/D#1 consists of current biological treatment, while BPT-B/D#2 entails advanced biological treatment. BPT-B/D#3 adds effluent filtration to the processes required for BPT-B/D#2.

Three BCT options for A/C facilities and two BCT options for B/D facilities were evaluated for direct dischargers.[2] All of these options require advanced biological treatment. In addition to the advanced biological treatment, BCT-A/C#1 adds effluent filtration and BCT-A/C#2 adds a polishing pond. BCT-A/C#3 adds both effluent filtration and a polishing pond to the use of advanced biological treatment. BCT-B/D#1 requires only advanced biological treatment, while BCT-A/C#2 adds effluent filtration to the advanced biological treatment.

Four BAT options, which include advanced biological treatment as a minimum, were evaluated for direct discharging A/C facilities. BAT-A/C#1 requires the use of advanced

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[2]The Development Document (U.S. EPA, 1995) refers to these options as BCT-A/C #3, #4, and #5 and BCT-B/D #2 and #3 because several less stringent BCT options (equivalent to BPT-A/C #1 and #2 and BPT-B/D #1) here were considered before the preferred BPT option was selected. These options are not considered here because they were equal to or less stringent than the selected BPT options, thus are associated with no incremental costs. This document does not address options that are not incremental to BPT.

TABLE 4-1

REGULATORY OPTIONS CONSIDERED IN THE ECONOMIC IMPACT ANALYSIS

Type of Option	Name	Description
Direct Dischargers		
Best Practicable Technology	BPT-A/C#1	Current biological treatment
	BPT-A/C#2	Advanced biological treatment + cyanide destruction
	BPT-A/C#3	Advanced biological treatment + cyanide destruction + effluent filtration
	BPT-A/C#4	Advanced biological treatment + cyanide destruction + polishing pond
	BPT-A/C#5	Advanced biological treatment + cyanide destruction + effluent filtration + polishing pond
	BPT-B/D#1	Current biological treatment
	BPT-B/D#2	Advanced biological treatment
	BPT-B/D#3	Advanced biological treatment + effluent filtration
Best Conventional Technology*	BCT-A/C#1	Advanced biological treatment + effluent filtration
	BCT-A/C#2	Advanced biological treatment + polishing pond
	BCT-A/C#3	Advanced biological treatment + effluent filtration + polishing pond
	BCT-B/D#1	Advanced biological treatment
	BCT-B/D#2	Advanced biological treatment + effluent filtration
Best Available Technology	BAT-A/C#1	Advanced biological treatment + cyanide destruction with nitrification where necessary
	BAT-A/C#2	Advanced biological treatment + cyanide destruction + in-plant steam stripping
	BAT-A/C#3	Advanced biological treatment + cyanide destruction + in-plant steam stripping/distillation
	BAT-A/C#4	Advanced biological treatment + cyanide destruction + in-plant steam stripping/distillation + activated carbon
	BAT-B/D#1	Advanced biological treatment
	BAT-B/D#2	Advanced biological treatment + in-plant steam stripping

TABLE 4-1 (cont.)

Type of Option	Name	Description
Best Available Technology (Cont.)	BAT-B/D#3	Advanced biological treatment + in-plant steam stripping/distillation
	BAT-B/D#4	Advanced biological treatment + in-plant steam stripping/distillation + activated carbon
New Source Performance Standard	NSPS-A/C#1	Advanced biological treatment + cyanide destruction + in-plant steam stripping/distillation
	NSPS-A/C#2	Advanced biological treatment + cyanide destruction + in-plant steam stripping/distillation + activated carbon
	NSPS-B/D#1	Advanced biological treatment + in-plant steam stripping/distillation
	NSPS-B/D#2	Advanced biological treatment + in-plant steam stripping/distillation + activated carbon
Indirect Dischargers		
Pretreatment Standards for Existing Sources	PSES-A/C#1	In-plant steam stripping + cyanide destruction
	PSES-A/C#2	In-plant steam stripping/distillation + cyanide destruction
	PSES-A/C#3	In-plant steam stripping/distillation + cyanide destruction + end-of-pipe advanced biological treatment
	PSES-A/C#4	In-plant steam stripping/distillation + cyanide destruction + end-of-pipe advanced biological treatment + activated carbon
	PSES-B/D#1	In-plant steam stripping
	PSES-B/D#2	In-plant steam stripping/distillation
	PSES-B/D#3	In-plant steam stripping/distillation + activated carbon
Pretreatment Standard for New Sources	PSNS-A/C#1	In-plant steam stripping/distillation + cyanide destruction
	PSNS-A/C#2	In-plant steam stripping/distillation + cyanide destruction + end-of-pipe advanced biological treatment
	PSNS-A/C#3	In-plant steam stripping/distillation + cyanide destruction + end-of-pipe advanced biological treatment + activated carbon
	PSNS-B/D#1	In-plant steam stripping/distillation
	PSNS-B/D#2	In-plant steam stripping/distillation + activated carbon

*In the Development Document (EPA, 1995), BCT-A/C#1, 2, and 3 in this table actually correspond to Options 3, 4, and 5, and BCT-B/D#1 and 2 in this table correspond to #2 and #3. The options not listed in this table were never considered in this report because they are equal to or less stringent than the requirements of the selected BPT option, and thus no incremental costs are incurred over BPT.

biological treatment, as well as cyanide destruction and nitrification where necessary. BAT-A/C#2 includes the same processes at BAT-A/C#1, along with in-plant steam stripping (both steam stripping and distillation control ammonia, however, so nitrification is not necessary). BAT-A/C#3 replaces steam stripping with in-plant steam stripping/distillation. BAT-A/C#4 adds activated carbon treatment to the processes required in BAT-A/C#3. Four BAT options based on the use of advanced biological treatment also were evaluated for direct discharging B/D facilities. BAT-B/D#1 involves the use of advanced biological treatment alone. BAT-B/D#2 adds in-plant steam stripping to advanced biological treatment. BAT-B/D#3 replaces steam stripping with in-plant steam stripping/distillation. Finally, BAT-B/D#4 adds activated carbon treatment to BAT-B/D#3.

Also for direct dischargers, two NSPS options that use advanced biological treatment at a minimum were evaluated for A/C facilities. NSPS-A/C#1 involves the use of cyanide destruction and in-plant steam stripping/distillation, along with advanced biological treatment. NSPS-A/C#2 adds to this option activated carbon treatment. Two NSPS options also were evaluated for B/D facilities. NSPS-B/D#1 involves the use of advanced biological treatment plus in-plant steam stripping/distillation. NSPS-B/D#2 adds activated carbon treatment to this option. The selected NSPS options are discussed in Section Eleven, Impacts on New Sources.

Four PSES options were evaluated for A/C facilities. PSES-A/C#1 consists of the use of in-plant steam stripping and cyanide destruction. PSES-A/C#2 consists of the use of in-plant steam stripping/distillation. PSES-A/C#3 adds end-of-pipe advanced biological treatment to PSES-A/C#2. PSES-A/C#4 adds activated carbon to the processes required for PSES-A/C#3. For B/D facilities, three PSES options were evaluated. PSES-B/D#1 requires the use of in-plant steam stripping. PSES-B/D#2 requires the use of in-plant steam stripping/distillation, while PSES-B/D#3 consists of the use of activated carbon along with in-plant steam stripping/distillation.

Three PSNS options were evaluated for A/C facilities that are indirect dischargers. PSNS-A/C#1 involves the use of in-plant steam stripping/distillation and cyanide destruction, while PSNS-A/C#2 adds end-of-pipe advanced biological treatment to the processes required for PSNS-A/C#1. PSNS-A/C#3 adds activated carbon treatment to PSNS-A/C#2. Two PSNS

of in-plant steam stripping/distillation, while PSNS-B/D#2 consists of the use of both in-plant steam stripping/distillation and activated carbon. The selected PSNS options are evaluated in Section Eleven, Impacts on New Sources.

Although all of these options are evaluated in the EIA, EPA has selected the following options for inclusion in the regulation:

- For direct discharging A/C facilities, BPT-A/C#2 is selected for conventional pollutants and BAT-A/C#2 is required for nonconventional pollutants.
- For direct discharging B/D facilities, BPT-B/D#2 is selected for conventional pollutants and BAT-B/D#1 is required for nonconventional pollutants.
- NSPS-A/C#1 is selected for new A/C facilities that are direct dischargers (this option is identical to BAT-A/C#3).
- NSPS-B/D#1 is selected for new B/D facilities that are direct dischargers (this option is identical to BAT-B/D#3).
- PSES-A/C#1 is selected for A/C facilities that are indirect dischargers.
- PSES-B/D#1 is selected for B/D facilities that are indirect dischargers.
- PSNS-A/C#1 is selected for new A/C facilities that are indirect dischargers (this option is identical to PSES-A/C#2).
- PSNS-B/D#1 is selected for new B/D facilities that are indirect dischargers (this option is identical to PSES-B/D#2).

As can be seen in Table 4-1, the selected BAT options include all of the processes mandated in the selected BPT options.

EPA also investigated an alternative regulatory scenario for existing sources and is soliciting comments on this alternative. The alternative regulatory scenario for existing sources consist of BAT-A/C#3, BAT-B/D#1, PSES-A/C#2, and PSES-A/C#2. Thus, in this alternative scenario (with the exception of BAT-B/D#1), in-plant steam stripping is replaced by in-plant steam stripping/distillation. The impacts of this alternative regulatory scenario (referred to as the in-plant steam stripping/distillation scenario) are discussed briefly in comparison with the selected regulatory scenario for existing sources.

4.1.2.2 The Cost Annualization Model

Table 4-2 presents the cost annualization model using assumed data for illustrative purposes. The inputs and assumptions for the analysis are listed above the spreadsheet. The first input is the *facility code* for the facility analyzed. The second line is the type of facility (e.g., A/C direct or B/D indirect). The third line presents the regulatory *option* or alternative for which the annualized costs are calculated.[3] The fourth and fifth lines are the option's *capital* and *O&M* costs, developed by Radian Corp. (Development Document, EPA, 1995). These costs are provided in terms of 1990 dollars for comparison with 1990 survey data.

The *life of the asset* is determined according to the Internal Revenue Code's classes of depreciable property. Fifteen-year property is assumed to have a class life of 20 to 25 years—a typical life span for the equipment considered in the costing analysis. According to the U.S. Master Tax Guide, 15-year property includes such assets as municipal wastewater treatment plants (page 311, Commerce Clearinghouse, Inc., 1991). Thus, for the purposes of calculating depreciation, most components of the capital cost for a pollution control option would be considered 15-year property.

The *discount rate* is used in calculating the present values of the cash flows. The discount rate reflects pharmaceutical facilities' average cost of capital. The discount rate used in the EIA is based on the discount rates reported by pharmaceutical facilities in the Section 308 Survey. Reported discount rates of less than 4 percent and more than 19 percent, however, were not included in the discount rate calculation. Discount rates of less than 4 percent were thought to be too low for inclusion in the calculation because banks were charging a prime rate of nearly 11 percent and the Federal Reserve Bank of New York had instituted a discount rate of nearly 7 percent during that time. Similarly, discount rates of more than 19 percent were considered to represent a hurdle rate (the rate of return desired for a project before it will be undertaken), rather than a true discount rate. Once these discount rates were excluded, the mean and median of the remaining discount rates reported in the survey were calculated. The mean was 11.4 and

[3]The terms "option" and "alternative" are used interchangeably in this section.

TABLE 4-2

SAMPLE SPREADSHEET FOR ANNUALIZING COSTS

Inputs

Facility Code:	30387
Facility Type:	A/C
Discharge Type:	Direct
Option:	BAT-A/C#1
Initial Capital Cost ($) (Line A):	$614,487
Annual Operation & Maintenance Cost ($) (Line B)	$58,710
Life of Asset (yrs.)	15
Real Discount Rate:	11.4%
Marginal Income Tax Rates:	
Federal	34.00%
State	6.75%
Combined (Line C)	40.75%

1	2	3	4	5	6	7	8
Year	*Depreciation* Rate	Depreciation *For Year* (Line A *Col 2)	Tax Shield From *Depreciation* (Line C *Col 3)	*O&M Cost* (Line B)	O&M *Tax Shield* (Line C *Col 5)	Cash Outflow *(Line A in Yr 1;* Line B in Yrs 2-16)	Cash Outflow After *Tax Shields* (Col M-(Col G+Col K))
1	0.000%	$0	$0	$0	$0	$614,487	$614,487
2	10.000%	$61,449	$25,040	$58,710	$23,924	$58,710	$9,745
3	9.643%	$59,254	$24,146	$58,710	$23,924	$58,710	$10,640
4	9.272%	$56,975	$23,217	$58,710	$23,924	$58,710	$11,568
5	8.886%	$54,601	$22,250	$58,710	$23,924	$58,710	$12,536
6	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627
7	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627
8	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627
9	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627
10	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627
11	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627
12	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627
13	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627
14	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627
15	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627
16	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627
Sum	100.00%	$614,487	$250,403	$880,650	$358,865	$1,495,137	$885,869
Present Value[a]		$317,124	$129,228	$413,017	$168,304	$1,027,504	$729,971

Present Value of Incremental Costs (Present Value of Col 8):	$729,971
Annualized Cost [a]:	$101,207

Note: Spreadsheet assumes that a modified accelerated cost recovery system (MACRS) is used to depreciate capital expenditures (see Section 4.1.2.3).
[a] See Table 4-3 for formulas.

the median was 11.2. This EIA uses the discount rate of 11.4 percent, which generates a slightly more conservatively high estimate of annual costs.

The final inputs to the model are the federal and average state *tax rates*, which are used in determining the facility's tax benefit or tax shield. A facility is allowed to offset taxable income both with incremental O&M costs and with the depreciation of the equipment itself (page 310, Commerce Clearinghouse, Inc., 1991). These tax rates represent the marginal federal tax rate (the rate applied to corporate income above $335,000)[4] and the average state corporate income tax rate (see Appendix A). A facility could be located in one state, while its corporate headquarters is located in a second state and the corporation's holding company is located in a third state. Given the uncertainty over which state tax rates apply to a given facility's revenues, the average state tax rate is used in the cost annualization model.

4.1.2.3 Annualizing Costs

Two assumptions were made in annualizing compliance costs. The first assumption is that the facility owners will be using the Modified Accelerated Cost Recovery System (MACRS) to depreciate capital investments, which reduces the effective cost to the facility of purchasing and operating the pollution control equipment. The second is that a 1-year delay occurs between the purchase of pollution control equipment and its operation. The details of these assumptions and their impact on the results of the MACRS cost annualization model are presented in Appendix A.

In Table 4-2, the spreadsheet contains numbered columns that calculate the cost of the investment to the facility. The first column lists each year of the equipment's life span, from its

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[4]The cost annualization model uses the 34-percent marginal federal income tax rate. Adjustments to this rate could not be made to account for S corporations because the survey did not identify corporate type.

installation through its 15-year depreciable lifetime.[5] Column 2 represents the portion of capital costs that can be written off or depreciated each year. These rates are based on MACRS as derived in Appendix A. Multiplying these rates times the capital cost gives the annual amount the facility can depreciate (Column 3). These amounts will be used to offset annual income. Column 4 shows the tax benefit provided from the depreciation expense—the overall tax rate times the depreciation amount for the year.

Column 5 of Table 4-2 is the annual O&M expense. These costs are constant, except in Year 1 when no O&M costs are incurred because the equipment is not yet in service. Column 6 is the tax shield or benefit provided from expensing the O&M costs. Column 7 lists the facility's total expenses associated with the additional pollution control equipment. It is assumed that capital costs are incurred during the first year when the equipment is installed, and continue for the life of the equipment. Added to this for all years except Year 1 is each year's O&M expense. Column 8 lists the annual cash outflow minus the tax shields from the O&M expenses and depreciation, because the facility will recoup these costs as a result of reduced income taxes.

Once the yearly cost to the facility has been determined, it is transformed into a constant cost stream. The bottom line in Column 8 represents the present value of the costs over the equipment's life span. The annualized cost is calculated as the 15-year annuity that has the same present value as the bottom line in Column 8 of Table 4-2. The annualized cost represents the annual payment required to finance the cash flows after tax shields. In essence, paying the annualized cost every year and paying the amounts listed in Column 8 for each year are equivalent. In this example, the capital investment of $614 thousand and annual O&M cost of

[5]An asset's depreciable life can differ from its actual life. The pollution control equipment considered in this analysis is in the 15-year property class; however, the actual life could extend to 25 years. Under these circumstances, up to 10 years of O&M expenses would be excluded from the present value calculations. The effect of excluding such costs, however, would not be large, since in Year 16, a dollar is worth only $0.20 (assuming a 11.4 percent discount rate). Furthermore, by adding more years to the calculation, the annualized cost is lowered, because, even though O&M costs are incurred during the extra years, payments for the capital investment will be spread over a longer time period.

$59 thousand (1990 $) result in an annualized cost of $101 thousand.[6] Table 4-3 presents the equations used to calculate present value and annual cost.

The present value of the cost for incremental pollution control is used in the closure analysis (Section Five). The *social* cost of the regulation differs from the *compliance* cost. The social cost is the full value of resources used, ignoring tax shields, which affect only the distribution of burdens between industry and government[7]. The cost to society, therefore, is always higher than the cost to industry. Results of the calculation of aggregate compliance costs are presented below in Section 4.2.

4.2 TOTAL ANNUALIZED COMPLIANCE COSTS

Total annualized compliance costs are calculated by aggregating the annualized compliance costs for all affected facilities, based on the output of the cost annualization model. Table 4-4 presents the results of this aggregation for A/C direct dischargers by category and by option. BPT-A/C#1 represents the baseline regulatory scenario. BPT-A/C#1 also is a proposed option for this regulation and, consequently, has been evaluated as such in this EIA. Because BPT-A/C#1 has already been implemented, however, it generates no economic impacts. As the table shows, the total posttax annualized costs for the 24 A/C direct discharge facilities, excluding the zero costs associated with BPT-A/C#1, range from $3.5 million for BCT-A/C#1 to $76.1 million for BAT-A/C#4. Average costs per facility range from $0.1 million to $3.2 million per year, depending on the option, not including BPT-A/C#1.

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[6]Note that the annualized cost can be determined in two ways. The first way is to calculate the annualized cost as the difference between the annuity value of the cash flows (Column 7) and the tax shields (Columns 4 and 6). The second way is to calculate the annuity value of the cash flows after tax shields (Column 8). Both methods yield the same value.

[7]When social costs are derived, the appropriate discount rate is the social discount rate, currently held to be 7 percent by OMB.

TABLE 4-3

PRESENT VALUE EQUATIONS USED IN THE COST ANNUALIZATION MODEL

$$NET\ PRESENT\ VALUE = v_1 + \sum_{i=2}^{n} \frac{v_i}{(1+int)^{i-1}}$$

where:
$v_1 ... v_n$ = series of cash flows
int = interest range
n = number of cash flows
i = current iteration

$$ANNUALIZED\ PAYMENT = principle\ x\ \frac{int}{1-(int+1)^{-n}}$$

where:
int = periodic interest rate
n = term

TABLE 4-4

COMPLIANCE COSTS FOR A/C DIRECT DISCHARGERS (1990 $)

Option Number	Total Capital Costs	Total O&M Costs	Total Posttax Annualized Costs	Average Annual Cost per Facility*
BPT Option Costs				
BPT-A/C#1	$0	$0	$0	$0
BPT-A/C#2	$14,742,689	$7,046,870	$5,681,474	$236,728
BPT-A/C#3	$21,891,929	$7,488,423	$6,717,116	$279,880
BPT-A/C#4	$37,455,760	$21,764,186	$16,665,409	$694,392
BPT-A/C#5	$44,204,216	$23,420,779	$18,359,400	$764,975
BCT Option Costs				
BCT-A/C#1	$16,875,845	$2,957,486	$3,551,327	$147,972
BCT-A/C#2	$32,439,676	$16,545,942	$13,102,463	$545,936
BCT-A/C#3	$39,188,132	$19,054,074	$15,288,512	$637,021
BAT Option Costs				
BAT-A/C#1	$15,050,112	$8,544,621	$6,580,502	$274,188
BAT-A/C#2	$56,392,127	$35,689,088	$26,779,144	$1,115,798
BAT-A/C#3	$68,035,029	$57,980,678	$40,931,284	$1,705,470
BAT-A/C#4	$92,851,663	$114,229,651	$76,143,696	$3,172,654

*Total Posttax Annualized Costs divided by the total number of A/C direct discharge facilities.

Note: These numbers are for all facilities and do not reflect closures predicted by the analyses in this report.

Source: ERG estimates based on Radian Corp. capital and operating costs estimates for pollution control equipment.

Table 4-5 presents the same information for the 14 B/D direct dischargers. Again, BPT-B/D#1 is the baseline, as well as a proposed option for this regulation. Total posttax annualized costs, excluding the zero costs associated with BPT-B/D#1, range from $0.3 million to $2.9 million, or about $23 thousand to $207 thousand per facility per year, depending on the option chosen.

As discussed earlier in this section, all direct discharging facilities discharge both conventional and nonconventional pollutants and therefore must implement both BAT and BPT selected options. The selected BAT options include all of the processes required in the selected BPT options. Consequently, the results of the cost analysis for the selected BAT options (BAT-A/C#2 and BAT-B/D#1) represent the full costs (i.e., include BPT-A/C#2 and BPT-B/D#2) for all existing direct discharging facilities.

Table 4-6 presents compliance costs for indirect dischargers, both A/C (88 facilities) and B/D (153 facilities). The total posttax annualized costs to all A/C facilities range from $34.6 million to $123.0 million per year, or $0.4 to $1.4 million per year per facility on average. For the B/D facilities, the aggregate costs range from $7.9 to $63.5 million annually, at an average cost per facility per year of approximately $52 thousand to $415 thousand.

Table 4-7 outlines the costs for the selected regulatory options. Total aggregate costs are approximately $70.0 million per year, at an average annual cost per facility of approximately $0.25 million. In comparison, under the alternative regulatory scenario (the in-plant steam stripping/distillation scenario), aggregate costs are $111.9 million per year at an average annual cost per facility of approximately $0.4 million.

4.3 REFERENCES

U.S. EPA. 1995. U.S. Environmental Protection Agency. Development Document. Washington, DC. February.

Commerce Clearinghouse, Inc. 1991. U.S. Master Tax Guide. Chicago, 1990.

TABLE 4-5

COMPLIANCE COSTS FOR B/D DIRECT DISCHARGERS (1990 $)

Option Number	Total Capital Costs	Total O&M Costs	Total Posttax Annualized Costs	Average Annual Cost per Facility*
BPT Option Costs				
BPT-B/D#1	$0	$0	$0	$0
BPT-B/D#2	$605,700	$519,349	$366,228	$26,159
BPT-B/D#3	$2,976,515	$754,333	$760,837	$54,346
BCT Option Costs				
BCT-B/D#1	$559,015	$448,905	$320,426	$22,888
BCT-B/D#2	$2,929,830	$683,889	$715,035	$51,074
BAT Option Costs				
BAT-B/D#1	$644,446	$1,104,801	$708,758	$50,626
BAT-B/D#2	$1,741,330	$937,108	$731,606	$52,258
BAT-B/D#3	$3,002,607	$1,950,161	$1,454,688	$103,906
BAT-B/D#4	$10,310,180	$3,058,423	$2,892,869	$206,634

*Total Posttax Annualized Costs divided by the total number of B/D direct discharge facilities.

Note: These numbers are for all facilities and do not reflect closures predicted by the analyses in this report.

Source: ERG estimates based on Radian Corp. capital and operating costs estimates for pollution control equipment.

TABLE 4-6

COMPLIANCE COSTS FOR INDIRECT DISCHARGERS (1990 $)
(PSES)

Option Number	Total Capital Costs	Total O&M Costs	Total Posttax Annualized Costs	Average Annual Cost per Facility*
A/C Facilities				
PSES-A/C#1	$70,795,915	$46,441,499	$34,564,845	$392,782
PSES-A/C#2	$90,082,486	$81,860,584	$57,137,102	$649,285
PSES-A/C#3	$143,989,655	$105,781,635	$76,844,867	$873,237
PSES-A/C#4	$186,990,945	$177,615,256	$123,048,025	$1,398,273
B/D Facilities				
PSES-B/D#1	$25,160,649	$8,956,179	$7,922,101	$51,778
PSES-B/D#2	$30,429,899	$16,986,223	$13,137,467	$85,866
PSES-B/D#3	$61,970,107	$98,119,347	$63,463,066	$414,791

*Total Posttax Annualized Costs divided by the total number of indirect discharge facilities.

Note: These numbers are for all facilities and do not reflect closures predicted by the analyses in this report.

Source: ERG estimates based on Radian Corp. capital and operating costs estimates for pollution control equipment.

TABLE 4-7

COMPLIANCE COSTS FOR SELECTED REGULATORY OPTIONS (1990 $)

Option Number	Total Capital Costs	Total O&M Costs	Total Posttax Annualized Costs	Average Annual Cost per Facility*
BAT-A/C#2	$56,392,127	$35,689,088	$26,779,144	$1,115,798
BAT-B/D#1	$644,446	$1,104,801	$708,758	$50,626
PSES-A/C#1	$70,795,915	$46,441,499	$34,564,845	$392,782
PSES-B/D#1	$25,160,649	$8,956,179	$7,922,101	$51,778
Total**	$152,993,137	$92,191,568	$69,974,848	$250,806

* Total Posttax Annualized Costs divided by the total number of facilities for each subcategory.
** Total number of facilities includes seven nondischarging facilities.

Note: These numbers are for all facilities and do not reflect closures predicted by the analyses in this report.

Source: ERG estimates based on Radian Corp. capital and operating costs estimates for pollution control equipment.

SECTION FIVE

ANALYSIS OF FACILITY-LEVEL IMPACTS

This section outlines the facility-level economic impact methodology and reports the results of the analysis. An overview of the methodology and how it relates to subsequent analyses is discussed in Section Four. The facility closure analysis takes output from the cost annualization model to predict facility failures (see Section 5.1). Section 5.2 summarizes the number of baseline closures and additional closures resulting from compliance with various BPT, BCT, BAT and PSES control options.[1] Conclusions of the facility-level analysis are presented in Section 5.3.

This section discusses the impacts on 282 facilities in the survey universe.[2] Of these 282 facilities, 148 facilities are not directly considered by the facility closure model. These 148 facilities comprise two groups: certifying facilities and single-facility firms. These groups and the reasons they are not directly considered by the model are described below.

EPA exempted facilities from providing facility-level data if the company owners certified that the regulation would have no impact on the facility. Sixty-five facilities (which represent 72 facilities in the survey universe) certified no economic impact on the facility (i.e., the rulemaking will be economically achievable for the company and its certified facilities). Another 76 facilities in the survey universe indicated that their owner firm and the facility are the same entity (i.e., the firm owns only one facility). In these cases, the firm-level analysis in Section Six was determined to be the appropriate level at which to evaluate impacts on these facilities. These 76 "firm/facilities," as well as the 72 certifying facilities, are placed automatically in the "no-closure" category by the facility closure model. This approach avoids double counting of impacts at both

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[1]Options for new sources are evaluated in Section Eleven. See Section Four for a description of all regulatory options.

[2]A total of 286 facilities are represented by 244 facilities in the Section 308 survey. Four survey facilities provided insufficient data in the Section 308 survey and are not included in this analysis.

the firm and facility level. Results of the analysis show impacts relative to all 282 facilities in the analysis.

5.1 FACILITY CLOSURE MODEL

Facility closures typically are estimated by comparing the facility's "salvage value" to the present value of its future earnings. The salvage value represents the expected amount of cash the owner would receive if the facility were closed and liquidated. The present value of earnings represents the value in current dollars of the expected stream of earnings that the facility can generate over a specified period of time. If the salvage value is greater than what the facility is expected to generate in earnings, then it is assumed that the owner would liquidate the facility and invest those resources in an investment with a higher expected return.[3] This methodology, however, is considered less realistic for facilities where firm and facility are the same entity. It is assumed that the firm-level analysis better reflects the decisionmaking at these establishments. Thus, although all facilities are analyzed here, the firm/facilities pass through the facility level analysis unaffected and are analyzed in Section Six. Note that any firm failures among these firm/facilities are distinguished from other types of firm failures in Section Six, and employment losses are counted in Section Seven.

Sections 5.1.1 and 5.1.2 describe the calculation of both sides of the closure equation (i.e., salvage value and the present value of future earnings). Section 5.1.3 discusses how closures are evaluated using the closure equation and Section 5.1.4 presents a closure calculation for a hypothetical facility. Figure 5-1 provides a schematic diagram of the methodology and components used in the closure analysis.

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[3]When a facility is liquidated for its salvage value, EPA assumes that the facility is no longer operated; thus, closure-related impacts could result. In contrast, facilities that are sold because a new owner presumably can generate a greater return are considered *transfers*. Transfers cause no closure-related impacts, even if the transfer was prompted by increased regulatory costs.

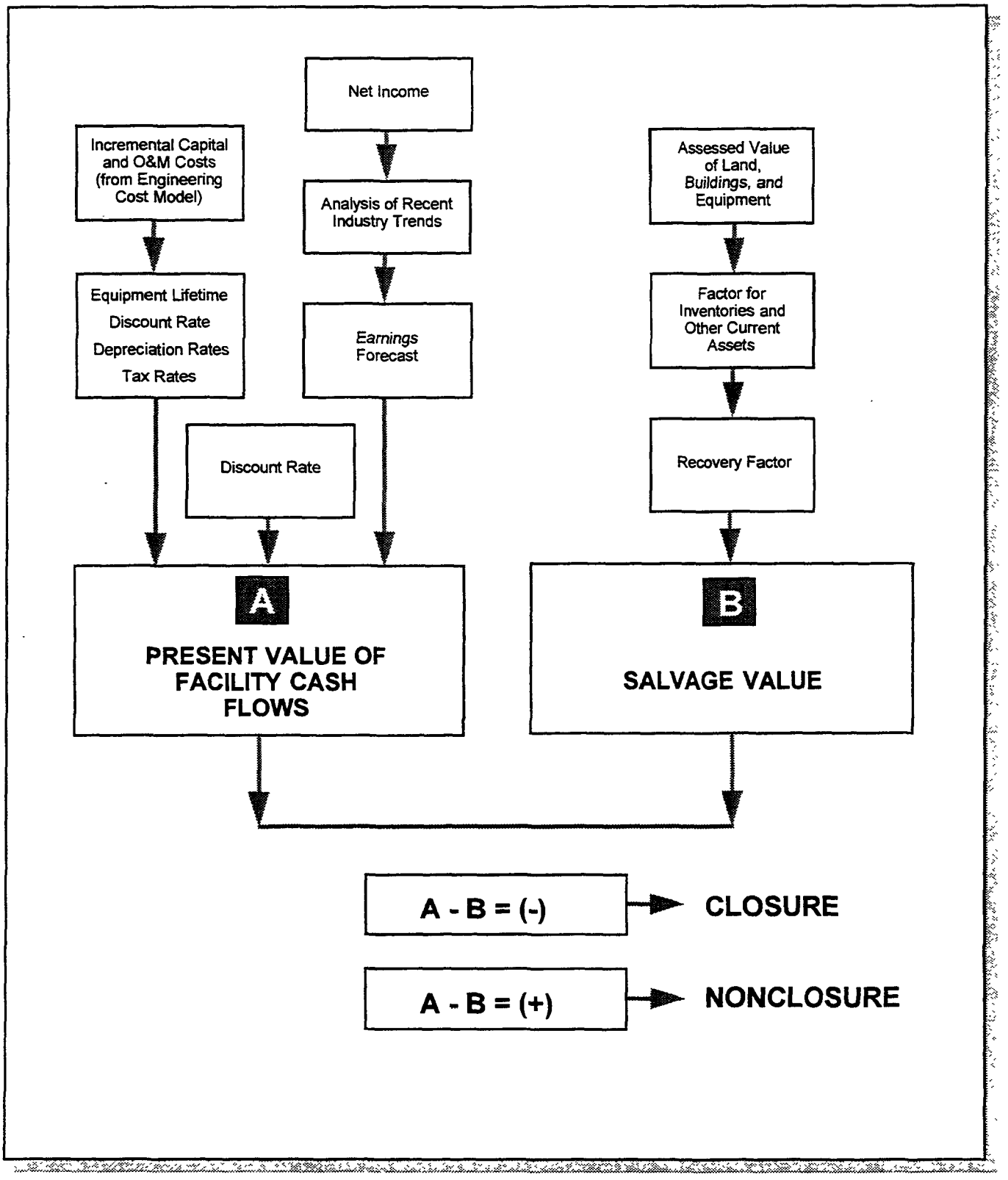

Figure 5-1. Basic facility closure analysis methodology.

5.1.1 Salvage Value

Salvage value is calculated assuming the pharmaceutical facility will be closed permanently. Thus, assets are evaluated based not on their potential for contributing to operations, but only on their market value in a liquidation sale of land, buildings, equipment, and inventories. Salvage value is discussed assuming that all cash transactions are realized in the current year and that discounting is not required. In fact, many facilities could face multiyear obligations that are not dismissed upon closure. The salvage value is the net cash realized by the plant owner after all assets are sold and obligations met.

In theory, salvage value includes the value of current (i.e., short-term) assets and fixed (i.e., long-term) assets. Current assets, defined as those assets not expected to be held beyond one year, include cash, short-term Certificates of Deposit (CDs), inventory, and other assets. Fixed assets include financial instruments expected to be held beyond a year and assets such as of buildings, equipment, and land.

Short-term assets held on balance sheets generally will be considered part of the facility's working capital and therefore are part of the facility's asset base. Long-term financial assets, such as deferred bond expense, stocks, bonds, and intangibles, might be held on the balance sheet of either the facility or the owner company.

The Section 308 Pharmaceutical Survey did not consistently collect data on current and fixed assets at the facility level. Typically, these data are held at the owner-company and parent-company levels. Out of the 163 noncertified facilities surveyed, only 36 independently owned, single-establishment companies reported facility-level data on fixed and current assets. For these 36 facilities, salvage value was calculated[4] as the sum of total reported current assets and a

[4]These data ultimately were not used directly in the facility closure analysis because of the decision to evaluate firm/facilities in the firm-level analysis.

portion of fixed assets.[5] For the remaining 127 facilities, other measures of fixed and current assets were used to calculate salvage value as described below.

5.1.1.1 Valuing Fixed Assets

The model uses data on the assessed value of land, buildings, and equipment reported in the Section 308 Survey to approximate the value of fixed assets for the 127 facilities not reporting fixed assets.[6] Assessed value of the facility is determined by local tax assessors. Most facilities pay local property taxes based on the assessed value of the facility's fixed assets. Nonetheless, a number of facilities (33) failed to report assessed value in the survey. These facilities might not have been assessed for tax purposes in recent years.

A regression equation capable of modeling assessed value with a reasonable degree of confidence could not be developed. Although one might think that assessed value would be somewhat related to the size of the plant as measured by the number of employees and other variables, in fact, assessed value may have more to do with local real estate conditions, politics, and the competence of the local tax assessor. Rarely does assessed value correspond neatly to actual market value, and market value itself is not easily predicted from size and other available data.

Given the inadequacy of regression analysis, a simpler approach was developed for imputing assessed value. In this approach, facilities with assessed value data (134 facilities) were

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[5]As explained below, a recovery factor of 20 percent is applied to reported fixed assets. Current assets are valued at 100 percent.

[6]Although assessed value is not a perfect approximation of fixed assets, it should be noted that potential difficulties also arise when the book value of assets is used to estimate the salvage value of a facility. The book value understates the true value of some assets while overstating the value of others. For instance, a facility's land could have been purchased as long ago as the 19th century and would have since appreciated in value tremendously. Other assets, however, might have no market value, but could continue to carry a book value because they have not yet been completely depreciated.

divided into eight groups corresponding to manufacturing process (i.e., AC or BD) and employment size (i.e., 1-18, 19-168, 169-748, and >748) and then the median assessed value from each of those groups was used to estimate assessed value for the 33 facilities not reporting these data. Table 5-1 shows the mean and median assessed values for each of the eight groups. EPA selected the median value. It is the more robust estimator (i.e., it is less sensitive to outliers than the mean).

This approach assumes that there is some relationship between assessed value and employment size and production process. However, this relationship is assumed to be nonparametric. Regression analysis requires parametric assumptions that are unsupported by the data. The median value approach is simple, robust, and avoids parametric assumptions.

5.1.1.2 Valuing Current Assets

Current assets include cash and near-cash financial assets, accounts receivable, and inventories. The valuation of these assets is based on their probable value during an auction/liquidation process. Because cash and near-cash financial instruments would not decline in value in the event of liquidation, they command their face value even in a distress sale. Accounts receivables and inventories (including both inventories of raw materials and finished products) are likely to decline in value to some degree depending on factors such as company and industry experience with bad debt problems, economic conditions, and the geographic proximity of potential purchasers of raw materials or finished products.

Current assets are carried in accounting statements based on their original purchase cost or, in the case of finished goods, on their manufacturing cost. They are made up of two components: intangibles (e.g., cash, receivables, and short-term investments) and inventories (e.g., raw materials, supplies, fuels, work-in-progress, and finished goods).

Because most intangible current assets are quite liquid and do not decline in value when liquidated, it is assumed they would be recovered at their face value. Some items, such as CDs and other short-term investments, could even appreciate in value compared to their cost as

TABLE 5-1

ASSESSED VALUE BY EMPLOYMENT SIZE AND PROCESS CATEGORIES

Category	Sample Size	Assessed Value		Number of Imputed Values
		Mean	Median	
A/C				
1-18	3	$644	$811	1
19-168	30	$21,309	$12,274	5
169-748	21	$50,915	$28,228	4
> 748	10	$268,622	$187,792	4
B/D				
1-18	5	$1,441	$1,485	3
19-168	24	$7,355	$4,215	4
169-748	30	$44,223	$25,948	8
> 748	11	$90,645	$72,843	4

Source: Section 308 Pharmaceutical Survey.

recorded on the books because of accumulated interest. Accounts receivable, however, could be worth less than their book value, depending on each facility's accounting practices for recognizing bad accounts. Overall, the combined book value of these intangible current assets is likely to approximate their actual market value (i.e., they are valued at 100 percent in the salvage value calculations).

Inventories are not as marketable as the rest of current assets because of their unique or specialized purposes. In the event of liquidation, a facility would have to sell its inventories at a fraction of their recorded book value. In anticipation of this, the survey asked facilities to report the value of inventories at cost or fair market value, whichever was lower. Thus, this EIA will use the value of inventories as reported.

As noted above, current assets data were available for only 36 of the 163 noncertified facilities. Table 5-2 shows data on current assets and assessed value of land, buildings, and equipment for 18 of these 36 facilities (assessed value data was unavailable for the other 18 facilities). As can be seen, inventories and other current assets tend to be as large as the assessed value of land, buildings, and equipment for most of these facilities—the median ratio of current assets to assessed value is approximately 100 percent. The EIA uses this median current assets to assessed value ratio for the 18 companies listed in Table 5-2 as a proxy for current assets in the other 127 facilities. Further refinement of the model is not possible given the small sample.

5.1.1.3 Salvage Value Calculation

Once fixed assets were defined, either using direct survey data on assessed value, or by extrapolation, a 20-percent recovery factor was applied to the facilities' fixed assets. The recovery factor is intended as an approximation of the percentage of fixed asset value recovered in a liquidation. This figure has been used in previous Office of Water EIAs (see U.S. EPA, 1993) and is considered a conservative estimate allowing for very rapid liquidation of assets. One hundred percent of the current assets estimate, as discussed in Section 5.1.1.2, was then added to the recoverable portion of fixed assets to compute an estimate of salvage value.

TABLE 5-2

CURRENT ASSETS AND
ASSESSED VALUE
(Thousands of 1990 $)

Number	Current Assets/ Assessed Value of Land, Buildings, and Equipment
1	4.0%
2	12.9%
3	31.2%
4	48.2%
5	84.1%
6	90.6%
7	93.0%
8	96.3%
9	102.3% *
10	118.6%
11	122.1%
12	124.5%
13	154.4%
14	179.8%
15	179.9%
16	196.5%
17	262.3%
18	266.8%

* Median value.

Source: Section 308 Pharmaceutical Survey.

Facility closure costs are not included in the salvage value estimates. These costs reduce the overall salvage value of the facility and are difficult to estimate even by facility executives. These costs can include pension administration, payout costs, and site cleanup before sale. As a result of their omission, the calculated salvage value could be high, which would overstate the likelihood of closure. This approach provides a more conservative estimate (by biasing economic impacts upward) of the potential facility closures.

5.1.2 Present Value of Forecasted Earnings

The present value of each facility is equal to its future stream of earnings in current dollars. The valuation assumes that the facility continues to be used for the manufacture of pharmaceuticals. The methodology uses recent earnings and other data to estimate future earnings, and then applies discount rates to derive their present value. The components of this analysis include measuring earnings, establishing a time frame for the analysis, projecting earnings, discounting earnings, and incorporating the incremental costs of regulation.

Because of the number of assumptions that must be made in calculating salvage value and because it is not always clear that a parent company would liquidate a "captive" facility," a salvage value approach might not be appropriate. A captive facility does not operate as a profit center but transfers its products to the firm or another facility and values these shipments at the cost of production. This arrangement might be common in a vertically integrated firm structure. Appendix B presents a sensitivity analysis of facility closures based on salvage value set equal to zero. Assuming a salvage value of zero is equivalent to assuming that a facility will not close unless its present value of net income equals zero. The sensitivity analysis (Appendix B) shows that the closure analysis is not very sensitive to no or lower salvage value assumptions. Thus, the salvage value approach is considered an appropriate measure of facility-level impacts.

5.1.2.1 Definition of Economic Earnings

Two approaches typically are used to estimate the present value of future plant operations:

- Net income, calculated as revenues less manufacturing cost of goods sold; selling, general, and administrative expenses; depreciation; interest; and taxes.
- Cash flow, which equals net income plus depreciation.

Estimates of the present value generated from future plant operations generally are based on cash flow projections. Depreciation is added to net income because it reflects previous, rather than current, spending and does not actually absorb any portion of incoming revenues.

Net income figures also can be used to project the value of continued plant operations. This approach assumes that ongoing reinvestment in plant and equipment will be necessary and that in the long run, depreciation costs should be reflected as a charge against earnings (i.e., annual maintenance is not sufficient to ensure a facility's efficiency and capacity in the long run). This approach, however, might overestimate potential closures in some newer facilities, which would report higher depreciation figures and thus lower earnings. Another factor that could affect either net income or cash flow is inter-facility transfers of product among facilities owned by the same firm. The Section 308 Pharmaceutical Survey asked respondents for their value of shipments including transfers to other facilities owned by the same firm, but these transfers often are valued at the cost of production, rather than at market value. Net income or cash flow, therefore, could be understated at these facilities which could lead the closure model to overstate total facility closures.

In the closure model, future earnings are based (to the extent possible) on net income because it is a somewhat more conservative estimate of earnings than cash flow. Reported net income data is available for only the 36 independently owned facilities. For the remaining 127 facilities, the model approximates net income as the reported value of shipments minus the total costs of production. The survey asked respondents to include depreciation of land and buildings in the costs of production; depreciation of equipment is not specifically requested. If

depreciation is included by the respondent, value of shipments minus total costs of production should approximate net income. If depreciation of equipment is omitted from the costs of production, the estimate will lie somewhere between net income and cash flow.

5.1.2.2 Earnings Forecast

The EIA uses a flat earnings forecast over the defined 16-year period (15 years plus 1 years of installation—see Section 4.1.2.2). In Table 5-3 one can see that, overall, net income grew in real terms between 1988 and 1990 in the surveyed facilities. In general, the surveyed facilities experienced strong growth in net income in nearly all employment size categories between 1988 and 1990. This growth rate is consistent with Commerce data that shows real growth in shipments for the industry as a whole of 5 percent between 1988 and 1990. Between 1988 and 1989, however, the surveyed facilities showed a small, real decline in net income. The median growth rate between 1988 and 1989 was -0.2 percent, and a number of facilities showed actual losses. Growth surged between 1989 and 1990, however, to more than make up for the previous declines.

Despite the earnings dip in 1988-1989 among some facilities, the flat earnings growth projection is expected to be a reasonable, and possibly conservative, approach to estimating the present value of future earnings for several reasons. First, the pharmaceutical industry as a whole is expected to grow in real terms at a modest rate over the next few years, barring the institution of major price controls (see Section Three).[7] In the longer term, as the "baby boom" generation ages, demand for pharmaceuticals is likely to increase.

Second, a large portion of the survey respondents showed appreciable real growth in net income over the 3-year period captured by the survey. Among respondents for whom net income

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[7]It is beyond the scope of the EIA to predict major price shocks such as those possible with the institution of comprehensive health system changes. It should be noted, however, that many pharmaceutical firms have limited or are considering limiting price increases to the rate of inflation (see Section Three). If this type of limit on price increases is proposed, the incremental impact on earnings growth in the industry might not be as severe as would be expected without the voluntary controls.

TABLE 5-3

CHANGE IN NET INCOME BY EMPLOYMENT SIZE CATEGORY: 1988-1990

Employment Size	Number of Facilities**	Change in Real Net Income*		
		Median	Range	
			Minimum	Maximum
0 - 19	13	8.0%	-87.6%	1250.6%
20 - 99	41	-9.1%	-403.5%	374.4%
100 - 499	59	4.4%	-9589.0%	591.7%
500 - 750	15	3.3%	-60.4%	120.0%
>750	17	6.4%	-7.1%	97.7%
All	145	5.3%	-9589.0%	1250.6%

* Six facilities had a change of infinity (i.e., net income in the base year was zero).
** Includes only those facilities with net income data for all three years.

Source: Section 308 Pharmaceutical Survey.

could be calculated for all three years, real net income growth ranged up to 1,251 percent between 1988 and 1990, with a median real growth rate of approximately 5.2 percent.[8]

Finally, using an assumption of declining earnings at some facilities could lead to more facilities closing under the baseline scenario, potentially understating the impacts of the regulation. This would occur if, in fact, the declines seen in 1988-1990 are not transitory. Although an assumption of flat earnings over the time period of the analysis might understate baseline closures for some facilities, it is unlikely that all facilities showing a decline in the 1988-1990 period would continue to decline over the analysis timeframe. Thus the general trends predicted for the industry as a whole are considered a more accurate predictor of earnings growth over the next 16 years than the 3-year history at any one facility.

Several reasons lead to the rejection of a rising earnings projection. First, the facilities might be running at or near full capacity and significant growth would not be possible without making major capital investments in buildings and production equipment. Second, for many facilities, a flat earnings projection is quite conservative, leading to a conservative assessment of postcompliance closures.

In addition to flat earnings growth, The model employs several other assumptions and procedures as well:

- **Zero cost passthrough.** The facility is assumed to be unable to raise prices to recoup incremental pollution control costs. It is as if there is a supply of foreign-made pharmaceuticals waiting at the U.S. border; if domestic facilities raise their prices, imports will flood into the domestic market. As discussed in Section Three, this assumption might not be realistic given that many firms act as price setters in certain drug markets. This assumption, therefore, is extremely conservative.[9]

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[8]Nineteen of the 163 respondents did not report sufficient data to calculate the change in net income between 1988 and 1990. These 19 respondents were removed from the sample prior to calculating the median net income growth rate.

[9]Because impacts were found to be so small, alternative assumptions on cost passthrough were not investigated (see Section 5.2).

- **Constant 1990 dollars.** Data from 1988 and 1989 are inflated using the change in the Consumer Price Index for SIC 283.

- **Discounting.** Net income is discounted over a 16-year period, since, as explained in Section 5.1.1, the capital expenditures associated with additional pollution control for the pharmaceutical industry are depreciated over a 15-year lifetime plus a 1-year construction period. The same cost of capital factor used in the cost annualization model is also used to discount earnings. This factor takes into account the rate of inflation.

5.1.3 Evaluating Closures

The model evaluates closure on a facility-specific basis. As discussed above, salvage value and net income are estimated for each facility. In the baseline analysis, the basic model calculates the present value of the earnings stream (using the 3-year average net income from the survey) over the 16-year time frame and subtracts that present value from the calculated salvage value. If salvage value exceeds the present value of net income, the model classifies the facility as a "closure" in the baseline. These "closure" facilities are eliminated from the subsequent postcompliance closure analysis, as a real-life closure under this scenario could not be attributed to the regulation. Note that all facilities whose 3-year average net income is negative are assumed to close in the baseline.

For postcompliance closure analysis, the model uses the facility-specific annualized costs for each BPT, BCT, BAT, and PSES option to calculate declines in net income. Annualized compliance costs are subtracted from the present value of net income to arrive at the present value of postcompliance net income. Salvage value minus the present value of postcompliance net income is then calculated, and, again, where the salvage value exceeds the present value of net income, the model classifies the facility as a closure. The number of estimated closures under each regulatory scenario is recorded by employment size and option.

5.1.4 Sample Closure Analysis

Figure 5-2 presents an example of the calculations undertaken to determine closure. The salvage value net income and compliance costs of a hypothetical facility are used to calculate whether closure is likely to occur. As can be seen in this case, this facility is projected to remain open in the baseline and postcompliance analyses.

5.2 RESULTS

5.2.1 Baseline Closures

The analysis indicates that 38 facilities, or 13 percent of the total, will close in the baseline. The highest number of closures occurs in the B/D indirect discharge facilities employing 19-167 employees. In this group, 12 facilities, or 23 percent of the total number of facilities in this group, are estimated to close in the baseline (see Table 5-4). Nearly all the closures occur among indirect dischargers (36 of the 38 facilities estimated to close are indirect discharging facilities), and the highest number of these closures occur among the facilities employing 19 to 167 employees. (As noted earlier, total facilities include firm/facilities, but these establishments are analyzed in Section Six.)

5.2.2 Postcompliance Closures

Tables 5-5 through 5-7 present estimates of postcompliance facility closures by type of discharger (A/C direct dischargers, B/D direct dischargers, and indirect dischargers) by each option under consideration for each group. As shown in Table 5-5, one A/C direct discharging facility closes (in the 1-18 employees size category) under the most stringent option, BAT-A/C#4. No other regulatory options considered for A/C direct dischargers are expected to result in closures of A/C direct discharging facilities. Table 5-6 presents the analysis for B/D direct dischargers. No B/D direct facilities are predicted to close as a result of any of the proposed regulatory options. Table 5-7 presents results for indirect dischargers. A B/D indirect

FACILITY NO. 0001

Key parameters ($millions)

Estimated salvage value (ESV):	$ 1.33
Present value of net income (PVNI):	$ 14.23
Annualized cost of compliance (ACC):	$ 0.45
Present value of annualized compliance cost (PVAC):	$ 4.29

Sample Calculation

Baseline Calculation	Postcompliance Calculation
14.23 (PVNI) > 1.33 (ESV) ⇒ **No Closure**	[14.23 (PVNI) - 4.29 (PVAC)] > 1.33 (ESV) ⇒ **No Closure**

Figure 5-2. Sample Facility Closure Calculation.

TABLE 5-4

FACILITY CLOSURES: BASELINE ANALYSIS

Facility Subcategory	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.	% of Total	No. of Closures	Total No.	% of Total	No. of Closures	Total No.	% of Total	No. of Closures	Total No.	% of Total	No. of Closures	Total No.	% of Total
Direct Discharge															
A/C	0	2	0%	1	7	14%	0	11	0%	0	3	0%	1	23	4%
B/D	0	0	0%	0	1	0%	0	6	0%	1	7	14%	1	14	7%
Indirect Discharge															
A/C	1	4	25%	11	38	29%	1	24	4%	0	22	0%	13	88	15%
B/D	1	13	8%	12	53	23%	9	62	15%	1	23	4%	23	151	15%
Zero Discharge															
A/C	0	0	0%	0	2	0%	0	1	0%	0	0	0%	0	3	0%
B/D	0	1	0%	0	1	0%	0	1	0%	0	0	0%	0	3	0%
All Facilities															
TOTAL	2	20	10%	23	102	23%	10	105	10%	2	55	4%	38	282	13%

Note:
1. Analysis assumes certified facilities do not close.
2. Analysis excludes four facilities (one A/C direct discharger, two B/D indirect dischargers, and one A/C zero discharger) because of lack of financial data.

Source: ERG estimates.

TABLE 5-5

FACILITY CLOSURES FOR A/C DIRECT DISCHARGERS: POST-COMPLIANCE ANALYSIS

Option Number	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total
Regulatory Option BPT															
BPT-A/C#1	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BPT-A/C#2	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BPT-A/C#3	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BPT-A/C#4	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BPT-A/C#5	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
Regulatory Option BCT															
BCT-A/C#1	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BCT-A/C#2	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BCT-A/C#3	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
Regulatory Option BAT															
BAT-A/C#1	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BAT-A/C#2	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BAT-A/C#3	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BAT-A/C#4	1	2	50%	0	6	0%	0	11	0%	0	3	0%	1	22	5%

* These facility numbers reflect those facilities projected to remain open following the baseline analysis.

Note:
1. Analysis assumes certified facilities do not close.
2. Analysis excludes one facility because of lack of financial data.

Source: ERG estimates.

TABLE 5-6

FACILITY CLOSURES FOR B/D DIRECT DISCHARGERS: POST-COMPLIANCE ANALYSIS

Option Number	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total
Regulatory Option BPT															
BPT-B/D#1	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BPT-B/D#2	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BPT-B/D#3	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
Regulatory Option BCT															
BCT-B/D#1	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BCT-B/D#2	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
Regulatory Option BAT															
BAT-B/D#1	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BAT-B/D#2	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BAT-B/D#3	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BAT-B/D#4	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%

* These facility numbers reflect those facilities projected to remain open following the baseline analysis.

Note: Analysis assumes certified facilities do not close.

Source: ERG estimates.

TABLE 5-7

FACILITY CLOSURES FOR INDIRECT DISCHARGERS: POST-COMPLIANCE ANALYSIS (PSES)

Option Number	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total
A/C Facilities															
PSES-A/C#1	0	3	0%	0	27	0%	0	23	0%	0	22	0%	0	75	0%
PSES-A/C#2	0	3	0%	0	27	0%	0	23	0%	0	22	0%	0	75	0%
PSES-A/C#3	0	3	0%	0	27	0%	0	23	0%	0	22	0%	0	75	0%
PSES-A/C#4	0	3	0%	0	27	0%	0	23	0%	0	22	0%	0	75	0%
B/D Facilities															
PSES-B/D#1	0	12	0%	0	41	0%	0	53	0%	0	22	0%	0	128	0%
PSES-B/D#2	0	12	0%	0	41	0%	0	53	0%	0	22	0%	0	128	0%
PSES-B/D#3	0	12	0%	1	41	2%	0	53	0%	0	22	0%	1	128	1%

* These facility numbers reflect those facilities projected to remain open following the baseline analysis.

Note:
1. Analysis assumes certified facilities do not close.
2 B/D analysis excludes two facilities because of lack of financial data.

Source: ERG estimates.

facility (employing 19-167 employees) is expected to close under PSES-B/D#3. No other closures are expected under any other options for indirect dischargers. Thus closures occur only under the most stringent options considered, and only A/C direct and B/D indirect dischargers will experience significant impacts under these options.

As discussed in Section Four, the following options have been selected by EPA: BPT-A/C#2, BPT-B/D#2, BAT-A/C#2, BAT-B/D#1, NSPS-A/C#1, NSPS-B/D#2, PSES-A/C#1, PSES-B/D#1, PSNS-A/C#1, and PSNS-B/D#1. (NSPS and PSNS options are discussed in Section Eleven.) As discussed in Section 4.2, the cost impacts of the selected BAT options (BAT-A/C#2 and BAT-B/D/#1) also cover the cost impacts of the other BPT and BCT selected options for direct dischargers. Thus the impacts of BAT-A/C#2, BAT-B/D#1, PSES-A/C#1, and PSES-B/D#1 are evaluated as the selected regulatory options. As Table 5-8 shows, no facility closures are expected to occur as a result of the selected regulatory options (see Section Six for a discussion of any impacts on firm/facilities). Additionally, no facility closures are expected to occur as a result of the alternative regulatory scenario (the in-plant steam stripping distillation scenario; see Appendix C).

5.3 REFERENCES

U.S. EPA. 1993. Economic Impact and Regulatory Flexibility Analysis of Proposed Effluent Guidelines and NESHAP for the Pulp, Paper, and Paperboard Industry. Office of Water, November.

TABLE 5-8

FACILITY CLOSURES FOR SELECTED OPTIONS: POSTCOMPLIANCE ANALYSIS

Facility Subcategory	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total
Direct Discharge															
A/C	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
B/D	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
Indirect Discharge															
A/C	0	3	0%	0	27	0%	0	23	0%	0	22	0%	0	75	0%
B/D	0	12	0%	0	41	0%	0	53	0%	0	22	0%	0	128	0%
Zero Discharge															
A/C	0	0	0%	0	2	0%	0	1	0%	0	0	0%	0	3	0%
B/D	0	1	0%	0	1	0%	0	1	0%	0	0	0%	0	3	0%
All Facilities															
TOTAL	0	18	0%	0	78	0%	0	95	0%	0	53	0%	0	244	0%

* *These facility numbers reflect those facilities projected to remain open following the baseline analysis.*

Note:
1. Analysis assumes certified facilities do not close.
2. Analysis excludes four facilities (one A/C direct discharger, two B/D indirect dischargers, and one A/C zero discharger) because of lack of financial data.

Source: ERG estimates.

SECTION SIX

ANALYSIS OF FIRM-LEVEL IMPACTS

The firm-level analysis evaluates the effects of regulatory compliance on firms owning one or more affected pharmaceutical facilities. It also serves to identify impacts not captured in the facility analysis. For example, some companies might be too weak financially to undertake the investment in the required effluent treatment, even though the investment might seem financially feasible at the facility level. Such circumstances can exist at companies owning more than one facility subject to regulation. Given the range of possible firm-level responses, the firm-level analysis is an important component of the EIA.

Parent company (i.e., the owner of the owner company) impacts are not analyzed. As one progresses up the corporate hierarchy and assets increase, the impacts of a given facility closure or major facility-level capital investment become more dilute. For the 63 single establishment firms in the survey universe (the firm/facilities), however, analysis at the facility level, firm level, and corporate parent level coincide. As noted in Section Five, analysis of these firm/facilities was deferred to the firm-level analysis.[1]

The firm-level analysis summarized in Section 6.1 assesses the impacts of facility closures on each firm and the impact of compliance costs at all facilities owned by the firm that do not close. These impacts are assessed using ratio analysis, which employs two indicators of financial viability: the rate of return on assets (ROA) and the interest coverage ratio (ICR). Results and conclusions of the firm-level analysis are presented in Sections 6.2 and 6.3.

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[1]The total number of firms discussed in this section is 187. Three firms provided insufficient data and thus were not analyzed and are not included in this count. Included in the 187 firms are 38 firms that certified all their facilities as not incurring impacts from the regulation. However, since two of these certified provided financial data, they were analyzed in the firm failure model. Thus, a total of 36 certifiers are excluded from some of the analyses.

6.1 RATIO ANALYSIS METHODOLOGY

The ratio analysis is conducted from the perspective of creditors and equity investors who would be the source of capital to finance a company's treatment system investment. To attract financing for a treatment system, a company must demonstrate financial strength both before and, on a projected basis, after the treatment system has been purchased and installed. The ratio analysis simulates the analysis an investor and or creditor would employ in deciding whether to finance a treatment system, or make any other investment in the firm.

A baseline ratio analysis evaluates the company's financial viability before the investment, and a postcompliance analysis predicts the company's financial condition subsequent to the investment. The baseline analysis identifies companies whose financial condition, independent of pending regulatory actions, is extremely weak. Such companies are at risk of financial failure even without the additional cost of the regulation. Before the baseline firm-level analysis is undertaken, baseline facility closures are accounted for, since these closures affect baseline net income, earnings, and assets. Firms that are projected to fail in the baseline analysis are excluded from the postcompliance analysis. The postcompliance analysis identifies those companies, otherwise financially sound, whose financial viability is threatened by regulatory compliance. Such companies would be weakened by the burden of financing wastewater treatment equipment purchases and operating and maintaining the system. These companies are characterized as significantly affected by the revised effluent standards.

The postcompliance analysis has two components. The first component uses the results of the facility closure analysis to identify losses in net income and earnings before interest and taxes (EBIT), and assets stemming from a facility closure (baseline impacts from closures are accounted for in the baseline analysis and are carried forward into the postcompliance analysis). The next component uses the annualized compliance costs from all facilities that are projected to remain open to identify their losses of net income and EBIT. The postcompliance net income

and EBIT reflecting facility closures and higher production costs is then used to calculate postcompliance financial ratios.[2]

The ratio analysis relies on two financial measures: ROA and ICR.[3] ROA is a comprehensive measure of company financial performance, whereas ICR is an indicator of a company's ability to manage financial commitments. Both measures are of great importance to creditors and investors in deciding whether to provide investment capital. The methods for calculating both baseline and postcompliance ROAs and ICRs are described in more detail below.

6.1.1 Explanation of Ratios

6.1.1.1 Return on Assets (ROA)

ROA is a measure of the profitability of a company's capital assets, independent of financial structure. It is computed as the ratio of net income to assets:

$$ROA = \frac{Net\ Income}{Total\ Assets}$$

If a company's ROA is lower than that of its competitors, the company might not be able to provide the expected investment return to its creditors and investors. Unless significant improvement in performance is likely, investors and creditors generally will avoid providing financing to such companies. Alternatively, investors and creditors might seek higher returns (in the form of higher interest rates or higher required returns on equity) to compensate for the additional risk associated with the capital they provide. The higher cost of capital might in turn

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[2]Note that where one facility has a statistical weight of 2, the model assumes that both facilities are owned by the same firm, conservatively assigning impacts of two facilities to one firm, except in the case of the firm/facilities, in which case, two firm/facilities are assumed.

[3]The reason for choosing these two financial ratios over other available ratios is explained more fully in Section 3.2.4.

decrease the likelihood that such companies will be able to invest in the treatment options required for compliance with an effluent guideline.

ROA is perhaps the single most comprehensive measure of a company's financial performance. ROA provides information about the quality of management, the competitive position of a company within its industry, and the economic condition of the industry in which the company competes. In addition, ROA incorporates information about a company's operating margin and asset management capability: the ratio of income to sales (operating margin), multiplied by the ratio of sales to assets (asset turnover), equals ROA. If a company cannot sustain a competitive ROA, on both a baseline and postcompliance basis, it probably will have difficulty financing the pollution control investment. This is true regardless of whether financing is to be obtained as debt or equity.

6.1.1.2 Interest Coverage Ratio (ICR)

ICR is the ratio of EBIT to interest obligations:

$$ICR = \frac{EBIT}{Interest}$$

ICR is equally as important to creditors and investors as ROA because it indicates the extent to which the company can be expected to manage its financial burdens without risk of financial failure. If a company's operating cash flow does not comfortably exceed its contractual payment obligations (e.g., interest and lease obligations), the company is seen as vulnerable to any significant decline in sales or increase in costs.[4] Should sales decline or costs rise, there are two possible results: (1) returns to the equity owners of the company either will be eliminated or sharply reduced, and (2) the company will be prevented from meeting its contractual payment obligations. In the first case, earnings might fall or become negative, with a consequent reduction or elimination of dividends and/or reinvested earnings. The market value of the

[4]For this analysis, a company's operating cash flow is considered to be value of shipments minus production costs, with the exception of interest, lease expense, and depreciation, where distinguishable.

company's equity also is likely to fall, causing a capital loss to investors. In the second case, failure to make contractual credit payments will expose the company and its equity owners to the risk of bankruptcy, forced liquidation of assets, and probable loss of the entire equity value of the company.

6.1.2 Recalculating Ratios Incorporating Compliance Costs

The data necessary to calculate baseline and postcompliance ROAs and ICRs are available from the survey and engineering costs analyses. For the baseline analysis, ROA and ICR are computed with the survey data after baseline facility closures are considered. Baseline closures can reduce net income at the firm level (if net income at the facility was positive). Additionally liquidation of assets leads to some reduction in the firm's total assets because when assets are liquidated, their total market value might not be realized. For the postcompliance analysis, the relevant survey data (net income, EBIT, total assets, and interest expenses) are adjusted to reflect annual compliance costs estimated at the facility level as well as any changes in net income and assets caused by facility closures, if any.

In the facility analysis, compliance costs are estimated in two categories: capital costs (facility and equipment), and annual operating and maintenance costs.[5] The sum of these annualized costs over the nonclosing facilities owned by each company is used to adjust the survey data as follows:

[5]The operating and maintenance (O&M) cost category includes discharge costs (e.g., the cost of sludge disposal) and monitoring costs.

(1) *Postcompliance Net Income or EBIT = Net Income or EBIT - Σ of Nonclosing Facilities' Annual Compliance Costs - [(Σ of closing facilities' net income or EBIT) x tax factor[6]]*

(2) *Postcompliance Total Assets = Total Assets + Σ Nonclosing Facility Capital Compliance Costs - Σ of Closing Facilities' Nonrecoverable Fixed Assets*

(3) *Postcompliance Interest Expense = Interest Expense + Σ Annual Nonclosing Facility Interest Expense for Pollution Control Technologies*

6.1.3 Evaluating Baseline and Postcompliance Ratios

6.1.3.1 Baseline Analysis

To evaluate the baseline viability of the companies analyzed, the baseline ROA and ICR values are compared against the lowest quartile (25th percentile) values for the pharmaceutical sector (SIC 283) in 1992 as reported by Robert Morris Associates (RMA, 1992) for ICR and Dun & Bradstreet (D&B, 1993) for ROA.[7] The benchmark values for ROA and ICR are 0.027 and 1.8, respectively. Those companies for which the value of either the ROA or the ICR is less than the first quartile value from RMA and D&B are judged to be vulnerable to financial failure, independent of the application of a pharmaceutical effluent guideline. Because both measures are judged to be critically important to financial success and the ability to attract capital, failure with regard to either measure alone is reason for finding the company to be financially vulnerable.

Where sufficient data were available, three-year average (1988-1990) ROAs and ICRs were calculated and used as the baseline ratios. In some cases, however, companies did not provide sufficient net income, EBIT, assets, and interest payments data to calculate three-year ROA and ICR averages. In these cases, two-year ratio averages were used where possible. For

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[6]Tax factor used for net income only. This factor accounts for the fact that any loss or gain of income will be net of taxes. Note that baseline closures are accounted for during the baseline analysis, so the net income, earnings, and asset adjustments for baseline closures are already incorporated into the net income, EBIT, and assets at the beginning of the postcompliance analysis. Thus, the closing facilities to be addressed in this equation are only those facilities that close in the postcompliance analysis.

[7]The affected firms make up only a portion of these larger pharmaceutical industry categories. EPA determined that a substantial portion of the pharmaceutical industry does not discharge or does not discharge pollutants of concern (see Section Two).

several companies, only a single year of data was available. In three cases, the owner companies failed to provide sufficient data to calculate either ROA or ICR ratios. These firms were removed from the analysis.

6.1.3.2 Postcompliance Analysis

Standard Methodology

The postcompliance analysis is undertaken primarily for those companies that are not found to be vulnerable in the baseline analysis. For these healthier companies, if either of the postcompliance ROA and ICR values fall below their respective benchmarks, then the company is judged to be vulnerable to financial failure as a consequence of regulatory compliance; these companies are said to sustain a "significant impact" as a result of the regulation. This standard analysis is identified as Baseline and Postcompliance Analysis 1, and the results of this analysis are presented in Section 6.2.1.

Alternative Methodologies

The 25th percentile value for ROA and ICR is only one possible means of defining poor financial performance and condition. Use of these benchmarks implies that the weakest one-fourth of companies in an industry are automatically in poor financial condition and at risk of financial failure. By definition, such companies are in poorer condition than 75 percent of their competitors. In spite of this, some (and possibly all) companies in the lowest quartile might still be in good financial condition, particularly during periods of strong industry economic performance. Alternatively, during a period of weak economic performance, more than 25 percent of the companies in an industry might be in poor condition and at risk of failure.

Additionally, some firms in vertically integrated conglomerates might not be showing profits (i.e., although manufacturing and R&D are undertaken at the owner company level, sales are accounted for primarily at the parent company level). The firm thus acts as "captive" to the

parent company. Furthermore, because of the research-intensive nature of the pharmaceutical industry, a startup firm might show many more years of loss before turning a profit. This characteristic is associated with the very long lead times from the creation of a new drug product to its introduction to market. Investors are aware of these long lead times and are likely to be more tolerant of early losses because of the chances of high profit in the long term. For these reasons, the firms that, under the standard methodology, are considered likely to fail in the baseline (and thus are not analyzed in postcompliance scenarios using the standard methodology) are looked at more closely.

This analysis of marginal firm is undertaken as a sensitivity analysis because there is no way of knowing whether these firms really can be credited with significant impacts from compliance costs. This analysis provides an upper bound of potential impacts from compliance costs.

The worst-performing firms are divided between those with negative ROA and/or ICR (which are the result of negative net income or EBIT) and those with positive ROA and ICR. For firms that have positive net income and/or EBIT, but whose ROA or ICR fall below benchmarks, Postcompliance Analysis 2 looks at the relative percentage change in ROA or ICR as a result of compliance costs or facility closures. This analysis is undertaken to determine the severity of impact (under a worst-case options scenario), assuming these firms do not, in fact, close in the baseline. A percentage change in ROA or ICR of 5 percent or less is considered minimal impact. A change of more than 5 percent is considered a major impact. The results of this analysis are presented in Section 6.2.2.

Changes in ROA or ICR ratios that are already negative are difficult to present meaningfully. However, the proportion of the postcompliance net income or EBIT loss attributable to compliance costs provides a qualitative sense of impact. This analysis is presented as Postcompliance Analysis 3, and results are summarized in Section 6.2.3. Those firms that have a substantial net loss of income or earnings before even relatively large compliance costs are incurred are most likely to fail whether or not compliance costs are incurred. Firms with minimal losses, on the other hand, might be able to survive, but only if compliance costs are not substantial. In this analysis, if worst-case compliance costs (i.e., the highest cost options are

chosen for all facilities) are 5 percent or less of the postcompliance net income or EBIT loss, we determine that if the firm were to remain open, compliance costs would not be a major factor in its continued viability. A change of more than 5 percent is considered a major impact.

All firms identified as potentially experiencing a major impact in Postcompliance Analyses 2 and 3 are investigated further to determine the likelihood of baseline failure. Several measures pointing to likely firm failure in the baseline are investigated. Unless two or more of the following are true, the firm is considered highly likely to fail, even given the reservations noted above:

- Research and development expenditures are much higher than average
- The firm has facilities with startup dates of 1987 or later
- Rising net income (more than 10 percent per year) is noted
- Rising working capital (more than 10 percent per year) is noted

Any facilities not identified as highly likely to fail in this analysis were then further assessed on a case-by-case basis to determine if they constitute a potential upper bound on overall impacts from the proposed effluent guidelines.

Profitability Analysis Methodology

One final analysis (Profitability Analysis) is undertaken to determine impacts on profitability among firms estimated to have no significant impact from compliance costs in Postcompliance Analysis 1 (significant impact here means likely to fail). Compliance costs, although not necessarily leading to the likelihood of firm failure, might have other major impacts on a firm's financial outlook. Using the selected regulatory options, this analysis investigates the percentage change in ROA among the healthy firms to assess impacts on profitability. Again, a 5 percent change is used as a benchmark. A change of 5 percent or less is considered a minimal impact. A change of more than 5 percent is considered a major impact (although potentially less significant than firm failure).

Also note that even if a company is considered likely to fail, this does not necessarily mean that its nonclosing facilities also will close. In the cases where a firm is considered likely to fail, we assume that the company's viable facilities could be sold as part of the company liquidation process and operated successfully under different ownership. Alternatively, some facilities might be sold (and continue to operate) to raise the necessary capital to finance the installation of pollution control equipment at the remaining facilities. Thus firm closures are not considered an indicator of additional facility-level impacts. The one exception to this approach is the analysis involving firm/facilities. To be conservative, failing firm/facilities are assumed to be liquidated (similar to a facility closure). In fact, firm/facilities might offer themselves for sale, thus extending the life of the facility (although possibly not the firm). Thus it is possible that impacts on firm/facilities might be overstated.

6.2 RESULTS

The results of the firm-level analysis are presented in three sections. Section 6.2.1 presents the basic firm-level analysis (Baseline and Postcompliance Analysis 1). This analysis uses the standard methodology, outlined previously, in which baseline failures are estimated using the lowest quartile ROA and ICR values for the industry as benchmarks. The postcompliance portion of Analysis 1 is then developed using only the firms that are determined to have ROAs and ICRs above benchmarks in the baseline (i.e., the financially healthy firms). Section 6.2.2 presents Postcompliance Analysis 2, which investigates potential impacts on firms with positive net income or earnings that appear likely to fail in the baseline under Analysis 1. Section 6.2.3 presents the results of Postcompliance Analysis 3. Firms with negative net income or earnings are analyzed in this third analysis to determine how much more negative their income or earnings might become if they incur the estimated compliance costs. Finally, Section 6.2.4 presents the results of the profitability impacts analysis. Firms that continue to appear financially healthy following the installation and operation of pollution control equipment (i.e., those that are not expected to fail as a result of the proposed regulation) are investigated to determine the impact of compliance costs on their profitability as measured by declines in ROA. This analysis is a measure of additional impact short of firm failure.

6.2.1 Baseline and Postcompliance Analysis 1—Standard Methodology

The baseline analysis for Analysis 1, which separates financially healthy firms from those likely to fail regardless of whether the regulation is promulgated, is presented in Table 6-1. As the table shows, out of 187 firms in the survey universe, 54 (29 percent) are considered likely to fail even before the impact of the effluent guideline requirements is considered[8]. These firms are projected to fail in the baseline and are not considered in the postcompliance portion of Analysis 1.

Tables 6-2 through 6-4 show the impacts associated with each proposed option, assuming that only one option is in effect at any one time (i.e., if a firm owns an A/C direct and a B/D direct facility, the impact of the BAT option for the A/C facility is tallied separately at the firm level from the impact of the BAT option for the B/D facility. These tables reflect results of analyses for firms owning A/C direct facilities (Table 6-2), B/D direct facilities (Table 6-3), and indirect discharging facilities (Table 6-4).

As the tables show, only one firm owning an A/C direct discharger is expected to fail and only as a result of the most stringent option considered (see Table 6-2); no B/D direct dischargers are expected to fail under any option (see Table 6-3). A maximum of only four firms with A/C indirect facilities and six firms with B/D indirect facilities are expected to experience significant impacts (i.e., to be likely to fail) under the most stringent regulatory options for these industry subcategories (PSES-A/C#4 and PSES-B/D#3—see Table 6-4). These 10 firms represent 7.5 percent of all firms with A/C indirect facilities, 7.6 percent of all firms with B/D indirect facilities, and 7.5 percent of all postcompliance firms.

Table 6-5 examines the impacts generated by EPA's selected options. As can be seen in the table, when all selected options are applied to the firms concurrently, two A/C indirect firms

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[8]Although this percentage seems high, it is an artifact of the benchmark. On average 25 percent of pharmaceutical firms could be expected to fail if a 25th percentile benchmark is chosen. The choice of this benchmark is thought to be realistic, however, given the high rates of entry and exit seen in this industry (see Section Three). These failure rates do not imply that over one-quarter of the industry will fail in any one year; rather over a reasonable period, these weaker firms are considered likely to fail, even if the regulation is not imposed.

TABLE 6-1

BASELINE ANALYSIS

	Total Number of Firms	Financially Healthy Firms		Firms Likely to Fail		
		# of Firms	% of Group	# of Firms	% of Group	% of All Firms*
Firms with A/C Direct Facilities	19	15	78.9%	4	21.1%	2.1%
Firms with B/D Direct Facilities	11	7	63.6%	4	36.4%	2.1%
Firms with A/C Indirect Facilities	70	53	75.7%	17	24.3%	9.1%
Firms with B/D Indirect Facilities	107	72	67.3%	35	32.7%	18.7%
Firms with A/C Nondischarging Facilities	4	2	50.0%	2	50.0%	1.1%
Firms with B/D Nondischarging Facilities	3	3	100.0%	0	0.0%	0.0%
All Firms**	187	133	71.1%	54	28.9%	28.9%

* Out of all firms in the analysis (187 firms).
** Number of firms for All Firms might be less than the total firms by subcategory because some firms have more than one type of facility. Total number of All Firms includes firms that have nondischarging facilities

Note: Analysis excludes three firms because of lack of financial data.

Source: ERG estimates.

TABLE 6-2

POSTCOMPLIANCE ANALYSIS 1
A/C DIRECT DISCHARGE REGULATORY OPTIONS (15 AFFECTED FIRMS)*

Regulatory Option	Total Number of Firms*	No Significant Impact		Significant Impact		
		# of Firms*	% of Group	# of Firms*	% of Group	% of All Firms**
BPT Options						
BPT-A/C#1	15	15	100.0%	0	0.0%	0.0%
BPT-A/C#2	15	15	100.0%	0	0.0%	0.0%
BPT-A/C#3	15	15	100.0%	0	0.0%	0.0%
BPT-A/C#4	15	15	100.0%	0	0.0%	0.0%
BPT-A/C#5	15	15	100.0%	0	0.0%	0.0%
BCT Options						
BCT-A/C#1	15	15	100.0%	0	0.0%	0.0%
BCT-A/C#2	15	15	100.0%	0	0.0%	0.0%
BCT-A/C#3	15	15	100.0%	0	0.0%	0.0%
BAT Options						
BAT-A/C#1	15	15	100.0%	0	0.0%	0.0%
BAT-A/C#2	15	15	100.0%	0	0.0%	0.0%
BAT-A/C#3	15	15	100.0%	0	0.0%	0.0%
BAT-A/C#4	15	14	93.3%	1	6.7%	0.7%

* Number of firms remaining after baseline analysis that have A/C direct discharge facilities.
** Out of all firms in the postcompliance analysis (133 firms). Note that the numbers of facilities in Tables 6-2 through 6-4 total more than 133, because several firms have more than one type of facility.

Source: ERG estimates.

TABLE 6-3

POSTCOMPLIANCE ANALYSIS 1
B/D DIRECT DISCHARGE REGULATORY OPTIONS (7 AFFECTED FIRMS)*

Regulatory Option	Total Number of Firms*	No Significant Impact		Significant Impact		
		# of Firms*	% of Group	# of Firms*	% of Group	% of All Firms**
BPT Options						
BPT-B/D#1	7	7	100.0%	0	0.0%	0.0%
BPT-B/D#2	7	7	100.0%	0	0.0%	0.0%
BPT-B/D#3	7	7	100.0%	0	0.0%	0.0%
BCT Options						
BCT-B/D#1	7	7	100.0%	0	0.0%	0.0%
BCT-B/D#2	7	7	100.0%	0	0.0%	0.0%
BAT Options						
BAT-B/D#1	7	7	100.0%	0	0.0%	0.0%
BAT-B/D#2	7	7	100.0%	0	0.0%	0.0%
BAT-B/D#3	7	7	100.0%	0	0.0%	0.0%
BAT-B/D#4	7	7	100.0%	0	0.0%	0.0%

* Number of firms remaining after baseline analysis that have B/D direct discharge facilities
** Out of all firms in the postcompliance analysis (133 firms). Note that the numbers of facilities in Tables 6-2 through 6-4 total more than 133, because several firms have more than one type of facility.

Source: ERG estimates.

TABLE 6-4

POSTCOMPLIANCE ANALYSIS 1
PSES INDIRECT DISCHARGE REGULATORY OPTIONS

Regulatory Option	Total Number of Firms*	*No Significant* Impact		*Significant* Impact		
		# of Firms*	% of Group	# of Firms*	% of Group	% of All Firms**
PSES-A/C Options						
PSES-B/D#1	53	51	96.2%	2	3.8%	1.5%
PSES-B/D#2	53	51	96.2%	2	3.8%	1.5%
PSES-B/D#3	53	50	94.3%	3	5.7%	2.2%
PSES-B/D#4	53	49	92.5%	4	7.5%	3.0%
PSES-B/D Options						
PSES-B/D#1	79	78	98.7%	1	1.3%	0.7%
PSES-B/D#2	79	78	98.7%	1	1.3%	0.7%
PSES-B/D#3	79	73	92.4%	6	7.6%	4.5%

* Number of firms remaining after baseline analysis that have indirect discharge facilities.
** Out of all firms in the postcompliance analysis (133 firms). Note that the numbers of facilities in Tables 6-2 through 6-4 total more than 133, because several firms have more than one type of facility.

Source: ERG estimates.

TABLE 6-5

POSTCOMPLIANCE ANALYSIS 1*
SELECTED REGULATORY OPTIONS

	Total Number of Firms	No Significant Impact		Significant Impact		
		# of Firms	% of Group	# of Firms	% of Group	% of All Firms**
Firms with A/C Direct Facilities	15	15	100.0%	0	0.0%	0.0%
Firms with B/D Direct Facilities	7	7	100.0%	0	0.0%	0.0%
Firms with A/C Indirect Facilities	53	51	96.2%	2	3.8%	1.5%
Firms with B/D Indirect Facilities	72	71	98.6%	1	1.4%	0.7%
All Firms+	133	130	97.7%	3	2.3%	2.3%

* This scenario analyzes impacts from regulating A/C Direct facilities under options BAT-A/C#2 and BPT-A/C#2, B/D Direct facilities under options BAT-B/D#1 and BPT-B/D#2, A/C Indirect facilities under option PSES-A/C#1, and B/D Indirect facilities under option PSES-B/D#1.
** Out of all firms in the postcompliance analysis (133 firms).
+ Number of firms for All Firms might be less than the total firms by subcategory because some firms have more than one type of facility. Total number of All Firms includes firms that have nondischarging facilities

Note: Analysis excludes three firms because of lack of financial data.

Source: ERG estimates.

and one B/D indirect firm are expected to be likely to fail as a result of the proposed effluent guidelines. Additionally, the one B/D indirect firm is a firm/facility, which is therefore assumed to be liquidated (i.e., closed). Note, however, that this is an upper-bound estimate of significant impacts, since zero-cost passthrough is assumed. A market-based model might show fewer or even no firm failures. The same results are obtained under the alternative regulatory scenario (the in-plant steam stripping/distillation scenario; see Appendix C).

6.2.2 Postcompliance Analysis 2

Tables 6-6 and 6-7 present the results of the analysis of firms that are estimated to fail in the baseline analysis but that have positive EBIT or net income. This analysis investigates whether compliance cost impacts on these marginal firms would be onerous, if they did not fail for other reasons. As Table 6-6 shows, changes in ICR (shown in absolute value) in these marginal firms are insignificant in many cases. Nearly a third of the firms (9 firms) in this group show no change in ICR. More than two-thirds are estimated to incur changes in ICR of 5 percent or less (20 firms). A total of nine firms, or about 31 percent of marginal firms with positive EBIT, would be expected to incur substantial impacts (i.e., greater than 5 percent change) if they do not fail for other reasons (see Section 6.2.4 for a more in-depth analysis of how likely these firms are to fail in the baseline).

Table 6-7 presents a similar analysis for ROA among marginal firms with positive net income. Nine firms in this category incur changes in ROA (again in absolute values) of 5 percent or less (45 percent). Eleven firms (55 percent of the marginal firms with positive ROA), however, would be expected to incur substantial impacts (i.e., decline in ROA greater than 5 percent) if these firms do not fail for other reasons (see Section 6.2.4 for a more in-depth analysis of how likely these firms are to fail in the baseline).

TABLE 6-6

POSTCOMPLIANCE ANALYSIS 2: PERCENT CHANGE IN ICR AMONG FIRMS THAT FAIL IN THE BASELINE ANALYSIS

	Number of Firms						
		Percent Change in ICR					
	Total	0	>0 - <=5	>5 - <=10	>10 - <=20	>20 - <=50	>50
Firms with A/C Direct Facilities	3	0	3	0	0	0	0
Firms with B/D Direct Facilities	4	0	3	0	0	1	0
Firms with A/C Indirect Facilities	6	1	1	1	0	1	2
Firms with B/D Indirect Facilities	21	8	6	2	0	5	0
All Firms*	29	9	11	2	0	5	2

*Number of firms for All Firms might be less than the total firms by subcategory because some firms have more than one type of facility.

Note:
1. Firms that failed the baseline analysis are analyzed here if [(base EBIT and net income>0)and(base ICR or ROA<bench)]or[(base net income<=0)and(base EBIT>0)].
2. Because only firms with positive EBIT can be analyzed here, those with negative EBIT are analyzed for percent decline in EBIT in Table 6-8.

Source: ERG estimates.

TABLE 6-7

POSTCOMPLIANCE ANALYSIS 2: PERCENT CHANGE IN ROA AMONG FIRMS THAT FAIL IN THE BASELINE ANALYSIS

	Number of Firms						
		Percent Change in ROA					
	Total	0	>0 - <=5	>5 - <=10	>10 - <=20	>20 - <=50	>50
Firms with A/C Direct Facilities	3	0	2	1	0	0	0
Firms with B/D Direct Facilities	2	0	1	0	1	0	0
Firms with A/C Indirect Facilities	6	1	1	1	1	1	1
Firms with B/D Indirect Facilities	13	5	0	2	2	1	3
All Firms*	20	6	3	3	2	2	4

*Number of firms for All Firms might be less than the total firms by subcategory because some firms have more than one type of facility.

Note:
1. Firms that failed the baseline analysis are analyzed here if [(base EBIT and net income>0)and(base ICR or ROA<bench)]or[(base EBIT<=0)and(base net income>0)].
2. Because only firms with positive net income can be analyzed here, those with negative net income are analyzed for percent decline in net income in Table 6-9.

Source: ERG estimates.

6.2.3 Postcompliance Analysis 3

Tables 6-8 and 6-9 present the results of an analysis of declines in EBIT and net income for firms where EBIT or net income is already negative in the baseline. The analysis measures absolute changes in EBIT and net income. As Table 6-8 shows, 19 firms (76 percent) with negative EBIT would incur changes in EBIT of 5 percent or less (i.e., EBIT becomes more negative, but only by 5 percent or less of the firm's existing loss). Only six firms (24 percent of firms with negative EBIT) are thus estimated to incur substantial impacts if they do not fail for other reasons (see Section 6.2.4 for a more in-depth analysis of how likely these firms are to fail in the baseline).

Table 6-9 presents the change in net income among firms with negative net income in the baseline. Twenty-nine firms (85 percent) are associated with a change in net income of 5 percent or less. Only five firms (or 15 percent) would be expected to incur substantial impacts if they do not fail for other reasons (see Section 6.2.4 for a more in-depth analysis of how likely these firms are to fail in the baseline).

6.2.4 Further Investigation into Likelihood of Firms Failing in the Baseline

As Sections 6.2.2 and 6.2.3 indicate, 9 firms with positive EBIT projected to fail in the baseline analysis are expected to incur a change in ICR of greater than 5 percent; 11 firms with positive net income will incur a change in ROA of greater than 5 percent; 6 firms with negative EBIT will incur changes in EBIT of more than 5 percent, and 5 firms with negative net income will incur changes in net income of more than 5 percent.

Many of these firms overlap in these counts, thus only 16 firms identified as likely to fail in the baseline are considered likely to incur major impacts if they do not actually fail. These 16 firms are analyzed in more detail in Table 6-10. In this table various measures of potential financial viability are assessed. Where two or more items are noted as "yes," it is assumed that baseline failure might not occur and that some unusual factors, such as facility startup costs or unusually high R&D expenditures, are causing a superficial appearance of poor financial health.

TABLE 6-8

POSTCOMPLIANCE ANALYSIS 3: PERCENT CHANGE IN EBIT AMONG FIRMS THAT FAIL IN THE BASELINE ANALYSIS

	Number of Firms						
		Percent Change in EBIT					
	Total	0	>0 - <=5	>5 - <=10	>10 - <=20	>20 - <=50	>50
Firms with A/C Direct Facilities	1	0	0	1	0	0	0
Firms with B/D Direct Facilities	0	0	0	0	0	0	0
Firms with A/C Indirect Facilities	11	5	3	0	0	1	2
Firms with B/D Indirect Facilities	14	7	5	0	1	0	1
All Firms*	25	12	7	1	1	1	3

*Number of firms for All Firms might be less than the total firms by subcategory because some firms have more than one type of facility.

Note: Firms that failed the baseline analysis are analyzed here if (base EBIT<=0).

Source: ERG estimates.

TABLE 6-9

POSTCOMPLIANCE ANALYSIS 3: PERCENT CHANGE IN NET INCOME (NI) AMONG FIRMS THAT FAIL IN THE BASELINE ANALYSIS

	Number of Firms						
		Percent Change in Net Income					
	Total	0	>0 - <=5	>5 - <=10	>10 - <=20	>20 - <=50	>50
Firms with A/C Direct Facilities	1	0	0	1	0	0	0
Firms with B/D Direct Facilities	2	0	2	0	0	0	0
Firms with A/C Indirect Facilities	11	5	4	0	1	0	1
Firms with B/D Indirect Facilities	22	10	10	0	1	1	0
All Firms*	34	15	14	1	2	1	1

*Number of firms for All Firms might be less than the total firms by subcategory because some firms have more than one type of facility.

Note: Firms that failed the baseline analysis are analyzed here if (base net income<=0).

Source: ERG estimates.

TABLE 6-10

ADDITIONAL MEASURES OF FINANCIAL VIABILI TY AMONG FIRMS THAT FAIL IN THE BASELINE ANALYSIS

Firm	R&D to Costs Ratio Greater than Average	R&D to Costs Ratio	One or More Facility Started	Rising Net Income (More than 10% per year)	Average % Change in Net Income*	Rising Working Capital (More than 10% per year)	Average % Change in Working Capital**
1 ***	no data	no data	yes	no data	no data	no data	no data
2	no	0.00%	no	no	-57.98%	no	7.51%
3	no	0.00%	no	yes	328.60%	no	-21.21%
4	no	0.94%	no	yes	78.63%	no	8.60%
5	no	12.18%	no	yes	489.69%	yes	23.88%
6	no	1.98%	no	no	-355.37%	no	-108.94%
7	no	0.00%	no	no	-58.80%	yes	31.59%
8	no	7.81%	no	yes	153.17%	no	-4.33%
9	no	0.00%	no	no	-485.67%	no	-101.08%
10	yes	56.53%	no	no	7.58%	no	-13.64%
11	yes	15.92%	no	no	-95.38%	no	0.23%
12	no	0.00%	no	yes	206.55%	yes	170.20%
13	yes	39.27%	no	no	-88.61%	no	-19.39%
14	no	1.38%	no	yes	31.33%	yes	19.57%
15	no	0.01%	no	no	9.09%	no	-9500.27%
16	no	0.00%	no	no	-11.39%	no	-7.42%

* Average % change in net income in both period '88-'89 and '89-'90.
** Average % change in working capital in both period '88-'89 and '89-'90.
*** This firm provided insufficient data to determine these measures.

Source: Section 308 Pharmaceutical Survey.

As the table shows, three firms (Numbers 5, 12, and 14) showed substantial increases in net income and working capital over the 3-year period of data collection (one firm had insufficient data to confirm or deny the baseline failure assessment). Net income at two of the three firms, although showing improvements, remained quite negative in all 3 years and no other mitigating factors (such as a new facility or high R&D expenditures that might explain the negative income) were present. Thus there is no evidence that their financial health is other than what was determined in the baseline analysis. The third firm, however, showed outstanding growth in net income, going from negative to strongly positive in 1990. The firm's 1990 financial picture, therefore, was considered more likely to represent its future trend than the average of the three years of financial data. If this assumption is used, the firm would pass the baseline analysis with an ROA of 22 percent and no debt payments (i.e., ICR = infinity). When compliance costs are considered, its ROA drops only to 21 percent and its ICR is excellent. Thus even if this firm were not to fail in the baseline, if its financial health continues strong in future years, this firm should have no difficulty affording to comply with the regulation.

In summary, the results of this last analysis indicate that the baseline analysis was reasonably accurate in identifying firms in poor health. Thus the results of Postcompliance Analysis 1 can be reasonably assumed to represent an upper bound on firm-level impacts from the selected regulatory options.

6.2.5 Profitability Analysis

Table 6-11 presents the results of an analysis to determine the effects of the selected regulatory options on profitability, measured as ROA, among firms that are considered healthy in the baseline and in Postcompliance Analysis 1. As the table shows, 82 firms (nearly 85 percent of all healthy, noncertifying firms) are associated with declines in ROA of 5 percent or less. Fifteen firms are anticipated to have more substantial impacts; only one firm is expected to experience impacts of greater than 50 percent. Only one direct discharging firm (an A/C direct) will have a change in ROA of greater than 5 percent. Firms with indirect discharging facilities bear more impacts. Six A/C indirect dischargers are expected to experience changes in ROA exceeding 5 percent. Eight firms with B/D indirect discharges are expected to experience a

TABLE 6-11

PROFITABILITY ANALYSIS - PERCENTAGE DECLINE IN ROA, BY TYPE OF FACILITY OWNED AMONG FIRMS THAT PASS THE BASELINE ANALYSIS

	Number of Firms						
		Percent Change in ROA					
	Total	0	>0 - <=5	>5 - <=10	>10 - <=20	>20 - <=50	>50
Firms with A/C Direct Facilities	10	1	8	0	0	1	0
Firms with B/D Direct Facilities	3	0	3	0	0	0	0
Firms with A/C Indirect Facilities	36	8	22	3	0	3	0
Firms with B/D Indirect Facilities	53	22	23	3	1	3	1
All Firms*	97	35	47	6	1	7	1

*Number of firms for All Firms might be less than the total firms by subcategory because some firms have more than one type of facility. Total number of All Firms includes firms that have nondischarging facilities.

Note:
1. This table analyzes firms that passed the baseline analysis, excluding the 36 firms that only have certified facilities.
2. Analysis excludes three firms because of lack of financial data.

Source: ERG estimates.

change in ROA of more than 5 percent. When certifying firms are included in the analysis, the 15 firms estimated to incur major impacts on ROA are only 11 percent of all firms in the postcompliance analysis. Furthermore, if some passthrough of compliance costs are possible, these impacts could be much lower.

Although these firms have large declines in ROA, it is useful to note that the average baseline ROA among these firms is 27 percent, which is well above industry average. Thus even with large declines, postcompliance ROA is probably substantial.

These results are broken down by firm size in Section Nine in the discussion of the regulatory flexibility analysis.

6.3 REFERENCES

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SECTION SEVEN

EMPLOYMENT AND COMMUNITY-LEVEL IMPACTS

This section of the EIA investigates employment and community-level impacts resulting from compliance with the proposed effluent limitations guidelines for the pharmaceutical industry. Compliance with the proposed effluent guidelines imposes a cost at both the facility and the firm level. The expenditures to meet the regulatory standards might result in facility closures and firm failures and thereby a loss in employment. This primary loss in employment can lead to reduced production in the industries that supply inputs to the pharmaceutical industry, thus leading to secondary employment losses. These secondary losses are calculated by using product input-output tables that take into account geographic and industrial patterns and the associated employment changes. When total primary and secondary losses are compared to employment levels in the communities in which the firms and facilities are located, community-level impacts can be determined. These losses are, however, offset to some extent by the need to hire workers to manufacture, install, and maintain the pollution control equipment. This increase in economic activity results in employment gains in the related industries and is factored into this analysis.

The analysis in this section is divided into three parts. Section 7.1 examines primary and secondary employment losses, presenting the methodology and results of the employment losses and community-level impacts resulting from baseline and postcompliance facility closures and firm failures. Section 7.2 analyzes labor requirements and potential employment benefits from the manufacture, installation, and maintenance of the necessary pollution control equipment. Finally, Section 7.3 presents the net employment impacts of the proposed regulation.

7.1 PRIMARY AND SECONDARY EMPLOYMENT LOSSES

7.1.1 Introduction

Primary employment losses occur only within the targeted pharmaceutical manufacturing industry. Secondary impacts include employment losses in other industries providing inputs to the pharmaceutical manufacturing process and other supporting industries such as community-based services that lose income when layoffs occur; these losses would result from any significant decline in demand for inputs as well as from regional reductions in personal income.

Primary and secondary employment losses are summed to obtain the total impact on community employment levels resulting from implementation of the effluent guidelines. Although secondary employment losses do not necessarily occur at the community level (since national multipliers cannot differentiate between input sources within and outside the community), they are included in this analysis to present a conservative estimate of all potential employment losses.

7.1.2 Methodology

7.1.2.1 Primary Employment Losses

Primary employment losses consist of employee layoffs associated with the facility closures estimated in the facility-level analysis and firm failures in the firm-level analyses. These job losses are estimated from survey data on annual employment hours.

Three types of employment losses (measured in hours) are estimated and summed to estimate total employment losses. Losses are calculated for facilities, for facilities that are also firms (known here as firm/facilities—see Section Five), and firms where the firm and the facility are not the same entity (multifacility firms). Facility closures are considered a liquidation (not a

sale), thus all employees of the facility are assumed to lose their jobs. Total direct job losses are equal to the total employment at the closed facility.[1]

Firm/facilities (where the firm and the facility are the same entity) are not analyzed in the facility closure analysis, but in the firm failure analysis. Thus, these firm/facilities are not assumed to be liquidated based on the facility-level analysis. Instead they are analyzed to determine whether they can absorb the costs of compliance and still be considered financially healthy, i.e., not likely to fail (based on an analysis of standard financial ratios). If firm/facilities are shown to be likely to fail under a regulatory option, the total employment of the firm/facility is counted as an employment loss and added to those losses accounted for under the facility closure analysis. Note that this assumption is conservative. If the present value of net income at the firm/facility is not too low after accounting for compliance costs, the facility might be purchased by another firm.

Multifacility firms also are analyzed to determine whether they are likely to fail under the various regulatory options. Employment losses at the firm level are more difficult to quantify, since the Section 308 Survey did not obtain information on firm-level employment. Therefore 10 percent of the total employment at all the facilities owned by the firm was used as a proxy for employment strictly related to the administrative functioning of the firm:

Total employment of all facilities * 0.1 = Total nonfacility employment at the firm level.

If a firm is shown to be likely to fail, we assume that this nonfacility employment is lost, representing administrative and executive staffing at the firm level only. Note that facilities that

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[1]Plant closures are estimated based on an analysis of the salvage value of the facility vs. the present value of net income at the facility. If the salvage value of the facility exceeds the present value of net income of the facility (estimated based on data from the Section 308 Survey), the firm is projected to liquidate the facility. Thus closures are considered the loss of a facility in contrast to a sale, which is considered the transfer of a facility to new ownership. All facilities that are projected to remain in operation in the baseline case (i.e., without the regulation) are assigned annual costs of compliance with the effluent guideline option under consideration. These costs in turn reduce facility net income. If the salvage value is greater than the new present value of net income, these facilities are considered to close and the closures are assigned to the regulatory option under consideration (see Section Five).

do not close as a result of the proposed guidelines are assumed to be sold intact with no loss of employment when their owner company fails. Thus no additional employment losses are associated with firm failure beyond the 10 percent factor discussed above. This estimate of firm-level employment losses also is added to the number of employee losses projected under the other two analyses.

Total employee hours lost because of a facility closure or firm failure (i.e., the sum of pharmaceutical production and nonproduction hours) are converted to fulltime equivalents (FTEs), assuming that 2,080 hours (52 weeks/year x 40 hours/week) equals one FTE. The analysis is divided into two stages. The first stage analyzes the employment losses associated with baseline closures and failures (i.e., those closures and failures that are expected to occur even without the proposed effluent guidelines). The second stage calculates the closures associated with compliance with the selected options. These postcompliance employment losses in employment are then converted into FTEs.

7.1.2.2 Secondary Employment Losses

Secondary losses in employment occur in other industries providing inputs to the pharmaceutical manufacturing industry and are caused by reduced demand for these inputs. Secondary impacts are assessed through multiplier analysis, which measures the extent of impacts in other industries as a function of impacts in the primary industry. Multiplier analysis provides a straightforward framework as long as the direct effects are small and certain limiting assumptions about technology are valid (e.g., constant returns to scale, fixed input ratios).

The multiplier used in this analysis is based on input/output tables developed by the Department of Commerce, Bureau of Economic Analysis (BEA, 1992). The BEA multipliers are estimated using the Regional Industrial Multiplier System (RIMS II) developed by the Regional Economic Analysis Division of the BEA. The multipliers reflect the total national change in the

number of jobs given a change in the number of jobs for a particular industry.[2] In this analysis, the industry directly affected is the Drugs Industry (SIC 283).[3] The multiplier reported by BEA for this industry is 5.95.[4] The total number of job losses, both primary and secondary, is computed as the primary losses in pharmaceutical industry jobs (measured in FTEs) multiplied by 5.95:

Total job losses = 5.95 * Primary losses in the Pharmaceutical Industry

These secondary losses are calculated both for the baseline analysis and for each option, postcompliance.

7.1.2.3 Measuring Impacts at the Community Level

The significance of employment losses on the community is measured by their impact on the community's overall level of employment. Data necessary to determine the community impact include the community's total labor force and employment rate. The community employment information used in this analysis is from the end-of-year 1990, as estimated by the Bureau of Labor Statistics. For purposes of this analysis, the community is defined as the *Metropolitan Statistical Area (MSA)* in which the facility is located and is assumed to represent the labor market area within which residents could reasonably commute to work.[5] If the facility is located in a *Primary Metropolitan Statistical Area (PMSA)* within the MSA, then the PMSA

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[2] Employment multipliers for a given industry show the number of full- and part-time jobs that the industry provides, both directly and indirectly, given a $1 million change in final demand.

[3]Multipliers based on direct employment changes are available at an aggregated industry level only.

[4]The use of this national multiplier might overstate the number of jobs affected within the community because some of the inputs might be from sources outside the community or even outside the country. No multipliers that differentiate among the locations of input sources are known to exist.

[5]MSAs are defined by the U.S. Office of Management and Budget.

total labor force is used. If a facility is not located within an MSA, then the community's total labor force is defined as the total labor force of a county (or township, for eastern states).

This analysis too, is divided into a baseline and postcompliance analysis. For simplicity, baseline losses are analyzed only if there is a postcompliance closure or failure in the same community. In that case baseline losses are subtracted from current employment numbers to reduce the base employment and possibly the base employment rate in the community of concern. An increase in the community employment rate equal to or greater than one percent is considered significant. This impact would correspond to a considerable change in the community employment rate.

7.1.3 Results

7.1.3.1 Employment Impacts

Baseline Losses: Primary and Secondary Employment Losses

As discussed above, employment losses are counted when a facility closes (100 percent of facility employment), when a firm/facility fails (100 percent of facility employment) and when a firm fails (10 percent of facility employment for all facilities owned).

Table 7-1 presents the results of primary employment losses in the baseline. As the table shows, before any compliance costs are incurred, 14,381 jobs are estimated to be lost, out of a total employment of 147,804 workers[6] (9.7 percent of total employment in the affected portion of the industry). These losses are associated with 38 facility closures, 21 firm/facility failures, and 33 firm failures. The baseline analysis predicts that secondary job losses will total 85,567, using the multiplier of 5.95 (as discussed in Section 7.1.2). These baseline losses constitute an

[6]In the affected portion of the pharmaceutical industry. Employment at other pharmaceutical firms not covered by the proposed effluent guidelines is not counted here.

TABLE 7-1

CLOSURES AND PRIMARY EMPLOYMENT LOSSES: BASELINE FACILITY AND FIRM ANALYSIS

Facility or Firm Type*	Facility Analysis		Firm/Facility Analysis		Firm Analysis		Total Failures/Employment Losses	
	Facility Closures	Job Losses from Facility Closures	Firm/Facility Failures/Closures	Firm/Facility Job Losses	Firm Failures	Firm Job Losses	Total Firm/Facility and Firm Failures	Job Losses from All Failures and Closures
Direct Discharge								
A/C	1	46	1	126	3	100	4	272
B/D	1	1,300	0	0	4	297	4	1,597
Indirect Discharge								
A/C	13	1,212	8	1,562	9	389	17	3,162
B/D	23	5,944	11	2,799	24	1,126	35	9,869
Zero Discharge								
A/C	0	0	1	38	1	13	2	51
B/D	0	0	0	0	0	0	0	0
All Facilities								
TOTAL**	38	8,501	21	4,525	33	1,355	54	14,381

* For firms this categorizes firms according to the types of facilities the firm owns.

** Total number of firms in the firm analysis might be less than the total firms by subcategory because some firms have more than one type of facility.

Source: ERG estimates.

insignificant portion (0.07 percent) of national employment (which totaled 117.9 million in 1990), thus these losses have a negligible impact on national-level employment rates.

Table 7-2 presents baseline employment losses categorized by facility employment size (thus it excludes firm-level losses and includes only facility and firm/facility losses). The largest percentage of baseline job losses as a proportion of total employment within an employment size group is in the two smallest employment categories (1 to 18 and 19 to 167 employees). A total of 72 out of 237 jobs, or 30 percent, are expected to be lost in the baseline among the smallest employment size group (1-18 employees), and 3,402 out of 8,523 jobs, or 40 percent, among the next smallest employment size group (19-167 employees).

Postcompliance Losses: Primary and Secondary Employment Losses

Tables 7-3 and 7-4 cover employment losses among the A/C and B/D direct dischargers, respectively. Among the A/C direct dischargers, only BAT-B/D#4 results in any impacts. One facility is expected to close and one firm/facility is expected to fail, leading to total employment losses of 62 FTEs. No facility closures or firm failures are expected to occur as a result of any of the regulatory options for B/D direct dischargers, thus no employment losses are predicted for this group.

Table 7-5 presents employment losses associated with PSES options for indirect dischargers. Losses range from those for PSES-A/C#1, which is expected to result in two firm failures and an estimated loss of 78 FTEs (based on the 10 percent employment loss factor used for firm failures) to those for the most stringent option, PSES-A/C#4. This latter option results in four firm/facility or firm failures. These establishments are associated with job losses totaling 224 FTEs.

Employment losses for B/D indirect dischargers range from 13 FTEs under PSES-B/D#1, which is expected to result in one firm/facility failure, to 392 FTEs associated with PSES/B/D#3. This most stringent option results in a total of six firm or firm/facility failures.

TABLE 7-2

PRIMARY EMPLOYMENT LOSSES: BASELINE ANALYSIS

Facility Subcategory	Primary Employment Losses by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Losses	Total No.	% of Total	No. of Losses	Total No.	% of Total	No. of Losses	Total No.	% of Total	No. of Losses	Total No.	% of Total	No. of Losses	Total No.	% of Total
Direct Discharge															
A/C	0	11	0%	172	568	30%	0	4,216	0%	0	3,797	0%	172	8,592	2%
B/D	0	0	0%	0	64	0%	0	2,800	0%	1,300	9,417	14%	1,300	12,282	11%
Indirect Discharge															
A/C	11	54	20%	1,553	3,178	49%	201	10,165	2%	1,008	43,861	2%	2,773	57,258	5%
B/D	61	157	39%	1,638	4,465	37%	3,320	20,610	16%	3,723	43,425	9%	8,743	68,657	13%
Zero Discharge															
A/C	0	0	0%	38	85	45%	0	187	0%	0	0	0%	38	272	14%
B/D	0	14	0%	0	163	0%	0	567	0%	0	0	0%	0	745	0%
All Facilities															
TOTAL	72	237	30%	3,402	8,523	40%	3,521	38,546	9%	6,031	100,499	6%	13,026	147,804	9%

Note:

1. Analysis assumes no employment losses occur for certified facilities.
2. Analysis excludes four facilities (one A/C direct discharger, two B/D indirect dischargers, and one A/C zero discharger) because of lack of financial data.

Source: ERG estimates.

TABLE 7-3

CLOSURES AND PRIMARY EMPLOYMENT LOSSES FOR A/C DIRECT DISCHARGE OPTIONS: POSTCOMPLIANCE FACILITY AND FIRM ANALYSIS

OPTION	Facility Analysis		Firm/Facility Analysis		Firm Analysis		Total Failures/Employment Losses	
	Facility Closures	Job Losses from Facility Closures	Firm/Facility Failures/Closures	Firm/Facility Job Losses	Firm Failures	Firm Job Losses	Total Firm/Facility and Firm Failures	Job Losses from All Failures and Closures
Regulatory Option BPT								
BPT-A/C#1	0	0	0	0	0	0	0	0
BPT-A/C#2	0	0	0	0	0	0	0	0
BPT-A/C#3	0	0	0	0	0	0	0	0
BPT-A/C#4	0	0	0	0	0	0	0	0
BPT-A/C#5	0	0	0	0	0	0	0	0
Regulatory Option BCT								
BCT-A/C#1	0	0	0	0	0	0	0	0
BCT-A/C#2	0	0	0	0	0	0	0	0
BCT-A/C#3	0	0	0	0	0	0	0	0
Regulatory Option BAT								
BAT-A/C#1	0	0	0	0	0	0	0	0
BAT-A/C#2	0	0	0	0	0	0	0	0
BAT-A/C#3	0	0	0	0	0	0	0	0
BAT-A/C#4	1	3	1	59	0	0	1	62

Source: ERG estimates.

TABLE 7-4

CLOSURES AND PRIMARY EMPLOYMENT LOSSES FOR B/D DIRECT DISCHARGE OPTIONS: POSTCOMPLIANCE FACILITY AND FIRM ANALYSIS

OPTION	Facility Analysis		Firm/Facility Analysis		Firm Analysis		Total Failures/Employment Losses	
	Facility Closures	Job Losses from Facility Closures	Firm/Facility Failures/Closures	Firm/Facility Job Losses	Firm Failures	Firm Job Losses	Total Firm/Facility and Firm Failures	Job Losses from All Failures and Closures
Regulatory Option BPT								
BPT-B/D#1	0	0	0	0	0	0	0	0
BPT-B/D#2	0	0	0	0	0	0	0	0
BPT-B/D#3	0	0	0	0	0	0	0	0
Regulatory Option BCT								
BCT-B/D#1	0	0	0	0	0	0	0	0
BCT-B/D#2	0	0	0	0	0	0	0	0
Regulatory Option BAT								
BAT-B/D#1	0	0	0	0	0	0	0	0
BAT-B/D#2	0	0	0	0	0	0	0	0
BAT-B/D#3	0	0	0	0	0	0	0	0
BAT-B/D#4	0	0	0	0	0	0	0	0

Source: ERG estimates.

TABLE 7-5

CLOSURES AND PRIMARY EMPLOYMENT LOSSES FOR INDIRECT DISCHARGE OPTIONS: POSTCOMPLIANCE FACILITY AND FIRM ANALYSIS

OPTION	Facility Analysis		Firm/Facility Analysis		Firm Analysis		Total Failures/Employment Losses	
	Facility Closures	Job Losses from Facility Closures	Firm/Facility Failures/Closures	Firm/Facility Job Losses	Firm Failures	Firm Job Losses	Total Firm/Facility and Firm Failures	Job Losses from All Failures and Closures
A/C Facilities								
PSES-A/C#1	0	0	0	0	2	78	2	78
PSES-A/C#2	0	0	0	0	2	78	2	78
PSES-A/C#3	0	0	1	86	2	78	3	164
PSES-A/C#4	0	0	2	146	2	78	4	224
B/D Facilities								
PSES-B/D#1	0	0	1	13	0	0	1	13
PSES-B/D#2	0	0	1	13	0	0	1	13
PSES-B/D#3	1	85	3	232	3	75	6	392

Source: ERG estimates.

Table 7-6 summarizes the facility- and firm-level primary employment losses for the selected regulatory option (BAT-A/C#2, BAT-B/D#1, PSES-A/C#1 and PSES-B/D#1). As the table shows, all the employment losses occur in the indirect discharge category. Two firms (owning A/C indirect discharging facilities) are predicted to fail as a result of complying with PSES-A/C#1, leading to an estimated loss of 78 FTEs. One B/D indirect firm/facility also is predicted fail as a result of PSES-B/D#1, leading to a loss of 13 FTEs. Total estimated primary employment losses thus total 91 out of 133,423 jobs in the affected industry (accounting for baseline employment losses), or 0.07 percent of total employment for the affected portion of the industry. Secondary losses are estimated at 541 FTEs, using the multiplier of 5.95. These losses are negligible when compared to total U.S. employment and will have no impact on national-level employment rates. The same results are obtained when the alternative regulatory scenario (in-plant steam stripping/distillation) is considered (see Appendix C).

Note that two out of three firms and firm/facilities projected to fail under the selected regulatory scenario employ fewer than 750 employees. The affected firms range in size from 13 to 755 total employees (measured as FTEs).

7.1.3.2 Community-Level Impacts

The three firms estimated likely to fail as a result of the selected regulatory options are located in two areas, a small county with an employed population of about 45,000 and an unemployed population of about 4,400 and the CMSA of New York and Northern New Jersey with nearly 8 million employed persons. In the first case, the employment rate drops by 0.01 percent due to a loss of 69 FTEs. In the other case, employment rate changes are negligible (FTEs lost total 22). Thus no community-level impacts are expected.

TABLE 7-6

CLOSURES AND PRIMARY EMPLOYMENT LOSSES FOR SELECTED OPTIONS: POSTCOMPLIANCE FACILITY AND FIRM ANALYSIS

Facility or Firm Type*	Facility Analysis		Firm/Facility Analysis		Firm Analysis		Total Failures/Employment Losses	
	Facility Closures	Job Losses from Facility Closures	Firm/Facility Failures/Closures	Firm/Facility Job Losses	Firm Failures	Firm Job Losses	Total Firm/Facility and Firm Failures	Job Losses from All Failures and Closures
Direct Discharge								
A/C	0	0	0	0	0	0	0	0
B/D	0	0	0	0	0	0	0	0
Indirect Discharge								
A/C	0	0	0	0	2	78	2	78
B/D	0	0	1	13	0	0	1	13
Zero Discharge								
A/C	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
B/D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
All Facilities								
TOTAL**	0	0	1	13	2	78	3	91

* For firms this categorizes firms according to the types of facilities the firm owns.

** Total number of firms in the firm analysis might be less than the total firms by subcategory because some firms have more than one type of facility.

Source: ERG estimates.

7.2 LABOR REQUIREMENTS AND POTENTIAL EMPLOYMENT BENEFITS

7.2.1 Introduction

Firms will need to install and operate pollution control systems to comply with an effluent limitations guideline for the pharmaceutical industry. The manufacture, installation, and operation of these systems will require use of labor resources. To the extent that these labor needs translate into employment increases in affected firms, an effluent guideline for the pharmaceutical industry has the potential to generate employment benefits. If realized, these employment benefits might at a minimum partially offset the employment losses that are expected to occur in facilities affected by the rule. The employment effects that would occur in the manufacture, installation, and operation of treatment systems are termed the "direct" employment benefits of the rule. Because these employment effects are directly attributable to the pharmaceutical industry rule, they are conceptually parallel to the primary employment losses estimated as a result of the rule. This section looks at the employment gains (benefits) associated with the selected regulatory options only.

In addition to direct employment benefits, the proposed guidelines might generate other employment benefits through two mechanisms. First, employment effects might occur in the industries that are linked to the industries that manufacture and install compliance equipment; these effects are termed "indirect" employment benefits. For example, a firm that manufactures the pumps, piping, and other hardware that make up a treatment system will purchase intermediate goods and services from other firms and sectors of the economy. Thus, increased economic activity in the firm that manufactures the treatment system components has the potential to increase activity and employment in these linked firms and sectors. Second, the increased payments to labor in the directly and indirectly affected industries will lead to increased purchases from consumer-oriented service and retail businesses, which in turn lead to additional labor demand and employment benefits in those businesses. These effects are termed "induced" employment benefits.

In view of these possible employment benefits, EPA estimated the labor requirements associated with compliance with the proposed regulatory options as outlined in Section Four.

The following discussion summarizes the findings from this effort. Labor requirements—and thus the possible employment benefits—were estimated in two steps. First, the direct employment effects associated with the manufacture, installation, and operation of the pharmaceutical industry compliance equipment were estimated. These effects are discussed in Section 7.2.2. Second, EPA considered the additional employment effects that might occur through the indirect and induced effect mechanisms outlined above; these effects are discussed in Section 7.2.3.

7.2.2 Estimating Direct Labor Requirements

As discussed above, an effluent guideline for the pharmaceutical industry will create demand for labor services for manufacturing, installing, and operating compliance equipment. EPA analyzed each of these components of direct labor requirements separately. The sum of the estimated requirements for the three labor categories represents the estimated total direct labor requirement, and thus the potential direct employment benefit, from compliance with the effluent guideline.

7.2.2.1 Direct Labor Requirements for Manufacturing Compliance Equipment

The direct labor requirements for manufacturing compliance equipment are estimated based on the cost of the equipment and labor's expected contribution to the equipment's value in its manufacture. Labor's contribution was estimated in dollars and was converted to an FTE equivalent based on a yearly labor cost. Each component of the calculation is discussed below.

Cost of Compliance Equipment

The cost of compliance equipment was presented in Section Four for each of the regulatory options. Compliance equipment requirements and their associated costs for each facility included in the Section 308 Survey were used where applicable. For the labor

requirements analysis, compliance costs and their associated labor requirements were considered only for those facilities *that were not assessed either as a baseline closure or as a postcompliance closure.* That is, the analysis considers the labor requirement effects associated only with those facilities that were assessed as likely to comply with the rule and continue pharmaceutical production activities. These costs were weighted, where appropriate, according to the number of facilities each sampled facility represents in the underlying pharmaceutical industry population and summed to give an aggregate compliance equipment cost for the industry. The total estimated one-time capital equipment cost in 1990 dollars for complying with the selected regulatory options for A/C and B/D direct dischargers and A/C and B/D indirect dischargers is $153.0 million (see Table 4-7).[7]

Labor's Expected Contribution to the Equipment's Value

Input-output tables assembled by BEA provide information on the composition of inputs used to produce the outputs of industries in the U.S. economy (BEA, 1991a, b [1982 data])[8]. The inputs tallied in the input-output tables include the purchase of intermediate goods, materials, and services from other industries as well as the use of labor by the subject industry. In particular, the *direct requirements* matrix identifies the value of each input, including labor, that is required to produce a one-dollar value of output for a subject industry. From discussions with the EPA technical contractor on this effluent guideline project, the "Heating, Plumbing, and Fabricated Structural Metal Products Industry" (BEA Industry Classification 40) was identified as the industry with output that most nearly matches the types of equipment needed for compliance with the pharmaceutical industry effluent guideline. From the direct requirements matrix, the

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[7]The $153.0 million is the one-time outlay for purchasing the capital equipment estimated to be needed for compliance with the regulation and is not the *annual* cost of the capital equipment. In the economic impact analysis, the capital outlay is annualized over a 16-year period (including a one-year lag between equipment purchase and operation attributable to installation) and the resulting value, which is part of the total annual cost of compliance, is much less than the $153.0 million value.

[8]The 1982 tables are the most current information on the interindustry input-output structure of the U.S. economy.

labor input, titled, *Compensation of Employees,* accounts for $0.31016 of each dollar of output value from the Heating, Plumbing, and Fabricated Structural Metal Products Industry. Multiplying labor's share of output value (0.31016) times the value of equipment purchases for complying with the rule yields labor's contribution to manufacturing the compliance equipment, measured in terms of gross compensation.

The estimated total costs of acquiring compliance equipment is $153.0 million. However, this includes costs for facilities that will close in the baseline, regardless of regulatory cost. After baseline and postcompliance facility closures and firm/facility failures are accounted for and their compliance costs excluded, the total capital cost of purchasing the equipment is $133.4 million. Only 90 percent of these costs are for the equipment itself. The remaining 10 percent is for installation (see Section 7.2.2.2 for more details). Thus total expenditures on equipment are $120.0 million. Labor's contribution is estimated to be $37.2 million ($0.31016 percent x $120.0 million).

The manufacture of compliance equipment is considered a one-time event that occurs at the beginning of industry's compliance activities. Accordingly, the labor requirements for manufacturing compliance equipment should be viewed as a one-time requirement. Elsewhere in this economic impact analysis, the labor effects associated with facility impacts are presented on an annual basis, with the expectation that these job effects would persist over the period of analysis. Accordingly, for consistent assessment of the possible labor requirement effects from manufacturing compliance equipment, it was necessary to annualize the one-time labor effect. Consistent with the annualization procedures elsewhere in the economic impact analysis, the one-time labor compensation value of $37.2 million was annualized over a 16-year period at a social discount rate of 7 percent as recommended by OMB (OMB, 1992). The social discount rate is used rather than the industry discount rate because the social impacts are being assessed here, and not impact on industry. The resulting annual value of gross labor compensation in manufacturing compliance equipment is $3.9 million.

Conversion to Fulltime Employment Equivalent Basis

To convert the gross payment to labor to FTEs, the payment to labor was divided by an estimated yearly labor cost. The yearly labor cost is based on the same labor cost, $27.74 per hour, used in the engineering cost analysis to estimate the cost of operating compliance equipment. The $27.74 per hour is a comprehensive labor cost including an allowance for fringe benefits (e.g., holidays, vacation, and various insurance) and payroll taxes, and was calculated in 1990 dollars. Assuming a 2,080 hour work-year, the gross annual labor cost per full-time employment position is $57,699. On a one-time, one-year basis (i.e., not annualized), the $37.2 million labor outlay for manufacturing compliance equipment is estimated to require 645 FTEs. On an annualized basis, the $3.9 million of gross labor cost for manufacturing compliance equipment is estimated to require 68 FTEs.

7.2.2.2 Direct Labor Requirements for Installing Compliance Equipment

EPA estimated the direct labor requirements for installing compliance equipment in a parallel manner to that used for analyzing the labor requirements for manufacturing compliance equipment. Each component of the calculation is discussed below.

Cost of Installing Compliance Equipment

The cost of installing compliance equipment was estimated in conjunction with estimating the purchase cost of compliance equipment. Specifically, on the basis of the kind, scale, and cost of compliance equipment assessed for a facility, the technical contractors estimated an installation cost for the equipment. The installation costs are calculated based on the assumption that installation is typically equal to 10 percent of the total capital cost. This assumption is taken from Peters and Timmerhaus (1980), which states that installation costs are typically 6 to 14 percent of fixed capital costs for new plant construction or construction of additions to existing

facilities.[9] The estimated installation costs averaged about 10 percent of the purchase cost of the compliance equipment ($133.4 million) for a total of $13.3 million.

Labor's Expected Contribution to the Equipment's Value

The BEA industry group that EPA used as the basis for estimating labor's share of cost in installing compliance equipment is the "Repair and Maintenance Construction Industry" (BEA Industry Classification 12). In this industry group, gross payments to labor account for $0.42233 of each dollar of output value, as recorded in the direct requirements matrix for the national input-output tables. Multiplying labor's share of value (0.42233) by the estimated total installation cost ($13.3 million) yields a gross labor cost for compliance equipment installation of $5.6 million. Like the purchase cost of compliance equipment, the installation cost is a one-time outlay and, accordingly, an annualized value was calculated using the 16-year amortization period and the 7 percent social discount rate. The resulting annual value for the labor cost of installing compliance equipment is $0.6 million.

Conversion to Fulltime Employment Equivalent Basis

Conversion to an FTE equivalent basis is based on the same yearly labor cost, $57,699, as used in estimating the labor requirements for the manufacturing of compliance equipment. On a one-time, one-year basis, 98 FTEs are estimated to be required for installing the equipment needed to comply with the selected regulatory options based on the $13.3 million gross labor cost. Annualized over 16 years, the corresponding labor requirement for installing compliance equipment is 10 FTEs.

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[9]Personal communication with Radian Corp. (May 20, 1994); This engineering text was used to help develop many of the costs analyzed in this EIA, especially for developing distillation treatment equipment costs.

7.2.2.3 Direct Labor Requirements for Operating Compliance Equipment

The technical contractor estimated the annual labor hours required to operate compliance equipment as the basis for assessing the annual operating and maintenance costs of the pharmaceutical industry regulatory options. On an FTE basis, the estimated annual labor requirement for operating compliance equipment is 1.8 million hours per year. Thus 889 FTEs will be created annually for the maintenance of compliance equipment. This value is assumed to recur annually over the period of analysis (16 years). The corresponding total annual estimated payments to labor is $51.3 million (1990 dollars).

7.2.2.4 Total Direct Labor Requirements

Summing the three components yields the total direct labor requirements for complying with the proposed pharmaceutical industry effluent guideline as represented by the selected regulatory options (see Table 7-7). On an FTE basis, the estimated total annual labor requirement is 967 FTEs. The corresponding total annual estimated payments to labor is $55.8 million (1990 dollars). To the extent that these labor requirements manifest as new labor needs in the U.S. economy, the 967 FTEs have the potential to offset employment losses that might otherwise occur because of the rule.

7.2.3 Estimating the Secondary (Indirect and Induced) Labor Requirement Effects

In addition to direct labor effects, the pharmaceutical industry effluent guidelines might also generate labor requirements through the indirect and induced effect mechanisms thereby generating secondary employment. The secondary effects associated with an economic activity are analyzed by using multipliers. Multiplier estimates generally vary with the industry in which the direct economic activities are expected to occur and with the economic characteristics of the location of the direct activities.

TABLE 7-7

ANALYSIS OF POSSIBLE EMPLOYMENT GENERATION EFFECTS OF AN EFFLUENT GUIDELINE FOR THE PHARMACEUTICAL MANUFACTURING INDUSTRY (1990 $)

	Labor Cost Component				Direct Labor Requirement	
	Total Weighted Expenditures ($)	Labor's Share of Output Value	One-Time Basis ($)	Annual Labor Cost ($)	One-Time Basis (FTEs)	Annual Basis (FTEs)
Manufacturing	120,036,467	0.31016	37,230,510	3,941,134	645	68
Installation	13,337,385	0.42233	5,632,778	596,273	98	10
Operation (annually)	51,277,085	1	51,277,085	51,277,085	889	889
Total direct labor effects	184,650,937		94,140,373	55,814,492	1,632	967

Source: ERG estimates.

A range of multipliers was used in this analysis to illustrate the possible aggregate employment effects of the effluent guideline. A recent EPA study used multipliers ranging from 3.5 to 3.9 to calculate the possible indirect and induced employment effects of direct activity investments in general water treatment and pollution control (EPA, 1993). A study of "clean water investments" commissioned by the National Utility Contractors Association (NUCHA; Apogee Research, Inc., 1992) documented total employment effect multipliers ranging from 2.8 to 4.0. Using the high and low values for these multipliers, the indicated aggregate employment effects associated with the direct labor requirement of 967 FTEs would range from 2,708 to 3,868 FTEs.

A more conservative assessment of these possible employment effects would recognize that the three categories of labor requirements analyzed in Section 7.2.2 are likely to have different indirect labor demand effects. In particular, the direct labor demands for manufacturing and installing compliance equipment result from additional economic activity in those industries. Accordingly, it is reasonable to expect that the additional economic activity in manufacturing and installing equipment will translate into increased activity in the industries that are linked to the direct effect industries and, hence, lead to additional labor demand in those industries through the indirect effect mechanism. In contrast, the increased labor demand in the pharmaceutical industry for operating compliance equipment does not result from increased economic activity in that industry. As a result, increased labor demand in the pharmaceutical industry resulting from the effluent guideline might not translate into increased labor requirements in the industries that are linked to the pharmaceutical industry. In this case, the appropriate employment multiplier for the equipment-operations component of direct labor requirements should exclude the indirect effect mechanism and include only the induced effect mechanism. Multipliers cited in the NUCHA study referenced above suggest that a multiplier based only on the induced effect mechanism might fall in the range of 2.4 to 2.9. Using this lower multiplier range for the equipment-operations component of direct labor requirements and the higher, 2.8 to 4.0 range for the manufacturing and installation components, the estimated

aggregate employment effects of the pharmaceutical industry effluent guideline would range from 2,352[10] to 2,890[11] FTEs.

Primary employment gains estimates might be high because the 967 FTEs per year that are gained might not actually create new jobs. Many facilities and firms, even when they remain viable after compliance with the guidelines might need to cut back on production. These potential cut-backs create slack time for the workers who might then divert their time towards maintenance of the compliance equipment. Because data do not exist to estimate the number of production hours, the number of production hour losses due to production line closures and other production reductions cannot be estimated. It is, perhaps, more realistic to assume that gains at the facility level (for operating and maintaining pollution control equipment—889 hours) do no more than offset similar losses in production hours. More realistic primary gains are therefore estimated at 78 FTEs.

Thus the lower end of the employment gains range might not be low enough. In the worst case, it is assumed that the lower end of the range for induced labor effects relating to the manufacturing and installing of equipment (2.8) is applied, and only this labor component is counted as primary employment gains (78 FTEs). At the high end of the range, the primary labor gains for all labor components are counted and the high-end multipliers are used (2.9 for operating labor and 4.0 for manufacturing and installation). These assumptions produce employment gains range between 218 and 2,890 FTEs.

7.3 NET EFFECT OF EMPLOYMENT LOSSES AND GAINS

In the worst case, the primary employment gains (78 FTEs) are expected to partially offset employment losses (91 FTEs). Primary and secondary gains of between 218 and 2,890 FTEs are expected to offset to some extent the primary and secondary loss of 541 FTEs estimated in Section 7.1. The net effect on employment therefore might range from a loss of 323

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[10]78 x 2.8 + 889 x 2.4.

[11]78 x 4 + 889 x 2.9.

FTEs to a gain of 2,349 FTEs. The net employment impact is negligible when compared to national-level employment and will have no impact on national-level employment rates.

Under the alternative regulatory scenario (in-plant steam stripping/distillation), the number of losses are the same, but the number of gains are slightly higher because of the somewhat greater expenditures on equipment and installation (see Appendix C). A total of 83 FTEs (annual) would be expected to be added as a result of equipment manufacturing requirements. A total of 13 FTEs (annual) would be expected to be added as a result of installation needs and the number of FTEs for operation remain the same as in the selected scenario. Thus, total gains under the alternative scenario would be 96 to 985 FTEs. Primary and secondary gains would be 269 to 2,962 FTEs. Thus, the net effect of the alternative regulatory scenario might range from a loss of 272 FTEs to a gain of 2,421 FTEs.

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SECTION EIGHT

ANALYSIS OF FOREIGN TRADE IMPACTS

Pharmaceutical products are traded in an international market, with producers and buyers located worldwide. Changes in domestic pharmaceutical production due to the effluent guidelines might therefore affect the balance of trade. Exports might decrease as previously exported products are no longer manufactured, and imports might increase as domestic purchasers seek new sources of pharmaceuticals discontinued as a result of facility and/or company closures.

These foreign trade effects are the focus of this section of the EIA. The total change in value of U.S. pharmaceutical exports resulting from the guidelines is estimated. The significance of this change is then scrutinized by comparing it with total value of current U.S. pharmaceutical exports. Ideally, the analysis would extend to consideration of changes in imports, as well as additional export losses from facilities experiencing impacts short of closure, such as product line closures. Analysis of these issues, however, would require an international market model. This is beyond the scope of the current analysis.

Section 8.1 presents the methodology used to estimate the change in the value of exports and evaluate the significance of this impact. Results of the analysis are presented in Section 8.2.

8.1 *METHODOLOGY*

For facilities expected to close that exported a portion of their pharmaceutical production in 1990, the value of 1990 pharmaceutical exports is estimated. The estimate for each facility is obtained directly from survey data: the total value of pharmaceutical shipments reported by the facility is multiplied by the percentage of pharmaceutical shipments exported and these values are summed across closing facilities to obtain an estimate of the total value of U.S.

pharmaceutical exports no longer produced. This value is then compared to the total value of U.S. pharmaceutical exports produced in 1990.

The analysis assumes that none of the decreased production of exported pharmaceutical products is replaced by alternative U.S. products. This "worst-case" assumption is very conservative and is likely to overestimate the reduction in exports. If the impact on foreign trade is not significant in this worst-case scenario, then more realistic scenarios would also indicate no significant impacts. Likewise, increases in imports are assumed to be equivalent to the decline in exports (consistent with the zero cost-passthrough assumption used in the facility- and firm-level impact models). The existing balance of trade is then adjusted to reflect the increase in the value of imports and decline in the value of exports. A comparison of pre- and post-regulation trade balances will reveal the extent of the regulation's impact on the U.S. balance of trade.

8.2 RESULTS

The impact of effluent guidelines on pharmaceutical exports and the U.S. balance of trade is negligible. As discussed in Sections Five and Six, no facilities are expected to close as a result of the selected regulatory options and only one firm/facility (a B/D indirect facility) is expected to fail. As can be seen in Table 8-1, this firm has pharmaceutical exports totaling $76 thousand. The loss of these exports has virtually no effect on U.S. pharmaceutical exports, which, according to the U.S. Department of Commerce, totalled $5.7 billion in 1991 (see Section Three). Results are the same under the alternative regulatory scenario.

TABLE 8-1

LOSS IN FOREIGN SHIPMENTS FOR SELECTED OPTIONS (Thousands of 1990 $): POSTCOMPLIANCE ANALYSIS

Facility Subcategory	Exports Lost	Total Exports	% of Total
A/C	$0	$65,249	0.00%
B/D	$0	$9,175	0.00%
A/C	$0	$443,450	0.00%
B/D	$76	$431,834	0.02%
A/C	$0	$2,444	0.00%
B/D	$0	$846	0.00%
TOTAL	$76	$952,998	0.01%

* These numbers reflect those foreign shipments projected to remain following the baseline analysis.

Note:
1. Analysis assumes no foreign shipments are lost for certified facilities.
2. Analysis excludes 12 facilities (1 A/C direct discharger, 1 B/D direct discharger, 1 A/C indirect discharger, 8 B/D indirect dischargers, and 1 A/C zero discharger) because of lack of financial data.

Source: ERG estimates.

SECTION NINE

REGULATORY FLEXIBILITY ANALYSIS

9.1 INTRODUCTION

The Regulatory Flexibility Act requires the federal government to consider the impacts on small entities (as defined in 13 CFR Part 121) as part of rulemaking procedures. The goal of the analysis is to ensure that small entities potentially affected by a new regulation will not be disproportionately burdened. Small entities have limited resources, and it is the responsibility of the regulating federal agency to avoid, if possible, disproportionately or unnecessarily burdening such entities.

The effluent guidelines and standards for the pharmaceutical industry will affect how small firms in this industry treat their wastewater. Section 9.2 discusses the analyses that must be undertaken according to EPA guidance; Section 9.3 presents the analyses required for an Initial Regulatory Flexibility Analysis (IFRA), Section 9.4 presents a profile of the affected small firms; and Section 9.5 determines the aggregate and firm-level impacts on small firms.

9.2 SUMMARY OF EPA GUIDELINES ON RFA REQUIREMENTS

EPA guidelines now require EPA Offices to perform Regulatory Flexibility Analyses (RFAs) for regulations that have *any* effect on *any* small entities. Formerly, EPA determined whether an RFA should be performed by determining whether the rule in question had a significant economic impact on a substantial number of small entities. When using this approach, EPA spent time trying to determine whether the rule did have a significant impact on a substantial number of small entities. With the new approach, EPA can bypass much of this preliminary analysis and proceed to address the impacts on the affected entities.

EPA's approach is divided into two stages: an Initial Regulatory Flexibility Analysis (IRFA), performed for a proposed rule, and a Final Regulatory Flexibility Analysis, (FRFA),

performed for a final rule. This EIA is being prepared for a proposed rule, so an IRFA must be performed at this time.

The IRFA is divided into six requirements:

- Explain why the Agency is considering taking action.
- State succinctly the objectives of, and legal basis for, the proposed rule.
- Describe and, where feasible, estimate the number of small entities to which the proposed rule will apply.
- Describe the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirements and the type of professional skills necessary for preparation of reports or records.
- Identify, to the extent possible, all relevant federal rules that might duplicate, overlap, or conflict with the proposed rule.
- Describe any significant alternatives to the proposed rule that accomplish the stated objectives of applicable statutes while minimizing the rule's economic impact on small entities.

Specific analyses suggested by the guidelines for characterizing impacts include the following:

- A closure analysis (at the firm level) using ratio analysis (see Section Six). To characterize impacts for this IRFA, this section summarizes the information in Section Six, comparing the relative post-regulatory health of small firms with that of larger firms.
- A discounted cash flow analysis examining the consequences of the annual costs of compliance. This analysis investigates the impacts on cash flow by determining the present value of total compliance costs at a firm as a percentage of the present discounted value of cash flow (in this EIA, net income is used as a more conservative estimate of income—see Section Five for a further discussion).
- A socioeconomic analysis, if the number of affected firms leads to changes in: employment conditions, income, social service expenditures, tax revenues, and/or balance-of-trade levels.

The first two items are discussed in Section 9.5. Many of the socioeconomic impacts are, however, expected to be minimal because of the very small number of firms affected by the regulation (a small subset of the pharmaceutical industry only). However, potential impacts on communities are discussed in Section Seven and distributional impacts, including the potential for increases in payments by state and federal governments for Medicare and Medicaid, are discussed in Section Ten.

9.3 IRFA INFORMATION REQUIREMENTS

9.3.1 Reasons for Taking Action and Objectives of and Legal Basis for the Proposed Rule

The Federal Water Pollution Control Act Amendments of 1972 established a comprehensive program to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters" (Section 101[a]). To implement the Act, the U.S. EPA is required to issue effluent limitations guidelines, pretreatment standards, and new source performance standards for industrial dischargers.

9.3.2 Estimates of the Affected Population of Small Businesses

A basic step in conducting an IRFA is to estimate the affected population. Small firms are defined in 13 CFR Part 121 either by their employment size or their revenues. In SIC 2833 and 2834, small firms are defined as those employing 750 or fewer persons; in SIC 2835 and 2836, those employing 500 or fewer persons are defined as small. For simplicity, this IRFA designates all pharmaceutical firms as small if they employ fewer than 750 persons. For greater awareness of where impacts are occurring, this analysis further breaks down small firms into employment groups. These groups are as follows:

- 0-18 employees
- 19-99 employees

- 100-499 employees
- 500-750 employees
- > 750 employees

This analysis therefore will consider all categories except the > 750 category as small for the purposes of identifying the affected small business population.

The numbers of firms in each grouping are presented in Table 9-1. These numbers reflect all firms in the survey universe including those expected to fail in the baseline. As the table shows, out of 190[1] firms in the survey universe, 76 percent are small firms.[2] The largest percentage of firms are in the 100-499 employees size group (37 percent of all firms in the survey universe).

9.3.3 Projected Recordkeeping and Reporting Requirements

The proposed effluent guidelines for the pharmaceutical industry are revisions to existing effluent guidelines, thus most recordkeeping and reporting requirements are not incremental to existing guidelines. The exception is new monitoring requirements. The costs of monitoring have been estimated by EPA's technical contractor and are reported on a per-facility basis (EPA, 1995). Monitoring costs to industry total $9.0 million annually and average 15 percent of the total annual compliance cost for the selected options (computed as a median of firm-by-firm percentages among firms incurring compliance costs). Costs for monitoring by size of firm are shown in Table 9-2. As the table shows, large firms incur the largest proportion of monitoring costs (61 percent of total monitoring costs). Monitoring costs are a larger share of total annual

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[1]This number differs from the number of firms analyzed in Section Six because three firms with insufficient data were dropped from the Section Six analysis.

[2]The number of small firms might be overestimated. Because of data limitations in the Section 308 survey, firm size was computed on the basis of total employment at each firm's facilities plus 10 percent of that total facility employment (see Section Seven for the method used for computing nonfacility employment at firms). Many firms, however, could own other nonpharmaceutical facilities or other pharmaceutical facilities that are not covered by the proposed effluent guidelines. Thus, total employment at one firm could be underestimated.

TABLE 9-1

SIZE DISTRIBUTION OF FIRMS IN THE SECTION 308 PHARMACEUTICAL SURVEY

Employment Size of Firm	Number of Surveyed Firms						All Subcategories	
	Direct Dischargers		Indirect Dischargers		Zero Dischargers		Number of Firms*	% of Total Surveyed Firms
	A/C	B/D	A/C	B/D	A/C	B/D		
0 - 18	2	0	4	10	0	1	17	9%
19 - 99	2	0	14	18	1	0	34	18%
100 - 499	7	2	21	40	3	1	70	37%
500 - 750	3	2	10	12	0	1	24	13%
> 750	5	7	21	30	0	0	45	24%
All Firms <= 750	14	4	49	80	4	3	145	76%
All Firms	19	11	70	110	4	3	190	100%

* Number of firms might be less than the total firms by subcategory because some firms have more than one type of facility.

Source: Section 308 Pharmaceutical Survey.

TABLE 9-2

INCREMENTAL RECORDKEEPING AND REPORTING COSTS

Employment Size of Firm	# Firms with Nonzero Compliance Costs	Total Monitoring Costs	% of Total Industry Monitoring Costs	Total Pretax Compliance Costs*	Monitoring Costs as % of Compliance Costs**
0 - 18	9	$105,215	1%	$527,596	1.2%
19 - 99	26	$984,005	11%	$8,025,577	16.7%
100 - 499	47	$1,623,545	18%	$11,725,311	25.4%
500 - 750	17	$844,635	9%	$9,668,052	19.8%
> 750	40	$5,478,385	61%	$83,456,895	10.2%
All Firms <= 750	99	$3,557,400	39%	$29,946,536	20.0%
All Firms	139	$9,035,785	100%	$113,403,432	14.8%

* Pretax compliance costs are annualized at 11.4%.

** Percentage calculated as the median of monitoring costs divided by compliance costs for each firm in the group rather than average monitoring costs divided by average compliance costs. Analysis does not include firms with zero compliance costs.

Note: These numbers are for all facilities and do not reflect closures predicted by the analyses in this report.

Source: ERG estimates based on Radian Corp. estimates of capital and operating costs for pollution control equipment (including operating costs).

compliance costs at small firms (20 percent) than at large firms (10 percent). The highest proportion (25.4 percent) of monitoring costs as a percentage to compliance costs is experienced among firms in the 100-499 employees size group. In general, however, small firms do not appear to be disproportionately affected by recordkeeping and reporting requirements compared to large firms, since small firms incur only 39 percent of total industry monitoring costs yet make up 76 percent of the affected industry. Monitoring costs as a percentage of total compliance costs are much lower (6.7 percent for all firms) under the alternative regulatory scenario (steam stripping/distillation) because monitoring costs do not change but compliance costs are greater (see Appendix C).

9.3.4 Other Federal Requirements

EPA is aware of no federal rules that duplicate, overlap, or conflict with the proposed effluent guidelines for the pharmaceutical industry.

9.3.5 Significant Alternatives to the Proposed Rule

For A/C direct dischargers EPA did not select the lowest-cost option because incremental impacts from BAT-A/C#2 compared to BAT-A/C#1 were negligible. For B/D direct dischargers, EPA determined that impacts from more stringent options would not be measurably greater than those from the least costly option. However, the Agency also concluded that existing levels of pollutants of concern were sufficiently low in this group's discharges that the selection of the lowest-cost option not only guaranteed the lowest possible impacts on small firms but also still met the stated objectives of the Clean Water Act. A no-action alternative would not meet the stated objectives of the Act.

For indirect dischargers EPA selected the least costly alternatives under consideration short of not regulating these discharges. These alternatives are considered the least expensive option for indirect dischargers (small or large) that meet the stated objectives of the Clean Water Act (the no-action alternatives would not meet these objectives).

Because some firms in the smaller size groups already achieve a level of pollution control equivalent to that in the proposed effluent guidelines and because impacts overall are low for all size groups (see discussion in Section 9.5) impacts, while slightly more noticeable among certain small firms, are not considered excessively disproportionate.

Thus the Agency believes the stated objectives of the Clean Water Act are met with this proposed rule, while the impacts to small firms have been considered, where possible.

9.4 PROFILE OF SMALL PHARMACEUTICAL FIRMS

Tables 9-3 through 9-5 provide general information about the financial condition of small pharmaceutical firms in the Section 308 survey as compared to large firms (all firms are considered here, not just the financially healthy firms). As Table 9-3 shows, median total assets and liabilities rise with size, as does median net income. In general, small firms tend to have lower ROA than large firms, although the 500 to 750 employees size group has a considerably higher ROA than firms with over 750 employees. The poorest performing groups are the 19 to 99 employees and the 100 to 499 employees size groups, which have a median ROA of 4 percent.

Predictably, average pharmaceutical costs and revenues tend to rise with the size of the firm (see Table 9-4). Pharmaceutical revenues comprise 60 percent of total income in large firms, whereas in small firms the proportion rises as high as 87 percent in the 500 to 750 employees size groups, indicating that these firms hold fewer diverse interests than firms in other size groups. A diversity of holdings can minimize impacts from the proposed effluent guidelines for the pharmaceutical industry. The less diverse holdings among the 0 to 18 and the 500 to 750 employees size groups make these firms somewhat more vulnerable to impacts from the proposed effluent guidelines.

Table 9-5 profiles values of shipments and exports by size of firm. The proportion of shipments exported shows no clear tendency to increase with size, with the 19 to 99 employees size group averaging the highest percentage of exported shipments (4 percent exported), although

TABLE 9-3

PROFILE OF PHARMACEUTICAL FIRMS BY SIZE:
FINANCIAL INDICATORS ($000 1990)

Employment Size of Firm	Median Total Assets	Median Total Liabilities	Median Net Income	Median Base ROA
0 - 18	$892	$294	$42	6%
19 - 99	$8,755	$6,921	$282	4%
100 - 499	$72,347	$34,549	$1,926	4%
500 - 750	$268,217	$48,406	$21,054	15%
> 750	$823,484	$268,484	$136,560	10%
All Firms <= 750	$54,355	$17,259	$882	5%
All Firms	$95,340	$34,549	$2,469	5%

Note: Analysis excludes eight firms because of lack of financial data.

Source: Section 308 Pharmaceutical Survey.

TABLE 9-4

PROFILE OF PHARMACEUTICAL FIRMS BY SIZE:
PHARMACEUTICAL COSTS AND REVENUES ($000 1990)

Employment Size of Firm	Median Pharmaceutical Costs	Median Pharmaceutical Revenues	Median Total Revenues	% Pharmaceutical Revenues to Total Revenues*
0 - 18	$368	$898	$1,068	78%
19 - 99	$5,961	$6,217	$12,790	50%
100 - 499	$20,050	$24,665	$60,263	58%
500 - 750	$58,744	$159,698	$326,652	87%
> 750	$166,763	$367,568	$911,056	60%
All Firms <= 750	$9,210	$21,304	$46,595	64%
All Firms	$25,281	$39,768	$80,189	64%

Footnotes:
* Median for each group is based on percentage calculated for each firm in the group rather than median pharmaceutical revenues divided by median total revenues.

Note: Analysis excludes seven firms because of lack of financial data.

Source: Section 308 Pharmaceutical Survey.

TABLE 9-5

PROFILE OF PHARMACEUTICAL FIRMS BY SIZE:
SHIPMENTS AND EXPORTS ($000 1990)

Employment Size of Firm	Median Exports	Median Value of Shipments	Exports as % of Value of Shipments*
0 - 18	$0	$611,594	0.0%
19 - 99	$184,594	$7,244,567	4.0%
100 - 499	$48,321	$24,485,315	0.2%
500 - 750	$897,835	$120,707,495	1.1%
> 750	$2,395,200	$242,835,603	1.1%
All Firms <= 750	$75,716	$15,155,041	0.8%
All Firms	$104,860	$33,622,023	1.0%

Footnote:
* Median for each group is based on percentage calculated for each firm in the group rather than median exports divided by median shipments.

Note:
1. Analysis excludes three firms because of lack of financial data.
2. Analysis excludes firms with certified facilities.

Source: Section 308 Pharmaceutical Survey.

total value exported does tend to increase with size (with one exception). On average, exports are 0.8 percent of shipments at small firms, which is nearly the same as to that for large firms.

Table 9-6 presents the results of the baseline firm failure analysis by firm size. Small firms tend to be projected to fail in the baseline disproportionately relative to large firms. Although only 32 percent of small firms are considered likely to fail in the baseline, 45 out of a total 54 baseline firm failures are expected among small firms, which is over 80 percent of projected baseline failures. The group with the largest proportion of baseline firm failures is the 19 to 99 employees size group, in which nearly 50 percent of the group is projected to fail. Firms in the 100 to 499 employees size group also are somewhat weaker than firms in the other size groups (32 percent of the group is expected to fail). The healthier firms tend to be those in the very smallest size category and the two largest size categories (500 to 750 employees and more than 750 employees). This pattern of financial health also can be seen in Table 9-3, which shows these size groups with the highest median ROA.

9.5 IMPACTS ON SMALL PHARMACEUTICAL FIRMS

Two measures of impact are used to determine whether disproportionate impacts are occurring among small firms: the firm failure analysis and the discounted net income analysis. These analyses are discussed below.

9.5.1 Firm Failure Analysis

In Section Six, the EIA examined firm-level impacts by comparing postcompliance financial ratios to industry benchmarks and calculating the postcompliance change in firm-level profitability. As discussed in this section, three firms are predicted to experience significant impacts as a result of the proposed effluent guidelines under the selected options. These firms would be at risk of financial failure, and, at the very least, would experience difficulty obtaining financing for wastewater treatment capital investments. (The two firms in question have fewer than 750 employees). One firm has fewer than 18 employees, one firm has 19 to 99 employees,

TABLE 9-6

BASELINE FIRM FAILURES BY SIZE OF FIRM

Employment Size of Firm	Total Number of Firms	Financially Healthy Firms		Firms Likely to Fail	
		# of Firms	% of Groups	# of Firms	% of Groups
0 - 18	17	14	82.4%	3	17.6%
19 - 99	33	17	51.5%	16	48.5%
100 - 499	68	46	67.6%	22	32.4%
500 - 750	24	20	83.3%	4	16.7%
> 750	45	36	80.0%	9	20.0%
All Firms <= 750	142	97	68.3%	45	31.7%
All Firms	187	133	71.1%	54	28.9%

Note:
1. Analysis excludes three firms because of lack of financial data.
2. Analysis assumes that firms with certified facilities pass baseline.

Source: ERG estimates.

and one firm has over 750 employees. Thus, two-thirds of the significant firm impacts are among small firms. Overall, very few small firms are affected. Out of 97 small firms in the postcompliance analysis, the 2 failing small firms represent only 2 percent of all small firms. This result is the same under the alternative (in-plant steam stripping/distillation) regulatory scenario.

The EIA also examined the change in profitability among affected firms as a result of the proposed effluent guidelines. Change in profitability was measured in Section Six as the change between baseline and postcompliance annual ROA. A change of greater than 5 percent was identified as a significant impact. As seen in Table 9-7, which breaks out the profitability results reported in Section Six into size categories, 14 out of 15 of the firms experiencing substantial declines in ROA are considered small firms, which is 14 percent of all small firms in the postcompliance analysis (97 small firms, when certifiers are included). Nearly all firms with declines in ROA greater than 5 percent are in the 19 to 99 or 100 to 499 employees size group. Only eight small firms (8 percent) would experience a decline of more than 20 percent. Under the alternative regulatory scenario (in-plant steam stripping/distillation), 18 small firms (19 percent of all small firms) would experience a decline in ROA of more than 5 percent and 9 firms (9 percent) would experience a decline of more than 20 percent (see Appendix C).

9.5.2 Discounted Net Income Analysis

Table 9-8 shows the distribution of present discounted value of compliance costs as a percentage of the present discounted value of net income (NPV) by firm size.

Except in the 19 to 99 employees size category, the total present value of compliance costs as a percentage of NPV is, on average, smaller among small firms. It is not surprising that the 19 to 99 employees size group is more heavily affected since it is one of the weaker groups financially and has the highest median compliance costs of all small firm groups. In most cases, the present value of compliance costs is less than 1 percent, on average, of NPV, computed on a firm-by-firm basis. Furthermore, this percentage is lower for small firms (0.04 percent) than for large firms (0.25 percent). Under the alternative regulatory scenario (in-plant steam stripping/

TABLE 9-7

PROFITABILITY ANALYSIS -- PERCENTAGE DECLINE IN ROA, BY EMPLOYMENT SIZE OF FACILITY

Employment Size of Firm	Number of Firms						
		Percent Change in ROA					
	Total	0	>0 - <=5	>5 - <=10	>10 - <=20	>20 - <=50	>50
0 - 18	10	6	1	0	1	1	1
19 - 99	15	3	3	0	4	4	1
100 - 499	35	17	13	2	1	2	0
500 - 750	18	7	10	0	1	0	0
> 750	19	2	16	0	1	0	0
All Firms <= 750	78	33	27	2	7	7	2
All Firms	97	35	43	2	8	7	2

Note:
1. This table analyzes firms that passed the baseline analysis, excluding the 36 firms that only have certified facilities.
2. Analysis excludes three firms because of lack of financial data.

Source: ERG estimates.

TABLE 9-8

PRESENT VALUE OF COMPLIANCE COSTS AS A PERCENTAGE OF PRESENT VALUE OF POSTCOMPLIANCE NET INCOME

Employment Size of Firm	Median Compliance Costs (PV)	Median Postcompliance Net Income (PV)	Compliance Costs as % of Net Income*
0 - 18	$0	$427,787	0.00%
19 - 99	$385,101	$6,883,179	2.11%
100 - 499	$3,324	$58,170,339	0.01%
500 - 750	$54,327	$432,987,636	0.01%
> 750	$1,160,172	$1,432,475,847	0.25%
All Firms <= 750	$48,836	$46,148,682	0.04%
All Firms	$84,814	$102,982,098	0.06%

* Median for each group is based on percentage calculated for each firm in the group rather than median compliance costs divided by median postcompliance net income.

Note:
1. Analysis excludes three firms because of lack of financial data.
2. Analysis excludes all firms with certified facilities.
3. Analysis includes only those firms that pass both the baseline and postcompliance analyses.

Source: ERG estimates.

distillation scenario), small firms have compliance costs averaging 0.1 percent of NPV and large firms, 0.5 percent (see Appendix C).

The above analyses indicate that although the small firms do bear a large portion of the firm failures, these major impacts occur among a very small proportion (2 percent) of small firms. Additionally, the present value of compliance costs compared to the present value of net income are expected to be smaller, on average, among small firms than among large firms. Therefore, overall, EPA finds that impacts on small firms are not disproportionate to those on large firms under either the selected or alternative regulatory scenarios.

9.6 REFERENCES

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SECTION TEN

ANALYSIS OF DISTRIBUTIONAL IMPACTS

Up to this point, the EIA has been conducted assuming zero cost passthrough (i.e., that facilities cannot raise pharmaceutical prices in an effort to recoup regulatory costs). As pointed out in Section Three, however, the assumption that pharmaceutical manufacturers act as pure price takers in perfectly competitive markets probably would not hold true in most cases. Many markets for specific drugs are characterized by monopolistic or oligopolistic conditions in which manufacturers exercise considerable control over drug prices. The zero cost passthrough model was employed nonetheless because product-specific demand elasticity data are lacking, and because this assumption tends to overstate facility impacts rather than understate them (i.e., it provides for a worst-case scenario of facility- and firm-level impacts).

Conversely, the assumption that facilities will bear the entire cost of incremental regulatory costs might understate the economic impacts on consumers of pharmaceuticals. If the more realistic assumption that manufacturers will raise pharmaceutical prices in response to increased regulatory costs is employed, then one needs to consider who will be affected by these price increases and whether higher drug prices will affect certain demographic groups more than others. For example, the elderly account for very large portion of all drug use. This group, therefore, might be particularly hard hit by increases in drug prices. It might be reasonable to assume that the uninsured population will also be particularly hard hit by increases in drug prices because they have no immediate financial recourse and might have to make difficult decisions between pharmaceuticals and other daily necessities. Ultimately, state and federal governments might bear the costs of increased drug prices through Medicaid, Medicare, and other health insurance programs.

This section first investigates the extent to which drug prices could rise assuming perfectly inelastic demand. Given perfectly inelastic demand, the EIA calculates the rise in drug prices as the ratio of total compliance costs to total cost of pharmaceutical production in the affected facilities and in the pharmaceutical industry as a whole (e.g., if compliance cost are 1 percent of

production costs, then drug prices are assumed to rise by 1 percent). The analysis then investigates the impacts of increased drug prices on various demographic groups such as the elderly, the population living under the poverty level, disadvantaged minorities, the uninsured, and state and federal governments. In the absence of any quantitative data on price elasticities and existing drug prices, the discussion is necessarily qualitative in nature. The discussion assumes that pharmaceutical manufacturers are able to pass through all of the increased regulatory costs associated with the various wastewater treatment options.

10.1 INCREASES IN DRUG PRICES

Table 10-1 shows compliance costs as a percentage of total pharmaceutical costs by regulatory option. The average ratio for each facility subcategory ranges from 0.2 to 3.4 percent. For all the selected regulatory options, the ratio of compliance costs to total pharmaceutical costs is 1.6 percent. Table 10-1 also shows the distribution of the number of facilities by compliance costs to pharmaceutical costs. As can be seen, 41 facilities (20 percent of all facilities in this analysis) would incur compliance costs greater than 1 percent of total pharmaceutical production costs, and three facilities (1 percent of all facilities) would incur compliance costs greater than 10 percent of total pharmaceutical production costs. A little over one quarter of all facilities would experience no increase in total pharmaceutical production costs as a result of the effluent guidelines. Under the alternative regulatory scenario (steam stripping/distillation) the percentage of compliance costs to total pharmaceutical production costs would average 2.5 percent (see Appendix C).

Reliable data on total U.S. pharmaceutical production costs are not available. Thus, the EIA cannot precisely compute compliance costs as a percentage of total U.S. pharmaceutical production costs. Nevertheless, it is clear that if worst-case compliance costs average 1.6 percent of the total pharmaceutical costs of the regulated sector, this ratio would be significantly lower if compliance costs were compared to production costs for the entire industry.

TABLE 10-1

COMPLIANCE COSTS AS A PERCENTAGE OF TOTAL PHARMACEUTICAL PRODUCTION COSTS, BY FACILITY

Regulatory Option	Compliance Costs/Total Costs										
	0.0%		>0.0% - 0.1%		>0.1% - 1.0%		>1.0%- 10.0%		>10%		
	# Facilities	% Total	# Facilities	% Total	# Facilities	% Total	# Facilities	% Total	# Facilities	% Total	Average Ratio*
BAT-A/C#2	0	0%	1	7%	5	36%	7	50%	1	7%	3.4%
BAT-B/D#1	0	0%	4	44%	5	56%	0	0%	0	0%	0.2%
PSES-A/C#1	14	23%	6	10%	21	34%	19	31%	1	2%	1.6%
PSES-B/D#1	43	36%	28	24%	34	29%	12	10%	1	1%	0.6%
All Facilities											
All	57	28%	39	19%	65	32%	38	19%	3	1%	1.6%

* Average Ratio does not include those facilities with zero option costs.

Note:
1. Analysis excludes certified facilities and zero dischagers.
2. Analysis also excludes six additional facilities (one A/C direct discharger, two A/C indirect dischargers, and three B/D indirect dischargers) because of lack of financial data.

Source: ERG estimates.

10.2 IMPACTS ON SPECIFIC DEMOGRAPHIC GROUPS

Although in the aggregate, the potential overall increase in drug prices attributable to increased regulatory costs is minuscule, the potential increase in specific drug prices might have a significant impact on certain demographic groups. As noted above, three facilities will experience compliance costs in excess of 10 percent of total pharmaceutical manufacturing costs. If the drugs produced by these facilities are unique (i.e., protected from direct competition either through patents or a lack of close substitutes) then these facilities might be able to increase the price of their drugs in order to offset compliance costs. Table 10-2 presents the result of an examination of the products produced by facilities that incur compliance costs greater than 10 percent of total pharmaceutical production costs and presents which groups predominantly use the types of products made at these facilities.

Because of confidentiality, the name or type of drug is not presented. The unknown category deals with products that might be inputs to drugs rather than drugs themselves (i.e., they are primarily reported as chemical names).

As Table 10-2 shows, children (including infants and adolescents), women, and the elderly are likely to be the major consumers of many of these products. According to Health Insurance Association of America (HIAA, 1991), the groups least likely to have health insurance are hispanics (31.2 percent of whom lack health insurance), young adults 16-24 years of age (20.5 percent of whom lack health insurance), young adults 25-34 years of age (17.3 percent of whom lack health insurance), and African Americans (17.5 percent of whom lack health insurance); African Americans, hispanics, and children are most likely to be covered by government insurance, and African Americans, hispanics, and the elderly are least likely to have insurance related to employment. Government insurance programs tend to spend less on drugs and other medical nondurables than do private insurers, according to this same source, and about 93 percent of people with work-related medical insurance have some type of drug insurance.

When all these factors are accounted for, it appears that those who lack any health insurance, those who are covered by government insurance, and those who are covered by nonwork-related medical insurance might be least likely to have drug coverage. This group

TABLE 10-2

DISPROPORTIONATE USERS OF POTENTIALLY HIGHLY AFFECTED PRODUCTS

	Total Numbers of Affected Products	Infants, Children, or Adolescents	The Elderly	Young Adult/Adult Women	Middle-Aged Women	African-Americans	Other	Unknown
Number of Products Used Disproportionately by Group	18	6	9	6	2	1	2	8
Percentage of All Affected products	100%	33%	50%	33%	11%	6%	11%	44%

Source: Overton, 1994.

NOTE: Each product might be used disproportionately by several groups.

would include: hispanics, African Americans, the elderly, young adults (16-34), and children (under 16). When the predominant consumers of the products expected to be affected by potentially sizeable cost increases are compared to the groups most likely to lack drug insurance, young adult women, children, and the elderly are likely to be the most heavily affected by potential cost increases, if such increases can be passed through to consumers.

Because, on average, any potential price increases are likely to be very low (1.6 percent on average), impacts on mass consumers of drugs such as HMOs, governments, and, indirectly, third-party insurers, should be minimal.

10.3 REFERENCES

HIAA, 1991. *Source Book of Health Insurance Data.* Health Insurance Association of America.

Overton, V. Demographics of the Major Users of Selected Drugs. Memorandum dated August 8, 1994 (confidential business information).

SECTION ELEVEN

ANALYSIS OF IMPACTS ON NEW SOURCES

The selected options for new sources are NSPS-A/C#1, NSPS-B/D#1, PSNS-A/C#1, and PSNS-B/D#1. In all cases, the requirements for new sources are more stringent than those for existing sources. However, the difference in cost between new source requirements and existing source requirements for typical facilities are relatively small when compared to the average facility costs of production. In most cases, existing facilities would be required to retrofit in-plant steam stripping systems, whereas new sources would have to install in-plant steam stripping/distillation systems. Because designing in pollution control equipment in a new source is typically less expensive than retrofitting the same equipment in an existing source, the cost differential between the selected requirements for existing sources and those higher existing source options that are technically equivalent to new source requirements should be an upper limit on the differential annual cost faced by new sources. Where this differential is not substantial relative to the typical costs of doing business in this industry, no significant barrier to entry is likely to exist.

The average per-facility compliance costs were investigated to determine what the cost differentials would be between proposed new source and existing source requirements. The average per-facility cost differentials ranged from about a $34,000 to a $590,000 difference (for A/C direct dischargers), depending on the type of facility (see Table 11-1). The maximum $590,000 difference generates the highest percentage of compliance cost differential to pharmaceuticals manufacturing cost—about 1.4 percent of total manufacturing costs and about 3.0 percent of pharmaceutical manufacturing costs. Since this cost differential is likely to be less than that assumed here, this small premium estimated to be paid by new sources is not likely to have much impact on the decision to enter the market. Furthermore, these same options, when applied to existing sources, were found to have nearly identical impacts on existing sources as the selected options for existing sources. Thus no significant barriers to entry are estimated to result from the proposed new source requirements.

TABLE 11-1

ESTIMATED COST DIFFERENTIAL BETWEEN REQUIREMENTS FOR EXISTING AND NEW SOURCES (thousands of 1990 $)

Type of Facility	Average Cost Differential	Average Pharmaceutical Manufacturing Cost	Average Total Manufacturing Cost	Cost Differential As Percentage of Pharmaceutical Manufacturing Costs	Cost Differential As Percentage of Total Manufacturing Costs
A/C Direct	$599	$19,650	$42,855	3.0%	1.4%
B/D Direct	$53	$50,218	$59,135	0.1%	0.1%
A/C Indirect	$257	$39,493	$45,234	0.7%	0.6%
B/D Indirect	$34	$29,048	$47,703	0.1%	0.1%

Source: Section 308 Survey and ERG estimates.

Under the alternative regulatory scenario (in-plant steam stripping/distillation) only BAT-B/D is less stringent than requirements for new sources. The cost differential between BAT and NSPS requirements is estimated to be $53 thousand, or about 0.1 percent of pharmaceutical or total manufacturing costs.

APPENDIX A

ASSUMPTIONS USED OR CONSIDERED FOR USE IN THE COST ANNUALIZATION MODEL

APPENDIX A

ASSUMPTIONS USED OR CONSIDERED FOR USE IN THE COST ANNUALIZATION MODEL

A.1 MODIFIED ACCELERATED COST RECOVERY SYSTEM (MACRS)

The cost annualization model presented in Section Four is based on an assumption that firms will use the Modified Accelerated Cost Recovery System (MACRS) to depreciate their pollution control equipment for tax purposes. The Internal Revenue Service Tax Code requires firms to use either the MACRs depreciation method or a straight-line method to depreciate assets that were put into service after December 31, 1986. MACRS, however, offers companies an advantage over the straight line method, because a company's income might be reduced under MACRS by a greater amount in the early years when the time value of money is greater. Table A-1 illustrates the advantage of using MACRS. Although the absolute amount depreciated under the straight line method and MACRS is equivalent ($614,487), MACRS provides a $9,745 benefit (in present value) because of the timing differences in writing off the investment. The example in Table A-1 uses a midyear convention for putting the equipment into operation, which assumes only 6 months of depreciation in the first year (as well as only 6 months in the last year).

A.2 TIMING

The second assumption used in the cost annualization model is one of timing. Although, the midyear convention frequently is used when calculating depreciation (as was done above), it is not appropriate for the analysis in Section Four. Approximately one year would be required to build and install most of the equipment considered in the regulatory alternatives. Additional time might be required for design, permitting, and site preparation. The cost annualization model, therefore, assumes a 1-year delay from the capital expenditure to the beginning of operation. As shown in Table A-2, the capital expenditure is listed in Year 1, but depreciation

TABLE A-1

COMPARISON OF STRAIGHT LINE DEPRECIATION VS. MODIFIED ACCELERATED COST RECOVERY SYSTEM (MACRS)

Capital Cost (Line A):	$614,487
Discount Rate:	11.4%
Equipment Lifetime (Line B):	15
Marginal Tax Rates:	
Federal	34.0%
State	6.8%
Overall (Line C)	40.8%

1	2	3	4	5
Year	**Annual Depreciation (MACRS) (Line A * 0.05)**	**Annual Depreciation (Straight-Line) ((Line A/Line B)/2)**	**Tax Shield (MACRS) (Line C * Col 2)**	**Tax Shield Straight-Line (Line C * Col 3)**
1	$30,724	$20,483	$12,520	$8,347
2	$58,376	$40,966	$23,788	$16,694
3	$52,539	$40,966	$21,409	$16,694
4	$47,315	$40,966	$19,281	$16,694
5	$42,584	$40,966	$17,353	$16,694
6	$38,283	$40,966	$15,600	$16,694
7	$36,255	$40,966	$14,774	$16,694
8	$36,255	$40,966	$14,774	$16,694
9	$36,316	$40,966	$14,799	$16,694
10	$36,255	$40,966	$14,774	$16,694
11	$36,316	$40,966	$14,799	$16,694
12	$36,255	$40,966	$14,774	$16,694
13	$36,316	$40,966	$14,799	$16,694
14	$36,255	$40,966	$14,774	$16,694
15	$36,316	$40,966	$14,799	$16,694
16	$18,127	$20,483	$7,387	$8,347
Sum	**$614,487**	**$614,487**	**$250,403**	**$250,403**
Present Value[a]	**$328,531**	**$304,615**	**$133,876**	**$124,131**
Net benefit of using MACRS v. straight line (Col 4-Col 5) ($year 1)		**$9,745**		

TABLE A-2

SAMPLE SPREADSHEET FOR ANNUALIZING COSTS WITH INTEREST PAYMENTS

Inputs

Facility Code:	30387
Facility Type:	AC/Direct
Option:	BAT/Opt.1
Initial Capital Cost ($) (Line A):	$614,487
Annual Operation & Maintenance Cost ($) (Line B)	$58,710
Equipment Lifetime (Class Life - yrs	15
Real Discount Rate (Line C):	11.4%
Marginal Income Tax Rates:	
Federal	34.00%
State	6.75%
Combined (Line D)	40.75%

Financing:	
Amount financed	$614,487
Annualized (Line E)[a]	$85,196

1	2	3	4	5	6	7	8	9	10
Year	Depreciation Rate	Depreciation For Year (Line A *Col 2)	Tax Shield From Depreciation (Line D *Col 3)	O&M Cost (Line B)	O&M Tax Shield (Line D *Col 5)	Cash Outflow (Line A in Yr 1; Line B in Yrs 2-16)	Cash Outflow After Tax Shields (Col M-(Col G+Col K))	Interest Payments (Line C *Line E)	Interest Payment Tax Shield (Line D *Col 9)
1	0.000%	$0	$0	$0	$0	$614,487	$614,487	$9,712	$3,958
2	10.000%	$61,449	$25,040	$58,710	$23,924	$58,710	$9,745	$9,712	$3,958
3	9.643%	$59,254	$24,146	$58,710	$23,924	$58,710	$10,640	$9,712	$3,958
4	9.272%	$56,975	$23,217	$58,710	$23,924	$58,710	$11,568	$9,712	$3,958
5	8.886%	$54,601	$22,250	$58,710	$23,924	$58,710	$12,536	$9,712	$3,958
6	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627	$9,712	$3,958
7	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627	$9,712	$3,958
8	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627	$9,712	$3,958
9	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627	$9,712	$3,958
10	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627	$9,712	$3,958
11	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627	$9,712	$3,958
12	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627	$9,712	$3,958
13	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627	$9,712	$3,958
14	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627	$9,712	$3,958
15	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627	$9,712	$3,958
16	5.655%	$34,746	$14,159	$58,710	$23,924	$58,710	$20,627	$9,712	$3,958
Sum	100.00%	$614,487	$250,403	$880,650	$358,865	$1,495,137	$885,869	$155,398	$63,325
Present Value		$317,124	$129,228	$413,017	$168,304	$1,027,504	$729,971	$78,037	$31,800

	After Tax Shield	*Before Tax Shield*
Present Value of Incremental Costs (Line F)[a]:	$729,971 (PV of Col 8)	$1,027,504 (PV of Col 7)
Annualized Cost (Line G)[a]:	$101,207 (Ann of Line F)	$142,459 (Ann of Line F)
Annualized Interest Tax Shield (Line H)[a]:	$4,409 (Ann of Col 10)	
Annulized Cost After Interest Tax Shield[a]:	$96,799 (Line G-Line H)	

Note: Spreadsheet assumes that a modified accelerated cost recovery system (MACRS) is used to depreciate capital expenditures.
[a] See Table 4-3 for formulas.

and annual O&M costs are not listed until Year 2 (assumed to be the first full year of operation).[1] The 1-year delay also changes each year's depreciation rates (see column 2).

A.3 DERIVATION OF DEPRECIATION RATES

Table A-3 shows the derivation of depreciation rates used in the cost annualization model. The calculation uses the assumption that a 150 percent declining balance (DB) method (MACRS) is used, switching to a straight-line method in Year 5 as allowed by Section 168(b)(2) of the Internal Revenue Code. The switch point is determined by the year in which depreciation calculated by the straight-line method equals or exceeds that determined by the declining balance method. More in-depth information on how to calculate a MACRS depreciation rate can be found in the U.S. Master Tax Guide (Commerce Clearinghouse, Inc., 1991).

A.4 AVERAGE STATE TAXES

The cost annualization model uses an average state tax rate (see Section Four). State corporate income taxes are presented in Table A-4. As the table shows, the average rate over all states is 6.75 percent.

A.5 ADDITIONAL CONSIDERATIONS

The cost annualization model does not consider how the facility will raise the capital to finance the new pollution control requirements. A facility could finance its investment through a bank, take money out of working capital, or issue a corporate bond. In any case, the present value analysis assumes a cost to the facility of 11.4 percent (the discount rate) to use the money, whether that amount is paid as interest or is the opportunity cost of the internal funding.

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[1]Assuming the equipment goes into service midway through the first year, the annualized cost would decrease slightly because a 5-percent depreciation of the capital investment would more than exceed a half year of O&M expenses.

TABLE A-3

CALCULATION OF MACRS DEPRECIATION RATES

Assumptions:

1. Property goes into service at beginning of year
2. 150% double declining balance (DB) method (MACRS)
3. 15-year property
4. Assume $10,000 unadjusted basis
5. Columns 4 and 7 switch to straight-line in Year 5

1	2	3	4	5	6	7
Year	Years Remaining At Beginning Of Year	Straight-Line Rate (1/Col 2)	150% DB Rate On Adjusted Basis (1/Col 2 * 1.5)	Annual Depreciation[a]	Adjusted Basis at Year End[b]	150% DB Rate On Unadjusted Basis[c] (Col 5/$10,000)
0		0.00%	0.00%		$10,000	
1	15	6.67%	10.00%	$1,000	$9,000	10.00%
2	14	7.14%	10.71%	$964	$8,036	9.64%
3	13	7.69%	11.54%	$927	$7,109	9.27%
4	12	8.33%	12.50%	$889	$6,220	8.89%
5	11	9.09%	9.09%	$565	$5,655	5.65%
6	10	10.00%	10.00%	$565	$5,089	5.65%
7	9	11.11%	11.11%	$565	$4,524	5.65%
8	8	12.50%	12.50%	$565	$3,958	5.65%
9	7	14.29%	14.29%	$565	$3,393	5.65%
10	6	16.67%	16.67%	$565	$2,827	5.65%
11	5	20.00%	20.00%	$565	$2,262	5.65%
12	4	25.00%	25.00%	$565	$1,696	5.65%
13	3	33.33%	33.33%	$565	$1,131	5.65%
14	2	50.00%	50.00%	$565	$565	5.65%
15	1	100.00%	100.00%	$565	$0	5.65%
Sum				**$10,000**		**100.00%**

[a] Ex: Year 1 = Year 0 in Col 4 * Year 1 in Col 6.
[b] Ex: Year 2 = Year 1 in Col 6 - Year 2 in Col 5
[c] Equivalent to column 2 in Table 4-2.

TABLE A-4

STATE CORPORATE INCOME TAXES

State	Corporate Income Tax	Basis for States With Graduated Tax Tables (Earnings)
Alabama	5.00%	
Alaska	9.40%	$90,000+
Arizona	9.30%	
Arkansas	6.00%	$100,000+
California	9.30%	
Colorado	5.00%	
Connecticut	11.50%	
Delaware	8.70%	
Florida	5.50%	
Georgia	6.00%	
Hawaii	6.40%	$100,000+
Idaho	8.00%	
Illinois	4.00%	Plus Excise Tax
Indiana	4.50%	
Iowa	12.00%	$250,000+
Kansas	6.75%	
Kentucky	8.25%	$250,000+
Louisiana	8.00%	$200,000+
Maine	8.93%	$250,000+
Maryland	7.00%	
Massachusetts	9.50%	
Michigan	2.35%	
Minnesota	9.80%	
Mississippi	5.00%	$10,000+
Missouri	5.00%	
Montana	6.75%	
Nebraska	7.81%	$50,000+
Nevada	0.00%	
New Hampshire	8.00%	
New Jersey	9.42%	
New Mexico	7.60%	$1Million+
New York	9.00%	
North Carolina	7.00%	
North Dakota	10.50%	$50,000+
Ohio	8.90%	Based on Stock Value
Oklahoma	6.00%	
Oregon	6.60%	
Pennsylvania	12.25%	
Rhode Island	9.00%	
South Carolina	5.00%	
South Dakota	0.00%	
Tennesee	6.00%	
Texas	0.00%	
Utah	5.00%	
Vermont	8.25%	$250,000+
Virginia	6.00%	
Washington	0.00%	
West Virginia	9.30%	
Wisconsin	7.90%	
Wyoming	0.00%	
Average:	**6.75%**	

Sources: Fortune Magazine, 1991;
State Tax Handbook, 1991.

According to current tax law, if the facility finances the investment using debt, the associated interest expenses can be deducted, thereby reducing taxable income. The tax shield on the interest payments thus would reduce the annualized cost of compliance. In contrast, the opportunity cost of using working capital is not available. Table A-2 illustrates the effect of 100-percent debt financing. In this case, the annualized compliance cost would drop by approximately 4 percent due to tax shields on the interest payments. To maintain a conservative cost estimate, tax shields on interest payments (Column 10) are not considered in the cost annualization model. If a facility used 100 percent debt financing, the present value of incremental costs would be further reduced, in the case illustrated, by $31,800.

A final consideration is Section 169 of the Internal Revenue Code which provides the option to amortize pollution control facilities over a 5-year period (IRS, 1988). Under this IRS provision, 75 percent of the investment could be rapidly amortized in a 5-year period using a straight line method. The 75-percent figure is based on the ratio of the allowable lifetime (15 years) to the estimated usable life (20 years) as specified in IRS Section 169, Subsection (f). Although the tax provision enables the facility to expense the investment over a shorter time period, the advantage is substantially reduced because only 75 percent of the capital investment can be recovered. Table A-5 illustrates this tax provision using hypothetical costs. The present value of the tax shield from depreciation increases only slightly, thereby decreasing the present value of annualized costs from $101,207 (see Table A-2) to $100,070 (see Table A-5). Because the benefit of the provision is so slight and facilities might not be able to get the required certification to take advantage of it, this provision was not included in the cost annualization model. Its exclusion results in a more conservative estimate of compliance costs.

A.6 REFERENCES

Fortune Magazine, 1991. Fortune Forcast. June 3. pp. 22-23.

Commerce Clearinghouse, Inc. 1991. U.S. Master Tax Guide. Chicago, 1990.

TABLE A-5

SAMPLE SPREADSHEET FOR ANNUALIZING COSTS USING THE IRS SECTION 169 PROVISION

Inputs

Facility Code:	30387
Facility Type:	AC/Direct
Option:	BAT/Opt.1
Initial Capital Cost ($) (Line A):	$614,487
Annual Operation & Maintenance Cost ($) (Line B):	$58,710
Equipment Lifetime (Class Life - yrs):	15
Real Discount Rate:	11.4%
Marginal Income Tax Rates:	
Federal	34.00%
State	6.75%
Combined (Line C)	40.75%

1	2	3	4	5	6	7	8
Year	Depreciation Rate	Depreciation For Year (Line A*Col 2*0.75)	Tax Shield From Depreciation (Line C*Col 3)	O&M Cost (Line B)	O&M Tax Shield (Line C*Col 5)	Cash Outflow (Line A in Yr 1; Line B in Yrs 2-16)	Cash Outflow After Tax Shields (Col 7-(Col 4+Col6))
1	0.000%	$0	$0	$0	$0	$614,487	$614,487
2	20.000%	$92,173	$37,561	$58,710	$23,924	$58,710	($2,775)
3	20.000%	$92,173	$37,561	$58,710	$23,924	$58,710	($2,775)
4	20.000%	$92,173	$37,561	$58,710	$23,924	$58,710	($2,775)
5	20.000%	$92,173	$37,561	$58,710	$23,924	$58,710	($2,775)
6	20.000%	$92,173	$37,561	$58,710	$23,924	$58,710	($2,775)
7	0.000%	$0	$0	$58,710	$23,924	$58,710	$34,786
8	0.000%	$0	$0	$58,710	$23,924	$58,710	$34,786
9	0.000%	$0	$0	$58,710	$23,924	$58,710	$34,786
10	0.000%	$0	$0	$58,710	$23,924	$58,710	$34,786
11	0.000%	$0	$0	$58,710	$23,924	$58,710	$34,786
12	0.000%	$0	$0	$58,710	$23,924	$58,710	$34,786
13	0.000%	$0	$0	$58,710	$23,924	$58,710	$34,786
14	0.000%	$0	$0	$58,710	$23,924	$58,710	$34,786
15	0.000%	$0	$0	$58,710	$23,924	$58,710	$34,786
16	0.000%	$0	$0	$58,710	$23,924	$58,710	$34,786
Sum	100.00%	$460,865	$187,803	$880,650	$358,865	$1,495,137	$948,470
Present Value[a]		$337,262	$137,434	$413,017	$168,304	$1,027,504	$721,765

Present Value of Incremental Costs (PV of Col 8) [a]:	$721,765
Annualized Cost[a]:	$100,070

Note: Spreadsheet assumes that a modified accelerated cost recovery system (MACRS) is used to depreciate capital expenditures.
[a] See Table 4-3 for formulas.

APPENDIX B

RESULTS OF SENSITIVITY ANALYSIS USING NO SALVAGE VALUE IN COMPUTING FACILITY CLOSURES

APPENDIX B

RESULTS OF SENSITIVITY ANALYSIS USING NO SALVAGE VALUE IN COMPUTING FACILITY CLOSURES

In Section Five, the EIA presented an analysis of facility closures using the assumption that salvage value plays a role in the decision for a multifacility firm to close and liquidate a marginally profitable or unprofitable facility. Using salvage value in a closure model might not accurately reflect closure decisions. First, salvage value is difficult to compute accurately. Second, under some circumstances (for instance if the facility acts as a captive to the owner firm, transferring goods to the owner firm rather than selling goods at market prices) the salvage value of a single facility might be irrelevant to closure decisions. To determine whether using salvage value makes any difference in the outcome of the facility closure analysis, this appendix presents a sensitivity analysis, where salvage value is assumed to be $0 for all facilities.

Table B-1 presents the results of this alternative analysis in the baseline. As the table shows, only 18 facilities, or 6 percent of all facilities in the analysis are expected to close under a zero salvage value assumption. In contrast, in Section Five, 38 facilities, or 13 percent of all facilities were estimated to close in the baseline.

In the postcompliance analysis, as Tables B-2 and B-3 show, there is no change from the results shown for A/C and B/D direct dischargers in Section Five. For the A/C indirects, however, where no facilities closed under any of the regulatory options in the Section Five analysis, one, one, two, and four facilities are expected to close under Options #1, #2, #3, and #4, respectively, when zero salvage value is assumed (see Table B-4). Four B/D indirects also are estimated to close under PSES-B/D#3 with a zero salvage value assumed, vs. only one in the Section Five analysis. Under the selected regulatory options, however, only one facility closes when a zero salvage value is assumed (see Table B-5). This difference in results from the original analysis is so slight that EPA chose to continue using the standard analysis used in previous effluent guidelines EIAs rather than to assume that salvage value plays no role in the decision to close a facility.

TABLE B-1

SALVAGE VALUE = 0
FACILITY CLOSURES: BASELINE ANALYSIS

Facility Subcategory	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.	% of Total	No. of Closures	Total No.	% of Total	No. of Closures	Total No.	% of Total	No. of Closures	Total No.	% of Total	No. of Closures	Total No.	% of Total
Direct Discharge															
A/C	0	2	0%	1	7	14%	0	11	0%	0	3	0%	1	23	4%
B/D	0	0	0%	0	1	0%	0	6	0%	1	7	14%	1	14	7%
Indirect Discharge															
A/C	0	4	0%	3	38	8%	0	24	0%	0	22	0%	3	88	3%
B/D	1	13	8%	8	53	15%	3	62	5%	1	23	4%	13	151	9%
Zero Discharge															
A/C	0	0	0%	0	2	0%	0	1	0%	0	0	0%	0	3	0%
B/D	0	1	0%	0	1	0%	0	1	0%	0	0	0%	0	3	0%
All Facilities															
TOTAL	1	20	5%	11	102	11%	3	105	3%	2	55	4%	18	282	6%

Note:
1. Analysis assumes certified facilities do not close.
2. Analysis excludes four facilities (one A/C direct discharger, two B/D indirect dischargers, and one A/C zero discharger) because of lack of financial data.

Source: ERG estimates.

TABLE B-2

SALVAGE VALUE = 0
FACILITY CLOSURES FOR A/C DIRECT DISCHARGERS: POST-COMPLIANCE ANALYSIS

Option Number	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total
Regulatory Option BPT															
BPT-A/C#1	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BPT-A/C#2	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BPT-A/C#3	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BPT-A/C#4	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BPT-A/C#5	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
Regulatory Option BCT															
BCT-A/C#1	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BCT-A/C#2	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BCT-A/C#3	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
Regulatory Option BAT															
BAT-A/C#1	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BAT-A/C#2	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BAT-A/C#3	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
BAT-A/C#4	1	2	50%	0	6	0%	0	11	0%	0	3	0%	1	22	5%

* These facility numbers reflect those facilities projected to remain open following the baseline analysis.

Note:
1. Analysis assumes certified facilities do not close.
2. Analysis excludes one facility because of lack of financial data.

Source: ERG estimates.

TABLE B-3

SALVAGE VALUE = 0
FACILITY CLOSURES FOR B/D DIRECT DISCHARGERS: POST-COMPLIANCE ANALYSIS

Option Number	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total
Regulatory Option BPT															
BPT-B/D#1	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BPT-B/D#2	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BPT-B/D#3	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
Regulatory Option BCT															
BCT-B/D#1	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BCT-B/D#2	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
Regulatory Option BAT															
BAT-B/D#1	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BAT-B/D#2	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BAT-B/D#3	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
BAT-B/D#4	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%

* These facility numbers reflect those facilities projected to remain open following the baseline analysis.

Note: Analysis assumes certified facilities do not close.

Source: ERG estimates.

TABLE B-4

SALVAGE VALUE = 0
FACILITY CLOSURES FOR INDIRECT DISCHARGERS: POST-COMPLIANCE ANALYSIS (PSES)

Option Number	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total
A/C Facilities															
PSES-A/C#1	1	4	25%	0	35	0%	0	24	0%	0	22	0%	1	85	1%
PSES-A/C#2	1	4	25%	0	35	0%	0	24	0%	0	22	0%	1	85	1%
PSES-A/C#3	1	4	25%	1	35	3%	0	24	0%	0	22	0%	2	85	2%
PSES-A/C#4	1	4	25%	3	35	9%	0	24	0%	0	22	0%	4	85	5%
B/D Facilities															
PSES-B/D#1	0	12	0%	0	45	0%	0	59	0%	0	22	0%	0	138	0%
PSES-B/D#2	0	12	0%	0	45	0%	0	59	0%	0	22	0%	0	138	0%
PSES-B/D#3	0	12	0%	2	45	4%	2	59	3%	0	22	0%	4	138	3%

* These facility numbers reflect those facilities projected to remain open following the baseline analysis.

Note:
1. Analysis assumes certified facilities do not close.
2 B/D analysis excludes two facilities because of lack of financial data.

Source: ERG estimates.

TABLE B-5

SALVAGE VALUE = 0
FACILITY CLOSURES FOR SELECTED OPTIONS: POSTCOMPLIANCE ANALYSIS

Facility Subcategory	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total
Direct Discharge															
A/C	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
B/D	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
Indirect Discharge															
A/C	1	4	25%	0	35	0%	0	24	0%	0	22	0%	1	85	1%
B/D	0	12	0%	0	45	0%	0	59	0%	0	22	0%	0	138	0%
Zero Discharge															
A/C	0	0	0%	0	2	0%	0	1	0%	0	0	0%	0	3	0%
B/D	0	1	0%	0	1	0%	0	1	0%	0	0	0%	0	3	0%
All Facilities															
TOTAL	1	19	5%	0	90	0%	0	102	0%	0	53	0%	1	264	0%

* These facility numbers reflect those facilities projected to remain open following the baseline analysis.

Note:
1. Analysis assumes certified facilities do not close.
2. Analysis excludes four facilities (one A/C direct discharger, two B/D indirect dischargers, and one A/C zero discharger) because of lack of financial data.

Source: ERG estimates.

APPENDIX C

ANALYSIS OF THE ALTERNATIVE REGULATORY SCENARIO

APPENDIX C

ANALYSIS OF THE ALTERNATIVE REGULATORY SCENARIO

Tables C-1 through C-8 present the results of analyses of the alternative regulatory scenario (steam stripping/distillation) discussed in the main body of this report.

TABLE C-1

FACILITY CLOSURES FOR ALTERNATIVE OPTIONS: POSTCOMPLIANCE ANALYSIS

Facility Subcategory	Facility Closures by Employment Size														
	1 - 18			19 - 167			168 - 750			>750			All		
	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total	No. of Closures	Total No.*	% of Total
Direct Discharge															
A/C	0	2	0%	0	6	0%	0	11	0%	0	3	0%	0	22	0%
B/D	0	0	0%	0	1	0%	0	6	0%	0	6	0%	0	13	0%
Indirect Discharge															
A/C	0	3	0%	0	27	0%	0	23	0%	0	22	0%	0	75	0%
B/D	0	12	0%	0	41	0%	0	53	0%	0	22	0%	0	128	0%
Zero Discharge															
A/C	0	0	0%	0	2	0%	0	1	0%	0	0	0%	0	3	0%
B/D	0	1	0%	0	1	0%	0	1	0%	0	0	0%	0	3	0%
All Facilities															
TOTAL	0	18	0%	0	78	0%	0	95	0%	0	53	0%	0	244	0%

* These facility numbers reflect those facilities projected to remain open following the baseline analysis.

Note:
1. Analysis assumes certified facilities do not close.
2. Analysis excludes four facilities (one A/C direct discharger, two B/D indirect dischargers, and one A/C zero discharger) because of lack of financial data.

Source: ERG estimates.

TABLE C-2

POSTCOMPLIANCE ANALYSIS 1*
ALTERNATIVE REGULATORY OPTIONS

	Total Number of Firms	No Significant Impact		Significant Impact		
		# of Firms	% of Group	# of Firms	% of Group	% of All Firms**
Firms with A/C Direct Facilities	15	15	100.0%	0	0.0%	0.0%
Firms with B/D Direct Facilities	7	7	100.0%	0	0.0%	0.0%
Firms with A/C Indirect Facilities	53	51	96.2%	2	3.8%	1.5%
Firms with B/D Indirect Facilities	72	71	98.6%	1	1.4%	0.7%
All Firms+	133	130	97.7%	3	2.3%	2.3%

* This scenario analyzes impacts from regulating A/C Direct facilities under options BAT-A/C#2 and BPT-A/C#2, B/D Direct facilities under options BAT-B/D#1 and BPT-B/D#2, A/C Indirect facilities under option PSES-A/C#1, and B/D Indirect facilities under option PSES-B/D#1.
** Out of all firms in the postcompliance analysis (133 firms).
+ Number of firms for All Firms might be less than the total firms by subcategory because some firms have more than one type of facility. Total number of All Firms includes firms that have nondischarging facilities

Note: Analysis excludes three firms because of lack of financial data.

Source: ERG estimates.

TABLE C-3

CLOSURES AND PRIMARY EMPLOYMENT LOSSES FOR ALTERNATIVE OPTIONS: POSTCOMPLIANCE FACILITY AND FIRM ANALYSIS

Facility or Firm Type*	Facility Analysis		Firm/Facility Analysis		Firm Analysis		Total Failures/Employment Losses	
	Facility Closures	Job Losses from Facility Closures	Firm/Facility Failures/Closures	Firm/Facility Job Losses	Firm Failures	Firm Job Losses	Total Firm/Facility and Firm Failures	Job Losses from All Failures and Closures
Direct Discharge								
A/C	0	0	0	0	0	0	0	0
B/D	0	0	0	0	0	0	0	0
Indirect Discharge								
A/C	0	0	0	0	2	78	2	78
B/D	0	0	1	13	0	0	1	13
Zero Discharge								
A/C	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
B/D	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
All Facilities								
TOTAL**	0	0	1	13	2	78	3	91

* For firms this categorizes firms according to the types of facilities the firm owns.

** Total number of firms in the firm analysis might be less than the total firms by subcategory because some firms have more than one type of facility.

Source: ERG estimates.

TABLE C-4

ANALYSIS OF POSSIBLE EMPLOYMENT GENERATION EFFECTS OF AN EFFLUENT GUIDELINE FOR THE PHARMACEUTICAL MANUFACTURING INDUSTRY (1990 $)
ALTERNATIVE OPTIONS

	Labor Cost Component				Direct Labor Requirement	
	Total Weighted Expenditures ($)	Labor's Share of Output Value	One-Time Basis ($)	Annual Labor Cost ($)	One-Time Basis (FTEs)	Annual Basis (FTEs)
Manufacturing	147,825,819	0.31016	45,849,656	4,853,537	795	84
Installation	16,425,091	0.42233	6,936,809	734,314	120	13
Operation (annually)	51,277,085	1	51,277,085	51,277,085	889	889
Total direct labor effects	215,527,995		104,063,550	56,864,936	1,804	986

Source: ERG estimates.

TABLE C-5

INCREMENTAL RECORDKEEPING AND REPORTING COSTS FOR ALTERNATIVE OPTIONS

Employment Size of Firm	# Firms with Nonzero Compliance Costs	Total Monitoring Costs	% of Total Industry Monitoring Costs	Total Pretax Compliance Costs*	Monitoring Costs as % of Compliance Costs**
0 - 18	9	$105,215	1%	$726,763	1.2%
19 - 99	26	$984,005	11%	$11,281,919	7.8%
100 - 499	47	$1,623,545	18%	$17,725,628	9.3%
500 - 750	17	$844,635	9%	$15,549,877	6.8%
> 750	40	$5,478,385	61%	$138,878,766	6.6%
All Firms <= 750	99	$3,557,400	39%	$45,284,187	8.6%
All Firms	139	$9,035,785	100%	$184,162,953	7.8%

* Pretax compliance costs are annualized at 11.4%.

** Percentage calculated as the median of monitoring costs divided by compliance costs for each firm in the group rather than average monitoring costs divided by average compliance costs. Analysis does not include firms with zero compliance costs.

Note: These numbers are for all facilities and do not reflect closures predicted by the analyses in this report.

Source: ERG estimates based on Radian Corp. estimates of capital and operating costs for pollution control equipment (including operating costs).

TABLE C-6

PROFITABILITY ANALYSIS FOR ALTERNATIVE OPTIONS -- PERCENTAGE DECLINE IN ROA, BY EMPLOYMENT SIZE OF FACILITY

Employment Size of Firm	Number of Firms						
		Percent Change in ROA					
	Total	0	>0 - <=5	>5 - <=10	>10 - <=20	>20 - <=50	>50
0 - 18	10	6	1	0	1	1	1
19 - 99	15	3	3	0	4	4	1
100 - 499	35	17	13	2	1	2	0
500 - 750	18	7	10	0	1	0	0
> 750	19	2	16	0	1	0	0
All Firms <= 750	78	33	27	2	7	7	2
All Firms	97	35	43	2	8	7	2

Note:
1. This table analyzes firms that passed the baseline analysis, excluding the 36 firms that only have certified facilities.
2. Analysis excludes three firms because of lack of financial data.

Source: ERG estimates.

TABLE C-7

PRESENT VALUE OF COMPLIANCE COSTS AS A PERCENTAGE OF PRESENT VALUE OF POSTCOMPLIANCE NET INCOME FOR ALTERNATIVE OPTIONS

Employment Size of Firm	Median Compliance Costs (PV)	Median Postcompliance Net Income (PV)	Compliance Costs as % of Net Income*
0 - 18	$0	$427,787	0.00%
19 - 99	$817,485	$5,675,197	11.12%
100 - 499	$3,324	$58,170,339	0.02%
500 - 750	$453,882	$432,324,319	0.05%
> 750	$1,893,578	$1,430,472,878	0.47%
All Firms <= 750	$54,327	$45,984,357	0.09%
All Firms	$597,190	$102,698,480	0.14%

* Median for each group is based on percentage calculated for each firm in the group rather than median compliance costs divided by median postcompliance net income.

Note:
1. Analysis excludes three firms because of lack of financial data.
2. Analysis excludes all firms with certified facilities.
3. Analysis includes only those firms that pass both the baseline and postcompliance analyses.

Source: ERG estimates.

TABLE C-8

COMPLIANCE COSTS AS A PERCENTAGE OF TOTAL PHARMACEUTICAL PRODUCTION COSTS FOR ALTERNATIVE OPTIONS, BY FACILITY

Regulatory Option	Compliance Costs/Total Costs										
	0.0%		>0.0% - 0.1%		>0.1% - 1.0%		>1.0%- 10.0%		>10%		
	# Facilities	% Total	# Facilities	% Total	# Facilities	% Total	# Facilities	% Total	# Facilities	% Total	Average Ratio*
BAT-A/C#2	0	0%	2	14%	5	36%	6	43%	1	7%	3.4%
BAT-B/D#1	0	0%	4	44%	5	56%	0	0%	0	0%	0.2%
PSES-A/C#1	14	23%	1	2%	15	25%	29	48%	2	3%	2.7%
PSES-B/D#1	39	33%	14	12%	40	34%	23	19%	2	2%	1.2%
All Facilities											
All	53	26%	21	10%	65	32%	58	29%	5	2%	2.5%

* Average Ratio does not include those facilities with zero option costs.

Note:
1. Analysis excludes certified facilities and zero dischagers.
2. Analysis also excludes six additional facilities (one A/C direct discharger, two A/C indirect dischargers, and three B/D indirect dischargers) because of lack of financial data.

Source: ERG estimates.